

INDUSTRY COMMISSION

MEDICAL AND  
SCIENTIFIC  
EQUIPMENT  
INDUSTRIES

REPORT No. 56

20 December 1996

**'PROTECTED — UNDER  
EMBARGO UNTIL  
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### **Forming the Productivity Commission**

The Industry Commission, the former Bureau of Industry Economics and the Economic Planning Advisory Commission have amalgamated on an administrative basis to prepare for the formation of the Productivity Commission. Legislation formally establishing the new Commission is before Parliament



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20 December 1996

The Honourable Peter Costello MP  
Treasurer  
Parliament House  
CANBERRA ACT 2600

Dear Treasurer

In accordance with Section 7 of the *Industry Commission Act* 1989, we have pleasure in submitting to you the report on the Medical and Scientific Equipment Industries.

Yours sincerely

Jeffrey Rae  
Presiding Commissioner

Helen Owens  
Commissioner

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## ABBREVIATIONS

ABS	Australian Bureau of Statistics
ACIRRT	Australian Centre for Industrial Relations Research and Training
ACS	Australian Customs Service
ADA	Anti-dumping Authority
ADCAL	Australian Development Capital Association Limited
ADMA	Australian Diagnostics Manufacturers Association
AHMAC	Australian Health Ministers' Advisory Council
AHTC	Australian Health Technology Committee
AIRG	Australian Industry Research Group
ANAO	Australian National Audit Office
ANTA	Australian National Training Authority
ANZSIC	Australian and New Zealand Standard Industrial Classification
ARLC	Australian Law Reform Commission
ARTG	Australian Register of Therapeutic Goods
ASEAN	Association of South East Asian Nations
ASTEC	Australian Science and Technology Council
ATG	Australian Technology Group
AUA	Authorised User Access
Austrade	Australian Trade Commission
BDU	Business Development Unit
BIE	Bureau of Industry Economics
BNP	Business Networks Program
BSI	British Standards Institution
BSTP	Bilateral Science and Technology Program
COAG	Council of Australian Governments
CRC	Cooperative Research Centre



CRCPESCCRC Program Evaluation Steering Committee

CSIRO	Commonwealth Scientific and Industrial Research Organisation
CTE	Clinical Trial Exemption scheme
CTN	Clinical Trial Notification scheme
DFAT	Department of Foreign Affairs and Trade
DHFS	Commonwealth Department of Health and Family Services
DIFF	Development Import Finance Facility
DIST	Department of Industry, Science and Tourism
EC	European Commission
EEC	European Economic Community
EEG	electro encephalograph gram
EFIC	Export Finance and Insurance Corporation
EFTA	European Free Trade Association
EIS	Enterprise Improvement Scheme
EMDG	Export Market Development Grants scheme
EU	European Union
FDA	Food and Drug Administration (US)
GAO	United States General Accounting Office
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GMP	Code of Good Manufacturing Practice
GPA	Government Procurement Agreement (1991)
GTE	Government Trading Enterprises
HHSASA	Hospitals and Health Services Association of South Australia
HIG	Hospitals Infection Group of the Prince Henry, Prince of Wales and Prince of Wales Children's Hospital
HIMA	Health Industry Manufacturers Association
IAC	Industries Assistance Commission
IC	Industry Commission

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IGCC	Industry–Government Consultative Committee
IRDB	Industry Research and Development Board
ITES	International Trade Enhancement Scheme
ISO	Industrial Supplies Office
ISO (VIC)	Industrial Supplies Office (Victoria) Limited
ISTAC	International Science and Technology Advisory Committee
ISTP	International Science and Technology Program
ITES	International Trade Enhancement Scheme
MDA	Medical Devices Agency
MDD	Medical Devices Directive
MIAA	Medical Industry Association of Australia
MRA	Mutual Recognition Agreement on conformance assessment
MRC	Medical Research Council
MRS	Manufacturers Registration Scheme
MSE	Medical and scientific equipment
NCCTG	National Coordinating Committee on Therapeutic Goods
NHMRC	National Health and Medical Research Council
NIC	National Investment Council
NIEIR	National Institute of Economic and Industry Research
NIES	National Industry Extension Scheme
NSW	New South Wales
NSW ISO	Industrial Supplies Office (New South Wales) Limited
OECD	Organisation for Economic Cooperation and Development
PC	Productivity Commission
PDF	Pooled Development Funds
PHRDC	Public Health Research and Development Committee
PH trans	public hearing transcripts
PMAA	Proprietary Medicines Association of Australia
PPSE	Photographic, professional and scientific equipment

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QUT	Queensland University of Technology
R&D	research and development
RT trans	roundtable discussion transcripts
SDi	Strategic Directions International Incorporated
SSAA	Scientific Suppliers Association of Australia
START	Strategic Assistance for Research and Development
sub.	submission
TCO	Tariff Concession Order
TCS	Tariff Concession System
TDB	Therapeutic Devices Branch
TDEC	Therapeutic Devices Evaluation Committee
TEXCO	Tariff Export Concession Scheme
TGA	Therapeutic Goods Administration
TGC	Therapeutic Goods Committee
TGD	Therapeutic Goods Determinations
TGO	Therapeutic Goods Order
the Act	The <i>Therapeutic Goods Act</i> 1989
the Regulations	Therapeutic Goods Regulations
TIEG	Technology Industries Exporters Group
UK	United Kingdom
US	United States of America
WTO	World Trade Organisation

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## OVERVIEW

Medical and scientific equipment is critical to economic prosperity and the quality of life. A productive economy needs sophisticated tools to measure, calibrate and control its products and industrial processes. High standards of medical care require advanced equipment and medical devices to support the work of well-qualified doctors and nurses.

This report looks at how the medical and scientific equipment industries can contribute to higher living standards and quality of life in Australia. The aim is to show how governments might assist the industries in attaining those goals.

### Globalisation of equipment markets

An advanced economy like Australia's uses many tens of thousands of medical and scientific devices. They range from the relatively simple — such as laboratory glassware and plastic blood bags — to the highly advanced — the spectrograph and laser surgical instruments for instance.

The demand for medical and scientific equipment depends on both the level and the rate of growth of national income. Governments also exert a major influence on demand, both directly as users of equipment and indirectly through their expenditure programs on health care, education, and research and development.

Although the United States (US), Europe and Japan dominate global demand for medical and scientific equipment, their dominance is eroding. In many developing countries, demand is growing much faster than national income — especially in the dynamic economies of East Asia.

As well as being the largest user, the US is also the world's largest producer of medical and scientific equipment. Europe ranks next, followed by Japan. The sheer range of these devices and their specialised nature mean that even the US market for many devices is relatively small — in most cases less than \$US150 million a year.

A few dozen multinational companies market a broad range of products and related services globally, in competition with many thousands of small-to-medium producers. Although the smaller producers generally make far fewer products, many are innovative, technically advanced and successful exporters.

The Uruguay Round of multilateral trade negotiations agreed to worldwide cuts in tariffs on medical and scientific equipment — after these cuts, global tariffs will average less than 3 per cent. The most significant of the remaining barriers to international trade are regulatory, but even they are being reduced by moves to harmonise the regulation of medical devices.

## Equipment industries in Australia

The Australian equipment industries have much in common with those in the US, Europe and Japan. Box 1 outlines the key features of the Australian industries.

Local activity divides between manufacturing and services — importing, distribution and after-sales service. As in other countries, local manufacture relies heavily on research and

Box 1	The Australian MSE industries at a glance		
	<i>Medical</i>	<i>Scientific</i>	<i>Total</i>
Domestic production	\$670 million	\$450 million	\$1.1 billion
Manufacturing management units	670	250	920
Employment in manufacturing	4000 persons	6400 persons	10 400 persons
Share of manufacturing management units with fewer than ten employees	90 per cent	75 per cent	85 per cent
Share of domestic output spent on R&D	8 per cent	9 per cent	8 per cent
Imports for domestic use	\$875 million	\$1.6 billion	\$2.5 billion
Exports			
– of domestic origin	\$450 million	\$300 million	\$750 million
– share of domestic output	65 per cent	65 per cent	65 per cent

development, innovation and a skilled workforce — far more than most of manufacturing.

Although multinationals dominate the industries there are many more small-to-medium manufacturers. The smaller ones are often highly competitive and innovative, even in technically

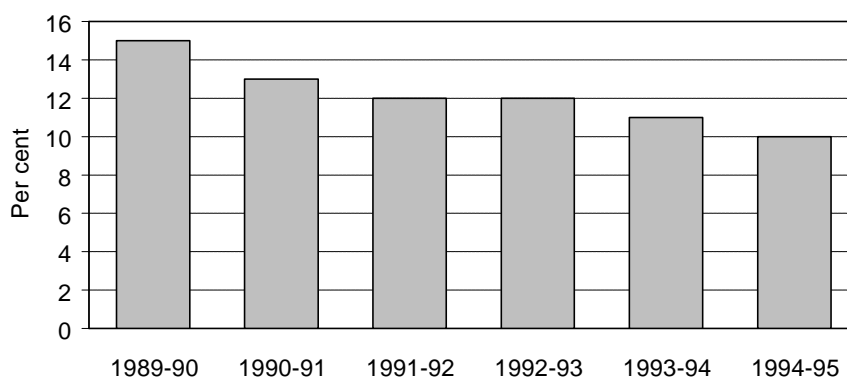
advanced equipment. Most domestic manufacturers are heavily dependent upon exports for commercial success. The major export markets for medical equipment are New Zealand and Asia — for scientific equipment they are Europe and the US.

The decade past has seen a transformation in many economic policies: the liberalisation of financial markets; the winding back of tariff protection; the removal of some inappropriate regulation; and moves to raise the efficiency of Australia's economic infrastructure. These changes have affected the Australian equipment industries directly and indirectly.

Tariffs have been reduced on all products (see Figure 1). Tariffs — including those on medical and scientific equipment — are now 5 per cent or less, except for cars, footwear, clothing and textiles. Ten years ago some tariffs on medical and scientific equipment were up to 30 per cent.

Figure 1

**MSE  
effective  
rates of  
assistance**



Against this background, the performance of the two industries is remarkable, if often unrecognised.

- The two industries are highly innovative. Their rate of spending on research and development as a proportion of turnover is eight times that of all manufacturing — and, on

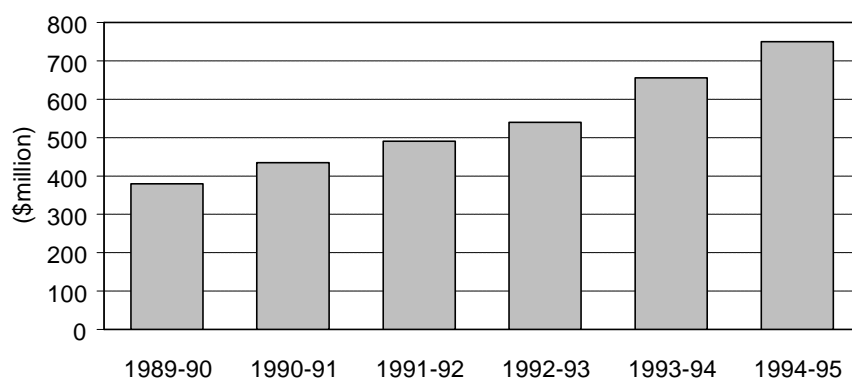
the face of it, comparable with that of the US medical and scientific equipment industries.

- The industries have depth in technical skills. The proportion of their employees with trade, degree or higher educational qualifications is three times that of all manufacturing.
- Most importantly they are strong export performers. The industries export five times as much of their output as does all manufacturing.

Over the past five years total equipment exports have nearly doubled and are now about \$750 million a year (see Figure 2). Many are innovative and advanced products (see Box 2).

**Figure 2**

**MSE exports**



## Box 2      **Examples of medical and scientific equipment exporters**

*AGEN Biomedical* makes monoclonal antibody-based diagnostics. Since 1986 it has grown at 30–40 per cent a year and currently has an annual turnover of approximately \$10million. AGEN spends about \$2.5million a year on research and development.

*Bioclone Australia* exports a range of monoclonal and polyclonal antibodies and a range of diagnostic kits. Bioclone has agreements or affiliations with many international diagnostic companies.

*Cochlear* produces ear implants (the 'bionic ear') for the profoundly deaf. Cochlear is the world leader in ear implants with exports to over 40 countries. In 1993 its exports were over \$40 million and the company expects them to reach \$100million by the year 2000.

*GBC Scientific Equipment* makes second generation atomic absorption spectrometry equipment, originally invented at the CSIRO in the 1960s. GBC is the third largest supplier of such equipment in the world and exports over 90per cent of its output.

*PanBio* specialises in research and development and global marketing of niche ELISA kits for infectious diseases. In 1995, PanBio was awarded the Telstra Australian Small Business Award for businesses with less than 30employees.

*SGE International* makes chromatography and related analytical products. It exports over 90 per cent of its output and its major markets are in Europe, the US and Japan.

*Varian* manufactures atomic absorption spectrometry and some medical equipment, mainly for radiotherapy. It is the second largest supplier of absorption spectrometry equipment in the world. Like GBC, Varian exports over 90per cent of its production.

In the light of these considerations, the key question for government is what it should do to promote productivity and efficiency in the industries. This inquiry suggests that the priority issues are regulation, government procurement and tariff protection.

## **Regulation of medical devices**

Most industrialised countries regulate the safety, quality and efficacy of medical devices. Australia does so via the *Therapeutic Goods Act* 1989 and its subordinate legislation. The legislation is administered by the Therapeutic Goods Administration (TGA) of the Department of Health and Family Services.

The legislation puts certain obligations on those who would market medical devices in Australia. They include:



- recording of all devices in a public register;
- specified standards for certain devices;
- evaluation of certain devices by the TGA prior to sale;
- observation of a quality management standard by manufacturers;
- licensing of manufacturers to show compliance with this quality management standard; and
- monitoring of devices in use.

The TGA has a monopoly on assessing compliance with the legislation. It is currently required to recover 50 per cent of its costs from fees and charges to industry, although this is to increase to 75 per cent over the next three years.

### *Problems with device regulation*

The statutory goals of safety, quality and efficacy are sound but there are well recognised shortcomings in some of the means used to achieve them.

The legislation deals with devices product by product, according to predetermined groupings. Consequently the law cannot readily handle technological change — it has to be amended whenever a new type of device emerges.

Some devices have to be formally exempted or excluded from the provisions of the law. This is due to its wide ambit and the poor correspondence between its controls and the risks associated with a device. The legislation automatically picks up many low risk therapeutic products — such as cotton balls, magnets, beauty therapy equipment, personal hygiene products and furniture. The *Trade Practices Act 1974* already provides adequate consumer protection in such cases.

The legislation mandates particular standards. But it does not offer a choice of others that provide equal protection — such as many international, European or US standards. As the setting of standards is cumbersome, some standards are quickly outdated or difficult to enforce. The inflexibility of these provisions imposes unnecessary compliance costs on industry.

The detailed requirements for devices in Australia differ markedly from those of its major trading partners. As a

consequence, Australian exporters and importers have to conform to multiple regimes. This adds to their compliance costs and inhibits trade.

Finally, there is no competition in conformance assessment. This means there is no choice for industry, and little commercial pressure on the TGA to provide its services in cost effective and timely ways. Industry is critical on both counts.

### *Mutual recognition of conformance assessment*

Australia and the European Union (EU) are concluding a Mutual Recognition Agreement on conformance assessment in several sectors, including for medical devices. The Agreement will allow bodies designated by the EU to assess the conformance of EU manufacturers to the Australian law on therapeutic goods. Similar bodies in Australia will be able to assess local manufacturers against the EU requirements for medical devices.

The Agreement will benefit Australian exporters but more needs to be done for its potential gains to be realised quickly. To this end, we propose that the Commonwealth allow competition in services to assess compliance with the therapeutic goods legislation. This needs to be accompanied by a restructuring of the TGA to establish its assessment activities as a commercially autonomous operation.

The Agreement will leave many manufacturers facing two sets of regulatory requirements — one for the Australian market and another for Europe. This raises the more fundamental question: is the EU model for device regulation the superior one?

### *Regulation of devices in the EU*

As in Australia, regulation in the EU aims to ensure the safety, quality and efficacy of medical devices. However, the EU uses a more light-handed approach than Australia to achieve these ends (see Box 3).

#### **Box 3**

#### **Regulation of medical devices in the European Union**

In the European Union (EU) the regulation of medical devices is part of a harmonised system for regulating the quality and safety of all products marketed in the Union. The foundations of the system are a series of Directives by the European Commission to EU member states. Each member state is responsible for implementing the legislation to give effect to the Directives.

The Directives relating to medical devices require that:

- devices must be designed and constructed so as not to compromise safety;
- the associated risk must be acceptable when weighed against the benefits of the device;
- design and construction should eliminate risk as far as practical and protect adequately where they cannot;
- devices must perform as the manufacturer intends; and
- performance must be maintained over the life of the device.

The Directives also provide for the:

- classification of devices;
- pre-market evaluation of devices;
- application of standards to devices and their manufacturing processes; and
- post-market monitoring of devices.

Medical devices are classified on the basis of their intended use, their risk, their degree of invasiveness, and the length of time they are likely to be in contact with the body.

All medical devices are subject to pre-market evaluation. For low and some medium risk devices, manufacturers may do their own. Others must be performed by a designated conformity assessment body.

The EU does not mandate particular standards for medical devices or their manufacture. Manufacturers may use one of a list of 'harmonised standards' which offer equivalent outcomes. Adoption of any one confers a presumption of conformity with the relevant requirements. Alternatively manufacturers can devise their own approach, provided it can be shown to provide an equivalent outcome.

A vigilance system requires manufacturers, conformity assessment bodies and others to report adverse incidents and to have systems for detecting problems in use. Manufacturers are responsible for taking any corrective action that is necessary.

Designated bodies assess medical device manufacturers and their devices against EU Directives. They are typically independent of the EU member states and compete with each other. On the basis of their certification, a manufacturer can market anywhere in the EU.

Member states have overall responsibility for regulating medical devices within their jurisdiction. Their main roles and functions include:

- overseeing medical device regulation within its jurisdiction;
- maintaining a register of approved devices;
- designating and auditing conformance assessment bodies;
- undertaking post-market surveillance;
- establishing product recall protocols; and
- supervising recalls and corrective action.

A 'safety clause' allows EU member states to refuse registration of a medical device on safety grounds but there are sanctions if the clause is used without just cause. The clause is only expected to be used in exceptional circumstances.

The EU system — known as the 'CE Mark' after the logo given to eligible devices — does not classify devices into groups,

licence manufacturers or mandate standards. It thereby avoids the problems encountered with the therapeutic goods law.

Manufacturers have to ensure their devices are safe and of an appropriate quality. They have the choice of several ways by which to demonstrate compliance with these requirements. One is by conforming to one of a list of harmonised standards. But any other approach that provides equivalent outcomes is also allowed. Finally, manufacturers can choose the body to assess their conformance, some of which are in the private sector.

EU member governments translate the Directives into national law, oversee the regulatory system, monitor devices in use, and approve and audit conformity assessment bodies.

### *International harmonisation with the EU model*

Countries outside the EU are moving to harmonise their regulation with that of the Union. Already 10 European nations outside the Union, as well as Japan, Canada, New Zealand, Israel and South Africa, have said they will do so. The US may adopt some elements of the EU model. For these reasons, the CE Mark has emerged as the international model for device regulation. It already covers a market of 500 million people in Europe

The aim of the Department of Health and Family Services is to adopt the EU Directives for medical devices, preferably by reference in the legislation on therapeutic goods.

We concur. Adoption of the EU Directives promises to protect the community better and lower the costs to consumers and taxpayers of doing so. At the same time it should promote Australian exports of medical devices. However, implementation needs to proceed quickly and we have made recommendations to that end.

## **Government procurement**

Directly or indirectly, governments fund most purchases of medical and scientific equipment in Australia. Some purchases are for use by the public sector — for example, government research bodies such as CSIRO, state schools and public

hospitals. Other purchases are funded by governments — for instance, for use by private schools and universities.

Industry has many concerns about the purchasing policies and practices of governments in relation to medical and scientific equipment. The strength and breadth of these concerns led a major industry association to propose a national inquiry into the issues — notwithstanding the many recent inquiries on government procurement.

On the basis of our own assessment, we identified the following problems in the procurement of medical and scientific equipment by government:

- a lack of transparency of procurement practices;
- inadequate machinery for suppliers to discuss issues and problems with procurement agencies;
- non-compliance by public sector organisations with government purchasing guidelines; and
- insufficient cooperation and coordination between governments on policy issues of common interest.

Problems were most pronounced in the health sector.

These problems highlight the need for governments to ensure their procurement guidelines are soundly based and to examine the adequacy of arrangements for ensuring their agencies comply with such guidelines.

In this regard, using government procurement as a means to assist industry compromises the core objective of procurement, namely to provide the taxpayer with value for money. Moreover, it is also an inefficient way of assisting industry.

On some issues of common interest in the procurement of medical and scientific equipment, coordination and cooperation between governments was found to be lacking. A nation-wide review aimed at achieving greater uniformity appears warranted. It should be carried out by the National Supply Group.

The nature and extent of these problems suggest shortcomings in the public health system. They point to failures in the organisation, management, funding and accountability of the public health system. Such matters would be best addressed by a broadly based review of the public health system.

## **Tariffs on medical and scientific equipment**

Because of its sheer variety, equipment used in a medical or industrial setting can be hard to identify in the official information on trade and tariffs. The value of imported medical and scientific equipment, which is clearly classified as such in the Customs Tariff, is at least \$1.8 billion. Total imports are certainly somewhat higher.

Prior to July 1996, virtually all imports entered duty free. Three quarters were classified as duty free by the Customs Tariff. The rest had a nominal tariff of 5 per cent but nearly all entered under some form of tariff concession. In July 1996, these concessions were modified — mainly to raise the concessional rate of duty from zero to 3 per cent.

The increase in the concessional duty rate has inflated costs to sections of the domestic medical and scientific industries. Some imported equipment and components are used to make other pieces of equipment. In such cases, the increase in concessional duty will simply inflate their manufacturing costs and erode the competitiveness of some companies within the industries.

At the same time, the changes will not appreciably benefit local production of any other equipment. There is little domestic production of the types of equipment that are imported. Where it does exist, most of it is unaffected by imports. Indeed many local manufacturers use imports to fill out their product range.

In our view the Commonwealth should eliminate the remaining tariffs that are clearly identified as being on medical and scientific equipment and parts.

Elimination would neutralise the increase in the concessional tariff. It would thereby restore the competitiveness of those sections of the industries that depend upon imports to make their own products. Elimination should also cut the administrative and compliance costs associated with tariffs.

## **Other issues**

We would like to draw attention to the other issues canvassed in the inquiry:

- the reuse of medical equipment labelled ‘single use only’;

- product liability litigation and the possible implications for Australia;
- the labour market and vocational training;
- the industries' access to capital;
- research and development, including the linkages between public research bodies and the industries; and
- assistance for exporting and business management.

## **Future prospects**

The future could well see intensified global competition in medical and scientific equipment markets. Intensified competition would put greater pressure on companies in the industries to locate their activities where the climate for business is most productive.

Australia's industries are highly integrated into the global market for medical and scientific equipment — hence they will not be immune from these pressures. While the industries are well placed to embrace the future successfully, there can be no grounds for complacency by them or by government.

For their part, governments must press on with the broad agenda of microeconomic reform. These reforms enhance the ability of these and other industries to contribute to the productivity and efficiency gains which underwrite higher living standards.

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## RECOMMENDATIONS

The Commission recommends that the Commonwealth Government should:

### **On the conformance assessment of medical devices**

1. Accredit eligible bodies in the public or private sector to assess the conformance of medical devices, their manufacturers and their sponsors, to the therapeutic goods legislation.
2. Require bodies to demonstrate appropriate competencies if they wish to be accredited to assess conformance to the therapeutic goods legislation.
3. Determine that the competencies to assess conformance to the therapeutic goods legislation are those referenced in the proposed Mutual Recognition Agreement on conformance assessment with the European Union.

### **On the reorganisation of the TGA**

4. Separate conformance assessment of the Therapeutic Goods Administration for medical devices from its core responsibilities for regulating medical devices and pharmaceuticals. These assessment activities should be assigned to a commercially autonomous enterprise funded solely by client fees and charges.
5. Assign the regulatory responsibilities of the Therapeutic Goods Administration to a statutory authority with operational independence from the Department of Health and Family Services.
6. Require the regulatory authority to: maintain a register of medical devices and their sponsors; accredit conformance assessment bodies; audit the assessment bodies to ensure the validity of their assessments; conduct post-market surveillance of devices; and manage the recall of devices.

### **On the Mutual Recognition Agreement with the European Union**

7. Implement, as soon as practical, the provisions relating to medical devices in the proposed Mutual Recognition Agreement on conformance assessment between Australia and the European Union.



### **On the regulation of medical devices**

8. Implement the approach of the European Union to regulating medical devices by mandating in legislation the relevant essential requirements in the Directives of the European Union.
9. Keep to a minimum any mandatory requirements for medical devices additional to those in the relevant Directives of the European Union and ensure that such requirements are consistent with the spirit of those Directives.
10. Discontinue licensing manufacturers of medical devices.
11. Leave the regulation of therapeutic devices not covered by the Directives of the European Union to the *Trade Practices Act 1974*.

### **On tariffs for medical and scientific equipment**

12. Reduce to zero the remaining tariffs on medical and scientific equipment in Chapter 90 of the Customs Tariff. The relevant sub-headings of the Customs Tariff are 9011 to 9033 inclusive (with the exception of items used in passenger motor vehicles).

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In addition, the Commission recommends that:

### **On government procurement**

14. To promote efficiency and transparency in their purchase of medical and scientific equipment, Australian governments should ensure that their procurement guidelines incorporate, as far as practicable, the 'best practice' guidelines recommended by the Commission in its 1996 report on *Competitive Tendering and Contracting by Public Sector Agencies*.
15. Each Australian Government should examine the adequacy of existing arrangements for ensuring that its public hospitals and agencies comply with its purchasing guidelines.
16. The National Supply Group should review the different approaches by governments in the procurement of medical and scientific equipment with a view to achieving greater uniformity of policy and practice, including in the use of common use contracts, product and quality standards, environmental requirements and electronic commerce.

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## FINDINGS

The Commission found that:

### **On government procurement**

1. There are problems in the procurement of medical and scientific equipment by governments. They involve:
  - a lack of transparency of procurement practices;
  - inadequate machinery for suppliers to discuss issues and problems with procurement agencies;
  - non-compliance by public sector organisations with government purchasing guidelines; and
  - insufficient cooperation and coordination between governments on policy issues of common interest.

These problems were most pronounced in the public health sector.

2. The Government Procurement Agreement and the National Supply Group have the potential to address problems in government procurement affecting the medical and scientific equipment industries.
3. The inclusion of industry assistance as an objective in government procurement compromises the core objective of value for money, and is an inefficient way of providing such assistance.
4. The problems in government procurement identified by this inquiry may be due to shortcomings in the organisation, management, funding and accountability of the public health system.

### **On labour market issues**

5. In the medical and scientific equipment industries:
  - formal enterprise bargaining is uncommon;
  - informal agreements appear widespread; and
  - although their workforces are relatively highly skilled, companies spend less on workplace training than the average of all manufacturing.

Except for the Commonwealth legislation relating to unfair dismissal, industrial relations and labour market regulation were not major issues for most participants in this inquiry.

### **On research and development**

6. There is no compelling case on efficiency grounds to reduce further the minimum expenditure threshold for the tax concession for research and development.
7. The evidence presented to the inquiry suggests that smaller companies in the medical and scientific equipment industries undertake more research and development as a proportion of their value of output than larger companies.
8. Future reviews of assistance measures for research and development should, among other things, examine their impact according to company size.
9. The recent changes to the tax concession for research and development appear to have increased the uncertainty associated with investing in research and development. This is likely to have an adverse impact on research and development in the medical and scientific equipment industries.
10. Overall, smaller companies in the medical and scientific equipment industries will be disadvantaged by redirecting savings from recent changes to the tax concession for research and development to the START program.

### **On finance, export and management assistance**

11. Access to seed and venture capital continues to be a significant obstacle to the development of the smaller, high technology companies within the medical and scientific equipment industries, notwithstanding recent government initiatives in this area.
12. Although there is an extensive range of government programs aimed at export and business management performance, companies in the medical and scientific equipment industries are generally unaware of or have difficulties obtaining information about them.
13. The difficulties the Commission has identified with government programs aimed at export and business management performance are most appropriately addressed in a comprehensive, rather than industry specific, review.

**On the reuse of single use devices**

14. The draft report by the National Health and Medical Research Council's expert panel on the reuse of medical devices labelled as 'single use only' did not adequately address a number of broader technical, regulatory and economic issues relating to reuse. To formulate satisfactory recommendations on reuse these broader issues should be subject to further review.



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# 1 THE INQUIRY

On 24 January 1996, the Assistant Treasurer referred the medical and scientific equipment industries to the Industry Commission (now being amalgamated into the Productivity Commission).

## 1.1 Scope of the inquiry

This report has two main aims. One is to examine the development potential of the Australian medical and scientific equipment industries in domestic and export markets. The other is to identify barriers to that potential being realised and, where appropriate, suggest measures to remove them. Both aims need to be addressed against a backdrop of what is best for the economy as a whole.

The terms of reference direct the Commission to report, among other things, on:

- local and global market trends;
- current institutional and regulatory measures and their impact;
- research and development and links with the scientific community;
- government efforts to improve export market access;
- competitive strengths and weaknesses of the industries; and
- advantages and disadvantages of Australia as an investment location.

In undertaking its task the Commission was directed to draw on international comparisons where appropriate. The full terms of reference are at Appendix A.

The terms of reference did not define the activities falling within the medical and scientific equipment industries, and the Commission did not seek to define precisely the equipment falling within the scope of the reference. It adopted a broad definition instead — encompassing both capital items and consumables within the ambit of its inquiry. Included was equipment ranging from single use medical consumables and basic laboratory glassware to technologically complex medical equipment and laboratory instrumentation. Covering such a broad range of equipment should ensure all major issues of importance to the industries were brought to the inquiry's attention.

As well as examining the activities of producers and suppliers, the Commission considered the activities and views of others that may affect the medical and scientific equipment industries such as users and government purchasing agencies.

## 1.2 Commission's approach

The Commission adopts an economy-wide approach in assessing policy issues and options. This approach means any solutions to problems which impede the development of the industries should aim to improve the wellbeing of the whole community — not just the medical and scientific equipment industries.

The Commission recognised the industries under reference are different from each other and face different circumstances — the *Therapeutic Goods Act* for medical devices is one such case. In the lead up to the inquiry, some Ministers emphasised the need for the inquiry to recognise these differences (see Appendix B). However, the industries also share considerable common ground, such as the importance of government as a source of demand for equipment. Thus, while the industries are treated separately in places, when discussing issues of shared interest the Commission has considered them together.

This inquiry required the Commission to identify the industries' potential for development and expose any barriers to their growth. In doing so, the Commission has not tried to map the future development of the industries. This is not an appropriate role for the Commission nor one in which it has the required expertise.

The future commercial direction of companies is best left to the companies themselves to choose. Governments, for their part, should seek to create an environment in which companies and industries have the opportunity to realise their full potential — for example, by removing any institutional or regulatory impediments and addressing areas where 'market failure' may exist. The Commission's approach has been to examine whether such an environment has been achieved and, if not, what actions the companies, the industries or governments can take to do so.

## 1.3 Conduct of the inquiry

The Commission released an issues paper in March 1996 and called for responses to that paper.

The Commission held extensive informal discussions with a variety of interested parties. These included government purchasing and regulatory agencies, industry organisations and a wide range of producers and users of medical and scientific equipment and related services. The Commission also held two roundtable discussions in May 1996 — one for the medical equipment industry and the other for the scientific equipment industry. By the end of August 1996, 46 submissions had been received.

A Draft Report was released mid-September 1996, inviting interested parties to examine and comment upon it. Public hearings to discuss participants' views were held in October 1996 in Sydney and Melbourne. By December 20 1996, a total of 81 submissions had been received.

Participants who have contributed to the inquiry through visits, submissions, roundtable discussions and public hearings are listed in Appendix C.

The Commission expresses its thanks to all participants for the information and assistance they provided in the course of the inquiry.

## **1.4 Sources of information**

The Commission has drawn on submissions and a wide range of published material relevant to the industries in Australia and overseas. These include the findings of recent Industry Commission reports dealing with topics relevant to the industries — such as competitive tendering (IC 1996a), research and development (IC 1995b) and the availability of capital (IC 1991b).

Comprehensive data describing the industries in Australia and worldwide are limited. Where data are available there are major statistical difficulties with reliability and comparability (see Box 1.1).

To describe and analyse the industries the Commission has relied heavily on published and previously unpublished Australian Bureau of Statistics (ABS) data, supplemented with information from industry associations. This reliance on official data has meant the industries described correspond to the industry groupings adopted by the ABS rather than narrower definitions adopted by medical and scientific equipment industry associations.

To augment this information the Commission engaged Coopers & Lybrand to conduct a survey of the medical and scientific equipment industries in Australia. Details of that survey and its results are in Appendix K and L. (The Commission released preliminary results of that survey in an information paper in early October 1996).

The vast majority of the two industries in Australia fall within the industry groups described by the ABS under ANZSIC divisions 2832, 2839 and 4612. These cover, respectively: Medical and surgical equipment manufacturing; Professional and scientific equipment manufacturing not elsewhere covered; and Professional equipment wholesaling (ABS and DSNZ 1993). In the absence of suitable alternative data, these three ANZSIC divisions provide a useful basis for describing the industries in Australia. A description of the activities within these divisions is in Appendix J.



Customs and ABS ANZSIC data were used to provide information on imports and exports of medical and scientific equipment. However, as customs data are collected on a *product* basis, and medical and scientific equipment products are listed under a number of Tariff Chapters — albeit highly concentrated within Chapter 90 — comparability with ABS *industry* data is difficult.

**Box 1.1      Data limitations**

Comprehensive data for the industries — in Australia or worldwide — are limited.

In Australia, the activities of the medical or scientific equipment industries do not all slot readily into the standard industry classifications used by the ABS. ABS data cannot therefore comprehensively describe the activities of these industries. For example, data on hospital bed manufacturing are aggregated with metal furniture manufacturing, and cannot be readily identified.

Data are also collected on the basis of the major activity of an establishment. Thus medical or scientific equipment production which is a minor part of a multi-product company's manufacturing activity will be recorded under another industry grouping.

To describe the industries in Australia, the Commission has augmented official data with that supplied by industry associations — the Medical Industry Association of Australia and the Scientific Suppliers Association of Australia. While valuable, this information has come from industry surveys which may not be representative of the respective industries. It also reflects narrower definitions of the industries than those of the industry associations.

For global data on the medical equipment industry, the Commission has drawn heavily on data from the US Health Industry Manufacturers Association (HIMA 1992, 1994). For the scientific equipment industry, the Commission has relied mainly on the US National Trade Data Bank from Infocom (1996) and information on the global analytical instrumentation market from Strategic Directions International (SDi 1996).

Global data are however often based on definitions different to those used to describe the local industries. Estimates from the various sources therefore differ quite considerably, and comparability is a major problem. The Commission's response to these data problems is to present best estimates or, where appropriate, a range of figures.

## 1.5 Structure of the report

Chapters 2 and 3 describe the state of the global and Australian medical and scientific equipment industries respectively, and some recent trends affecting these industries. This is a backdrop to the discussion of policy issues which follow.

Chapter 4 assesses the main regulatory arrangements and issues applying to the medical equipment industry and outlines international developments in that field. (The regulation of scientific equipment does not appear to be an issue of great significance.) The chapter includes a number of recommendations to improve the regulation of medical devices in Australia.

Chapter 5 considers government procurement arrangements in Australia, the concerns of participants on how those arrangements affect the two industries and the request of the Medical Industry Association of Australia for a further inquiry on procurement. In doing so it draws on other recent reviews relevant to government procurement and includes recommendations aimed at improving procurement policies and practices faced by suppliers of medical and scientific equipment.

Chapter 6 examines labour market issues for both industries. The main issues considered are the availability of labour and skills, and the environment in which terms and conditions of employment are determined.

Chapters 7 and 8 examine government measures of particular relevance to firms in the industries. These include those aimed at encouraging research and development, and those aimed at facilitating the access of firms to finance and improving their exporting and business management capabilities. These chapters also discuss changes to those measures introduced in the August 1996 Budget and their implications for the two industries.

Chapter 9 reviews tariffs and related arrangements, such as those dealing with tariff concessions and anti-dumping, and recommends tariffs be reduced on medical and scientific equipment imports.

Finally, Chapter 10 reviews future prospects for the industries. In doing so it describes the strengths and weaknesses of Australia as a location for production and considers some of the main influences — global and domestic — on the future development of the industries.



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## 2 MEDICAL EQUIPMENT: MARKETS AND INDUSTRY STRUCTURE

*The global market for medical equipment is highly segmented. The United States, Europe and Japan dominate global production and use of medical equipment. Globally — and in Australia — the majority of producers are small companies, although about 25 multinationals account for over half of world production. Medical equipment distributors form much the same pattern — small companies predominate but a few major companies account for the bulk of market share.*

*Australia is a mature market for medical equipment. It represents about 1 per cent of the global market, with which it is heavily integrated — most local demand is supplied by imports and the majority of production is exported.*

This chapter examines the characteristics of the global medical equipment market and the structure of the industries in the main producing countries. The Australian market and industry structure are also examined and are compared with their global counterparts.

### 2.1 Global market

The global medical equipment market comprises a wide variety of products which are highly diverse and represent a number of different segments. For example, in the United States (US) alone, which constitutes over 40 per cent of the global market, there are approximately 84 000 individual products. These form around 900 segments of naturally related products, such as mechanical heart valves and tissue heart valves. Of these segments, only 7 per cent have market potential of over \$US150 million — thus most are only modest in size (sub. 13).

International data classify medical equipment into six different product groups (see Table 2.1). Surgical and medical instruments, and hospital supplies and implantables are the two largest, accounting for over half of the global market.

Table 2.1      World medical equipment market, by product group, 1993

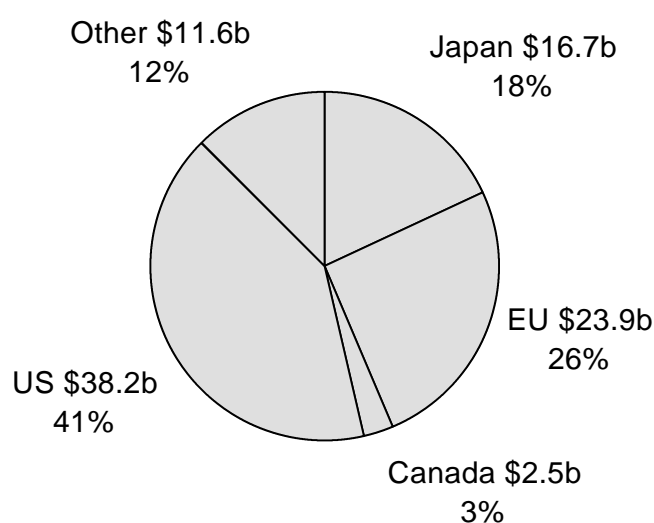
<i>Product</i>	<i>Percentage share of market</i>
Surgical and medical instruments	28
Hospital supplies and implantables	26
In-vitro diagnostics	17
Electromedical equipment	13
X-ray equipment	10
Dental equipment	6

Source: HIMA 1994

Global consumption of medical equipment was approximately \$US90 billion in 1993 (HIMA 1994).<sup>1,2</sup> This is small compared with some other products, such as pharmaceuticals with global consumption of over \$US200 billion in 1992-93 (IC 1996c).

The US, European Union (EU) and Japan are the 'big three' markets for medical equipment (see Figure 2.1). Together they accounted for 85 per cent of global consumption in 1993. A more detailed breakdown of global markets is provided in Table 2.2.

**Figure 2.1 Global market for medical equipment, 1993, \$US billion**



Source: HIMA 1994

<sup>1</sup> This includes medical consumables, devices and diagnostics.

<sup>2</sup> The latest data available.

Table 2.2 Major markets for medical equipment, 1993

<i>Country</i>	<i>Medical equip. market (\$USm)</i>	<i>Per capita GDP (\$US)</i>	<i>Population (million)</i>	<i>Health care % of GDP<sup>a</sup> (%)</i>	<i>Growth rate of market (%)</i>	<i>Per cap. consump. of equip. (\$US)</i>	<i>GDP growth rate (%)</i>
US	38 200	23 661	256	13	7	149	3
EU	23 900	19 762	346	8	5	69	-1
Japan	16 700	29 623	125	7	6	132	-1
Canada	2 500	21 826	27	10	5	94	3
<b>Australia</b>	<b>1 040</b>	<b>16 520</b>	<b>18</b>	<b>9</b>	<b>5</b>	<b>59</b>	<b>2</b>
Brazil	820	3 058	153	4	1	5	4
China	750	472	1 150	4	23	1	12
Korea	730	7 045	44	7	18	17	6
ASEAN <sup>b</sup>	659	1 248	332	—	18	2	7
Mexico	615	3 220	84	4	6	7	3
Taiwan	480	10 850	21	7	15	23	7
India	475	354	873	6	15	1	5
Hong Kong	374	15 250	6	6	17	62	8
Saudi Arabia	325	8 145	15	3	5	22	1
Argentina	270	3 193	33	4	10	8	5
Russia	220	2 563	149	3	-5	2	-14
Chile	208	3 802	14	5	15	15	6

*Notes:* equip. = equipment; Per cap. = Per capita; consump. = consumption.

*a* 1991.

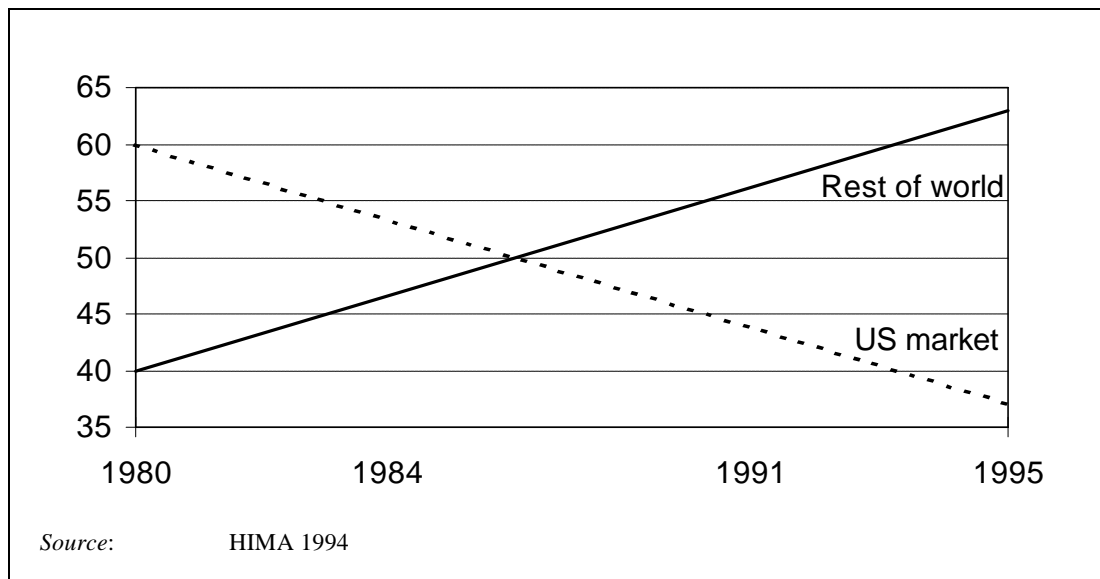
*b* ASEAN nations comprise Brunei, Indonesia, Malaysia, Philippines, Singapore and Thailand.

*Source:* sub. 13

The big three markets have experienced steady growth in recent years. For example, as shown in Table 2.2, in 1993 the US market grew by 7 per cent, the EU market by about 5 per cent and the Japanese market by about 6 per cent. Nevertheless, the relative importance of the US, EU and Japanese markets is declining — for example, the decrease in the relative size of the US market is illustrated in Figure 2.2. This trend is due to a combination of factors including:

- maturing markets — most needs for medical equipment have already been met in some countries;
- pressure on governments in Organisation for Economic Cooperation and Development (OECD) countries to contain health care budgets; and
- the growth of markets in economies undergoing rapid expansion, such as in the Asia-Pacific region, which has far outstripped growth in all of the ‘big three’ markets.

**Figure 2.2 United States market for medical equipment as a share of the global market**



As the US Health Industry Manufacturers Association (HIMA) has noted:

During the period 1985–1989, the big three markets experienced relatively strong growth, and the Asian markets were just reaching a level of wealth at which medical device consumption grows strongly. In recent years, as the major industrialised markets have been maturing and facing increasing cost-containment pressures, the developing markets of Asia have taken off. (HIMA 1994, p.3)

Countries such as China, Korea, Taiwan and Thailand are currently experiencing growth of 15–25 per cent in their consumption of medical devices, with consumption in the Asia region as a whole growing at an annual rate of 18 per cent during the period 1991–1993 (HIMA 1994, p.36).

In addition to the above markets, the markets of Hong Kong, Malaysia and India are currently growing at rates of between 15–25 per cent a year. Some Latin American countries are also emerging as rapidly growing markets for medical equipment. For example, in 1993 the Chilean market grew by 15 per cent and the market in Argentina by 10 per cent (see Table 2.2).

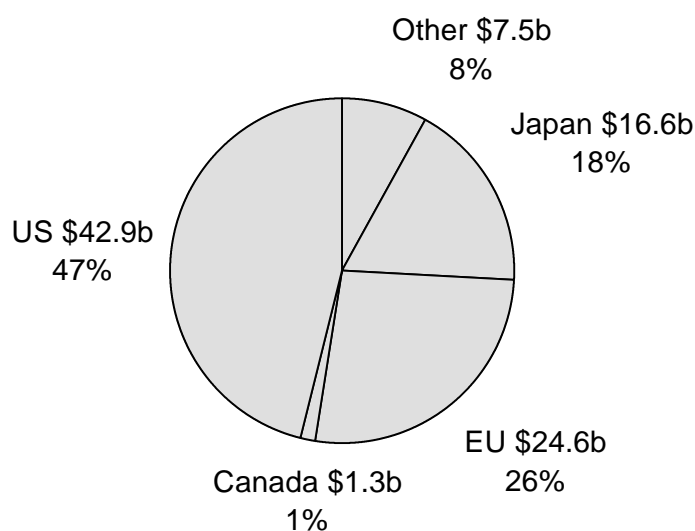
These emerging markets have considerable potential for growth as they are expanding from a low per capita consumption of medical equipment (HIMA 1992). As the economies of these countries, particularly in Asia, are predicted to continue to grow strongly, their demand for medical equipment in general is expected to increase rapidly in the immediate future.

## 2.2 Global production

US, EU and Japanese based companies are, in that order, the largest producers of medical equipment (see Figure 2.3). Companies in the US alone produce nearly

50 per cent of medical equipment globally, and production in all three accounts for around 90 per cent of world production.

**Figure 2.3 Global production of medical equipment, 1993, \$US billion**



Source: HIMA 1994

Global production of medical equipment has grown strongly in recent years, relative to overall economic growth. In 1993, production of medical equipment grew by 7 per cent, compared with an average world GDP growth rate of 1.2 per cent (HIMA 1994).

In the US, EU and Japan, locally owned and based producers supply the largest shares of their own markets (HIMA 1994). Nevertheless, foreign investment by the US industry has been substantial, and US owned companies have a significant presence in both the EU and Japan (sub. 13).

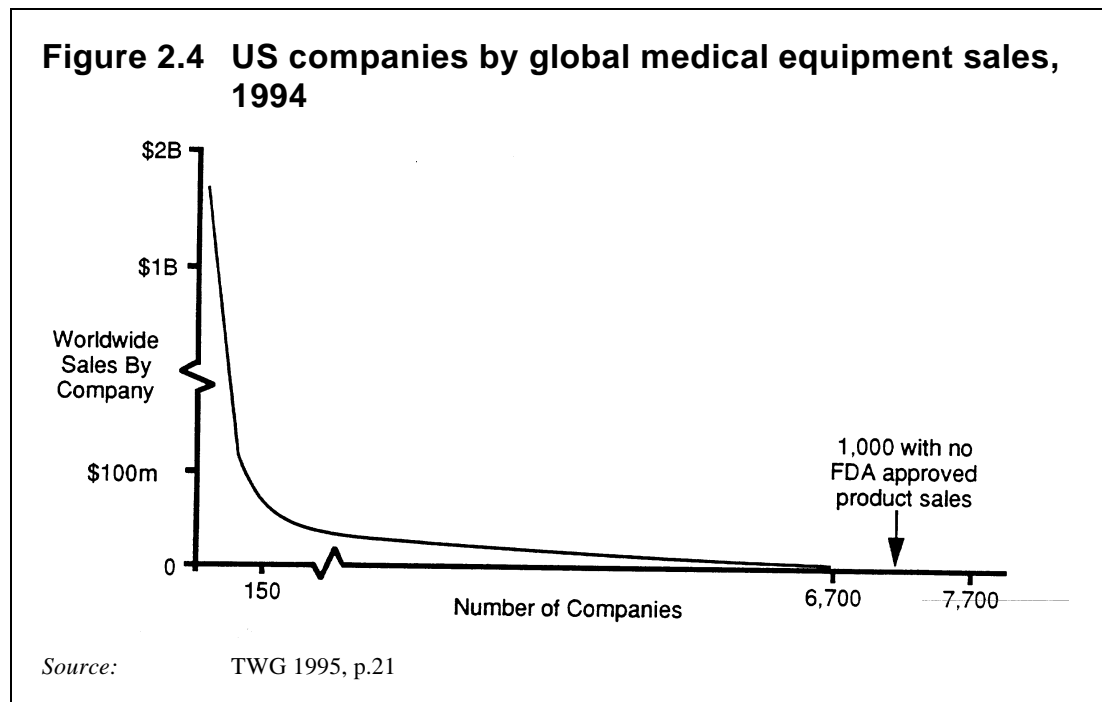
### Structure of production

Global production of medical equipment is dominated by a few large multinational enterprises. In 1993, for example, the 25 largest medical equipment companies in the world accounted for about 57 per cent of global sales (sub. 13). Of these, 13 were US-owned, illustrating the overwhelming presence of US multinationals in world production.

The structure of the US industry is broadly representative of the industry structures in the other major countries of production. The US industry is



characterised by a small number of large companies which dominate aggregate production and a large number of small-to-medium companies (see Figure 2.4).



A feature of the US industry is the number of medical equipment companies involved in other activities, including scientific equipment and pharmaceuticals. For example, Merck produces both medical and scientific equipment as well as pharmaceutical products, and Hewlett-Packard is involved in both medical and scientific equipment in addition to its main business in computers and related equipment.

US companies are competitive across the broad range of medical equipment product groups. However, they are relatively more competitive in implantable products (such products as pacemakers, heart valves and artificial joints), and in-vitro diagnostics. Japanese medical equipment companies, on the other hand, are more competitive in electromedical equipment (such as X-ray and monitoring equipment) and medical instruments. European companies are strong in the production of all types of equipment (HIMA 1994).

### **Mergers, acquisitions and strategic alliances**

A feature of the global production of medical equipment in recent years has been the considerable changes in the ownership and hence structure of production. These changes have arisen from the need for companies to reduce costs and become more competitive in order to increase market share or, in some cases, just

to survive. The outcome has been the rationalisation of global operations by some companies and, in other situations, companies have merged, acquired others or developed strategic alliances.

Recent examples of such activity include:

- the acquisition by Baxter Healthcare Corp. (US) of Psicor Inc. (US) and the subsequent formation of a joint venture with P.T. Kalbe Farma (Indonesia); and
- the sale by Tenet Healthcare Corp. (US) of its 53 per cent ownership of Australian Medical Enterprise Ltd. (Australia) to Mayne Nickless Ltd. (Australia) (BBI 1995, 1996).

The Medical Industry Association of Australia (MIAA) drew attention to the importance of linkages for medical equipment industries with the following quote from a report on the US industry:

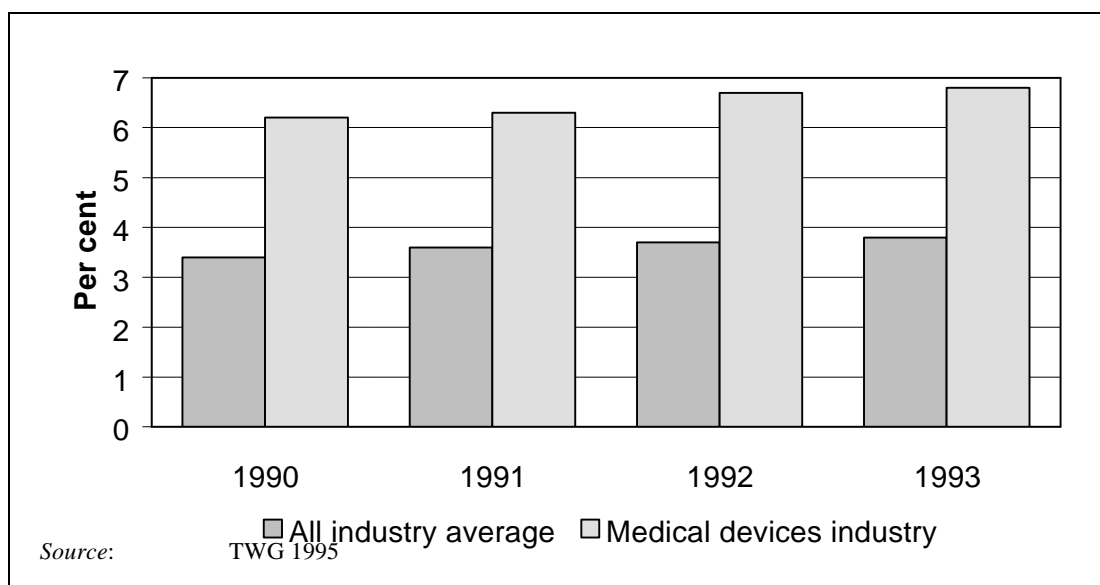
Because medical devices address highly fragmented, niche markets and utilise a wide array of specialised technology, the industry has developed a special infrastructure. This infrastructure ... relies on linkages among the industry and numerous other parties: the academic medical community, components and service suppliers, FDA [US Food and Drug Administration], payers, and investors. (sub. 13, pp.44–45)

## Research and development

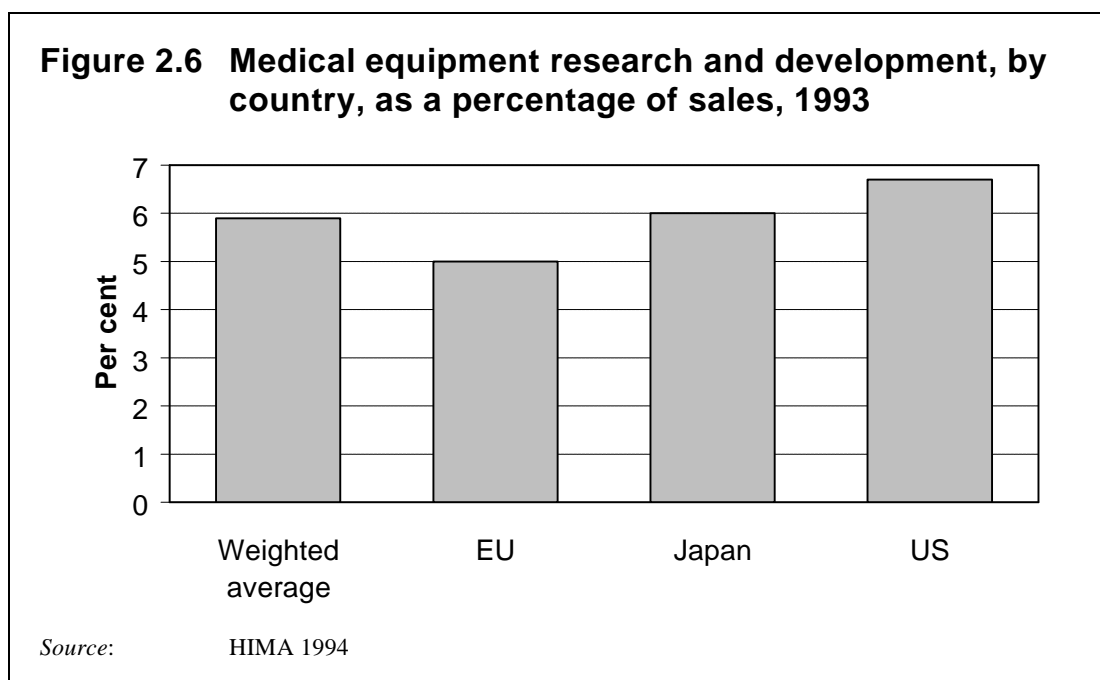
A feature of medical equipment manufacture is its high research and development (R&D) intensity compared with manufacturing in general (sub. 4). For example, over the period 1990 to 1993, the proportion of sales devoted to R&D expenditure in the US medical devices industry was significantly higher than the average for all US industries (see Figure 2.5).

US medical equipment companies also spend a greater percentage of sales revenue on R&D than companies in other high technology industries. For example, in 1992 R&D expenditure on medical products was about 7 per cent of sales which was greater than R&D expenditure in some other US industries recognised for their global competitiveness, such as the aerospace industry (4 per cent), the chemical industry (4 per cent) and the electronics industry (6 per cent) (HIMA 1994).

**Figure 2.5 Research and development spending in US industries, as a percentage of sales, 1990 to 1993**



Furthermore, US medical equipment manufacturers allocate a higher proportion of sales to R&D than do their counterparts in other major producing countries. The average of 7 per cent of sales spent on R&D by US medical manufacturers compares with 6 per cent spent by Japanese manufacturers and 5 per cent by EU manufacturers (see Figure 2.6).



Japanese manufacturers have noticeably increased their proportion of sales allocated to R&D: from an average of 4 per cent in the late 1980s to 6 per cent by

1993. Part of this increase was due to joint funding of research projects by Japanese companies and the Japanese Government (HIMA 1994).

## **2.3 Global trade**

Trade in medical equipment was estimated at over \$US22 billion in 1993 (HIMA 1994). This represents about 25 per cent of world production of \$US90 billion. Thus, any barriers to trade would have an important influence on the development of companies in the industry.

As a result of the General Agreement on Tariffs and Trade (GATT) Uruguay Round Agreement, tariff barriers in general in most countries are in the process of being substantially reduced. The Department of Foreign Affairs and Trade (DFAT) stated:

The Uruguay Round resulted in the biggest market access tariff reductions package ever achieved in GATT negotiations, being 30 times larger, in terms of trade covered, than outcomes achieved from previous negotiating rounds. In general, tariffs will be cut by between 35 and 60 per cent. (sub. 8, p.1)

DFAT listed the following results of the GATT trade liberalisation negotiations specifically relating to medical equipment:

- elimination of medical equipment tariffs in many major markets, including the US, EU, Japan, Hong Kong and Singapore;
- significant medical equipment tariff reductions in developing countries such as Malaysia, Thailand and Korea;
- the commitment of other developing countries not to raise tariffs above certain ceiling (bound) rates — more than 90 per cent of world trade will be subject to bound tariffs;
- an average global tariff cut of 63 per cent — average tariffs will fall to 2.5 per cent; and
- strengthened intellectual property rights, including limits on compulsory licensing of patents (sub. 8).

Despite the move towards tariff reduction globally, there remain some significant tariff barriers to medical equipment in a few countries, particularly in Asia. According to DFAT (sub. 8), the largest tariff barriers exist in China, Thailand, Korea and the US.

As indicated above, the US has agreed to eliminate tariffs on medical equipment. The US Government is currently in the process of reducing tariffs, and should reach duty-free status for most products by 1999. In China, on the other hand,

tariffs presently range from 3 to 70 per cent and there appears to be significant tariff escalation protecting this sector (sub. 8).

Some important non-tariff barriers to markets still remain. For example, the differing regulatory controls over medical products in different countries can act as non-tariff barriers and impede entry to some markets. The issue of international regulation of medical products and moves to harmonise the regulation of medical devices internationally are discussed in more detail in Chapter 4. Other examples of non-tariff barriers are slow payment by foreign Government purchasers, quota, licensing and control restrictions, and inadequate intellectual property protection (sub. 13, attach. 9).

## **2.4 Australian market**

There are a number of factors influencing the demand for medical equipment in Australia. According to many participants, government policy and activity in the provision of public health services is a major influence. As stated by the MIAA:

Government is not simply *a* customer of the industry; it is *the* customer, and the purchasing policies/practices of Australian healthcare authorities will be the most important single influence on the future development of the industry (sub. 13, p.3).

The MIAA (1994) survey indicates that public hospitals account for nearly 55 per cent of respondents' sales, followed by private hospitals with about 20 per cent and other professional outlets with about 10 per cent.

Results from a survey the Commission undertook of the medical and scientific equipment industries survey showed that the majority of respondents involved in medical equipment considered government health budgets to be the most important influence on domestic sales. The general level of economic activity and government procurement processes were also considered to have a major influence. The Commission's survey results are presented in more detail in Appendix L.

Other factors influencing domestic demand for medical equipment include:

- the age of medical capital equipment;
- income per capita;
- the age and health of the population — for example, with an ageing population there is an increase in the demand for medical services and equipment; and
- changes in technology — for example, newly developed synthetic materials are a low cost alternative to metals, but are less able to be re-used and are therefore higher volume products (IBIS 1995a).

## Market size and composition

The size of the Australian medical equipment market — which includes local production and imports consumed domestically — has been estimated at about \$1.1 billion in 1994-95 (HIMA 1994 and sub. 28). This represents about 1 per cent of the global market. During 1991–93, Australian consumption grew at an average annual rate of nearly 5 per cent (HIMA 1994).

Although a relatively small market, Australia's high per capita income means that a full range of medical equipment is demanded. Accordingly, a vast number of highly diverse products are available, many of which are specialised and service small market niches (sub. 28 and sub. 16).

Presented in Table 2.3 is a breakdown of the Australian medical equipment market in 1993 by product group. Of note is the broadly similar shares of the like products groups of the Australian market and those of the global market (see Table 2.1).

**Table 2.3**      Australian medical equipment market, by product group, 1993

<i>Product group</i>	<i>Percentage share of Australian market</i>
Surgical and medical instruments	27
Orthopaedic supplies	28
Diagnostic products	14
Electromedical equipment	13
X-ray apparatus/tubes	11
Dental equipment	7

*Source:*      Medistat 1995

Results from the Commission's survey indicate that in 1994-95, large medical equipment companies on average had Australian sales of \$13 million, medium companies' sales averaged \$2.5 million and small companies' averaged about \$600 000. About 43 per cent of respondent companies' Australian sales had increased by more than 25 per cent in the last three years, and for about 27 per cent of companies Australian sales had increased by less than 25 per cent. Australian sales had decreased over the last three years for about 9 per cent of respondents.

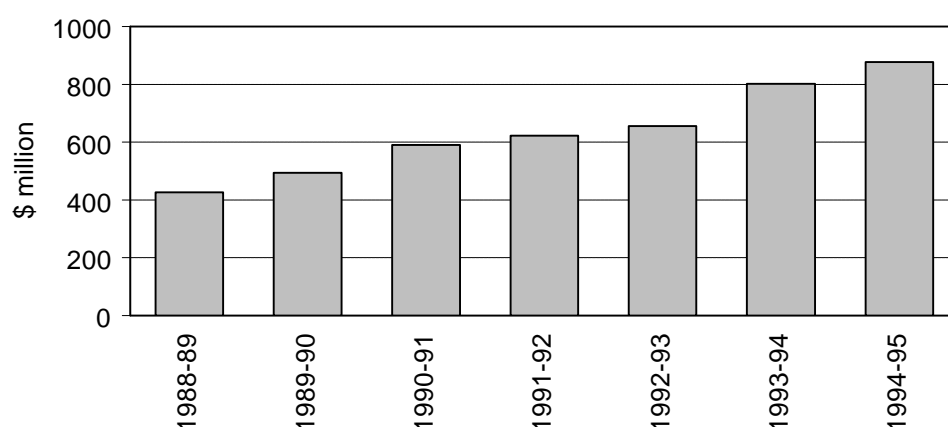
Survey respondents appeared positive about the expected trend in sales over the next three years. About 50 per cent of companies expected Australian sales to increase by more than 25 per cent, and a further 32 per cent expected an increase but by less than 25 per cent. Approximately 3 per cent of companies expected their Australian sales to decrease, but by less than 25 per cent.

## Imports

In 1994-95, total imports of medical and surgical equipment (ANZSIC 2832) were some \$955 million (ABS 1996b). However, about \$80 million were products for re-export — those that come in to and go out of the country without being either produced or consumed domestically. Therefore, the value of imports consumed domestically was about \$875 million. This represents around 80 per cent of the Australian market; the rest of which was supplied by local production.

Imports have thus supplied most of the market growth in medical equipment. Over the period 1988-89 to 1994-95, imports roughly doubled (see Figure 2.7). The rate of growth of imports over that time varied between 6 to 23 per cent a year, with an average annual rate of growth of about 13 per cent.

**Figure 2.7 Australian imports of medical equipment, 1988-89 to 1994-95**

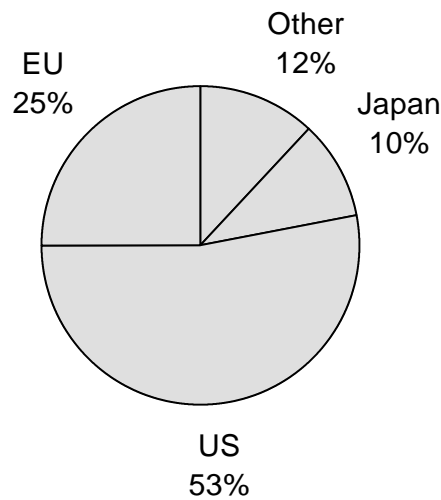


*Notes:* In 1994-95 dollars and imports excludes re-exports.  
*Source:* ABS 1996b

The source of Australia's imports corresponds broadly to the distribution of global production shown in Figure 2.3. In 1994-95, about 50 per cent of medical equipment came from the US, 25 per cent from the EU and 10 per cent from Japan (see Figure 2.8).<sup>3</sup> Imports from the US have grown at a greater rate than those from either Japan or the EU (see Figure 2.9). However, imports from 'Other' sources have grown the fastest.

<sup>3</sup> The data for imports by source do not exclude re-exports, as these figures were not readily available at such a disaggregated level.

**Figure 2.8 Australian imports of medical equipment, by source, 1994-95**



Source: ABS 1996b

## 2.5 Australian production

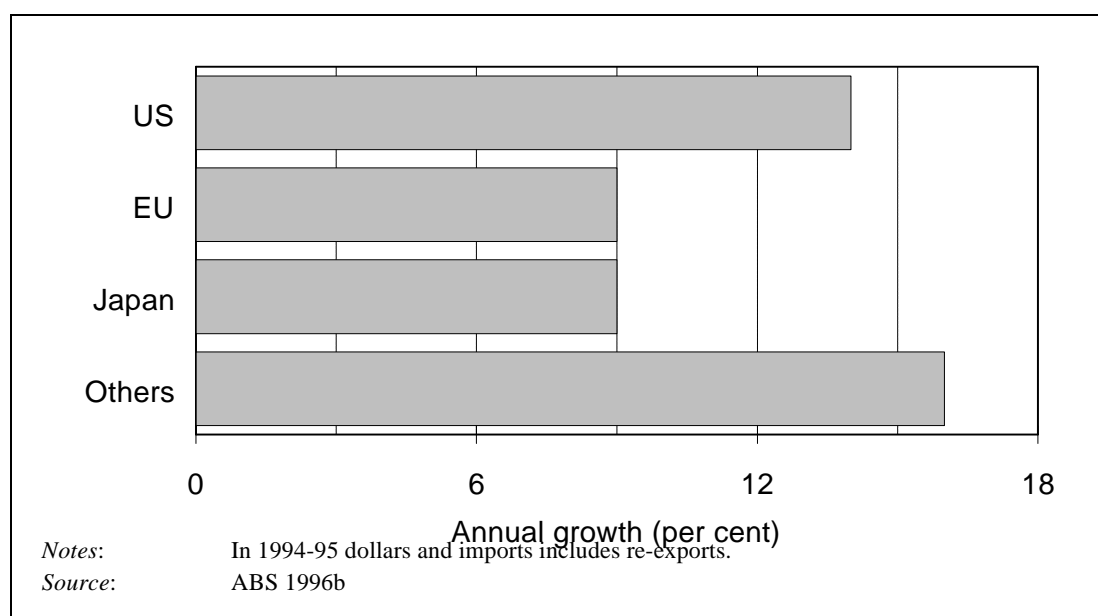
The structure of the Australian medical equipment industry is similar to that of the main producing countries, like the US. It, too, is characterised by a large number of small companies and a small number of large multinationals.

For 1995, the ABS estimated the number of management units of medical and surgical equipment manufacturers (ANZSIC 2832) in Australia at about 670.<sup>4</sup> More than 70 per cent of these management units had fewer than five employees, and more than 90 per cent had fewer than 10 (see Figure 2.10).

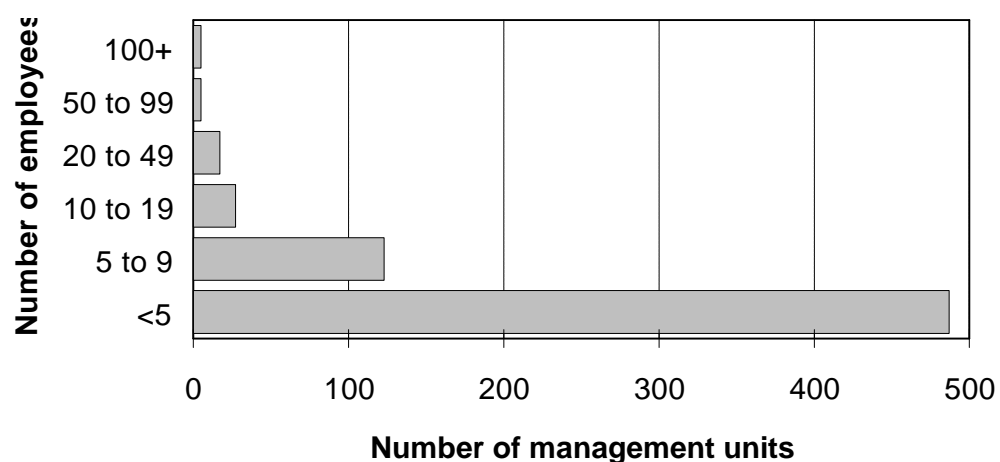
**Figure 2.9 Growth in Australian medical equipment imports, by source, 1988-89 to 1994-95**

<sup>4</sup> The ABS definition of a management unit is 'the highest-level unit within a business, having regard to industry homogeneity, for which accounts are maintained; in nearly all cases, it coincides with the legal entity owning the business ... In the case of large diversified businesses, however, there may be more than one management unit, each coinciding with a "division" or "line of business"'. (ABS 1996a, p.85)





**Figure 2.10 Medical and surgical equipment management units by number of employees, 1995**



*Source:* ABS 1995b

The MIAA believed the ABS estimate of 670 management units in ANZSIC 2832 was inconsistent with the number of licensed manufacturers registered with the Therapeutic Goods Administration (TGA). It stated:

We estimate — and I have had this confirmed in discussions with the TGA — that there are probably between 65 and 70 true manufacturers of medical devices that are required to be licensed in Australia (PH trans, p.196).

ANZSIC 2832 includes the manufacture of dentures, plates and the like by dental technicians. The ABS advised the Commission that the inclusion of these manufacturing activities would account for most of the difference in magnitude between the ABS data and the number of manufacturers of therapeutic goods registered with the TGA.

Other factors contributing to the difference could include:

- differences in the definitions of ‘management unit’ and ‘licensed manufacturer’;
- some products manufactured within ANZSIC 2832 may not be required to be licensed by the TGA; and
- some manufacturers are exempt from TGA licensing requirements (such as those in hospitals) or are not captured within the TGA’s responsibility (such as those selling only within one state).

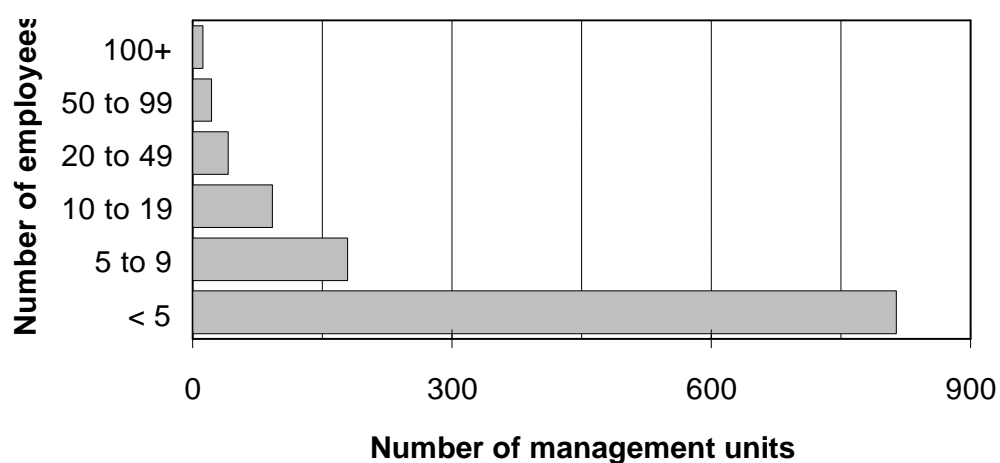
ANZSIC 2832 includes only companies whose main activity is manufacturing. The Commission recognises that a significant proportion of the medical equipment industry is made up of importers, suppliers and distributors. The Australian Bureau of Statistics (ABS) does not report statistics for these activities for medical equipment alone. The closest category is ANZSIC 4612 — professional equipment wholesaling — which includes wholesaling of medical, professional and scientific equipment.

In 1995 there were about 1160 wholesaling management units (ABS 1995b). Like manufacturing, over 85 per cent of these business units had less than 10 employees in 1995. The number of units with more than 100 employees was less than 1 per cent (see Figure 2.11). The majority of total turnover in wholesaling appears to be accounted for by these large companies which are generally Australian subsidiaries of multinationals (IBIS 1995b).

Despite the concentration of turnover in a few companies in manufacturing and wholesaling, the MIAA believe that ‘market power in the industry is dispersed rather than concentrated’ (sub. 13, p.32).

Many of the companies involved in manufacturing and importing are also involved in other activities. The MIAA (1994) survey suggests that few companies in the industry rely solely on local manufacturing of medical equipment. The results of the Commission’s survey also indicate the majority of companies in the industry are involved in more than one activity.

**Figure 2.11 Professional equipment wholesaling management units by number of employees, 1995**



Source: ABS 1995b

## Value of output

An indication of total Australian production is possible by summing published data on medical equipment exports with estimates of local production sold on the domestic market.

ABS data indicate exports of medical and surgical equipment in 1994-95 were about \$525 million. Of this figure, approximately \$80 million were re-exports. Therefore, exports of locally produced goods were around \$445 million.

The discussion in Section 2.4 suggested local production sold domestically was about \$225 million. Summing the two figures gives an estimate of local production of \$670 million. This value represents less than half of 1 per cent of total manufacturing turnover in Australia in 1994-95.

## Exports

The above estimates indicate around 65 per cent of domestic production was exported in 1994-95.<sup>5</sup> This is higher than the average for all manufacturing in the

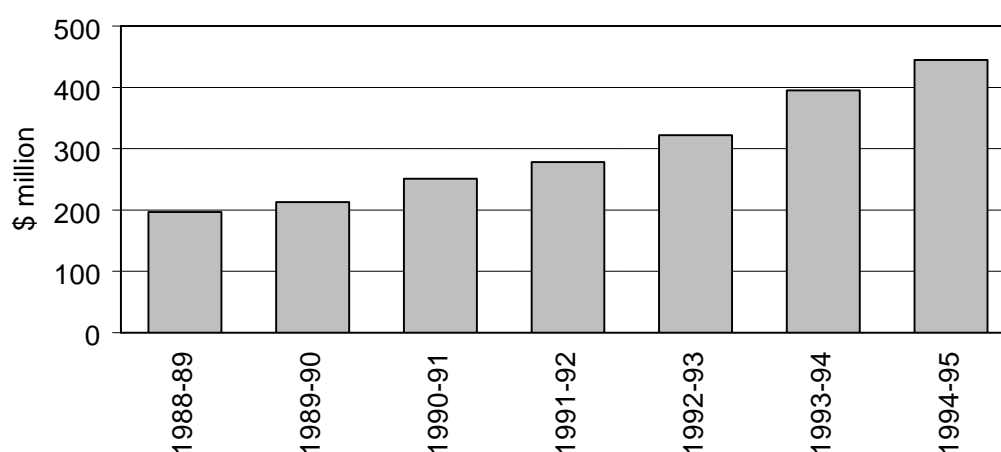
<sup>5</sup> MIAA (1994) and HIMA (1994) estimates of export orientation are significantly lower at between 30–35 per cent — this reflects their much lower estimates of export values, which are only about one-third of ABS export values.

same year, where exports represented some 12 per cent of production (ABS 1996a).

The Commission's survey results suggested that, on average, in 1994-95 exports of medical equipment from large companies were about \$2 million, from medium companies about \$545 000 and from small companies about \$55 000.

Over the period 1988-89 to 1994-95, exports of medical equipment more than doubled (see Figure 2.12). The average annual rate of growth was about 15 per cent, although the rate varied considerably within that period.

**Figure 2.12 Australian exports of medical equipment, 1988-89 to 1994-95**



*Notes:* In 1994-95 dollars and exports excludes re-exports.  
*Source:* ABS 1996b

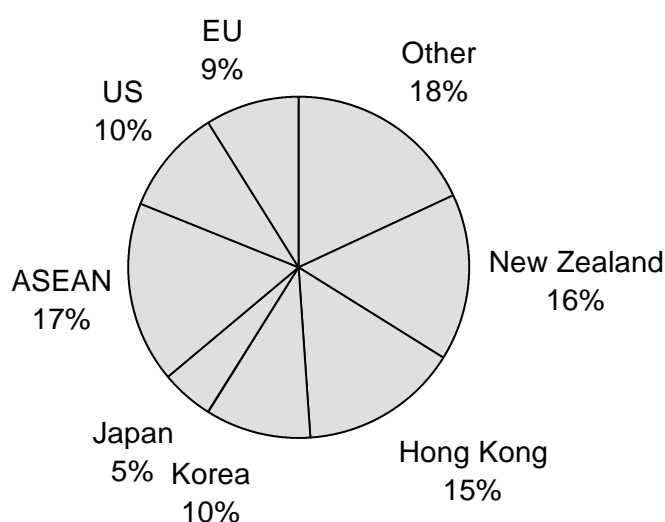
In the Commission's survey, nearly 50 per cent of the respondents involved in exporting said their exports have neither increased nor decreased in the last three years. About 33 per cent said their export sales have increased by more than 25 per cent, and about 8 per cent said their exports had increased by less than 25 per cent. The remainder said their exports had decreased; for most of these respondents the decrease was less than 25 per cent.

The majority of survey respondents were positive about the future. Approximately one third expected their export sales to increase by more than 25 per cent in the next three years, one third thought they would increase by less than 25 per cent and the remaining third expected their export sales to stay the same.

The MIAA (sub. 13) noted most exports are from a small number of companies, and make a substantial contribution to their total turnover. New South Wales State and Regional Development (sub. 28) stated that half of exports come from two companies, Cochlear and Teletronics — both subsidiaries of the Nucleus Group until Cochlear was floated in late 1995; the sale of Teletronics was announced in October 1996.

The majority of Australia's exports of medical equipment are to countries in the neighbouring region: the Association of South East Asian Nations (ASEAN), New Zealand, Hong Kong, Korea and Japan. Together these represent over 60 per cent of exports by value (see Figure 2.13).<sup>6</sup>

**Figure 2.13 Australian exports of medical equipment, by destination, 1994-95**



Source: ABS 1996b

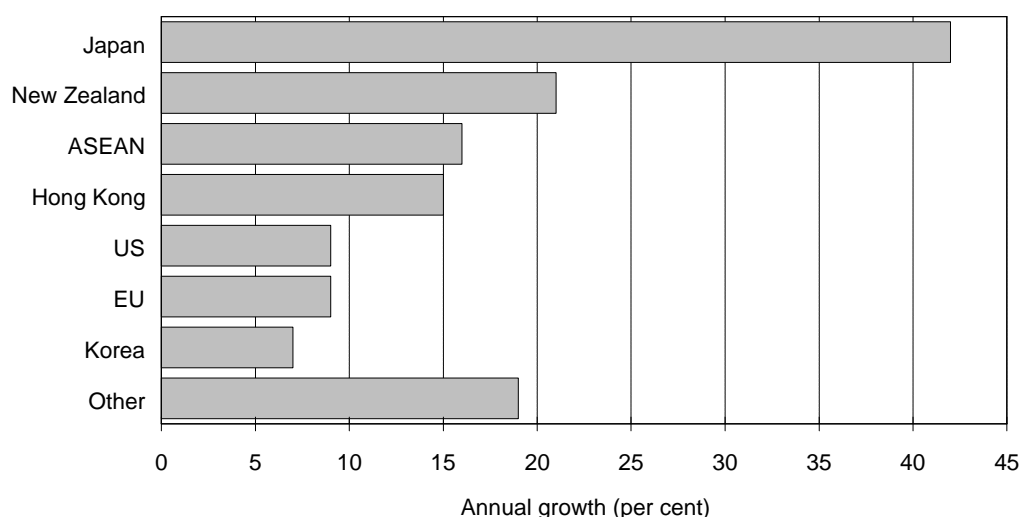
Japan is the fastest growing market for Australian exports of medical equipment. From 1988-89 to 1994-95, annual export growth to Japan averaged around 17 per cent. Over the same period, exports to each of New Zealand, ASEAN and Hong Kong increased by between 6 to 10 per cent a year (see Figure 2.14).

Given the significance of exports to Australian manufacturers of medical equipment, access to foreign markets is of importance to this industry. Section 2.3 discussed how the GATT Uruguay Round Agreement resulted in the biggest market access tariff reductions ever achieved. This has benefited

<sup>6</sup> The data for exports by source do not include re-exports, as these figures were not readily available at such a disaggregated level.

Australian suppliers with 82 per cent of Australia's medical equipment exports now allowed duty-free entry, compared with 17 per cent previously.

**Figure 2.14 Growth in Australian medical equipment exports, by destination, 1988-89 to 1994-95**



*Note:* In 1994-95 dollars and exports includes re-exports.

*Source:* ABS 1996b

## Employment

Establishments manufacturing medical and surgical equipment employed nearly 4000 people in 1993-94 (ABS 1996b). This was approximately 0.5 per cent of employment for all manufacturing industries.<sup>7</sup> Over the period from 1989-90 to 1993-94, employment fell by about 35 per cent, despite a slight increase in the final year (ABS 1996b).

Results from the Commission's survey showed the 73 medical equipment respondents employed about 2400 full-time equivalent people in 1996. Of those employed by these respondents, about 70 per cent of staff were employed on a full-time basis.

A characteristic of the labour employed in the Australian medical equipment industry is that a large proportion is skilled. ABS (1996b) data indicate that in 1995 just under 50 per cent of employees manufacturing photographic and

<sup>7</sup> By comparison, the proportion of turnover in the scientific equipment manufacturing industry was less than 0.5 per cent of all manufacturing (ABS 1996a). This indicates a relatively labour intensive industry.

scientific equipment (ANZSIC 283) — which includes medical, scientific, photographic and optical equipment — had trade, degree or higher qualifications. This compares with only 15 per cent of all manufacturing employees and 21 per cent of employees in all industries. Results from the Commission's survey also suggest there is a higher percentage of skilled labour in medical equipment companies. Labour skills are discussed further in Chapter 6.

Over 60 per cent of medical equipment manufacturers are located in New South Wales and Victoria (IBIS 1995a) — see Table 2.4. The pattern of employment generally follows the location pattern. Wholesale and distribution companies broadly follow the same location and employment pattern (IBIS 1995b).

**Table 2.4** Location of medical equipment manufacturers and industry employment in Australia, 1994

<i>Location</i>	<i>Location of companies (%)</i>	<i>Location of employment (%)</i>
New South Wales	36	42
Victoria	27	27
Queensland	13	14
Western Australia	11	8
South Australia	7	6
Tasmania	3	2
Australian Capital Territory	2	—
Northern Territory	1	—

*Note:* A dash indicates a negligible figure.

*Source:* IBIS 1995a

## Profitability

The Commission has looked at two different measures by which profitability is frequently measured — profit per employee and the capital expenditure to profit ratio. As information on these two measures is available from the ABS for only two data points, 1989-90 and 1992-93, the figures are not necessarily indicative of the change over that period. Furthermore, ABS data on profitability only include companies whose main activity involves medical equipment, and so the data may not capture the full picture of profitability in the industry.

Subject to these qualifications, the ABS data indicate profit per employee, where profit is defined as operating profit before tax and has been adjusted for inflation, decreased significantly from \$25 430 to \$860 over the period. If combined with

the decrease in employment over the same period, the data indicate a significant reduction in profit.

This decrease is also indicated by ABS data on the ratio of capital expenditure to profit. There is a substantial increase in the ratio of capital expenditure to profit between the two years, which indicates a substantial decrease in profitability.

Results from the MIAA (1994) survey generally corroborate the view that profitability of the industry is low. The survey found about 85 per cent of respondent companies made a profit in 1994. However, this figure is the highest of the five years covered by the survey. During the period 1990–1994, the number of companies making a profit in a year dropped to 70 per cent in 1990. Of those companies that made a loss in 1994, nearly 50 per cent were small companies with sales of less than \$5 million.

### **Innovation and research and development**

As in the international arena, companies in the Australian medical equipment industry compete via innovation and technology in order to maintain or increase market share. To do so generally requires companies to invest in R&D. For example, Nucleus stated:

In the area of medical equipment ... it is essential to maintain high levels of expenditure on both concept and product innovation to maintain market presence, let alone market leadership. Obsolete products do not sell in the highly sophisticated, competitive, aggressive and well informed world of the medical equipment market. (sub. 4, pp.10–11.)

According to Nucleus ‘it is necessary to spend on average between 12 to 15 per cent of sales turnover on R&D’ (sub. 4, p.11). Similarly, Diffraction Technology claimed it is essential to spend an average of 15 per cent of sales a year on new product development to keep abreast of international developments (sub. 6).

In 1992-93, R&D expenditure as a proportion of turnover for companies manufacturing medical and surgical equipment in Australia was approximately 8 per cent (ABS 1996b). This is a relatively high figure, as in the same year the corresponding figure for all manufacturing was about 1 per cent (ABS 1995a, 1996a).

Australia’s R&D intensity appears to compare favourably with that for the US industry. However, because of differing definitions of industries and what constitutes R&D, such comparisons should be treated cautiously.

R&D is discussed in more detail in Chapter 7.



## **2.6 Summary**

The global medical equipment market is diverse and segmented, with the US, EU and Japan dominating both consumption and production. The majority of producers are small companies. However, a small number of multinationals account for the bulk of production.

The Australian market represents about 1 per cent of the global market, and is highly integrated with it — about 80 per cent of consumption is supplied by imports and about 65 per cent of local production is exported. The industry is relatively knowledge intensive, and has a high R&D intensity compared with other industries.

Many of the characteristics of the global and Australian medical equipment industries are shared by the scientific equipment industry. This industry is examined in Chapter 3.

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### 3 SCIENTIFIC EQUIPMENT: MARKETS AND INDUSTRY STRUCTURE

*The global market for scientific equipment covers a diverse range of products, across the full spectrum of low technology to high technology products, that service many discrete segments. Globally, production and use of scientific equipment is concentrated in the United States, Europe and Japan. Production is dominated by a few large multinational enterprises, although most of the companies in the industry are small. Much of the industry relies heavily on technological innovation and is research and development intensive. The Australian market for scientific equipment is mature and highly integrated with the global market — most local demand is supplied by imports and the majority of production is exported.*

This chapter examines the characteristics of parts of the global scientific equipment market and the structure of the industries in the countries which dominate global production. The Australian market and industry structure are also examined, and are compared with global characteristics.

Many of the characteristics of the markets for, and production of, scientific equipment are similar to those of medical equipment, both globally and domestically (see Chapter 2). The key similarities are:

- the dominance of the United States (US), European Union (EU) and Japan in consumption and production;
- the diversity of products;
- the large number of small companies, and the significance of a few multinationals; and
- the importance of innovation, technology, and research and development.

#### 3.1 Global market

The global market for scientific equipment comprises a range of highly diverse products which comprise a number of discrete segments. Most scientific products ‘... are of comparatively high value, readily transported, and often produced in comparatively small volumes using rapidly changing technology’ (IBIS 1995c, p.6).

An indication of the range of scientific equipment was provided by the Scientific Suppliers Association of Australia (SSAA). It grouped scientific equipment into four main categories of related products: laboratory consumables, clinical diagnostics, laboratory equipment and analytical instruments. These are described in Box 3.1.

**Box 3.1      Categories of scientific equipment**

*Laboratory consumables* are products that are consumable in nature and include glassware, plasticware, general laboratory ware, filtration consumables, general laboratory reagents and solvents and chemicals.

*Clinical diagnostics* are instruments and specialist supplies such as blood and clinical chemistry analysers and related equipment.

*Laboratory equipment* are products that generally are electrically or battery operated. 'It includes balances, optical microscopes, centrifuges, ovens, water baths, glassware washers, stills, sample preparation equipment (mixers, mills) and similar items that, in the main, do not yield an analytical result' (Price Waterhouse 1995, p.10).

*Analytical instruments* are '... instruments and devices that measure a specific chemical value or a physical parameter of a substance or products, for example spectrophotometers, chromatographs, lab analysers, water analysis systems' (Price Waterhouse 1995, p.11)

Laboratory equipment and analytical instruments are generally acknowledged as scientific equipment, whereas laboratory consumables and clinical diagnostics contain some products which are not considered to be equipment, such as chemicals.

Source:                      Price Waterhouse 1995

International data on scientific equipment are limited, and mainly confined to analytical instruments. In the absence of more comprehensive data, the Commission has presented data on the global analytical instrument market. It is likely the characteristics of the production and markets of analytical instruments globally are indicative of the production and markets of scientific equipment more generally. Data has been drawn from a comprehensive report of the global market for laboratory analytical instruments produced by Strategic Directions International (SDi 1996).

Analytical instruments are usually categorised into one of eight product groups. These are shown in Table 3.1 along with their respective shares of the world market in 1994. In that year, the largest product market was liquid-phase chromatography and the smallest was mass spectroscopy.

Table 3.1 Global market for analytical instruments, 1994

<i>Product group</i>	<i>Market size (\$USm)</i>	<i>Share of global market (%)</i>
Liquid-phase chromatography	1 950	21
Molecular spectroscopy	1 362	15
Gas-phase chromatography	1 239	13
Molecular bioinstrumentation	1 168	13
Surface sciences	995	11
Atomic spectroscopy	960	10
Physical properties	558	6
Mass spectroscopy	322	3
Other	777	8
<b>Total market</b>	<b>9 331</b>	<b>100</b>

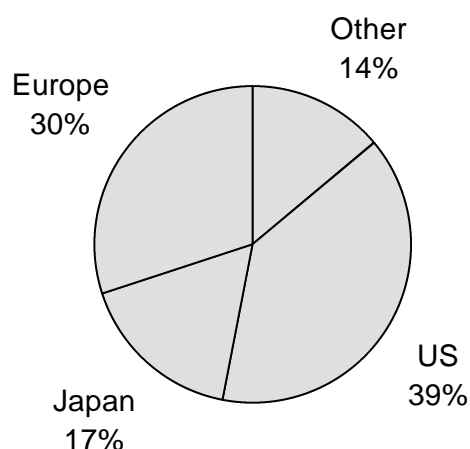
Source: SDi 1996

Global sales of analytical instruments in 1994 were approximately \$US9.3 billion, rising to between \$US10–11 billion in 1995 (Wilkinson 1996). This reflects an ongoing increase in global demand for analytical instruments in recent years. From 1989 to 1994, global sales grew at an average annual rate of about 6 per cent (SDi 1996). In 1995, sales grew an estimated 8–10 per cent (Wilkinson 1996).

As for medical equipment, the traditional and largest markets for analytical instruments are the US, Europe and Japan (see Figure 3.1). In 1994, the US represented almost 40 per cent of the global market, Europe approximately 30 per cent and Japan about 17 per cent (SDi 1996).

However, participants at the roundtable discussions considered that growth in most of the traditional markets for scientific equipment is currently subdued. The European market, the second largest market for analytical instruments, is in recession, while the large US and Japanese markets are expected to experience relatively low rates of growth.

Most of the current growth in the global market for analytical instruments appears to be in the smaller, but rapidly expanding, markets in Asia (excluding Japan) and Latin America. The growth in these emerging markets is due to a combination of growth in population and living standards, and reductions in protection. Their potential also lies in the fact that they are growing from a low usage of scientific equipment per head of population. The Latin American market is currently valued at \$US205 million a year, and is expected to grow at a rate of nearly 13 per cent a year through to 2000 (SDi 1996). Asian nations (excluding Japan) are expected to increase their demand for scientific equipment by nearly 11 per cent a year from 1994 to 2000 (SDi 1996). The largest markets are Korea and China; Taiwan is also significant.

**Figure 3.1 Global market for analytical instruments, 1994**

Source: SDi 1996

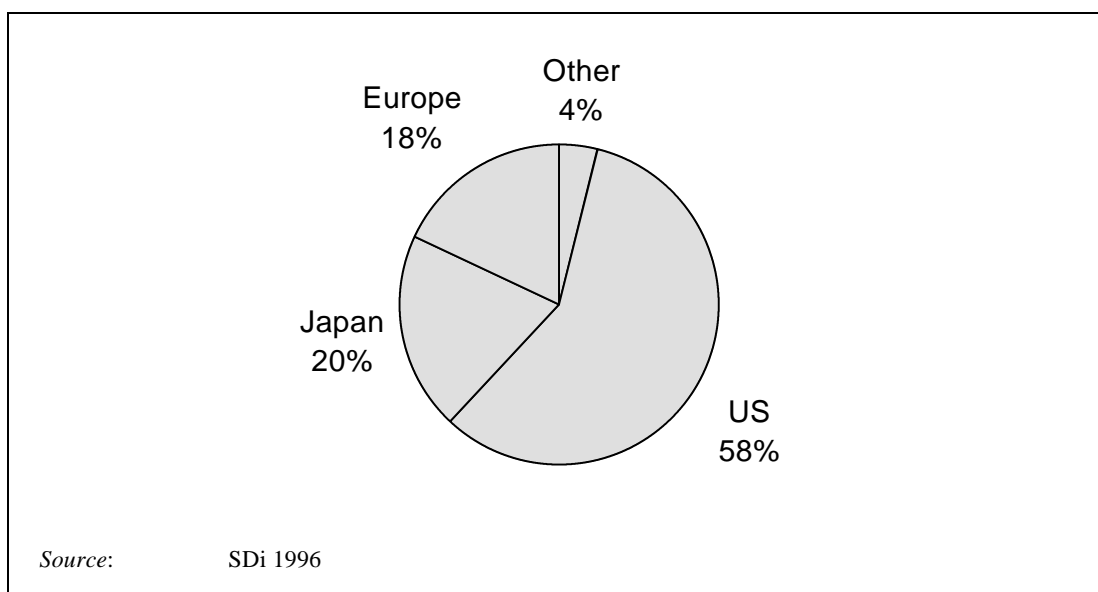
Participants at the scientific equipment roundtable believed the Eastern European market will exhibit strong growth in the latter half of the 1990s. Their reasons included the greater integration, both culturally and economically, between Western and Eastern Europe and the expected general increase in investment in Eastern Europe.

### 3.2 Global production

US companies are by far the largest producers of analytical instruments, and supplied an estimated 58 per cent of the world market in 1994 (see Figure 3.2). European and Japanese companies supplied roughly equal shares of about 20 per cent. Within Europe, German companies are the major manufacturers.

US and Japanese producers have a strong hold on their domestic markets, supplying about 80 per cent and 65 per cent of their respective local markets. European companies supply approximately 35 per cent of the European market for analytical instruments (SDi 1996).

**Figure 3.2 Global production of analytical instruments, 1994**



### Structure of production

A host of new entrants came into the global analytical instrument industry during the 1980s, spawned by innovation and rapid changes in technology. This trend has continued into the 1990s. However, overlaying this influx has been the recent move to industry consolidation in mature segments of the market. These two trends have led to global production being dominated by about 30 companies.

Analytical instrument companies may be classified according to whether they are broad-line, multiproduct or specialised producers (See Box 3.2). The top 10 manufacturers of analytical instruments in 1993 are presented in Table 3.2. The figures shown are for instrument sales only.

Information on the top 30 companies in 1993 showed their headquarters were either located in the US (11), Japan (7) or Europe (12). Although US companies accounted for just over one third of the top 30 companies, they were responsible for around 50 per cent of the sales of those companies (SDi 1996).

In 1995, the top four suppliers accounted for about 30 per cent of the market while the top 30 accounted for around 80 per cent (Wilkinson 1996 and SDi 1996). The structure of analytical equipment production is thus similar to that of medical equipment — both have a relatively small number of large companies accounting for the majority of sales, and a large number of small companies.

Another feature shared with medical equipment companies is the dominance of a few companies in distribution. For example, in 1995 three companies — Fisher

Scientific, Merck and VWR Scientific Products — distributed around 30 per cent of global sales of analytical instruments.

**Table 3.2** Top ten global analytical instrument companies, 1993

<i>Company</i>	<i>Company type</i>	<i>Strategic focus</i>	<i>Sales (\$USm)</i>
1. Perkin–Elmer	Broad–line	Life sciences	1 045
2. Hewlett–Packard	Multiproduct	Chromatography / Mass spectrometry	815
3. Shimadzu	Broad–line	Industrial applications	785
4. Thermo Electron	Broad–line	Spectroscopy / Mass spectrometry	745
5. Hitachi	Broad–line	Research applications	465
6. Fisons	Multiproduct	Atomic spectroscopy / Mass spectrometry	405
7. Varian	Multiproduct	Molecular spectroscopy / Nuclear magnetic resonance spectroscopy	400
8. Pharmacia	Multiproduct	Life sciences	390
9. JEOL	Multiproduct	Surface science research	345
10. Waters Corp.	Specialised	High performance liquid chromatography	315

*Source:* SDi 1996

### **Box 3.2** Classification of instrument companies

*Broad–line companies* manufacture a wide range of products across several categories, although they may focus on a few technologies. Only a small number of instrument companies qualify as broad–line manufacturers: Perkin–Elmer, Shimadzu, Hitachi, Varian Associates, Thermo Instrument Systems and Fisons Scientific Instrument Group.

*Multiproduct companies* are more narrowly focused in their activities, with product lines centred around a single category of instrumentation. Examples are Hewlett–Packard, Waters, Beckman, Pharmacia, Bio–Rad, Philips Analytical, Perstorp, Oxford Analytical and Mettler.

*Specialised instrument companies* limit their activities to one instrument category and also, generally, to one technology. Siemens is an example of a specialised instrument company, limiting its laboratory analytical instrument manufacturing to X–ray fluorescence spectrometers and X–ray diffractometers.

*Source:* SDi 1996

## **Innovation and research and development**

The scientific equipment industry is heavily knowledge based and companies rely on innovation to differentiate themselves in the market place and remain competitive (sub. 17). As a result a feature of the industry is a high level of expenditure on research and development (R&D).

The average proportion of sales spent on R&D for companies involved in analytical instrument production is about 9 per cent (SDi 1996). Although

comparisons with other industries are difficult, due to the possibility of differing definitions of R&D, this figure is higher than that for the global medical equipment industry (7 per cent) and more than double the average for all US industries (HIMA 1994).

### **Profitability**

In the 1980s, strong growth in the major economies of the world translated into strong growth in the analytical instrument industry. Operating profitability in the mid to late 1980s was about 10 per cent of sales. However, reduced economic growth in the major economies caused profitability to fall to just over 8 per cent in 1995 (SDi 1996).

Global profitability appears to have generally improved more recently, 'as companies have been forced to implement more sensible pricing policies, cut unnecessary expenditures, boost productivity and improve company-wide operating performance' (Wilkinson 1996, p.1).

Within the analytical instruments industry, US companies are the most profitable. One possible reason is US companies are generally larger than their European and Japanese counterparts, and sales for small companies have been found to be more erratic than for larger companies (SDi 1996).

### **Mergers, acquisitions and strategic alliances**

Mergers and acquisitions are an important feature of the global production of analytical instruments. In 1995, world wide mergers and acquisitions were valued at almost \$US1.3 billion, or over 10 per cent of the total value of all analytical instrument businesses (Wilkinson 1996 and SDi 1996).

Over the last 5 to 10 years, many specialised analytical instrument companies have been taken over by larger companies. An example is the acquisition by Thermo of Finnigan, which specialised in mass spectrometers (SDi 1996).

In 1993, Perkin-Elmer purchased Applied Biosystems and became the first analytical instrument company with annual revenue in excess of \$US1 billion. In February 1995, Thermo announced the purchase of the instrument businesses of Fisons. After absorbing Fisons, Thermo should be slightly larger than Perkin-Elmer, so that there will be two \$US1 billion companies producing analytical instruments (SDi 1996).

The formation of alliances is also a characteristic of companies involved in the analytical instrument business, with over 100 such arrangements estimated to occur each year (SDi 1996). For example, in 1995 Waters and Gelman Sciences



formed a strategic alliance under which Waters will be the worldwide marketing agent for some of Gelman's microfilters for high performance liquid chromatography; Perkin-Elmer agreed to have Fisher Scientific distribute some of its products; and PerSeptive Biosystems formed a strategic alliance with Boehringer Mannheim in which Boehringer Mannheim will share the distribution rights for a PerSeptive product, and the two companies will conduct joint R&D on biochemical products.

### **3.3 Global trade**

Trade in analytical instruments in 1993 was estimated at approximately \$US4.2 billion, representing about 45 per cent of world production of \$US9.3 billion (SDi 1996). Thus, any barriers to trade have an important influence on the development of companies in the industries.

As a result of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) negotiations, tariff barriers in general in most countries have been substantially reduced. The Department of Foreign Affairs and Trade (DFAT) stated:

The Uruguay Round resulted in the biggest market access tariff reductions package ever achieved in GATT negotiations, being 30 times larger, in terms of trade covered, than outcomes achieved from previous negotiating rounds. In general, tariffs will be cut by between 35 and 60 per cent. (sub. 8, p.1)

DFAT lists the following results of the GATT trade liberalisation negotiations specifically relating to scientific equipment:

- significant tariff cuts in many major markets — the average cut in tariffs is 47 per cent;
- commitments (bindings) against future tariff increases in a number of growing markets; and
- stronger intellectual property protection, including limits on compulsory licensing of patents (sub. 8).

Despite the move towards tariff reduction globally, there remain some significant tariff barriers to scientific equipment in a few countries, particularly in Asia. According to DFAT (sub. 8), the largest tariff barriers exist in China, Thailand, Korea and the US. The US is in the process of reducing its tariffs and should reach duty-free status for most products by 1999. By contrast, tariffs in China presently range from 3 to 70 per cent and there appears to be significant tariff escalation protecting this sector (sub. 8).

Some non-tariff barriers still exist. Examples are slow payment by foreign Government purchasers, quota, licensing and control restrictions, and inadequate intellectual property protection (sub. 13, attachment 9).

### **3.4 Australian market**

Australian Bureau of Statistics (ABS) data suggest that the Australian market for scientific equipment is similar in size to that for medical equipment. However, available international data suggest that the global market for scientific equipment is less than half the size of the global medical equipment market. If this is the case, it would mean the Australian scientific equipment market comprises a larger proportion of its total global market than is the case for medical equipment.

The SSAA did not believe this is the case. It stated:

We are aware of no circumstances that would see the ratios of the two industries relevant to each other, be any different in Australia than to the global market (sub. 63, p.3).

The SSAA comments highlight the difficulties in obtaining comprehensive, comparable and accurate data on the industries under reference.

Furthermore, the SSAA did not agree with the Commission's definition of *scientific equipment* used in describing the Australian market and industry structure — see Box 3.3 for a discussion of this issue.

While a range of factors affect the demand for scientific equipment in Australia, the most important are government policy and government purchases of equipment. For example, the SSAA (1995) survey suggested that close to 60 per cent of domestic demand for all categories of scientific equipment is

**Box 3.3 Definition of scientific equipment**

In response to the Draft Report, some participants claimed that the definition of *scientific equipment* adopted by the Commission was inappropriate. For example, the SSAA argued that it was too broad and as such the market and production of what it considered constituted scientific equipment had been overestimated. It believed the broad definition used by the Commission was more accurate for *scientific products*.

The definition used in the Draft Report included a range of technical equipment not necessarily used in scientific laboratories, such as process analysis and control instrumentation and test and measurement instrumentation. The SSAA considered that these did not constitute *scientific* equipment. Similarly, the definition included consumables, the majority of which the SSAA considered did not constitute scientific equipment.

In the absence of specific direction in the Terms of Reference, the Commission deliberately adopted a broader definition of scientific equipment than that preferred by the SSAA. It did so for a number of reasons:

- in considering a wide range of products and activities there was less risk of excluding relevant parts of the industries. Within the scientific equipment industry itself there was evidence of differing opinions of what is scientific equipment. For example, Crown Scientific disagreed with the SSAA's definition. It stated:

We have taken argument before to the SSAA that indeed ... we do not believe that their categories of scientific equipment are consistent with the products that are supplied within the market (sub. 57, p.3);

- the only comprehensive official data were ABS data. However, their availability was at a level of aggregation that was wider than the SSAA's narrower definition of scientific equipment; and
- it was useful to align the definition with that adopted by the previous Industries Assistance Commission inquiry into the two industries — this inquiry covered measuring, professional, scientific, dental, veterinary and medical equipment, appliances and parts.

Nevertheless, the Commission acknowledges the concerns expressed by the SSAA regarding the definition of scientific equipment adopted in this inquiry. Where possible, the SSAA's views on market and industry sizes according to its narrower definition has also been presented.

from government funded or subsidised organisations or government departments. It stated:

The extraordinary high level of government users in Australia (probably higher than in any other OECD economy), reveals the vulnerability of the whole scientific supply industry to any reduction in government funding for science (SSAA 1995, p.63).

The Commission's survey showed that the majority of respondents involved in scientific equipment considered the general level of economic activity to have the

most important influence on domestic sales. This was followed by government budget allocations for research and government budget allocations for health.

Other important factors affecting the size and rate of growth of the Australian scientific equipment market are changes in general economic activity in the economy and changes in technology.

### **Market size and composition**

The value of domestic sales — which includes local production and imports sold domestically — was estimated at about \$1 billion in 1993-94 (IBIS 1995c).<sup>1</sup> The same data source estimated the value of domestic sales one year later, in 1994-95, at about \$1.5 billion — an increase of 50 per cent.<sup>2</sup> Infocom (1996) gave a similar estimate for sales in 1995. An increase in demand of this magnitude is inconsistent with all other available information regarding the recent performance of the industry, and the figures are an indication of the poor data available.

The SSAA disagreed with the 1994-95 estimates of domestic sales of \$1.5 billion. According to its own survey of its members and data from a variety of sources, it estimated that domestic sales in 1994 were \$830 million (sub. 63) — this is of a similar magnitude to the IBIS estimate for 1993-94 of \$1 billion. The SSAA called into question the reliability of the data provided by Infocom (1996). It commented:

A comparison of the data included in the National Trade Data Bank [Infocom] figures for Australia, the United Kingdom and Germany show substantial anomalies, that put into question this data (sub. 63, p.3).

This comment is further indication of the poor data available.

Results from the Commission's survey suggest that in 1994-95 large scientific equipment companies on average had Australian sales of \$5 million, medium companies' Australian sales averaged \$2.6 million and small companies' averaged about \$600 000.

As with the global market for scientific equipment, the Australian market is highly segmented. However, available data sources only describe broad categories of equipment. The composition of scientific equipment sold in Australia in 1994 is suggested by the figures in Table 3.3. The first set of figures is based on data received from 30 respondents to a questionnaire issued by the SSAA to its members. The second set is the SSAA's estimates based on both the questionnaire results and additional data collected from a variety of sources. For

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<sup>1</sup> Based on an exchange rate of US\$0.75 = A\$1.00.

<sup>2</sup> Over a longer period, from 1981-82 to 1994-95, it estimated real average annual growth was just over 4 per cent (IBIS 1995c).

analytical instruments and laboratory equipment, these estimates markedly change the domestic market shares compared with those suggested by the respondents to the questionnaire.

**Table 3.3** Australian scientific equipment market, 1994

<i>Product</i>	<i>Share of domestic market</i>	
	<i>Questionnaire results</i>	<i>SSAA estimates</i>
	(%)	(%)
Analytical instruments	34	17
Clinical diagnostics	21	27
Laboratory consumables	19	19
Laboratory equipment	18	29
Service revenues	8	8

*Source:* SSAA 1995

Not all clinical diagnostics and laboratory consumables are as scientific equipment. Hence it is likely the market shares shown in Table 3.3 overestimate the share for these product groups and underestimate the share held by the remaining products, with respect to the total scientific equipment market.

In its survey, the Commission sought information on recent past and projected future changes in domestic sales in its survey. The results indicated that for 44 per cent of respondent companies, Australian sales had increased by more than 25 per cent in the last three years; for 20 per cent of companies, Australian sales had increased by less than 25 per cent. Sales had stayed the same for about 22 per cent, but had decreased for 14 per cent of respondents — for the majority of these by less than 25 per cent.

For expected domestic sales over the next three years, 82 per cent of respondents expected their Australian sales to increase — of these, nearly 45 per cent expected an increase of greater than 25 per cent.

## Imports

Imports of professional and scientific equipment (ANZSIC 2839) in 1994-95 were about \$1.75 billion (ABS 1996b). About \$105 million of those imports were products for re-export — those that come in and go out of the country without being either consumed or produced domestically — so the value of imports consumed domestically was estimated to be about \$1.65 billion. However, this is greater than the estimates of total market size noted above. One possible cause of the discrepancy is that ANZSIC 2839 contains some items which would not be classified as scientific equipment, such as optical fibre cable.

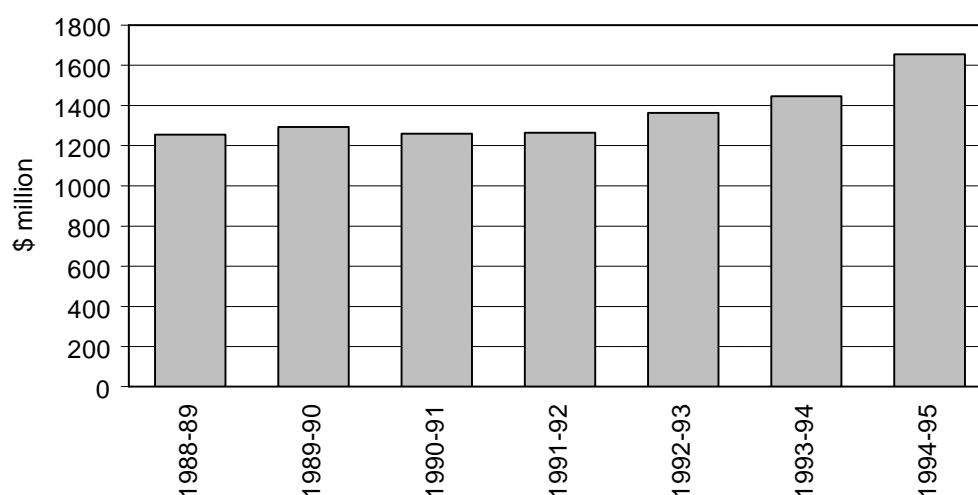
The SSAA also disagreed with the import figure of \$1.65 billion. Its estimate for 1994 of imports of scientific equipment, excluding re-exports, was only

\$713 million (sub. 63, p.4). The majority of the difference in these estimates is most likely due to the different definitions of scientific equipment discussed earlier. It could also partly be a result of import growth between 1994 and 1995.

Although the proportion of domestic demand met by imports is not available from official data, industry estimates suggest that the proportion is just under 90 per cent (Infocom 1996 and SSAA 1995).

ABS data indicated that for the period 1988-89 to 1994-95 imports (at constant prices) increased by just over 30 per cent (see Figure 3.3). The rate of growth varied over that time, from a decrease of 3 per cent to an increase of 15 per cent, with an average annual rate of growth of about 5 per cent.<sup>3</sup>

**Figure 3.3 Australian imports of scientific equipment, 1988-89 to 1994-95**



*Notes:* In 1994-95 dollars and imports excludes re-exports.

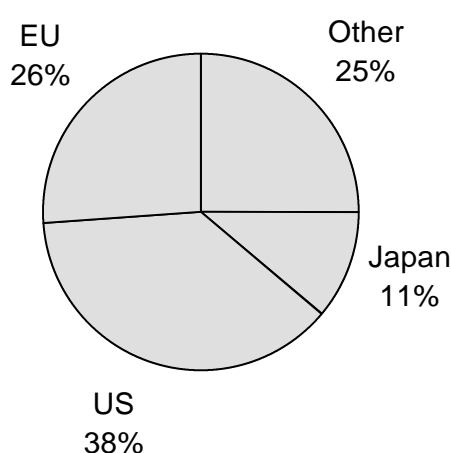
*Source:* ABS 1996b

An indication of the composition of equipment imported is available from the SSAA (1995) survey. Of the products imported by survey respondents, 37 per cent were analytical instruments, 22 per cent were clinical diagnostics, 17 per cent were laboratory equipment and 16 per cent were laboratory consumables. These shares are similar to the product shares for aggregate demand.

<sup>3</sup> These ABS data can not be directly compared with time series data from the SSAA (1995) survey, as the latter do not take account of either exchange rate differences or inflation.

The sources of Australia's imports of scientific equipment are given in Figure 3.4 for 1994-95. In that year, 75 per cent of imports came from the US, EU and Japan. Imports of scientific equipment from 'Other' countries and the US both grew at the fastest rates over the period 1988-89 to 1994-95 (see Figure 3.5). Imports from Japan decreased over the period, at an average annual rate of about 1.2 per cent.

**Figure 3.4 Australian imports of scientific equipment by destination, 1994-95**

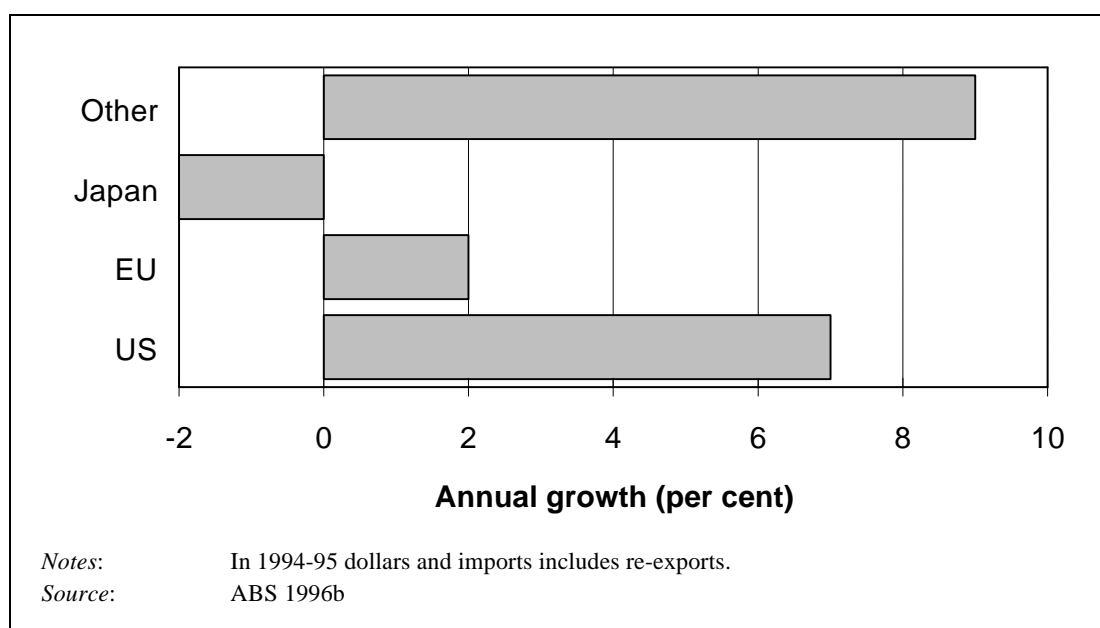


Source: ABS 1996b

### 3.5 Australian production

The structure of the industry producing scientific equipment in Australia broadly reflects that of the main producing countries, like the US. It is characterised by a large number of small companies and a small number of multinationals — a characteristic it shares with the medical equipment industry.

**Figure 3.5 Growth in Australian scientific equipment imports, by source, 1988-89 to 1994-95**



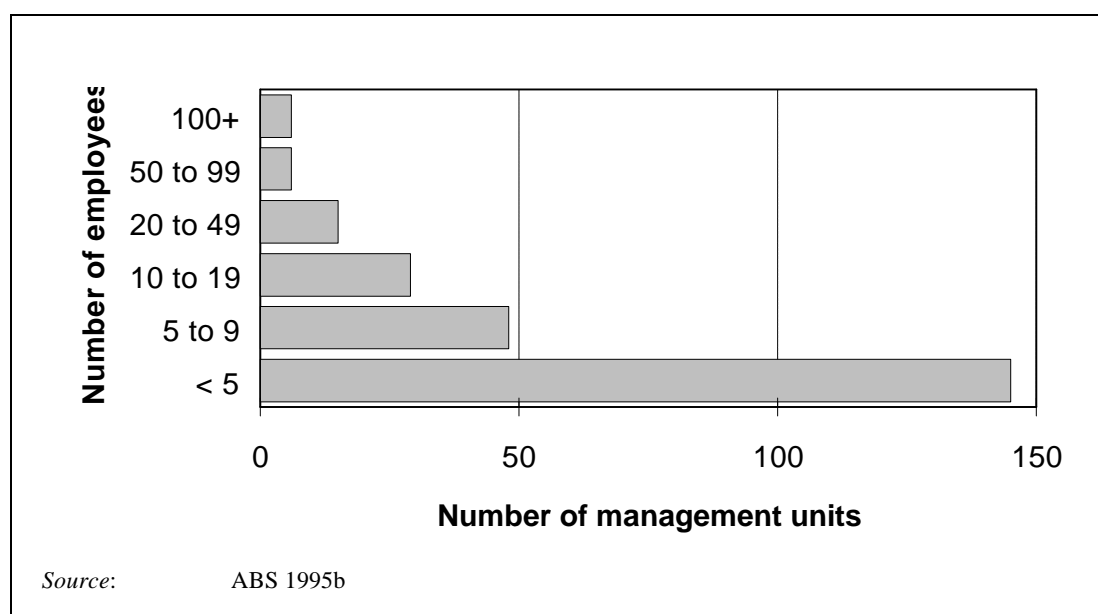
In 1995, the number of management units classified as manufacturing professional and scientific equipment in Australia (ANZSIC 2389) was around 250 (ABS 1995b).<sup>4</sup> More than 55 per cent of these had fewer than five employees, and more than 75 per cent fewer than 10 employees. Five management units had more than 100 employees (see Figure 3.6).

ANZSIC 2839 does not include companies whose main activity is not manufacturing. The Commission recognises a significant proportion of the scientific equipment industry is made up of importers, suppliers and distributors. The ABS does not report separate statistics for these activities for scientific equipment. The closest category is professional equipment wholesaling (ANZSIC 4612). This category includes wholesaling of medical, professional and scientific equipment. ABS estimates showed that the structure of management units in this category was similar to those manufacturing professional and scientific equipment and also to those manufacturing medical and surgical equipment (see Chapter 2).

**Figure 3.6 Professional and scientific equipment manufacturing management units by number of employees, 1995**

<sup>4</sup> The ABS definition of a management unit is 'the highest-level unit within a business, having regard to industry homogeneity, for which accounts are maintained; in nearly all cases, it coincides with the legal entity owning the business ... In the case of large diversified businesses, however, there may be more than one management unit, each coinciding with a "division" or "line of business" ' (ABS 1996a, p.85).





A number of the companies involved in scientific equipment are also involved in other activities, such as producing medical equipment; for example, Hewlett-Packard and Varian. This observation is supported by the results of the Commission's survey which indicate the majority of companies in the industry are involved in more than one activity.

### Value of output

An indication of total Australian production is possible by summing published data on scientific equipment exports with estimates of local production sold on the domestic market.

ABS data indicated that exports of professional and scientific equipment (ANZSIC 2839) in 1994-95 were about \$405 million. Of this figure, approximately \$105 million were re-exports. Therefore, exports of locally produced goods were around \$300 million.

Estimates from the SSAA (1995) and Infocom (1996) suggested that local production supplied around 10 per cent, or some \$150 million, of domestic sales of scientific equipment in 1995. Summing the two figures gives total domestic production of \$450 million in 1994-95, which represents less than half of one per cent of all manufacturing turnover in that year. This value corresponds with Infocom (1996) estimates of local production in 1995 of \$450 million.<sup>5</sup>

<sup>5</sup> Based on an exchange rate of US\$0.75 = A\$1.00.

The SSAA estimate of local production for its definition of scientific equipment is lower than the above. It suggested a figure of about \$260 million in 1994, of which about \$100 million was local sales (sub. 63).

Infocom (1996) estimates suggest that local production of scientific equipment has grown at rates of around 5 per cent since 1994. The Centre of Policy Studies estimated that the average growth rate in output of scientific equipment over the period 1986-87 to 1994-95 was 6 per cent (CoPS 1995). The Centre predicts a similar increase will occur over the period 1994-95 to 2002-03.

## **Exports**

The output estimates presented above indicate that around 65 per cent of domestic production of scientific equipment was exported in 1994-95. This is higher than the average for all manufacturing of 12 per cent of production (ABS 1996a).

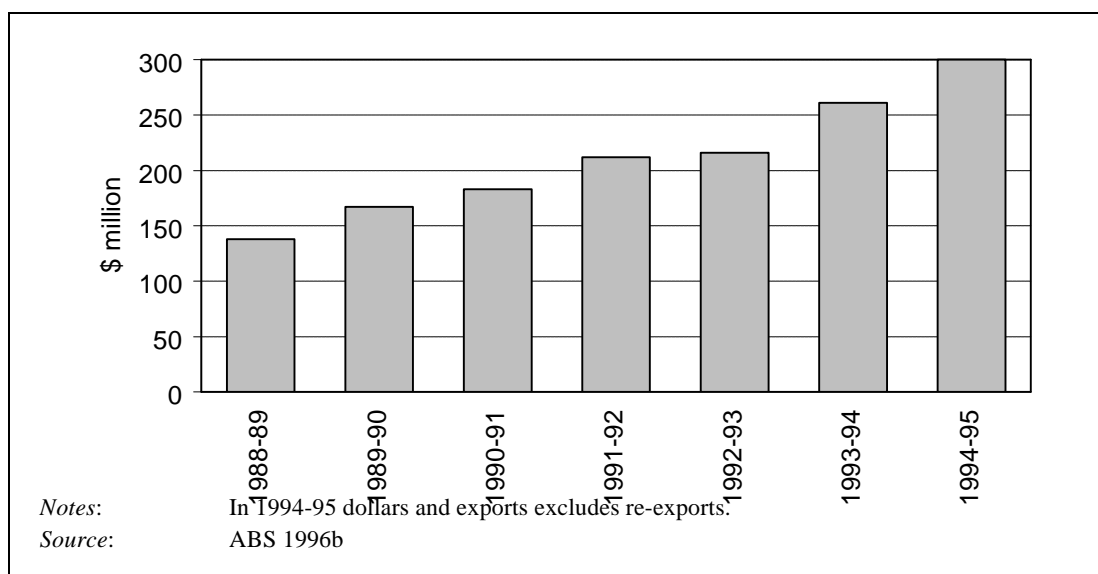
The Commission's survey indicates that, on average, large scientific equipment companies exported \$306 000 of equipment in 1994-95, medium companies averaged about \$1.1 million and small companies about \$50 000. The relatively small amount of exports by the large companies is most likely due to the fact that many are multinationals who primarily import from parent companies overseas, and do little manufacturing in Australia.

Over the period 1988-89 to 1994-95, Australian exports of scientific and professional equipment (in constant prices) roughly doubled (see Figure 3.7). The average annual rate of growth during the period was about 14 per cent, although considerable variation occurred within that period.

The Commission's survey results indicated that 41 per cent of respondents involved in exporting have increased their exports in the last three years — half by more than 25 per cent and half by less than 25 per cent. Export sales had remained the same for 56 per cent of respondents. For the remaining 3 per cent of respondents exports had decreased, but by less than 25 per cent.

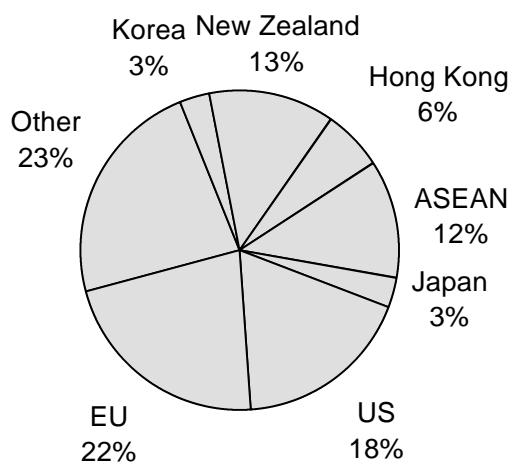
Respondents had mixed views about the future. Exactly half expected their export sales to remain the same. About 26 per cent expected an increase of more than 25 per cent, and 24 per cent of respondents thought sales would decrease but by less than 25 per cent.

**Figure 3.7 Australian exports of scientific equipment, 1988-89 to 1994-95**



Apart from 'Other' countries, the EU was the largest market for Australian exports of scientific equipment in 1994-95, accounting for 22 per cent of total exports (see Figure 3.8). The second largest export market was the US, followed by New Zealand and countries of the Association of South East Asian Nations (ASEAN).

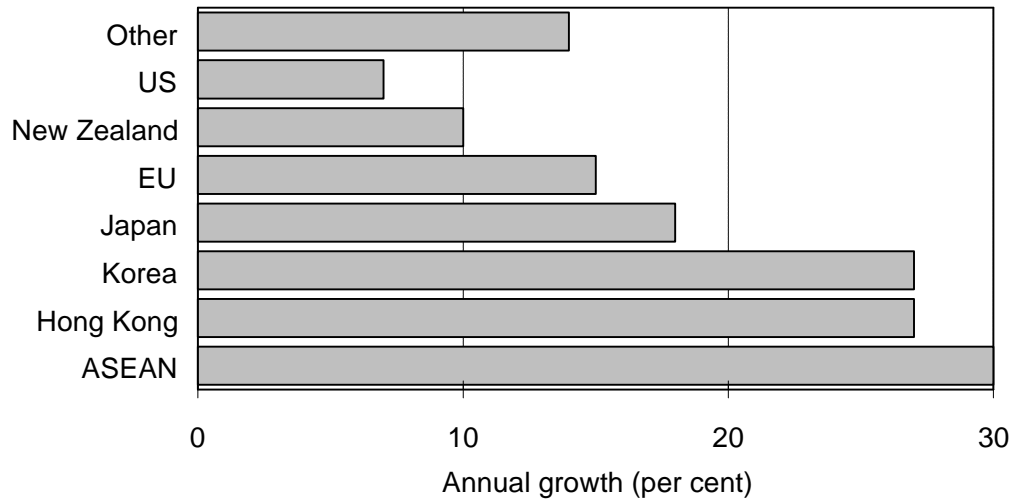
**Figure 3.8 Australian exports of scientific equipment by destination, 1994-95**



*Source:* ABS 1996b

The strongest growing export markets for scientific equipment in recent years have been the ASEAN countries, Hong Kong and Korea. From 1988-89 to 1994-95, exports to each of these three markets increased on average by more than 25 per cent a year (see Figure 3.9).

**Figure 3.9 Growth in Australian scientific equipment exports, by destination, 1988-89 to 1994-95**



*Notes:* In 1994-95 dollars and exports includes re-exports.

*Source:* ABS 1996b

Given the significance of exports to Australian manufacturers of scientific equipment, access to foreign markets is of importance to this industry. However, barriers to trade do not appear to be significant. The Technology Industries Exporters Group stated that:

Scientific equipment industries face few regulatory or trade barriers to markets overseas. The long-awaited signing of the 'Florence Agreement' overcame most of the barriers that used to exist. (sub. 17, p.2)

The GATT Uruguay Round Agreement resulted in the biggest tariff reductions ever achieved (see Section 3.3). This will benefit Australian suppliers as they now face an average tariff of less than 2 per cent in Australia's top six markets, and have duty free access for about one-third of Australian scientific equipment exports — about double that of before the Uruguay Round Agreement.

## Employment

Professional and scientific equipment manufacturing establishments employed about 6400 people in 1993-94 (ABS 1996b). This was approximately 0.8 per cent

of employment in all manufacturing industries.<sup>6</sup> Over the period 1989-90 to 1993-94, employment increased by about 18 per cent (ABS 1996b).

Employment estimates from the SSAA suggested a lower level of employment in 1994 of about 4560 people. Of this total, it estimated about 1050 people, or 23 per cent, were engaged in a manufacturing capacity. The SSAA believed employment has declined in recent years. It stated:

We are of the view that there is a continued decline in employment in the scientific industry of around 2-3 per cent a year (sub. 63, p.6).

Results from the Commission's survey showed that the 51 scientific equipment respondents employed about 1300 full-time equivalent people in 1996. Of those employed by these respondents about 70 per cent of staff, on average, were employed on a full-time basis at June 1996.

A characteristic of the labour employed in the Australian scientific equipment industry is that a large proportion is skilled. For example, at Silenus Laboratories in Victoria, about 80 per cent of the core staff have a Masters degree or higher. ABS (1996b) data indicate in 1995 just under 50 per cent of employees in photographic and scientific equipment manufacturing (ANZSIC 283) — which includes medical, scientific, photographic and optical equipment — had trade, degree or higher qualifications. This compares with only 15 per cent for all manufacturing employees and 21 per cent of employees in all industries. The Commission's survey also suggest that there is a higher percentage of skilled labour in scientific equipment companies. Labour skills are discussed further in Chapter 6.

Over 75 per cent of scientific equipment manufacturers are located in New South Wales and Victoria (see Table 3.4). Employment patterns generally follow location patterns, except for South Australia — this state has about 7 per cent of total scientific equipment manufacturing locations, but more than 21 per cent of total industry employment. Wholesale distribution companies broadly form the same pattern (IBIS 1995b).

**Table 3.4**      **Location of scientific equipment manufacturers and industry employment in Australia, 1994**

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<sup>6</sup> By comparison, the proportion of turnover in the scientific equipment manufacturing industry was less than 0.5 per cent of all manufacturing. This indicates a relatively labour intensive industry.

<i>Location</i>	<i>Location of companies (%)</i>	<i>Location of employment (%)</i>
New South Wales	42	45
Victoria	34	29
South Australia	7	22
Queensland	7	2
Western Australia	7	2
Tasmania	3	—
Australian Capital Territory	—	—
Northern Territory	—	—

*Source:* IBIS 1995c

## Profitability

The Commission examined two common measures of profitability — profit per employee and the capital expenditure to profit ratio. However, as information on these two measures is available from the ABS for only two data points, 1989-90 and 1992-93, the figures are not necessarily indicative of the change over that period. Furthermore, ABS data on profitability only include companies whose main activity involves scientific equipment, and so the data may not capture the full picture of profitability in the industry.

Subject to these qualifications, the ABS data indicate profit per employee, where profit is defined as operating profit before tax and has been adjusted for inflation, increased slightly from \$18 500 to \$20 000 over the period 1989-90 to 1992-93. The ratio of capital expenditure to profit increased slightly over the same period, which suggests a slight decrease in profitability.

The SSAA (1995) survey suggested that a significant proportion of companies in the industry made a loss in any particular year, although that proportion has decreased slightly in recent years. In 1992, 33 per cent of companies were made a loss, compared with 27 per cent in 1993 and 20 per cent in 1994. However, 20 per cent is still a worrying figure for the industry.

The SSAA explained the increase in profitability by saying it occurred ‘as the “pent-up” demand over the recessionary period was satisfied, particularly in the private sector’ (sub. 63, p.7). It believed profitability had declined since 1994-95, stating:

Anecdotal evidence from our members suggests improvement in profitability for the industry in 1994-95 but a decline in profit levels in the last fiscal year. The performance of the industry in the present year is sluggish with profit levels likely to be at a lower level than last year. (sub. 63, p.7)

Many participants believed profitability has worsened, not improved. For example, participants acknowledged that the heady days of exponential growth

were gone and the market for much scientific equipment is currently flat. GBC Scientific Equipment stated:

Price increases aren't something we have had for the last few years. Five years ago, every year we would get together and think, 'What are we going to do? It's January again. We're going to put our prices up.' Now it's sort of, 'Well, how much extra discount are we going to put in?' Despite that, you have got the fact that every year, costs do go up, real costs of operating in this country. (RT trans, p.79)

and:

... the general prognosis for the industry is ... tough times, the toughest times I have ever seen in business ... (RT trans, p.80).

Other factors considered by participants to have adversely affected profitability in the industry include a fluctuating Australian dollar and reduced government assistance. For example, the SSAA stated:

The Australian dollar has increased in strength over the past few years. It is considered that a position has now been reached that further increases in the value of the \$A against the US\$ and our other major trading partners will adversely affect export performance of scientific equipment. (sub. 63, p.5)

## **Innovation and research and development**

In the international arena, companies in the domestic industry compete for market share, and perhaps survival, through innovation and technology.

In 1992-93, R&D expenditure as a proportion of turnover for Australian scientific equipment manufacturers was approximately 9 per cent — the same as for global analytical instrument producers. The corresponding figure for all of domestic manufacturing was about 1 per cent (ABS 1995a, 1996a and 1996b).

R&D is discussed in more detail in Chapter 7.

## **3.6 Summary**

The global scientific equipment market is diverse and highly segmented, with the US, EU and Japan dominating both consumption and production. The majority of producers are small companies. However, a small number of multinationals dominate production.

Australia is a small but mature market. It is heavily integrated with the global market, with about 90 per cent of local consumption being supplied by imports and about 65 per cent of local production exported. The industry is relatively knowledge intensive, and has a high R&D intensity compared with other industries.

The scientific and medical equipment industries, both globally and in Australia, share many of the same characteristics. Both industries also face a number of similar issues, with the main exception being the regulation faced by suppliers of medical devices. These issues are explored in the following chapters.





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## 4 REGULATION OF MEDICAL DEVICES

*The need to regulate medical devices is well recognised. Although the regulatory systems in many countries aim to ensure the safety, quality and efficacy of medical devices, they do so differently. This chapter reviews the Australian regulatory approach, together with that being adopted in the European Union. The latter is increasingly being recognised as world best practice and already covers over 500 million people. Most developed countries, Australia included, have indicated their intention to harmonise with, or adopt, the European approach.*

This chapter discusses a range of issues in the regulation of medical devices.

The chapter commences with a description of the approach to regulating medical devices in Australia — for more details see Appendix D. After discussing the problems with the current approach, some solutions are proposed.

The first set of solutions is designed to improve the efficiency with which regulatory compliance is assessed. This discussion builds upon moves already underway to streamline the assessments which affect the trade in medical devices between Australian and the European Union (EU).

The second set of solutions addresses the fundamentals of the Australian regulatory approach. This discussion involves an examination of the EU approach of regulating medical devices and the advantages to Australia in adopting this approach (for more details on the EU approach see Appendix E).

The remaining two sections of this chapter address specific issues related to the regulation of silicone breast implants and devices labelled as only for single-use.

### 4.1 Regulation of medical devices in Australia

In Australia therapeutic goods are controlled by the *Therapeutic Goods Act 1989*. The intent of the Act is to set up:

... a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia, whether the goods are produced in Australia or elsewhere. (Section 4, *Therapeutic Goods Act 1989*)

In this context, the goals of quality, safety, efficacy and timely availability centre around balancing the risk of allowing a dangerous product (or one that fails to

offer a net benefit) onto the market against the risk of preventing or delaying a beneficial product from being marketed.

The Act defines a therapeutic good as anything used for the prevention, diagnosis or treatment of diseases and other bodily conditions. It covers drugs and medical devices and most of the Act applies equally to both.<sup>1</sup>

In addition to the Act, the main regulatory instruments are: Therapeutic Goods Regulations; Therapeutic Goods Orders (TGOs); and Therapeutic Goods Determinations (TGDs). These are subordinate legislation made under the Act.

The legislation is administered by the Therapeutic Goods Administration (TGA), an agency within the Commonwealth Department of Health and Family Services. At present, the TGA is the only body that assesses how medical devices and their manufacturers conform to the requirements of the legislation.

The Commonwealth is concluding a Mutual Recognition Agreement on conformance assessment with the EU (MRA) (see Section 4.3).<sup>2</sup> The Agreement will mean that devices made in the EU can be assessed by designated bodies in the EU against the requirements of the therapeutic goods legislation. It also provides for devices made in Australia to be assessed by the TGA (and potentially other bodies designated by the Commonwealth) for conformance with EU requirements.

## **Regulatory elements**

The regulation of medical devices in Australia has several important elements:

- coverage and classification of medical devices;
- pre-market evaluation and assessment;
- use of mandated standards for products and manufacturing processes;
- licensing of manufacturers;
- regulation of manufacture; and
- post-market surveillance.

These are discussed in turn.

### *Coverage and classification of medical devices*

The Act adopts a very broad definition for medical devices:

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<sup>1</sup> Australia is the only country to use the term ‘therapeutic devices’. Elsewhere and in this chapter they are called medical devices.

<sup>2</sup> New Zealand is also concluding a Mutual Recognition Agreement on conformance assessment with the EU. See Appendix F.

... an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with software required for proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in its function by such means ... (Section 3, *Therapeutic Goods Act* 1989).

Medical devices include: implants (such as heart valves, intraocular lenses, hip joints, dental materials, intra-uterine contraceptive devices); anaesthetic equipment; X-ray equipment; magnetic resonance imaging equipment; drug infusion pumps; syringes; bandages; catheters; examination gloves; in-vitro diagnostic kits; condoms; contraceptive diaphragms; and stethoscopes.

Many goods that are not meant to be regulated are captured by the broad definition. They have to be explicitly excluded by the Act or its Regulations.

Under the Act, the person responsible for supplying each device in Australia, who may not necessarily be its manufacturer, is called the sponsor. The sponsor has to ensure that a device is only manufactured or supplied after it has been entered on the Australian Register of Therapeutic Goods (ARTG).

The legislation categorises all medical devices into several 'groups'. Devices can be placed on the ARTG as either 'registered' or 'listed'. 'Registered' devices are more risky and include, for example, heart valves. 'Listed' devices are less risky and include, for example, ultrasonic devices. If a new medical device is not already 'grouped' it is classified as listable.

Registered devices are further categorised as 'high' or 'low level', according to the evaluation for entry on the ARTG. These categories broadly correlate with the risk. Typically, high level registered devices, such as pacemakers, are based on insufficiently proven or new technology. Low level registered ones include proven technology, for example disinfectants or barrier contraceptives.<sup>3</sup>

At 18 December 1996, the ARTG had 423 entries for 1253 registered devices and 7901 entries for 20 929 listed devices.

### *Pre-market evaluation and assessment*

To be placed on the ARTG, devices must be either evaluated or assessed by the TGA against the requirements of the legislation. Devices are 'evaluated' or 'assessed' depending on whether they are registrable or listable. A range of fees apply (see Box 4.1).

High level registrable devices receive a detailed evaluation of data on: design, materials and testing; manufacture and quality control; bio-compatibility and pre-

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<sup>3</sup> Disinfectants and barrier contraceptives are registrable because of the health risk involved if they fail in use. They prevent the spread of viruses and bacteria.

clinical tests; and human clinical trials. Listable devices only need a brief assessment of their quality and safety (sub. 16, p.3).

**Box 4.1 TGA fees and charges**

*Application fees* apply for a new registrable device to be registered and vary from between \$380 to \$1300 per device. The application fee for a listable device is \$200 and there is no additional fee for the assessment.

The *evaluation fee* for a new high level registrable device varies from between \$23 800 to \$28 800. For low level registrable devices, the pre-market evaluation is not as detailed and the fee is \$2200.

The fees are lower in the case of new devices which are a variation of a device already registered. They range from between \$2900 to \$17 000 for high level registrable devices and \$500 for a low level registrable device.

In addition, *annual fees* apply to remain on the ARTG: \$350 for registered devices and \$200 for listed devices.

The current *GMP audit fee* for a local manufacturer of ‘single step’ devices, of ingredients, or of components is \$1400 for the first four hours, plus \$450 every two hours there after. These local manufacturers also pay a license fee of \$2400 a year.

The majority of manufacturers carry out more than one auditable activity and are charged at higher rates. Audits of these manufacturing sites cost \$2700 for the first four hours and \$800 for every two hours thereafter. The licence fee for these local manufacturers is \$4700 a year.

In the absence of suitable evidence of compliance an overseas manufacturer is audited. For overseas manufacturers of ‘single step’ devices, of ingredients, or of components, the GMP audit fee is \$1800 for the first four hours and \$600 per two hours thereafter. Other overseas manufacturers are charged \$3400 for the first four hours and \$1100 per two hours there after. In addition the sponsor of any overseas manufactured device must pay transport, accommodation, salary, on-costs and other expenses for the TGA staff involved in travelling to the overseas manufacturing site.

***Standards for products and their manufacture***

The Act and TGOs mandate specified standards to ensure the safety, quality and efficacy of devices. The standards relate to the devices, as well as the raw materials, manufacturing processes and testing procedures used to make them.

The main source for standards is the British Pharmacopoeia, which is referenced in the Act. The Therapeutic Goods Committee (TGC), a statutory committee that reports to the Minister of Health and Family Services, is responsible for developing standards as required.<sup>4</sup> These standards are mandated as TGOs.

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<sup>4</sup> The TGC and the Minister are further advised by another statutory committee — the Therapeutic Device Evaluation Committee.

There are over a dozen TGOs relating to medical devices. Some cover all devices while others are group or product specific. The Orders include:

- standard for sterile therapeutic goods (TGO 11);
- general requirements for labels for therapeutic devices (TGO 37); and
- single-use syringes for the injection of insulin (TGO 41).

TGOs may be self-contained or reference a standard of an internationally recognised standard-setting body. For example, TGO 11 is largely self-contained and explains how sterility is to be tested and the results interpreted. By contrast, TGO 28 on contraceptive diaphragms simply states:

... the standard shall be Australian Standard 1808–1984 Contraceptive Devices — Diaphragms published by Australia Standards.

Standards control the manufacturing process. The principles are specified in Therapeutic Goods Determinations (TGD). Currently the relevant TGDs specify Codes of Good Manufacturing Practice (GMP) as defined by the European quality systems standard for the manufacture of medical devices (EN 46001). The GMP requirements vary with the type of device and the activity undertaken — sterile goods being subject to the most stringent requirements.

### *Licensing of manufacturers and GMP*

Manufacturers must be licensed to produce any medical device other than those exempted by the Regulations. The licence is for specific premises and defines the subcategories of goods or manufacturing activities to which it applies.

To obtain a licence the manufacturer has to be audited against the GMP Code. A licence will not be granted unless there is compliance with GMP and may be withdrawn for failure to continue to comply.

The TGA audits compliance with GMP. The timing of audits is based on risk. Surveillance audits are every two to twelve months where compliance is high. However, if the device is high risk and compliance low, audits are two-monthly until conformance improves. Full audits must take place every three years.

Overseas manufacturers are not licensed but are subject to GMP requirements. If evidence of suitable compliance is provided the overseas manufacturer is neither audited nor charged. When suitable evidence is not provided, the overseas manufacturer is audited by the TGA (at the sponsor's expense).

### *Post-market surveillance*

Sponsors are responsible for reporting deaths and serious injuries related to the use of a device and other device related problems. In addition, the TGA operates a program of random sampling to ensure compliance with standards.

The TGA has a uniform procedure for the recall of medical devices. The onus is on the manufacturer or sponsor to initiate and effect a recall. The TGA is also developing a system for tracking recipients of certain permanent implants so they may be located and rectified in the event of a problem.

## **4.2 Problems with Australia's regulatory approach**

The evidence presented to the Commission suggests that there are problems with the current regulatory approach in the following areas:

- coverage of medical devices;
- categorisation of devices;
- mandating of standards;
- limited regulatory harmonisation with Australia's trading partners;
- different treatment of local and overseas manufacturers; and
- barriers to competition in conformance assessment.

### *Coverage of devices*

The broad definition of medical devices means that the legislation captures more devices than needed. For example, cotton balls, magnets, beauty therapy equipment, personal hygiene products and furniture are covered where they are used, or intended to be used, for therapeutic purposes. This results in the need for many exemptions from the legislation which adds to the costs and complexity of administering the legislation. Moreover, such products are already adequately covered by the *Trade Practices Act 1974*.

### *Categorisation of devices*

The categorisation of devices in the therapeutic goods legislation means that new devices, especially those with new technologies, are often not easily handled. Such devices may require the legislation to be amended each time a new type is to be marketed in Australia. This is costly and cumbersome. As the Department of Health and Family Services stated:

... devices [are] dealt with by TGA on a product by product basis, according to predetermined classifications specified by regulation. New and changing technology or circumstances often require changes to the Act and/or regulations as a new product or problem emerges. (sub. 16, p.6)

### *Mandating of standards*

The legislation mandates certain standards but not others, even if they offer equal protection. This restricts the manufacturers and adds to their compliance costs. Furthermore, manufacturers are denied the opportunity to innovate to find better ways of meeting the aims (rather than the letter) of the standards. Although additional standards may be added by Regulation, this is slow and resource intensive.

On the mandating of standards, the Industry–Government Consultative Committee has stated that:<sup>5</sup>

Because of the cumbersome nature of our standards making system, the resource implications for the TGA and legal obligations placed on manufacturers and sponsors, Australia has succeeded in mandating relatively few standards. There have been no prosecutions for non compliance with device standards since the Act commenced. Many of those standards that we have mandated have been unsuccessful or outdated almost as soon as they are in place. There are many other important areas of standardisation which do not receive any attention because no attention is given to them by TGA. (sub. 15, attach. 20, p.4)

The Consultative Committee has also noted that the current system risks imposing extra compliance costs on Australian manufacturers and additional resource costs on the TGA to enforce compliance.

### *Limited harmonisation with regulation overseas*

A unique approach has been developed and implemented for a population of around 18 million. This compares, for example, with over 500 million people covered by the approach being implemented in the EU. As discussed later, the two approaches are quite different, even though their goals are essentially the same.

This has important economic implications for Australia given its reliance on the EU both as a major source of imported devices and a major export market for Australian devices. The greater the divergence in approach between the two, the greater the likelihood that it will impose additional costs on Australian users and exporters of medical devices.

The regulatory approach of the EU is rapidly becoming the accepted world standard. Many countries have adopted the approach, or are moving to harmonise with it. As the TGA has already recognised, this situation means that Australia

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<sup>5</sup> Industry–Government Consultative Committee comprising representatives of industry, the Departments of Finance and Industry, Science and Tourism, and the TGA. It reports to the Minister of Health and Family Services on TGA's performance, budget, fees and charges.



must also move to harmonise with it. Failure to do so will impose unnecessary costs on Australian exporters and users of many imported devices in meeting two different regulatory requirements.

### *Different treatment of local and overseas manufacture*

Domestic manufacturers must be licensed and pay the appropriate licence fee before they can produce regulated devices in Australia. Overseas manufacturers are exempted from these requirements (but not from the need to demonstrate compliance with the GMP Codes or the other provisions of the legislation).<sup>6</sup>

Licensing serves no useful regulatory purpose other than to raise revenue but it does so in a way that discriminates against local manufacture for no sensible purpose. Not surprisingly, domestic manufacturers objected (sub. 15).

### *Barriers to competition in assessment*

The TGA has a monopoly in conformance assessment services. Difficulties therefore exist in ensuring that the TGA's services are cost-effective and timely. Participants expressed concerns about both aspects of TGA's performance.

The TGA's fees and charges received the most criticism. The Medical Industry Association of Australia (MIAA) suggested an independent review of whether the costs of TGA's services should be recovered from the industry and, if so, the appropriate fees to be charged (sub. 13, p.4).

The MIAA also criticised the timeliness of TGA's evaluations of registrable devices (sub. 13). The College of Biomedical Engineers observed that:

There are undoubtedly bureaucratic difficulties with TGA such as long approval times and a tendency at times to pin difficult decisions on other bodies. Some of their strategies and policy guidelines show scant regard for cost implications. Also, there is a clear absence of risk management principles being applied to decisions. (sub. 46, p.9)

In the absence of competitively established benchmarks in these areas, it can be quite difficult to establish to what extent such criticisms may be valid. More fundamentally, while barriers to competition in conformance assessment remain, it is clear that the incentives for efficient and timely assessments will be weaker than they would be with competition.

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<sup>6</sup> A widespread misconception amongst inquiry participants involved in the medical devices industry, was that the *Therapeutic Goods Act* does not require overseas manufacturers to comply with GMP (see, for example, sub. 10, p.4, from the Industrial Supplies Office (Victoria) and sub. 15, p.4, from Tuta Laboratories).

### *Correcting the problems*

The Commission concludes that each of the above problems should be corrected. Sections 4.3 and 4.4 of this Chapter discuss its proposed ways to do so. Reforming the barriers to competition in conformance assessment is covered in the next section. The more fundamental issue of the regulatory regime itself is dealt with in the subsequent section.

## **4.3 Reforms to conformance assessment**

The proposed Mutual Recognition Agreement with the EU will reduce some of the international barriers, between Australia and the EU, to competition in conformance assessment for medical devices. It will not remove the barriers to bodies other than the TGA performing assessments within Australia for either the Australian or the EU markets — although it will facilitate their removal.

For as long as the TGA retains its monopoly over conformance assessment in Australia, the commercial incentives for the agency to provide its services in the most cost-effective and timely manner will be, at best, muted. Ultimately the lack of competition results in under-performance in such areas, the cost of which is borne by the users of devices. The industry has been critical of TGA's performance on both counts.

In the EU assessment bodies compete with each other on a commercial basis — they include public and private sector bodies, both not-for-profit and for-profit ones.

In the Commission's view, the introduction of effective and efficient competition in conformance assessment requires the following changes:

- the removal of any barriers to the entry of new conformance assessment bodies in Australia;
- the structural reform of TGA to promote competitive neutrality between its conformance assessment and those of other bodies; and
- the early removal of some of the international barriers to competition.

The Commission's proposals are elaborated below.

### **Removing the barriers to entry**

The Commission proposes the Commonwealth should allow any appropriately accredited body to perform assessments both against the therapeutic goods legislation as well as the EU requirements. To be accredited, aspiring assessment bodies should have to demonstrate that they are competent to assess conformance

against the therapeutic goods legislation. The accreditation competencies have already been defined for the purposes of Mutual Recognition Agreement with the EU. They can therefore be applied without amendment.

The Commission expects that conformance assessment bodies operating elsewhere — including those in the EU — are likely to be interested in operating in Australia. They should be allowed to do so without their having to set up an Australian-based operation. Nevertheless some are already here — Societe General de Surveillance currently provides conformance assessment in other areas through its Australian subsidiary. There are also Australian organisations which assess products other than medical devices that might be interested in graduating to these devices.

Assessment bodies would need to be designated to provide particular assessment services and audited on an ongoing basis. Such auditing is required to ensure that an assessment bodies continues to possess the appropriate competencies for their designated services. The requirements for ongoing auditing are also referenced in the Mutual Recognition Agreement.

The MIAA supported allowing competition in conformance assessments (sub. 51). The TGA also indicated its broad agreement:

The TGA welcome the Industry Commission report and was pleased that most of the recommendations are consistent with forward planning and policy of the TGA, which shows that we must be somewhere on the right track (PH trans, p.79).

However, the TGA submitted that competition should be delayed for two or three years following the implementation of the Mutual Recognition Agreement. It indicated that such a delay would allow both the EU and Australia to assess the performance of each other in meeting their obligations under the MRA prior to allowing other bodies to assess conformance (sub. 77, p.4–5).

The Commission agrees that a review of performance after two or three years could well be sensible but sees no reason why this should delay moves to accredit other conformance assessment bodies. This would simply defer the benefits of competition to Australian exporters and users of devices.

Some participants expressed concerns with the draft recommendations. Testing and Certification Australia were concerned whether the approach will afford an adequate level of safety. It suggested that is far too early to judge if the EU approach is effective (sub. 65). The Commission notes that these concerns are not shared by the TGA.

The College of Biomedical Engineers expressed concern that having conformity assessment bodies charging fees for services would adversely impact on small start-up companies (sub. 60). The Commission considers that manufacturers should be charged for conformity assessment services because they (and

ultimately their customers) benefit from having them. Subsidised assessments are a poor way of helping such a group of businesses because of their highly uncertain and variable impact on the target group.

**Recommendation 4.1**

The Commonwealth Government should accredit eligible bodies in the public or private sector to assess the conformance of medical devices, their manufacturers and their sponsors, to the therapeutic goods legislation.

**Recommendation 4.2**

The Commonwealth Government should require bodies to demonstrate appropriate competencies if they wish to be accredited to assess conformance to the therapeutic goods legislation.

**Recommendation 4.3**

The Commonwealth Government should determine that the competencies to assess conformance to the therapeutic goods legislation are those referenced in the proposed Mutual Recognition Agreement on conformance assessment with the European Union.

**Structural reform of the TGA**

Allowing competition in conformance assessment raises the question as to whether it would be appropriate for TGA to continue to be the regulator of conformance assessment while providing assessment services in competition with others.

In the interests of even-handed and efficient competition, there is a strong case for the principle of separating the regulation and provision of competitive activities. The detailed case for doing was most recently outlined by the Commission's report *Electricity Industry in South Australia* (IC 1996d). This principle underlies the national competition policy agreed by the Council of Australian Governments and is enshrined in its Competition Principles Agreement.

There are significant advantages in dividing these activities between two independent organisations. Full separation would:

- facilitate the setting of clear objectives, responsibilities and accountabilities for each activity;
- avoid potential conflicts of interest in the regulation of conformance assessment; and
- avoid the need for 'ring fencing' or 'Chinese walls' to separate regulatory and assessment activities.

The Commission concludes that conformance assessment activities currently performed by the TGA should be the responsibility of an autonomous organisation responsible to its Minister. The practical choices for this organisation are to set it up as a separate legal entity or as a business unit of an existing agency. This choice depends, in part, on the relative costs. In the draft report, participants were invited to comment on this aspect. Nevertheless, the Commission does not have enough information to make a recommendation on this aspect.

Either way, the organisation should be established on a commercial basis and be expected to recover all its costs in fees and charges to industry. There is no justification for any of these costs to be borne by government.

The Commission considers that the agency responsible for regulating medical devices needs to be operationally independent from its portfolio Department and to be directly responsible to the relevant Minister. In its recent report on the *Pharmaceutical industry* (IC 1996c), the Commission outlined the case for an independent TGA and recommended it be established a statutory authority. The Commission reiterates that recommendation here to ensure a credible and effective regulator.

The core responsibilities of the regulatory agency should include those regulatory activities currently undertaken by the TGA. They should also encompass the responsibility for regulating conformance assessment activities in the public and private sectors, as required to implement the Commission's recommendations above.

The MIAA supported the Commission's proposals to restructure the TGA but reserved comment on the proposal that the TGA become a statutory authority — the Association felt that it needed to evaluate this proposal further (sub. 51).

In response to the Commission's proposals the TGA indicated that:

The TGA is investigating the manner in which the regulatory and conformity assessment responsibilities are met and the implications of separation of these functions in meeting its responsibilities for ensuring the quality, safety and efficacy of medical devices in Australia and for certification of Australian manufactured devices for the European market.

The [statutory authority] model is being explored as one of a range of possible options to achieve greater independence and flexibility for the TGA. (sub. 52, p.2)

In relation to assigning assessment activities to a commercially autonomous enterprise funded solely by client fees and charges, the TGA suggested that a decision on this proposal should be delayed until the responsibilities of the regulatory and conformity assessment bodies are resolved (sub 52, p.2).

The Commission considers that the advantages of full separation and commercial operation of conformance assessment are clear cut and independent of the precise division of responsibilities between the two bodies.

### *Recovery of regulatory costs*

The TGA currently seeks to recover 50 per cent of its operating costs from industry. As announced by the Government in the August 1996 Budget, the recovery from industry is to increase to 75 per cent over three years.

The proposed restructure of the TGA would have implications for this policy. The issues that need to be addressed include which regulatory activities should be subject to cost-recovery and how their costs should be recouped.

Given the diverse nature of the regulatory activities, the beneficiaries may differ from activity to activity, some may not be easily identifiable. This may cause difficulties in developing arrangements that are both efficient and equitable. Based on the information available to it, the Commission was not in a position to make an assessment.

### *Competition Principles Agreement*

Under the Competition Principles Agreement a review must be undertaken before a public monopoly can be privatised or competition introduced into a market traditionally supplied by a public monopoly. Details of the Agreement and the issues to be considered in such a review are in Appendix E.

The Commission considers that its proposals for competition in conformance assessment and to restructure the TGA would be consistent with the Agreement.

#### **Recommendation 4.4**

The Commonwealth Government should separate conformance assessment of the Therapeutic Goods Administration for medical devices from its core responsibilities for regulating medical devices and pharmaceuticals. These assessment activities should be assigned to a commercially autonomous enterprise funded solely by client fees and charges.

#### **Recommendation 4.5**

The Commonwealth Government should assign the regulatory responsibilities of the Therapeutic Goods Administration to a statutory authority with operational independence from the Department of Health and Family Services.

#### **Recommendation 4.6**

The Commonwealth Government should require the regulatory authority to: maintain a register of medical devices and their sponsors; accredit conformance assessment bodies; audit the assessment bodies to ensure the validity of their assessments; conduct post-market surveillance of devices; and manage the recall of devices.

## **Removing international barriers to competition**

A Mutual Recognition Agreement on conformance assessment is being concluded between Australia and the EU. It covers simple pressure equipment, machinery, low voltage electrical equipment, medical devices, telecommunications terminal equipment, electromagnetic compatibility, automotive products and GMP for pharmaceuticals. The Agreement will allow other sectors to be added later.

With respect to medical devices, the Agreement provides for accredited bodies in the EU to assess devices manufactured in the EU against the requirements of Australian law. Likewise it provides for the TGA (and any other body accredited by the Commonwealth) to assess devices manufactured in Australia for conformance with EU requirements — also known as the ‘CE Mark’.

The Agreement will introduce elements of international competition in conformance assessment for devices traded between Australia and the EU. By doing so it will facilitate trade in devices between the two economies with benefits to Australian device users and exporters. Early implementation of the Agreement should be a priority. As the Technology Industry Exporters Group stated:

... It would be of great benefit to Australian manufacturers to be able to obtain CE marking here in Australia. However, negotiations have been hampered by the need to sign up several sectors at once. A firm date for signing the MRA is still not forthcoming. (sub. 17, p.2)

The Agreement was initialled on 23 July 1996. However, there are many procedural steps before it can come into effect. As at 20 December 1996, a draft of the national interest analysis has been completed by the Department of Industry Science and Tourism. In addition, there is general agreement at the level of officials on a draft Memorandum of Understanding between the Commonwealth, and States and Territories.

While implementation is proceeding, the urgency is increasing. The transition to the ‘CE Mark’ is occurring rapidly in Europe. The regime is expected to be fully in place by 14 June 1998. All devices sold within the EU from that date have to carry the ‘CE Mark’.

The effective date is likely to be much earlier due to commercial pressures. Some large customers in Europe have indicated that, after June 1997, they will not purchase devices without the ‘CE Mark’. Some Australian exporters have already had to have their devices assessed by EU conformity assessment bodies — this is costly as the relevant assessors have to be flown out to Australia. If the MRA were in place, these additional costs could be avoided.



In light of the above, the Commission considers that the implementation of the provisions of the Agreement relating to medical devices has become a matter of urgency. The sooner the formalities are concluded, the greater the benefits for Australian device exporters and users.

On this proposal the TGA commented that:

Steps are being taken to amend the [therapeutic goods] legislation to facilitate the implementation of the provisions of the Mutual Recognition Agreement (MRA) negotiated between Australia and the EU on conformance assessment for the medical devices sector. This will establish the procedures under which TGA will be able to undertake conformity assessment of medical devices manufactured in Australia for compliance with the EU and vice versa. (sub. 77, p.4)

**Recommendation 4.7**

The Commonwealth Government should implement, as soon as practical, the provisions relating to medical devices in the proposed Mutual Recognition Agreement on conformance assessment between Australia and the European Union.

#### **4.4 Reform of the regulatory system**

While the MRA will facilitate trade in medical devices with the European Union, it will still leave many manufacturers facing two sets of regulatory requirements — one for the Australian market and another for Europe.

The potential exists for Australia to go further in facilitating trade in devices by harmonising its regulatory system with that of the EU. Doing so may also open the possibility of correcting other flaws associated with the Australian approach. Before considering these issues, it is necessary to understand the EU approach to the regulation of medical devices.

#### **Regulation of devices in the EU**

Medical devices in the EU are part of a harmonised system of quality and safety legislation for all products. Conforming products bear the ‘CE Mark’.

The European Commission (EC) issues Directives to coordinate the regime throughout the EU. Directives are drafting instructions to EU member states who enact the legislation to implement them.

The Directives relating to medical devices, specify the essential requirements which have to be met by manufacturers, member states and conformity assessment bodies. These define the safety and quality outcomes to be achieved

in the design and manufacture of medical devices — they require the risks to be weighed against the benefits from use, the risks to be eliminated as far as practical and for protection against any residual risks.

The Directives also set out the processes to be followed by those involved in the manufacture, use, assessment and regulation of medical devices to achieve those outcomes. A summary of the general requirements is presented in Box 4.2.

**Box 4.2      Essential requirements for medical devices in the European Union**

- 1    Devices must be designed and manufactured so that, when used under the conditions and purposes intended, they will not to compromise:
  - the clinical condition or safety of patients; or
  - the safety and health of users or, where applicable, any others.
- 2    Any risks associated with the use of a device must be acceptable when weighed against the benefits to the patient and must be compatible with a high level of protection of health and safety.
- 3    The design and construction of devices must conform to the following principles:
  - to eliminate or reduce risks as far as possible;
  - to protect adequately against any risks that cannot be eliminated; and
  - to inform users of any residual risks.
- 4    Devices must perform as intended by their manufacturer.
- 5    The above characteristics and performance of devices must not be adversely affected to such a degree that the clinical condition or safety of patients are compromised during the intended lifetime of the device when subjected to the stresses of normal use.
- 6    The risk of any undesirable side-effect must be weighed against the intended performance of the device.

*Source:*                      Council Directive Concerning Medical Devices, 1993

***Role of EU member states***

Each member state has responsibility for regulating medical devices within its jurisdiction. This involves it:

- maintaining a register of devices approved for use in its jurisdiction;
- liaising and sharing information on related problems with member states;
- designating and auditing conformity assessment bodies;
- undertaking post-market surveillance and establishing product recall protocols; and

- issuing product alerts, and supervising recalls and corrective actions by manufacturers or importers.

### *Conformity assessment bodies*

The assessment of devices against the EU essential requirements is carried by designated ‘conformity assessment bodies’. These are typically independent of the member states and are designated to provide specified assessment services. Those already operating include public sector, not-for-profit, and for-profit bodies. They compete with each other on a fee for service basis.

When a manufacturer’s quality assurance system or device is assessed as conforming, the assessment body issues a certificate of conformity and a ‘CE mark’ may be affixed to the device. The device may then be marketed within all the member states of the EU.

### *Evaluation of devices and their manufacture*

The EC directives outline the processes involved in assessing devices against the essential requirements. The processes involve:

- principles to guide the coverage and classification of devices;
- a choice of routes for pre-market evaluation of high risk devices;
- self-assessment by manufacturers of low risk devices;
- a choice of standards (and of alternatives to them) for products and manufacturing processes; and
- post-market monitoring of device performance and adverse incidents.

### *Medical devices classified according to risk*

The Medical Devices Directive (MDD) covers most medical devices. It establishes four categories of devices (see Box 4.3).

Rules are used to determine what is a medical device and how it is to be categorised. Manufacturers classify devices on the basis of their intended use by following these rules. They have to take into account the risk of the device, its invasiveness and the length of time it is likely to be in contact with the body.

### *Pre-market evaluation*

Manufacturers choose which conformity assessment body to do the pre-market evaluation. They can negotiate a fee with the body and a ‘guaranteed’ time by which an assessment will be carried out.

In complying with the requirements for pre-market evaluation, manufacturers may choose one of a variety of assessment paths. The paths available are related to the risk class of device. For example, conformity can be assessed on the basis of a review of the manufacturer's full quality assurance system; or by a 'type examination'. The latter may involve product verification or assessment of production quality assurance.

#### **Box 4.3 EC classification of medical devices**

There are four device classes under the Medical Devices Directive.

**Class I** devices are generally regarded as low risk and include most non invasive products, certain invasive products, and reusable surgical instruments.

**Class IIa** devices are generally regarded as medium risk and include both invasive and non invasive products, generally for short-term use.

This class includes some wound dressings; certain products that channel and store blood for administration into the body; surgically invasive devices for transient or short-term use; most active medical devices that administer or exchange energy; and active diagnostic devices that supply energy (other than for illumination) absorbed by the body, such as ultrasonic imagers.

**Class IIb** devices are also regarded as medium risk, but this class covers active products therapeutically delivering energy or substances at potentially hazardous levels.

Devices placed in this class include blood bags, chemicals that clean or disinfect contact lenses, surgically invasive devices for long-term use, radiological equipment, and condoms and other contraceptive devices (except for intra-uterine devices, which are in Class III).

**Class III** devices are generally regarded as high risk and include products that are used to diagnose or monitor or that come in contact with the circulatory or central nervous system, such as vascular grafts.

This category also includes devices that incorporate medicinal products, such as bone-cement containing an antibiotic

Source: GAO 1996, p.31

#### *Self-assessment of low-risk devices*

For low and some medium risk products, manufacturers can decide themselves whether they meet the essential requirements. Self-assessing manufacturers proclaim their conformance and mark these devices with a 'CE Mark'. They do not have to demonstrate their conformance prior to marketing the device but have to keep adequate records to justify their decision, if called on to do so.

### *Use of standards*

The EU Directives do not mandate particular standards — rather it is the outcomes in the essential requirements that are mandatory.

Manufacturers have a choice of ways for meeting the requirements. They may use one of a list of ‘harmonised standards’ — doing so carries a presumption of conformity with the relevant requirements. Alternatively, they can develop their own way, provided they can demonstrate it delivers equivalent safety and quality outcomes.

### *Post-market monitoring and surveillance*

The Medical Devices directives provide for an adverse incident notification scheme and evaluation system. In essence, all adverse incidents have to be reported and systems have to be in place for detecting problems.

This vigilance system seeks to improve the protection of patients and others by reducing the likelihood of similar adverse incidents occurring. This is to be achieved by evaluation of incidents and dissemination of information.

Manufacturers are responsible for taking any corrective action that is necessary following an adverse report. Member states are obliged to monitor the effectiveness of the manufacturer’s follow-up on reported incidents.

## **Comparison of the two approaches**

There is general acceptance of the need to regulate medical devices and of the credibility of TGA’s efforts. As stated by the College of Biomedical Engineers:

The international recognition of the TGA means that their auditing to GMP, approval and licensing of manufacturers is generally accepted overseas. Australia’s reputation for quality manufacture is enhanced by the presence of [a] respected regulatory authority. (sub. 46, p.9)

There is also agreement on the need for Australia’s regulatory approach to remain world class (sub. 20, p.1). With this in mind, both the TGA and the industry consider that the current approach should be superseded by that in the EU. For example, the Australian Society for Biomaterials stated:

Regulatory frameworks are constantly evolving. It is our understanding that the TGA intends harmonising its regulatory processes around the European model, with a single pre market evaluation being sufficient for market approval in both Australia and Europe. We support this approach. (sub. 7, pp.2–3)

Both systems have similar goals but different means to achieve them. The EU approach provides for better definition of the outcomes to be achieved, and

greater choice and flexibility in attaining them. The Commission's comparison of the two is summarised in Table 4.1

### *Defining and categorising devices*

The EU defines medical devices on the basis of the manufacturers' intended use. In contrast, the therapeutic goods legislation casts a very wide net but requires a great number of goods to be specifically identified and others to be excluded. This involves additional administrative and compliance costs.

Both systems categorise devices by risk, but there is a significant difference in the way they do. The EU uses a set of principles to categorise each device individually, thereby easily accommodating new devices and technologies.

Under the Australian system, the groups of devices must be nominated in advance. This is a more rigid and imprecise. It is also slow and cumbersome because of the need for regulations to be constantly updated, as new devices and groups are added. These aspects increase the costs and uncertainty to manufacturers (or sponsors) experience.

In comparison, EU rule-based approach should result in lower costs and greater certainty for both regulators and manufacturers. Consistent application of the rules should help ensure that the regulatory outcomes are likely to be better.

### *Conformance options*

In addition to the choice over conformance assessors, the EU system offers greater choice over how conformance is achieved. This flexibility is provided without compromising the need to met the essential requirements. By contrast, the Australian system prescribes only one way for each outcome to be achieved. The Australian system is unable to accommodate the circumstances of individual manufacturers as well as the EU system.

The advantages of choice over inflexibility in regulation are clear and were extensively canvassed in the Commission's report on *Work, Health and Safety* (IC 1995b). Furthermore, changes in mandated standards are required to accommodate new ways of achieving safety and quality. Such a difference is likely to impose extra compliance costs on manufacturers.

**Table 4.1** Main features of the Australian and European Approaches to regulating medical devices

<i>Australia</i>	<i>European Union</i>
<b>Goals</b>	
Safety, quality, efficacy and timely availability.	Safety and quality. Net benefit in the presence of risk. Device performs as manufacturer claims.
<b>Legislative approach</b>	
Use of prescriptive standards and processes to achieve goals.	Outcome orientated; flexibility provided in the means by which requirements are met.
<b>Regulatory structures</b>	
All regulatory functions administered and conducted by the TGA, a division of the Commonwealth Department of Health and Family Services.	Regulatory functions administered by member state. Conformity assessment of manufacturers and devices conducted by independent third party conformity assessment bodies.
<b>Coverage</b>	
Definition provides broad coverage with numerous exemptions named as identified.	Definition provides explicit coverage.
<b>Risk classification</b>	
Names groups of devices which are divided into two (possibly three) risk related categories.	Rule based risk classification with four risk categories.
<b>Evaluation of devices</b>	
High risk or 'registrable' devices are evaluated by the Therapeutic Goods Administration for safety, quality and efficacy.	High risk categories of devices are assessed for their conformity with safety, quality and other requirements through a variety of routes.
Low risk or 'listable' devices are assessed as complying with safety and quality standards.	Low risk devices are assessed by the manufacturer for compliance with safety and quality requirements. Manufacturers must retain documentation to allow external assessment of their decision if required. More explicit onus on manufacturer to ensure that device is effective.
<b>Evaluation of manufacture</b>	
Manufacturing sites audited by the TGA against relevant Codes of Good Manufacturing Practice. Licensing to signify compliance with GMP.	Conformity assessment, by a conformity assessment body, of the manufacturers quality assurance system and quality controls to assess whether they conform with requirements.
<b>Post-market assessment</b>	
Oversight by Commonwealth and State governments. Random sampling by the TGA. Recall protocols. Manufacturer responsible for corrective action or recall.	Oversight by member states. Reporting obligations towards other member states. Provides for recall protocols. Manufacturer responsible for corrective action or recall.

### *Recognition as the world standard*

The EU system is widely recognised as best regulatory practice and is in the process of being adopted by countries outside the EU. The system has already been adopted by countries representing over 500 million people. Furthermore, most other developed countries have indicated their intention to harmonise with, or adopt, the EU system. This means that the trade facilitation benefits of the EU system are increasing.

### *Commission's assessment*

Based upon this comparison the Commission has assessed the various differences against the following criteria:

- protection of users;
- compliance costs;
- conformance costs; and
- administration costs.

The Commission's assessments are summarised in Table 4.2.

The EU approach was generally judged as being superior to that in the therapeutic goods legislation. The latter was not judged as being superior to the EU approach in any respect. In addition, the EU one is widely recognised as better for facilitating trade in medical devices.

The Commission considers that the EU approach is inherently superior to the therapeutic goods legislation. This conclusion is based on the assumption that the EU approach is fully and properly implemented. Even if the current Australian approach were to provide equal protection, the Commission would still prefer the EU one due to its lower compliance and administration costs.

The Department of Health and Family Services proposed that Australia should:

... harmonise the devices program more closely with the European model to ensure consistency of approach with most other developed countries. Initially the principles of the European Directives are being adopted as far as permitted under existing legislation. In the longer term, and following appropriate consultation, it is hoped to align Australia's existing legislation with the European system. (sub. 16, p.12)

Subsequently the TGA indicated that the Mutual Recognition Agreement was:

... the first step in this process of aligning the Australian requirements for the regulation of medical devices with those of the EU. The experience gained under the MRA will facilitate the drafting of the legislation necessary to transpose the essential requirements of the EU Medical device Directives into law in Australia. (sub. 77, p.4)

The agency informed the Commission that the Commonwealth Government:



... has proposed that the requirements for the regulations of the quality and safety of medical devices in supplied in Australia (regardless of country of manufacture) will be aligned with the requirements of the EU.

In common with the approach adopted by the competent authorities in each of the EU member states this will require the development of legislation to transpose the essential requirements of the EU directives into law in Australia. (sub. 77, p.4)

### **Commission's proposals for reform**

The Commission does not consider that it is necessary, or appropriate, to await the conclusion of this Agreement. Action could be taken now to capture the benefits for Australian manufacturers and device users of the EU approach.

The Commission can see no reason why Australia should not proceed as quickly as practicable to implement the essential requirements of the EU Directives for medical devices. Since the EU approach is fundamentally different, legislation will be required.

The TGA is currently preparing a regulatory impact statement to support the development of the necessary legislation. This process needs to be completed without delay. In the light of the findings from this inquiry the Commission considers that it would be perverse in the extreme if the formal process of assessing the impact of the proposed changes were to slow the introduction of what is clearly a more light handed approach to device regulation.

In preparing the relevant legislation it may be inappropriate to implement the EU Directives without taking account of differences between Australian and EU needs. The TGA observed that the legislation:

... will need to incorporate a 'safeguard clause' to ensure the Australia is able to take action in respect of any devices which are considered to present a public health risk, independent of the action taken in the EU.

The legislation will also need to take account of differences in the approach which may be required for specific medical devices such as silicone containing breast implants, tampons and possibly high risk implantable devices. (sub. 77, p.4)

Decisions about such adjustments should be based on an assessment of the relevant requirement against the implications for regulation in Australia. Nevertheless, the Commission believes that, for the same reasons that Australia should adopt the EU approach, any adjustments or departures should be kept to a minimum and be consistent with the spirit of the Directives.

The EU requires that manufacturers comply with GMP Codes but they do not have to be licensed. Rather they are issued with a CE Mark to signify that their devices comply with the essential requirements. Accordingly, the Commission considers there is no need for Australia to continue to licence manufacturers.

Some devices covered by the *Therapeutic Goods Act* are not covered by the EU Directives. Such goods are already covered by provisions of the *Trade Practices Act 1974*. The Commission considers that this is adequate.

**Recommendation 4.8**

The Commonwealth Government should implement the approach of the European Union to regulating medical devices by mandating in legislation the relevant essential requirements in the Directives of the European Union.

**Recommendation 4.9**

The Commonwealth Government should keep to a minimum any mandatory requirements for medical devices additional to those in the relevant Directives of the European Union and ensure that such requirements are consistent with the spirit of those Directives.

**Recommendation 4.10**

The Commonwealth Government should discontinue licensing manufacturers of medical devices.

**Recommendation 4.11**

The Commonwealth Government should leave the regulation of therapeutic devices not covered by the Directives of the European Union to the *Trade Practices Act 1974*.

Table 4.2 Assessment of the Australian and European Union approaches to regulating medical devices

<i>Approach Components</i>	<i>Assessment Criteria</i>							
	<i>Protection of Users</i>		<i>Compliance Costs of Manufacturers</i>		<i>Conformance Costs of Manufacturers</i>		<i>Administrative Costs of Government</i>	
	<i>Australia</i>	<i>EU</i>	<i>Australia</i>	<i>EU</i>	<i>Australia</i>	<i>EU</i>	<i>Australia</i>	<i>EU</i>
<i>Regulatory goals</i>	—	—	..	..	..	..	..	..
<i>Legislative approach</i>		✓		✓		✓	—	—
<i>Administrative structures</i>	—	—		✓		✓	—	—
<i>Coverage of devices</i>	—	—		✓		✓		✓
<i>Basis of risk classification</i>		✓		✓		✓		✓
<i>valuation of devices</i>	—	—		✓		✓		✓
<i>Evaluation of manufacture</i>	—	—		✓		✓		✓
<i>Post market assessment</i>	—	—		✓	—	—	—	—

.. — not applicable  
 — — denotes equivalent performance  
 ✓ — denotes superior performance  
 Source: Industry Commission

## 4.5 Specific issues related to regulation

Issues related to the regulation of medical devices were raised by a number of participants. They fell into two categories:

- silicone breast implants; and
- the reuse of medical devices labelled as single use only.

### Silicone breast implants

In the US product liability actions against companies involved in manufacturing silicone breast implants increased dramatically in the late 1980s. In September 1993 five companies (including Dow Corning) agreed to pay \$US4.25 billion in a global settlement of a series of class actions on silicone breast implants filed in the US.<sup>7</sup> Faced with thousands of lawsuits that were covered by this settlement, Dow Corning filed for Chapter 11 bankruptcy in May 1995 (sub. 18 attach. 4).

In April 1992, following reports from medical device companies, patients and clinicians, the US Food and Drug Administration (FDA) limited access to silicone breast implants until studies proved their safety and efficacy (sub. 18, document 3). Box 4.4 outlines the FDA's concerns.

#### **Box 4.4      Silicone breast implants: the concerns of the US Food and Drug Administration**

The US law governing medical devices requires manufacturers to prove affirmatively, with valid scientific data evaluated by the FDA, that their devices are safe and effective.

An evaluation by the FDA of evidence presented to it in 1991 and 1992 concluded that there were insufficient data about the risks and benefits of silicone breast implants. The FDA's main concerns were:

- local complications which, when they occur, could be directly attributable to the implants. These include implant rupture, capsular contracture, infection and surgical complications; and
- systemic diseases, where the association between the implant and disease is more difficult to establish.

The FDA also had concerns that manufacturers' quality control procedures were not adequate to prevent safety problems.

*Source:* sub. 18, document. 3

<sup>7</sup> Class actions, mass torts and representative actions allow groups of individuals to join together to pursue lawsuits involving essentially the same issues.

Similar concerns were expressed in Australia and the Therapeutic Devices Evaluation Committee (TDEC) reclassified silicone breast implants to the registrable category in 1991.

Dow Corning submitted that its experience of the silicone breast implant debate raised the following issues for this inquiry:

- the implications of product liability law for the medical devices industry;
- the implications of medical device regulation for product liability law; and
- the implications of product liability litigation for the cost of product liability insurance.

### *Product liability litigation and medical devices*

Dow Corning submitted that its experience of product liability litigation had important implications for the future development and marketing of medical devices. It also claimed that the right of litigants to pursue mass torts would increase the costs of product liability insurance which might result in the loss of silicone as a raw material for the medical (and scientific) equipment industries.

Until 1993, when it withdrew from the industry, Dow Corning was a major manufacturer of medical devices.<sup>8</sup> It was also a major supplier of biomaterials for other medical device manufacturers and supplied 80 per cent of the global market for medical grade silicone. In that year it withdrew silicones from implant, obstetric and gynaecology and contraception applications and at the same time withdrew implant grade materials from general sales, although it remains a supplier of some medical device materials.

In recent years, other companies have ceased to supply biomaterials for the manufacture of medical devices: in 1992 Dow Chemical withdrew Pellethane from implantable devices; and in 1994 DuPont withdrew Dacron, Delrin and Teflon from all implant applications. Shell and Monsanto have also left the biomaterials business (sub. 18, p.11).

### *The regulatory response*

Dow Corning claimed that:

- science has established no link between silicone implants and disease;<sup>9</sup>

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<sup>8</sup> Its products ranged from hydrocephalic shunts to silicone oil for coating syringe needles. In 1993 Dow Corning sold its medical device manufacturing business (sub. 18, p.1).

<sup>9</sup> Dow Corning referenced a number of studies to support its contention and included several as attachments to its submission.

- the TGA ‘moratorium’ on the sale of silicone breast implants, although consistent with decisions by Canada and the US, was inconsistent with those in the EU;
- the implied message of the ‘moratorium’ was that the devices are unsafe;
- the Department of Health and Family Services (DHFS), TGA and the National Health and Medical Research Council (NHMRC) had made an insufficient effort to dispel this message; and
- the implied message may have effected the outcome of lawsuits the company faced. (sub. 18)

Dow Corning called for the TGA to provide:

- a clear transparent rationale process and procedures ... crisis management plans and communication strategies;
- a panel of independent experts who can review the impact of regulatory decisions;
- timely factual scientific positions on products; and
- assistance to and cooperation with any other appropriate government body which may play an educative or information role. (sub. 59, p.3)

The company also called on the TGA to outline its generic position on safety.

#### *TGA’s response*

The TGA provided the Commission with an outline of the history of the regulation of silicone breast implants. This included a restatement of the basis for the decision by the TDEC to recommend that these devices be reclassified (see Box 4.5). The TDEC’s reasons were documented at the time, and a formal appeal mechanism on the TGA decision is provided for in the *Therapeutic Goods Act*.

The TGA believes that its position has been clearly stated:

... there are no silicone gel filled breast implants on the Australian Register of Therapeutic Goods but that applications would be accepted for evaluation in accordance with the requirements specified in DR4 — ‘*Australian requirements for evaluation of therapeutic devices*’. (sub. 80, p.2)

Moreover the TGA observed that no manufacturer has since applied to have its silicone breast implants evaluated as registered devices on the ARTG nor has any manufacturer appealed the decision to reclassify.

In response to Dow Corning’s comments on the regulatory framework, the TGA submitted that:

- there is a clear, documented, process which has been developed inclusive of extensive industry consultation, etc.;
- there is a panel of independent experts who advise the Minister (and the TGA) on policy and regulatory decisions;

- working through the Minister, timely statements are made on products as required; and
- the TGA does provide assistance and cooperation to other eminent bodies such as NHMRC as situations demand. (sub. 80, p.3)

The TGA felt that TDEC's decision was broadly consistent with those made in the US, Canada and France. It observed that the EU has classified silicone breast implants as high risk devices (that is, as Class III devices).<sup>10</sup>

#### **Box 4.5 Regulation silicone breast implants in Australia**

The TGA outlined the regulatory history of silicone breast implants.

- On the commencement of the *Therapeutic Goods Act* these implants were 'grandfathered' on the ARTG as listable devices without any evaluation. No controls had existed prior to this date.
- In response to increasing concerns about safety, the TGA wrote to the sponsors of these implants in July 1991 to seek evidence of their quality, safety and efficacy.
- Silicone breast implants were reclassified from listable to registrable on 24 December 1991.
- In February 1992 following the announcement of a moratorium on supply in the USA, the TGA agreed to a voluntary moratorium for six months initially, with the Australian sponsors. During this time some sponsors lodged submissions with the TGA for evaluation.
- Examination of the sponsors' submissions indicated a paucity of data in support of quality, safety and efficacy. Sponsors were given the opportunity to withdraw their applications rather than risk the loss of their evaluation fees.
- All the sponsors withdrew their applications and all silicone breast implants were removed from the ARTG.
- No applications for registration of silicone breast implants have since been made.

Source: sub. 80

The TGA also noted that regardless of any links to disease, it is aware of over 400 reports of Australian women claiming to have suffered injury or disfigurement from silicone breast implant gel leaking through their bodies:

... research shows that the local effects are more frequent than first supposed and that rupture and leakage can occur in very high percentages of implants within a relatively short space of time. This alone is sufficient reason for a regulatory agency adopting a cautious approach. (sub. 80, p.4)

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<sup>10</sup> Currently, France is expected to call for additional regulatory requirements on silicone breast implants at the EU level (EDDR 1996).

*Commission's assessment*

The Commission is not competent to judge the scientific validity of claims about possible links between silicone breast implants and injury or disease. It notes, however, that in the US a panel of neutral experts is being appointed to evaluate the published findings and give US courts impartial advice on this matter (Meier 1996).

The Commission is also not competent to comment on the merits of TDEC's decisions in relation to silicone breast implants nor would it be appropriate for it to do so. However, the Commission supports the requirements of the *Therapeutic Goods Act* that sponsors should have to demonstrate that their devices meet appropriate standards of risk management.

Clearly knowledge about the risks associated with a device and its management changes. Such changes should result in devices being reviewed, and reclassified where appropriate. A device that had previously been evaluated as meeting the appropriate standard, may, in the light of new evidence, be re-evaluated as no longer satisfying that standard. This does not necessarily mean that the device is unsafe or ineffective — it may simply mean that its safety and efficacy have not yet been clearly established.

This is a subtle but significant distinction. Some may erroneously conclude that the lack of a positive finding implies that the product is definitely unsafe. The manufacturer, sponsor and regulatory bodies should therefore make reasonable efforts to dispel any such erroneous conclusions.

*Product liability litigation and insurance*

Dow Corning suggested that the trend in the United States towards mass tort product liability lawsuits:

- has meant that product liability insurance in the US is prohibitively high for some products;
- is very likely to be followed in Australia; and
- would mean that product liability insurance in Australia would become prohibitively expensive.

The company suggested that the right to use mass tort litigation should be limited in various ways and recommended that the Commission refer the topic to Australian Law Reform Commission (ALRC).

*Cost of product liability insurance in the US*

Product liability litigation in the US has increased the uncertainty faced by some companies exporting medical devices to that market. However, the problems



created by the operation of the US legal system are beyond Australian control but are the same for any company wishing to sell into this market.

### *Litigation trends in Australia*

Whether Australia will follow the US trends is likely to depend on the extent to which the US legal system is similar to that in Australia. The Commission's report on *Product Liability* (1990) indicates that the US system is unlike other common law legal systems both in its detail and operation (see Box 4.6). Given these differences it is unclear that Australia will follow US litigation trends.

#### **Box 4.6      Operation of the United States legal system**

The Commission's report on *Product Liability* (1990) noted that the features of the US legal system appear to underlie many of the problems experienced in that country:

... A United States Department of Commerce (1978) report on product liability concluded that the rise in liability insurance premiums seemed to be due far more to large and unpredictable jury awards than to the legal basis of liability ... major social changes in the United States during the mid-seventies were reflected in the disposition of juries and judges, and were a major factor in the 'explosion' of jury awards at that time. (p.118)

This report also noted that the US legal system differs from systems in other common law countries in several important respects:

... [It] is widely acknowledged as the most litigious country in the world, and spends ten times as much per capita on litigation than does the United Kingdom (OECD 1989) ... The court system in the United States contributes to a lack of predictability in judgments ... judges in the United States do not have a high regard for precedent ...

A number of factors in the United States system tend to inflate damages awards ... juries generally determine the awards ... lawyer receives two-thirds of the compensation paid on average ... judgments are also beginning to take into account the proportion of the award the claimant will not receive ... some States have introduced a system of 'joint and several liability' ... the richest defendant has to pay if the others cannot, irrespective of the proportion of the loss attributable to the defendant ... damages awards are usually more generous ... there is greater use of punitive damages ...

Overall, damages awards in the United States have increased to very high levels and are unpredictable ... In one large metropolitan area, the average punitive damage is over one hundred times as large as it was twenty years ago, in constant dollars. (pp.117-8)

Even if there is an increase in the rate of litigation and the size of settlements in Australia, it would still have to be determined whether there had been any failure of the Australian legal system. Given that the Australian legal system is substantially different from the US, the US experience may provide little guidance. Any policy response would need to reflect the Australian situation.

Were product liability insurance premiums to rise in Australia, this would not necessarily be sufficient evidence of the need for a policy response. Premiums might rise for any of a number of reasons unconnected to the operation of Australia's legal system or the operation of insurance markets. For example, the risks involved in the misuse of certain devices have increased due to the risk of infection from HIV and new strains of hepatitis.

#### *Commission's assessment*

Product liability concerns not just the medical and scientific equipment industries but the whole economy.

#### **Box 4.7      Related Australian Law Reform Commission Inquiries**

The ALRC has conducted a number of inquiries into issues associated with those raised by Dow Corning in relation to product liability litigation trends. Completed reports on related issues include:

- ALRC 46 (1988) — *Grouped proceedings in the Federal Court*;
- ALRC 51 (1989) — *Product liability*; and
- ALRC 75 (1995) — *Cost shifting: Who pays for litigation* which examined issues relating to the cost allocation rule.

In addition, the ALRC is currently conducting a review of the adversarial system of litigation. This inquiry is examining the advantages and disadvantages of the present adversarial system of conducting civil, administrative review and family law proceedings before courts and tribunals exercising Federal jurisdiction. The inquiry also covers issues involving representative actions such as class actions or mass torts.

*Source:*                      sub. 78

The issues in product liability have been addressed in the past by the ALRC, for example in its report on Product Liability (ALRC 1989). The same issues were canvassed by the Industry Commission in its assessment of the proposals contained in the ALRC report (IC 1990). The details of a number of related reviews are provided in Box. 4.7.

The ALRC considers that the implications of product liability litigation broadly fall under its current review of the adversarial system of litigation. However, it notes that the issues raised in Dow Corning's submission would involve many specific elements being added to that inquiry's scope.

Consequently, the ALRC proposes that:

... it would be more appropriate for the Attorney-General to refer a focussed and separate inquiry to the ALRC examining these issues. We encourage the Industry Commission to approach the Attorney-General about the possibility of referring such an inquiry to the ALRC. (sub. 78, p.1)

*The Commission draws attention to the suggestion that the issues relating to product liability raised by Dow Corning be referred to the Australian Law Reform Commission for review.*

### **Reuse of medical devices labelled single use only**

Once almost all medical devices were reused. They began to be replaced by pre-sterilised and more convenient disposable and single-use devices about 30 years ago. Today many devices are labelled single use only. However, despite being labelled single use only, reuse of many of these devices is widespread (Collignon *et al.* 1996, NHMRC 1995).

Many inquiry participants raised the issue of devices labelled as single use only being reused.

Some expressed concern about the safety of reuse. The MIAA submitted that safety concerns justify a ban on the practice (sub. 72). Others expressed concerns about the scope for mislabelling-labelling devices 'single use only' and the costs associated with not re-using at least some of these devices (sub. 36 and sub. 73).

In August 1994, the NHMRC established an expert panel to advise on issues related to reuse of 'single use only' devices. The Expert Panel issued a draft report in October 1995. Its final report has been completed but has not yet been publicly released.

#### ***NHMRC Expert Panel***

The Expert Panel concluded that at least some critical devices labelled 'single use only' could be reused without adequate levels of safety being compromised if suitable protocols are adhered to. In addition, it concluded that on one expensive product alone there are substantial economic benefits to be gained from reuse. It said:

... reuse of expensive single-use items (Electro-physiology (EP) catheters being the example examined in detail) could be justified on cost-benefit grounds. These analyses suggested that the total national saving from reuse [of EP catheters alone] ranged from around \$9 million to \$15 million dollars per annum. (NHMRC 1995, p. 4)

Others in the health sector concurred. For example, the Hospital Infection Group of the Prince Henry, Prince of Wales and Prince of Wales Children's Hospitals submitted to the Expert Panel that:

Based on experience and commonsense, the current world-wide practices evolved for the reuse of items labelled 'single use only' with cost as the overwhelming determinant. Considerable savings can be made by the reuse of EP catheters and dialysis membranes reused on the same patient, whatever analysis is used. (HIG 1996, p.2)

Some non-critical devices labelled as single-use can also be reused. With these devices patient's safety is not at risk and reuse becomes a purely commercial decision. In these cases, patient safety is not at risk either because of product design, a lack of contact with the patient or because failure poses no threat to patient safety.

Although the Panel concluded that reuse of some critical devices could be justified, it also found that current resterilisation practice within hospitals and central sterile supply departments was inadequate. The problems were not restricted to 'single-use' devices.

The Panel also noted that despite widespread reuse and inadequate sterilisation practices, there was little documented evidence of major adverse events associated with reuse.

#### *Expert Panel's recommendations*

To address the widespread reuse and the inadequate practices identified, the Expert Panel's draft report offered the Australian Health Ministers two options.

Option one was a ban on the reuse of medical devices labelled as single-use. In this case the Panel recommended that:

... either appropriate resources to purchase sufficient single-use devices must be provided or a reduction in services be explicitly recognised. In light of current experience, such a policy [a ban] would require rigorous monitoring. (NHMRC 1995, p.7)

Option two was to allow reuse to continue subject to stricter regulation. Hospitals would be required to put in place protocols and quality assurance systems relating to sterilisation practice and reuse of devices. The TGA would:

- audit these protocols and quality-assurance systems; and
- license institutions (hospitals and sterile supply departments) wishing to reuse medical devices labelled as single-use.

#### *Ban reuse*

This option received less detailed examination than the other one. However, the Expert Panel did estimate that:

... up to \$100 million per annum would be needed to fully maintain services if no reuse of devices occurred (NHMRC 1995, p.3).

Unfortunately, the Panel's draft report did not detail the rationale for a total ban. For example, it did not examine the:

- option of bans on the reuse of some but not all devices;
- monitoring required, its cost or how it should be carried out;
- implementation problems with an immediate ban — for example, the ability of the industry to meet the increase in demand for critical devices (sub. 74);
- health risks and health benefits from a ban; or
- implications of the switch in the funding of the health sector.

Accordingly a total ban on reuse has yet to be shown to be justified. Reuse of at least some medical devices currently labelled as 'single use only', especially some non-critical devices, appears to involve negligible, if any, additional risk to patients.

#### *Stricter regulation of reuse*

In the Expert Panel's second option the TGA is to audit and license sterile supply departments involved in resterilisation of single-use devices.

The TGA has expressed concerns about the resource implications of having to supervise any significant proportion of the 1100 central sterile supply departments involved:

... We simply don't have the resources ... [Opposition to t]he licensing [recommendation] was basically a resource issue for us. We just simply couldn't handle it ... (PH trans, pp.118–9).

Asked whether the States and Territories might be able to fill this role, the TGA observed that:

... since the responsibility for manufacture of therapeutic goods passed to the Commonwealth in 1991, states have generally disbanded, wound down their quality system certification capability ... (p. 119).

Although the overall regulatory framework recommended might, in principle, be adequate, the resource implications have been left unaddressed by the Expert Panel's draft report.

#### *An alternative approach*

Both options outlined by the Expert Panel involve rather heavy handed regulation. An alternative would be a more light handed approach which drew upon the expertise and common interests of the users in the health sector.

Reuse of some devices seems to be cost effective but users need adequate information to determine appropriate re-sterilisation protocols and practices. Hospitals have legal and ethical incentives to comply with practical protocols and procedures on reuse. However, it would be costly and wasteful for these to be developed by each hospital on its own.

Providing users with adequate information relating to the implications of reuse would be consistent with the Expert Panel's objective of obtaining a consensus on a national approach to reuse. A consensus might be achieved if hospitals and sterile supply departments were offered an opportunity to develop codes, protocols and accreditation, so that they could self-regulate the practice of reuse. There could be a role for government (through the NHMRC or DHFS) to fund research into which devices are suitable for reuse and into the effects of reuse on material degradation (sub. 68).

This alternative is likely to reduce the compliance and administration costs of regulation compared to option two and save a significant amount on the cost of purchasing devices in comparison with option one.

### *Labelling of single-use devices*

The Australian Hospital Association submitted that:

There is an obvious conflict of interest for manufacturers in the decision to label devices as single use only. These are the commercial benefits of higher product sales from labelling as single use only and the legal benefits of shifting liability for continued use of that product to the hospital/user ... (sub. 67, p.3)

The Expert Panel did not adequately deal with the issue of manufacturers labelling their devices as 'single use only' in situations where reuse is possible with appropriate levels of safety. In such cases a label 'single use only' conveys little, if any, information about the risks of reuse in terms of infection control or device degradation.

An outstanding issue, therefore, is whether responsibility for determining whether a device can be safely reused should rest with the user or be shared with the manufacturer. This in turn raises questions of the extent to which the manufacturer has a duty to disclose any relevant information concerning the possible reuse of the device. It also raises questions about the role of the TGA, if any, in ensuring that labelling does not misrepresent a device's capabilities.

An associated issue relates to a manufacturer's legal liability in circumstances where it knows that a device labelled for single-use is habitually reused by those purchasing it.

*Competitive disciplines on labelling*

Every device manufacturer has a financial incentive to promote devices as single-use or disposable if it allows them to sell a greater volume of product. This may be reinforced by:

- concerns associated with HIV and Hepatitis;
- the risks of product liability litigation;
- stricter regulation in major markets such as the US;<sup>11</sup> and
- changes in cost structures in the medical device industry.

The extent to which they are able to do so depends on the strength of competition or the threat of competition. It also depends upon the extent of any countervailing market power exercised by those purchasing devices.

These factors will vary from product to product. In some product lines, one or two manufacturers dominate sales. In other product lines, competition between manufacturers might be vigorous.

Moves toward greater harmonisation with the EU and other changes recommended in this chapter should facilitate increased competition. This in turn will limit the opportunities for manufacturers to successfully misrepresent as ‘single use only’ a device which may be safely reused.

Problems of collusive behaviour, where evidence is available, can be dealt with by the *Trade Practices Act*.

*Procurement disciplines on labelling*

Even with a high degree of competition between manufacturers, those purchasing devices need to be vigilant in seeking out the best value for money calculated on a ‘whole of life’ basis.

During this inquiry, participants were generally critical of government procurement of medical devices. The Commission was given many examples of conservative procurement practices and a tendency to buy on the basis of price rather than value for money on a ‘whole of life’ basis.

The issues are examined more fully in Chapter 5.

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<sup>11</sup> For example, new regulations in the US governing how contaminated material should be handled (IC 1995d).

*Commission's assessment*

The draft report by the NHMRC's Expert Panel did not adequately address a number of broader technical, regulatory and economic issues relating to reuse.

To formulate satisfactory recommendations on reuse these broader issues should be subject to a comprehensive review. For example, such a review should, as a minimum, assess the actual risks and cost savings attributable to current practice, examine the range of feasible alternative solutions and estimate the economic costs and benefits of each.

**Finding 4.1**

The draft report by the National Health and Medical Research Council's Expert Panel on the reuse of medical devices labelled as 'single use only' did not adequately address a number of broader technical, regulatory and economic issues relating to reuse. To formulate satisfactory recommendations on reuse these broader issues should be subject to further review.





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## 5 GOVERNMENT PROCUREMENT

*Governments are the main source of demand for medical and scientific equipment in Australia. Their procurement policies and practices are thus important issues for the medical and scientific equipment industries.*

*Participants raised concerns about the policies and practices outlined in this chapter. Many of the concerns are not new, nor peculiar to these industries — similar concerns have been raised in other recent studies of government procurement.*

Governments in Australia account for more than 50 per cent of domestic demand for medical equipment. Most of this demand is accounted for by the 700 or so public hospitals in the states and territories. The equipment procured includes, for example, scanners, diagnostic instruments, theatre apparatus and consumables, and beds and other furniture used in public hospitals.

Similarly, some 60 per cent of domestic demand for scientific equipment is associated with the government sector. This includes purchases of measuring and control instrumentation for publicly funded research institutes, scientific laboratories and educational institutions.

This chapter outlines the nature of government procurement and related arrangements in so far as they affect the purchase of medical and scientific equipment. It then outlines participants concerns about these arrangements including a proposal for a national inquiry into these issues.

### 5.1 Procurement and related arrangements

As governments are the main source of domestic demand, they can have a major influence on the viability of medical and scientific equipment companies. This is particularly so for those which sell their products predominantly in the domestic market, or which use the domestic market as a springboard to exporting.

The Commonwealth, State and Territory governments have general guidelines relating to government procurement (see Box 5.5 and Appendix G). A common goal of these guidelines is to obtain value for money. Additional goals, for example, developing industry and achieving environment outcomes can conflict with the objective of achieving value for money.

In nearly all cases, these general guidelines apply to medical and scientific equipment purchases by government departments and agencies, including individual public hospitals. An exception occurs in Victoria, where purchases by public hospitals are not subject to the State Government procurement guidelines (RT trans, p.153).<sup>1</sup>

### **Organisational arrangements**

A range of government organisations may be involved in the procurement process. For medical equipment the organisations include central procurement agencies, health departments, industry and regional development departments, regional health networks, individual public hospitals and public hospital associations. The state or territory department responsible for industry and regional development may become involved if a contract has the potential to affect local industry development. Examples of the various arrangements applying in some States and Territories are provided in Appendix G.

In the case of the procurement of scientific equipment, government departments and agencies are usually subject only to general procurement guidelines and policies of the relevant government. Educational institutions and research institutions generally make their own decisions about procurement, subject to internal needs and budgetary circumstances.

In most states and territories, procurement of high volume common use items (standard items which are used across all government) is the responsibility of a central procurement agency. Smaller quantities may be purchased by individual agencies, public hospitals or the regional area health networks, as in New South Wales and Victoria.<sup>2</sup>

The procurement of more specialised equipment is usually the responsibility of individual agencies, subject to central government approval. While agencies are generally free to negotiate contract terms and conditions, most governments stipulate competitive tendering for government contracts above a minimum value. In the Australian Capital Territory and Tasmania, for example, public tendering is mandatory for contracts of \$50 000 or more.

New South Wales and Western Australia have peak purchasing councils to monitor and control the costs of procurement in public health (respectively, the New South Wales Health Peak Purchasing Council and the Western Australian

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<sup>1</sup> In Victoria, public hospitals are separate corporate entities whereas in most other states and territories, public hospitals are considered as part of their health department.

<sup>2</sup> For example, metropolitan health services in Sydney and Melbourne are delivered by regional health networks and are more centralised than in other capital cities.

Health Supply Council). In the case of Western Australia, non-profit organisations can make use of government contracts for common use items.

The Victorian Hospital Association and the Hospitals and Healthcare Association of South Australia, which represent public hospitals in their respective states, have trading arms authorised to purchase and distribute certain equipment. In both States, private hospitals that are authorised by the central supply agency can make use of government common use contracts to meet their equipment needs.

### **Administration of public health**

The administration of public health in Australia is primarily the responsibility of State and Territory Governments — effectively each State or Territory runs its own public health system. Nonetheless, the Commonwealth also plays a key role through its funding for Medicare, grants to the states and territories, and monitoring and leadership activities.

The central health agency provides an annual budgetary allocation to the public hospitals within its jurisdiction — normally divided into recurrent and capital expenditure. The distinction between recurrent and capital expenditures has until recently, been based on historical allocations. Most States and Territories are seeking to constrain the increasing costs of the public health system. One approach being increasingly implemented is casemix funding. This involves linking some of the recurrent funding to the level of output of public hospitals.

Governments in Australia have recognised the need to improve the performance of the public health system. To this end, a set of performance indicators for public hospitals is in the process of being developed (National Health Ministers' Benchmarking Working Group 1996). While these include efficiency indicators, none of these are intended to focus specifically on the efficiency of procurement of medical equipment (Steering Committee 1996). However, the efficiency indicators being developed do require the collection of aggregate data on recurrent and capital costs for public acute care hospitals.

In their role as the major providers of health care funding, governments also exert a major influence on the introduction of new medical technologies such as magnetic resonance imaging. Some reasons for, and effects of this influence, are outlined in Box 5.1.

#### **Box 5.1 Government control over the use of new medical technology**

The Commonwealth Government is the main provider of funding for health services and its health expenditure in recent years has been escalating in absolute terms and as a proportion of GDP (OECD 1995). Moreover, new technology in medical equipment is a

significant factor in this upward pressure on health costs — although it may also offer better health outcomes.

The Department of Health and Family Services noted:

With rapid technological development and finite health resources, a critical issue the Government faces is defining the place of new health care technologies ... in the Australian health care systems so that those with proven benefits and costs are promoted (sub. 16, p.17).

With respect to defining the place of new health technologies, the Department also noted that:

... there is increasing international recognition that there should be a more systematic approach to the assessment of new and emerging medical technologies and procedures and that decision-making should be based on evaluation rather than expert advice alone (sub. 16, p.16).

The Commonwealth Government's control over new technology and the role of Australian Health Technology Advisory Committee (AHTAC) — the Government's main advisory committee — was discussed at the medical equipment industry roundtable. At those discussions, Weber Consultants noted:

It has had a major impact on one of my clients, who make devices for sleep apnoea. That committee [AHTAC] reviewed the whole technology and the treatment of patients for sleep apnoea and recommended to the Department of Health that they have a Medicare rebate for this item. The Commonwealth Department of Health just simply said, 'No, it's too expensive'. The committee then said, 'But it should at least be used for treatment of patients who have had a severe case of the disease, there should be rebate'. Again the Department of Health said, 'No'. So it severely influenced the ability of the client to sell his product under a legitimate way, even though he had the support of that committee. It's purely a financial matter. (RT trans, p.149)

## 5.2 Participants' concerns

A range of participants expressed concerns about the purchasing policy and practice of governments in relation to both industries' products. These included the Medical Industry Association of Australia (MIAA) (sub. 23 and 51) and the Scientific Suppliers' Association of Australia (SSAA) (sub. 11 and 63).

These concerns covered several aspects of procurement policy:

- preference for local producers;
- industry development requirements;
- the inclusion of environmental requirements in tenders;
- use of standing orders ('common use contracts'); and
- the failure of governments to work together on national issues.

In addition, participants criticised the procurement practices of the relevant agencies (ie the practical administration of policy). The criticisms, which were often interrelated, included:

- a lack of transparency in the procurement process;
- concerns about probity;
- the inconsistent use of standards;
- a narrow view of value for money in procurement decisions;
- failure to use performance specifications in tendering; and
- lack of skills in supply management.

In its initial submission, the MIAA argued that these concerns warranted a national inquiry into government procurement policies and practices affecting medical products (sub. 13, p.73). This was proposed notwithstanding the many recent reports and reviews relating to government procurement (see Box 5.2). The MIAA considered such an inquiry should examine the way generic procurement policies are implemented by public sector agencies. It asked the Commission to evaluate whether a further inquiry is needed (sub. 43, p.1).

To help understand the nature and extent of concerns raised by participants and possible responses, the Commission sought comments on the MIAA submission from health departments, central procurement agencies, and organisations representing public and private hospitals.

The following sections examine the criticisms raised by participants. In doing so the Commission has been mindful of:

- whether there are gaps in the coverage in previous reviews;
- the extent to which concerns raised by participants may reflect failures of the procurement policies and practices of governments or broader concerns — for example, with the organisation, management and accountability of the public health system; and
- whether the concerns raised could be adequately addressed through existing review mechanisms.

**Box 5.2 Reports and reviews relating to procurement**

Several government studies in recent years have examined government procurement.

These include a major review of the procurement policies of the Commonwealth Government by the House of Representatives Standing Committee on Industry, Science and Technology. Its report, known as the Bevis Committee Report (Commonwealth of Australia 1994a), was released in March 1994. The Government responded to the report in December 1994 (Commonwealth of Australia 1994b).

The Industry Commission has also examined procurement in the context of its reports on *Defence Procurement* (IC 1993), *Computer Hardware, Software and Related Industries* (IC 1995c); *Competitive Tendering and Contracting by Public Sector Agencies* (IC 1996a) and *State, Territory and Local Government Assistance to Industry* (IC 1996e).

In the Commission's inquiry into the computer and related industries, participants complained about a number of the issues which have been raised in the present inquiry. The issues included insufficient recognition of quality and whole-of-life considerations; excessive use of technical specifications; the lack of skills of purchasing officers and alleged bias towards imports (IC 1995c, p.95).

In addition to the above reports, there are a number of other reviews under way which are relevant. These include:

- a review of the Government Procurement Agreement between the Commonwealth, State, Territory and New Zealand Governments;
- a review of purchasing policies in New South Wales and South Australia;
- a review of offsets arrangements, by the Department of Industry, Science and Tourism;
- a review considering whether Australia should sign the World Trade Organisation's Agreement on Government Procurement, by the Departments of Foreign Affairs and Trade and of Administrative Services; and
- an examination of the potential implications for Australia of accession to the World Trade Organisation's Agreement on Government Procurement, by the Industry Commission.

Another report which may be relevant is a study into the capital needs of Australia's public hospitals undertaken in the early 1990s (Deeble 1993). This study found the proportion of equipment considered to be obsolete had increased since the early 1980s. It concluded that a significant proportion of future purchases of equipment by public hospitals would be for replacing existing equipment.

**5.3 Issues in procurement policy**

The Commission has grouped the concerns of participants broadly into two groups: policy issues and administrative issues. In doing so, the Commission recognises such a categorisation is somewhat arbitrary as nearly all issues have both policy and administrative components.

The concerns of a policy nature are discussed below. Those of an administrative nature are discussed in the following section.

### **Preference for domestic industry**

Some governments have a policy which allows a formal preference margin to be applied on imported content. Currently, New South Wales, Queensland, and South Australia have a margin of 20 per cent. Western Australia, Tasmania and the Northern Territory have a formal preference margin of 10 per cent. In most jurisdictions these margins are rarely applied in practice (IC 1996f, p.47).

Where preferences exist, they are subject to the 1991 Government Procurement Agreement to which all Australian governments and New Zealand are signatories (see Box 5.3). This agreement provides that where a preference margin is given to Australian manufacturers, it should not discriminate between products from individual states/territories and New Zealand (Commonwealth of Australia 1991).

At the time of signing the agreement, the Commonwealth, Victorian, ACT and New Zealand Governments did not apply a preference margin. All governments have made a commitment not to offer a preference margin where services only are being procured (Commonwealth of Australia 1991, p.4). This agreement is currently under review.

State and Territory preferences may also soon be subject to restraints depending on Australia's response to APEC and World Trade Organisation agreements relating to government procurement.

In addition, the Industrial Supplies Office (ISO) in several states supports domestic manufacturers by promoting their potential capability to purchasers. In doing so they help local suppliers to understand government requirements and making bids to fulfil them.<sup>3</sup> These offices are funded by the respective State governments. The Industrial Supplies Offices in New South Wales and Victoria have appointed health industry consultants in recent years. The Commonwealth also provides some facilities to assist local manufacturers to gain access to government markets.

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<sup>3</sup> In Queensland, the ISO is titled the Industries Search and Opportunities Office.



**Box 5.3      Government Procurement Agreement 1991**

In 1991, the Commonwealth, State, Territory and New Zealand Governments signed the Government Procurement Agreement (GPA). It replaced the 1986 National Preference Agreement — which aimed to end the destructive procedure of state-specific purchasing preferences — and commits the signatories to:

- remove discrimination among themselves in government procurement;
- use ‘value for money’ as the main selection criterion;
- work in a coordinated way to improve government procurement policies and practices and achieve greater uniformity; and
- maximise opportunities for Australian and New Zealand industry development through procurement.
- The GPA is currently being reviewed in accordance with the provisions of the agreement. The terms of reference for this review of the GPA require advice on:
  - the appropriateness of its core principles;
  - its relevance, effectiveness and operation;
  - the impact of the changing policy environment (domestic and international), including industry development and trade liberalisation;
  - the locus of ministerial responsibility of the agreement; and
  - the perspectives of key stakeholders.

Under the terms of the GPA, the National Supply Group is responsible for monitoring and reporting on the agreement, and is conducting the current review.

The National Supply Group is made up of officials from Commonwealth, State, Territory and New Zealand supply departments, and a representative of the Standing Committee on Industry and Procurement. At present, the National Supply Group reports to the Chief Executive Officers of these supply departments. Matters which require Ministerial consideration are brought to the attention of individual Ministers by their respective Chief Executive Officers.

*Sources:* IC 1996e, p.79; Commonwealth of Australia 1991; IC submission to GPA review, November 1996

***Participants’ views***

Some participants stated that many government purchasing officers have an ‘imports are better’ mentality and that preferences had a role in countering that bias. For instance, the Technology Industries Exporters Group commented:

Culturally we have a long way to go before ‘buying Australian’ becomes a natural decision rather than automatically assuming imported products are better (sub. 17, p.4).

Other participants cited the preferential purchasing policies adopted by other countries as a reason for adopting similar policies in Australia. For example, the

Industrial Supplies Office of Victoria (RT trans, p.9) noted that in the US, government purchasing is subject to the *Buy America Act* which is of considerable assistance to smaller businesses. Similarly, Sydlore, in arguing for positive discrimination by government to purchase Australian made medical products, noted the benefits a Korean producer of ultrasound equipment had received because Korean government hospitals gave it preference (sub. 29).

Several companies operating overseas expressed reservations about the use of preferences, noting that they could be viewed by other countries as a non-tariff trade barrier. This might lead to reciprocal action by foreign governments.

Preference margins, while available in practice, are often not implemented because they conflict with the desire to get value for money or the lowest possible price. The MIAA noted:

... on the preference margin issue ... It's doing nothing for local industry, really. When it comes down to awarding contract commodity items, it's not value for money, it's not state of origin or whatever, it's price and it's price and it's price. It's nothing else. (RT trans, p.173)

The MIAA considered it was inappropriate to give a specific preference to domestic manufacturers. It argued that manufacturers were better served by long term commitments to purchase from local industry for items in which they are competitive (RT trans, pp.173–4).

Other participants stated they did not want a specific price advantage. For example, Tuta Laboratories argued what it wanted was for domestic manufacturers to be recognised in instances where it could provide comparable quality, performance and services (sub. 15, p.7). Rather than preferential margins, the New South Wales ISO favoured policies to promote competition for government contracts:

It is the success of Australian manufacturers in a commercially competitive environment that convinces NSW ISO that genuine opportunities are the best assistance such manufacturers can receive (sub. 35, p.2).

Several companies suggested that the importance of a domestic manufacturing capability in preventing a dependence on imports was not sufficiently recognised in government purchasing policies. In this regard, many participants expressed support for the activities of the Industrial Supplies Office network around Australia. The Australian Health Industry Development Forum, for example, commented:

... ISO's data on, and understanding of, the capabilities of the Australian manufacturing sector could prove to be as beneficial to domestic medical equipment/device manufacturers and to other product manufacturers in the health sector, as it has been to domestic manufacturers in other industries (sub. 30, p.6).

*Commission's comments*

Evidence on the effectiveness of domestic preference is limited. A study by the BIE (1988) of Commonwealth Government procurement and the Bevis Report (1994) highlighted the lack of reliable data for making firm conclusions about the effectiveness of preferential purchasing policies on local industry. The Bevis Committee (1994) commented that:

The devolved nature of current government purchasing practices makes it difficult to evaluate the efficiency and probity of a large proportion of government purchasing, let alone the extent to which such purchases might benefit the Australian economy (p.398).

Similarly, in its Draft Report on *State, Territory and Local Government Assistance to Industry*, the Commission has noted the difficulty of assessing the effectiveness of the Government Procurement Agreement because of inadequate information (IC 1996e, p.79).

In the Commission's previous inquiry into the medical and scientific equipment industries in 1987, some participants claimed that the extra costs of preferences provide government agencies with a strong financial incentive to exclude domestic products from serious consideration in tenders (IAC 1987, p.109).

Support to domestic industry may not be consistent with achieving value for money, if it means that government agencies have to purchase higher priced equipment. This has implications for taxpayers and consumers if preference margins result in higher operating and capital costs in government agencies. As a means of providing assistance for domestic industry it is both inequitable and inefficient, as preference margins only apply to domestic sales.

The Commission considers that the support of other countries for domestic manufacturers does not, of itself, justify Australia adopting similar policies. Rather, the important issue is whether providing specific preferences for domestic industry will result in net benefits to Australia as a whole. As noted above, the evidence of this is limited.

Of relevance here is the Commonwealth Government's response to the APEC Action Agenda on government procurement. This Agenda, which commits members to developing a common understanding on government procurement policies and systems, was adopted in October 1995. While the Commission is not privy to the details of the Commonwealth Government's draft response, it is likely to include negotiation with states and territories on a common approach to government procurement. This would cover elimination of preference margins.

Also relevant is whether the Commonwealth Government accedes to the World Trade Organisation's Agreement on Government Procurement. Formal preference margins are incompatible with Article III of the agreement, which

states that products from all signatories to the agreement should be treated equally with domestically produced goods (IC 1996f, p.48).

### Industry development requirements

Almost all state and territory governments use procurement guidelines to foster industry development in their jurisdictions (see Table 5.1). For example, the Northern Territory government emphasises, among other objectives, the need for government procurement to support local firms and employment, and to encourage new firms to the Territory (Northern Territory of Australia 1994).

**Table 5.1** Government procurement policies for the development of local industry

State or Territory	'Buy local if competitive' policy in use	Recognises benefit of local sourcing in assessing tender	Preference for non-metropolitan over metropolitan suppliers
NSW	no	no	yes
Vic	yes	no	yes
Qld	yes	yes, for Qld and Australian products	yes
WA	yes	yes, for WA products	yes
SA	no	no	no
Tas	no	no	no
ACT	yes	yes, for ACT products	no
NT	no	yes, for NT products	no

Source: IC 1996f, p.15

In addition, New South Wales has foreshadowed introducing an Economic Benefits Statement for all NSW Health tenders over \$100 000. The statement will require all tenderers to provide details of their activities, sales, market share and future industry intention. The NSW Peak Purchasing Council stated that the objective of this strategy is to encourage local manufacturing (sub. 26, p.1).

### *Participants' views*

The MIAA expressed dissatisfaction with the industry development requirements in government procurement. It stated:

If companies in the medical products industry are to make sensible investment decisions that best serve the needs of the Australian market, then government — as the industry's major customer — has to play its part by making clear to the industry what its requirements are. At present those requirements are not clear. (sub. 13, p.73)

More fundamentally, the MIAA considered the pursuit of industry development objectives through government procurement was incompatible with the rational development of the medical equipment industry (sub. 13, pp.76–7).

The MIAA and the Australian Private Hospitals Association also expressed concern that even where industry development requirements are met by companies they may not necessarily benefit. Companies may still fail to win government contracts where the overriding concern of health authorities is to minimise direct costs (sub. 13, p.74 and correspondence 18 July 1996).

NSW State and Regional Development noted that NSW will not pay a premium for goods in exchange for industry development. However, where an opportunity for investment is signalled by the Economic Benefits Statement, NSW Health will involve State and Regional Development to possibly secure the investment and may offer longer contracts to facilitate local investment (sub. 28, p.3).

### *Commission's comment*

The pursuit of industry development objectives through government procurement has been reviewed extensively in recent Commission reports.

The report on competitive tendering and contracting (IC 1996a) noted that using procurement to encourage industry development may seem beneficial to the recipient state. It has, however, the potential to distort industry structures and fragment both industries and companies at the state and national level, at considerable economic and social cost to Australia as a whole (IC 1996a, p.215).

Similarly, an assessment of state procurement policies in the report on computer industries (IC 1995c) concluded that attempts to link industry development objectives with government procurement are compromising the value for money objective. Doing so also limits the flexibility of companies' operations and is likely to result in a less efficient and dynamic industry (IC 1995c, pp.7–9).

These concerns relate to governments using procurement as a means of providing industry *assistance* in a discriminatory and non-transparent manner. This is not to deny, as Professor Marceau (sub. 9) noted, that governments have a legitimate role in encouraging industry development through their procurement as leading edge customers (along the lines suggested by Porter, 1990) or as nodes in Australia's system of innovation.

The use of government procurement to assist industry development more generally has been addressed by the Commission in its Draft Report on *State, Territory and Local Government Assistance to Industry* (IC 1996e). In that report, the Commission suggested that Australian governments should discuss the possibility of negotiating a broad based agreement to restrain the use of industry assistance measures. It also suggested that, regardless of progress on this issue,

governments should recommit to the Government Procurement Agreement (IC 1996e, p.xix).

Where industry development requirements are, however, a part of government procurement, the lesson from the competitive tendering and contracting report is the costs of meeting industry development obligations are likely to be higher where commitments are integrated into specific purchasing contracts. Such arrangements add to the cost and complexity of tendering, while affording companies the least flexibility in seeking internationally competitive activities. The greater the degree of flexibility that companies have in fulfilling their industry development obligations, the less likely that the pattern of development will be distorted away from activities that reflect their competitive advantage (IC 1996a, p.212).

To the extent industry development requirements in government procurement increase suppliers' costs and compromise the pursuit of value for money, costs to purchasing agencies will also increase.

Once again, Australia's responses to the APEC Action Agenda on government procurement and possible accession to the World Trade Organisation's revised Agreement on Government Procurement are also relevant. Commitments entered into in these fora would restrict state and territory governments from using procurement arrangements to provide industry assistance.

### **Environmental requirements**

Some governments specifically require that environmental aspects be considered in purchasing decisions.

The Western Australian Government's purchasing guidelines, for example, state that public authorities should not purchase or use goods known to involve the use of chlorofluorocarbons. The guidelines also state that preference should be given to recyclable products when other evaluation criteria are equal (State Supply Commission 1992).

The NSW Health Peak Purchasing Council has introduced Environmental Guidelines for all NSW Health purchasing authorities. The ACT government is developing an Environmentally Responsible Purchasing Policy and will seek from suppliers the type of information requested by NSW.

### ***Participants' views***

Some participants expressed concern about the inclusion of environmental criteria, on the basis that it imposed unjustifiable costs on suppliers.

The MIAA noted that industry accepts environmental considerations can be a factor in government purchasing decisions. It argued though that such environmental considerations should be developed within a framework of general guidelines determined by the highest levels of government. Such matters should not be determined by individual health authorities (sub. 13, pp.80–81). Additionally, the MIAA claimed suppliers may face costly demands as a result of the environmental requirements some health agencies have been tempted to include in their procurement guidelines.

The NSW Health Peak Purchasing Council stated that the Environmental Guidelines introduced for all NSW Health purchasing authorities appear to be at loggerheads with other NSW government instrumentalities. It also noted that Queensland and Victoria are developing guidelines at various levels which, in some instances, would require advice from suppliers which will add substantially to the cost of a tender (sub. 26, p.2). The ACT government noted that the sort of information it was requesting from suppliers was appropriate for assessing the value for money of tenders received (sub. 39).

Nursing the Environment (sub. 36) implied existing incentives were inadequate to restrict the use of polluting and wasteful medical disposables. It considered encouragement should be given to local industries producing bio-medical devices to make their products more reusable and recyclable. In this regard Nursing the Environment approved of draft environmental purchasing policy guidelines issued by NSW Health, which emphasise regard for the environmental impact of purchases within the overriding criterion of value for money.

### *Commission's comments*

There is a potential conflict between the environmental objectives within purchasing guidelines and the overall objective of pursuing value for money.

To help reduce this conflict, the environmental objectives of governments should be pursued through regulation that applies generally to all activities within their respective jurisdictions. This would help to:

- ensure that the environmental requirements are justified and do not discriminate against specific industries;
- reduce the costs to suppliers of meeting the requirements; and
- make costs of waste disposal more transparent.

Nevertheless, the Commission recognises that some governments may wish to use their purchasing policy to establish standards that go beyond those outlined in environmental laws. If this is the case, the additional requirements should be specified in the procurement guidelines, and the benefits and costs of those additional requirements made transparent.

### **Common use contracts**

A common use contract is a standing offer arrangement used by central procurement agencies to procure goods and services commonly used across a range of government departments and agencies.<sup>4</sup>

In most states and territories, agencies are encouraged to make use of common use contracts where possible. In some states and territories (for example, New South Wales, ACT and Western Australia), it is mandatory for agencies to use common use contracts where they have already been negotiated.<sup>5</sup>

The Commonwealth has absorbed common use contracts into a wider approved supplier scheme for information technology and major office machine products (Commonwealth of Australia 1994b). However, for other products, including medical and scientific equipment, common use contracts will continue.

The Western Australian health purchasing guidelines list the following as the main advantages to both buyers and suppliers of common use contracts:

- more attractive pricing and conditions as the result of aggregation of the purchasing power of an agency/agencies so as to achieve economies of scale;
- reduction in the administrative work involved in sourcing goods, calling quotations/tenders and evaluating bids each time there is a particular requirement for the good or service;
- establishment of standards and quality of goods and services procured by agencies; and
- reduction in the cost of tendering to industry and enhancement of longer-term purchaser-supplier relationships (WA Government Health Supply Council 1996, p.1).

### *Participants' views*

The MIAA considered that, because common use contracts are actually standing offer arrangements, they do not involve any commitment to purchase by government. Hence, it is difficult for suppliers to bid on the basis of lowest price (sub. 23, p.78). The MIAA also believed that common use contracts disadvantaged medical equipment manufacturers with a broad product range, as they needed to bid, or enter into multiple contracts, for their range of products.

These concerns suggest that in some instances, common use contracts may not result in best value for money. There were also a number of participants who felt that the difficulties with common use contracts are due to government agencies

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<sup>4</sup> Also referred to as a period contract in New South Wales (NSW Premier's Department 1995).

<sup>5</sup> In Western Australia, agencies in regional areas may purchase up to \$5000 per item from local suppliers, even where a statewide contract exists (Health Department of WA, sub. 37, p.2).



not complying with contracts that had already been let for the same item of equipment.

The MIAA commented that, even where a state government contract is awarded to a single supplier, a hospital might ignore that contract. The MIAA considers that the arrangements to monitor compliance with common use contracts is weak, and authorities ultimately rely on the willingness of affected suppliers to act as ‘whistle blowers’ (sub. 26, p.79). The NSW ISO argued that alternative suppliers are able to undercut the winning supplier because they did not make their lowest possible bid at the time of the initial contract (sub. 35, p.7).

The NSW Health Peak Purchasing Council noted that individual hospitals may sometimes obtain better pricing arrangements by directly negotiating with suppliers, where a contract has been shared by several suppliers and/or for various product categories (sub. 26, p.2).

In its response to the Draft Report, the MIAA noted:

The important issue is not whether common use purchasing is a useful technique but what **form** of common use purchasing is the most cost effective ... The fact is there is no standard form of common use contracting across the healthcare sector [and] ... various elements are mixed and matched in differing combinations not only from State to State but also within individual States ... Comparative analysis to identify the most appropriate form of common use purchasing may deliver substantial gains in efficiency. (sub. 51, p.5)

The MIAA expanded on this theme, stating:

The complexities of the current period contracts system with major differences in how different states and agencies go about the process is a very considerable cost on an industry to address all those various systems operating (PH trans, p.205).

### *Commission's comments*

In its report on *Defence Procurement* (IC 1993), the Commission noted two main advantages to government of common use contracts: the ability to obtain lower prices through collective purchasing and savings in administrative costs (IC 1993, p.117).

Common use contracts provide an effective means of achieving a government's objective of best value for money. However, it should not be necessary to mandate the use of such contracts. If common use contracts represent the best value for money, individual agencies seeking the same outcome may be expected to use the contracts voluntarily.

The Commission acknowledges the concern among participants that the variety of contracts used by some state and territory governments impose costs on suppliers. It notes, however, that this issue is already receiving attention (albeit at a much broader level than procurement for medical and scientific equipment)

through the National Supply Group. Through this group, the Commonwealth is currently pursuing cooperative arrangements with state and territory governments to put in place more cost effective common use arrangements.

### **Coordination between governments**

For some areas of procurement policy, governments in Australia have shown their willingness to cooperate on common policy issues and have put in place arrangements to achieve this.

The 1991 Government Procurement Agreement, outlined in Box 5.3, is an example of this cooperative approach. This agreement — which originated out of a desire of the states and territories to end the destructive procedure of state-specific purchasing preferences — has promoted a single government marketplace for Australian and New Zealand suppliers by eliminating the application of preference margins to out-of-state suppliers. It has also established a basis for the parties to work to improve government procurement policies and practices and achieve greater uniformity (Taylor and Barber 1996, p.4). (Annexe 4 to the agreement, which sets out the areas for possible greater uniformity, is attached to Appendix G).

Another arrangement in place for coordinating governments' approach to government procurement is the National Supply Group. The objectives of this advisory body include the pursuit of consistency in government procurement policy and lowering the cost of doing business with government.

### *Participants' views*

The SSAA noted that there is great diversity between governments in procurement (sub. 63, p.13). However, participants acknowledged diversity was not necessarily a problem. The MIAA, considered some degree of competition and variation on a theme is often advantageous (PH trans, 207). However, in many cases participants perceived that diversity to be a problem for firms supplying to many governments, and represented a failure of governments to coordinate their approaches to government procurement.

The New South Wales Health Industry Forum (1996, p.4) noted there has been an inconsistent and uncoordinated approach across governments in purchasing and providing incentives to suppliers. The preceding sections on preferences, industry development and common use contracting provide examples of this.

A number of participants drew attention to an apparent lack of cooperation in the realm of electronic commerce. The NSW Health Peak Purchasing Council claimed in this area the states are acting at cross purposes. It stated that there appears no evidence of coordinating efforts in electronic data interchange and the

standardisation of bar coding, and states seem to be pursuing their own agendas (sub. 26, p.2). The same position was expressed by the South Australian Health Commission (sub. 48) and the MIAA (sub. 26, p.84), both of which considered this issue should be addressed nationally. However, the ACT Government noted a nationally coordinated approach is already in place to resolve this issue via an inter-government working party reporting through the National Supply Group (sub. 39, p.6).

Some firms, such as Surgi Supplies International, expressed concern at 'the never-ending evaluation by Australian hospitals of the same product' (sub. 34, p.1). It suggested a central register of product evaluation results would reduce the need for repeated trials of products by hospitals (sub. 34, p.6). Similarly, the MIAA argued that there is scope to rationalise and better coordinate product evaluation arrangements. This would reduce the costs to industry of supplying products to government for trial purposes (sub. 26, p.79).

Baxter Healthcare considered that the lack of standardisation lead to higher inventories and the need to produce smaller batches. Similar versions of essentially the same product sometimes had to be produced to cater to the whims of the individual purchaser (RT trans, p.161). However, WA Health stated that there were often subtle differences between products. It cited multiple adhesive dressings as an example. These were needed to cater for the 'different and diverse applications within hospitals and because some patients are allergic to some adhesives' (sub. 37, p.4).

### *Commission's comments*

Given the above comments and earlier concerns, there are clearly aspects of government procurement which would benefit from a more coordinated approach. These are likely to be those where there are already similar needs between the jurisdictions and the potential exists to reduce duplication. Examples include aspects of electronic commerce (where some coordination appears underway) and product evaluations. Additionally, the apparent trend to use procurement as a form of industry assistance suggests a cooperative approach. This limits the potential to distort industry structures and fragment industries, companies and prevent escalation.

The Government Procurement Agreement appears to offer a ready vehicle to address the inconsistencies of concern to participants. It is an existing arrangement for cooperation and coordination in government procurement policy. Furthermore, its scope already encompasses the range of areas of concern brought to the Commission's attention in this inquiry.

The Government Procurement Agreement also has the advantage that it considers government procurement in a broad (rather than industry specific) context. At the

same time, the terms of that agreement require that industry bodies be consulted as part of the process to achieve greater simplicity and uniformity in procurement policies, practices and procedures. This would appear to meet participants' calls for policy deliberations on government procurement to include consultation with industry (eg MIAA, sub. 13 and NSW State and Regional Development, sub. 28).

## **5.4 Issues in procurement administration**

Participants also expressed a range of often interrelated concerns about how government procurement policies are administered. These concerns (such as a lack of transparency and discriminatory specifications) led to expressions of a lack of confidence in the process of government procurement and concerns about the degree of probity involved.

### **Transparency in purchasing**

The lack of transparency about decision making appears to be a more general feature of public hospital purchasing in Australia (see for example, the Independent Commission to Review Public Sector Finances 1993, p.208 and the South Australian Commission of Audit 1994, p.180). This is despite explicit guidelines adopted by all governments designed to introduce transparency into government procurement.

#### *Participants' views*

There was widespread concern among participants about the transparency of the government procurement process. The Australian Health Industry Development Forum, for example, noted:

The predominant feedback from the industry ... has been centred on the inconsistency and frequent lack of transparency in government practice (sub. 30, p.4).

Similarly, NSW ISO considered that many Australian medical and scientific industry manufacturers lack confidence in the procurement practices of the public sector health system and ascribed this to a lack of transparency in the system (sub. 35).

Along with other participants, NSW ISO believed inadequate information contributed to this lack of transparency. Complaints about the poor availability of information included that available:

- to government supply managers on the prices and capabilities of medical and scientific equipment available in Australia;
- to potential suppliers on prospective equipment needs by government; and

- to losing bidders about the reasons for their failure.

On the issue of better information to supply managers, a number of participants argued for the introduction of a computerised database of information on medical equipment capabilities and prices. For example, Sydlor (a distributor of ultrasound equipment) argued that:

Australian governments must compile a database of manufacturers and service providers in Australia and this database must be updated every six months to take account of changes in the dynamic commercial world (sub. 29, p.2).

The MIAA also considered there is scope to broaden the use of computerised information systems (sub. 13, pp.83–84).

On the issue of better information to suppliers on the prospective needs of governments, several participants considered public hospitals do not have the necessary information to determine those needs (Faulding, RT trans, p.9). Some complained of poor forward planning of procurement and *ad hoc* decision making (VHA, RT trans, p.151), claiming this disadvantaged local producers, which are typically small companies without large amounts of stock. Dr. Hall claimed that government health departments usually have no depreciation policy for major equipment, which makes estimating when major capital items will be required difficult (sub. 40).

Supply SA noted that it provides details of forecast requirements via a Forward Procurement Plan, but these estimates are often ‘rubbery’ and dependent on funding availability (correspondence, 2 July 1996). Similarly, the NSW Health Peak Purchasing Council noted:

In the past NSW Health has had difficulty in providing accurate and timely statistical data on purchases ... Although a standardised approach to information technology is currently taking place ... without the installation of a statewide Health Catalogue and/or statistical gathering mechanism forecasting is not easy. (sub. 26, p.1)

The NSW ISO argued it is difficult for suppliers to identify the decision makers in public hospitals, because the responsibility for making procurement decisions varies considerably (sub. 35, p.4). This added to the difficulty in determining the prospective sales for which a company may wish to tender.

To assist potential suppliers obtain information on prospective needs, the MIAA called for a detailed study of hospital expenditure on medical devices and diagnostics to be included in the National Health Information Work Program.

On the issue of information to losing bidders, participants considered improvement in this area was crucial if decision makers were to be accountable for their decisions. The NSW ISO said that small and medium size enterprises had difficulty in obtaining feedback regarding tender performance, and stated:

This leads to rumours regarding the probity of some health purchases (sub. 35, p.3).

Many other participants also expressed concerns about the probity of the process. Some provided anecdotal and confidential reports of suppliers offering 'inducements' to government purchasers in the public health system in order to secure a contract. While no hard evidence was offered, some participants claimed such inducements were rife (PH trans, p.187).

### *Commission's comments*

In its report into competitive tendering and contracting (IC 1996a) the Commission proposed a range of principles which, among other things, were designed to ensure transparency in the procurement process. These principles are presented in Box 5.4. The Commission considers that adherence to many of those principles, especially (a) to (d) and (l) to (q), would significantly increase transparency. Current guidelines embody these principles but it is apparent they are not always being adhered to in practice. This partly reflects the incentives operating within, say, hospitals and inadequate accounting systems. This suggests the problems of procurement need to be addressed at a broader level.

As the Commission noted in that report, concerns about probity would be reduced if the procurement process were more transparent, and if there are effective dispute resolution mechanisms (IC 1996a, pp.279, 332). The principles set out in Box 5.4 are in this sense similar to a code of conduct which Fairmont Medical Products considered was needed to address improper purchasing (PH trans, pp.190–91).

The Commission is aware of a range of measures already undertaken to improve the availability of information:

- the ACT Government has established a computerised, on-line Buyers and Sellers Information System to inform local suppliers of government business opportunities (sub. 23, p.2);
- the Victorian Healthcare Association (formerly the Victorian Hospitals Association) provides members with benchmark pricing of medical equipment sourced locally and overseas (RT trans, p.152);
- the Australian Healthcare Association (formerly the Australian Hospital Association) is aiming to introduce a comprehensive US database on medical products into Australia;
- the Department of Industry, Science and Tourism and Australian Business Ltd have a joint program to develop a health industry information clearing house which will operate via the Internet. ISO health consultants from NSW and Victoria are contributing to this program (sub. 35, p.3);

- the Western Australian Government is working towards introducing electronic commerce in the state (sub. 37, p.5); and
- the Australian Institute of Health and Welfare has estimated the value of capital equipment in Australia's public hospitals (National Health Ministers' Benchmarking Working Group 1996). Separate data are not available for purchases of medical and scientific equipment.

All Commonwealth, state and territory government purchasing guidelines endorse the principle of open and transparent procurement. Measures to

### **Box 5.4 Principles for competitive tendering and contracting**

In their approach to tendering, agencies should:

- a. specify the service in clear, accurate and easy-to-follow terms;
- b. consult both the intended clients (or their representatives) and potential providers in preparing the specifications and other aspects of the tender documentation (such as draft Requests For Proposal, Requests For Tender and contracts);
- c. adopt performance specifications wherever possible;
- d. use industry-wide standard forms of tender documentation (including contracts) and standardised tender processes where possible;
- e. select a type of contract appropriate to the characteristics of the service and nature of the market;
- f. include an appropriate mix of incentives and penalties when specifying the service contract;
- g. consider incorporating non-court dispute resolution procedures into service contracts;
- h. identify the risks involved in any contractual arrangement and allocate these risks to the party best able to manage them;
- i. use multi-stage tendering whenever feasible and short-list as quickly as possible;
- j. allow adequate time for bid preparation and between tender stages, taking into account the scope and difficulty of information requested from tenderers;
- k. seek no more than the information required at each tendering stage;
- l. publish tender evaluation schedules as early as possible and adhere to them;
- m. identify transition costs (including redundancy costs) and indicate in the tender documentation how they will be assessed at the tender evaluation phase;
- n. specify the selection criteria to be used in the tender evaluation and rank them in order of importance in the tender documentation;
- o. keep tenderers informed about the general progress of the tender process;
- p. advise unsuccessful bidders in writing as soon as they are eliminated from the evaluation process and debrief them on request; and
- q. consider employing, for major projects, an external audit of the costing of any in-house bid, an independent auditor on the evaluation panel and a probity audit of the tendering process overall.

*Source:* IC 1996a, p.349

improve the flow of information to buyers and sellers along the lines noted above will assist that process.

Given the similarities in the type of information which public hospitals require and the above initiatives, there could be benefits if governments were to pursue a more coordinated approach to the development of information systems.



The Commission is unable to comment on the need for a detailed study of hospital expenditure on devices and diagnostics under the National Health Information Work Program. To do so would require a full understanding of the benefits and costs of such a study compared with competing projects vying for resources under that program in an era of funding constraint.

### **Use of quality standards**

All governments in Australia require suppliers to be approved as meeting certain quality standards. State and territory governments usually give preference to suppliers who are certified to a formal quality standard, such as the AS3900 or ISO9000 series. Such standards do not certify the quality of a product, but instead relate to the process by which it is manufactured.

For example, the Queensland Government's purchasing policy states that:

Government agencies shall specify quality assurance systems aligned with or based on internationally recognised Quality System Standards except where risk analysis allows the acceptance of informal quality assurance systems. Governments should give a clear advantage to quality assured suppliers ... (Queensland Government 1992)

In October 1996, the Queensland Government announced it would lift strict enforcement of explicit quality assurance accreditation for purchases under \$10 000.

The Commonwealth requires quality certification where specified performance is critical and the risk of quality failure is high (Purchasing Australia 1993).

### *Participants' views*

Several participants complained about the high cost of certification to quality standards. For example, Biotel noted that the process of accreditation is extremely costly to smaller firms (sub. 12, p.11). Mr Barnes also said the process is costly, and considered that standards such as the 'TypeTest' Mark required for some medical electrical equipment to be superfluous (sub. 14, p.4).

Despite the cost, nearly all considered accreditation produced benefits for their company. In addition to those flowing from qualifying to supply to government, Biotel considered it is prudent to comply with all relevant safety standards to minimise legal liability (sub. 12, p.7). It envisaged long-term commercial benefits of complying with a standard such as ISO9000 (sub. 12, p.11).

The SSAA also noted the cost of being quality certified (sub. 11, p.7). However, its members saw benefits for the internal management of the firm, but considered that government purchasers generally do not give additional points to a supplier if it is quality assured.

Some participants complained about inconsistent application of quality assurance. For example, Sanitech cited a situation where government purchased equipment that did not comply with a particular Australian Standard, because of its preference for the lowest priced product (sub. 11, p.3).

William Green argued that:

... Recognition through [quality] certification programs lack real substance and credibility when those entrusted with the actual government purchasing decisions show little regard for Australian manufacturers (sub. 19, p.3).

In response to the Draft Report, Crown Scientific drew attention to an uncoordinated government approach to quality. It noted the Queensland Government prerequisite on quality assurance that most other states have not applied. Further, it noted the Queensland Government was not consistent in awarding contracts to tenderers who were quality certified (sub. 57, p.2).

On the issue of standards in general, the Australian Health Industry Development Forum (now the Health Business Unit of Australian Business Ltd) considered national consistency and enforcement of government purchasing policy regarding standards is essential (sub. 30, p.4).

### *Commission's comments*

The Commission supports a flexible approach, which recognises different risks of quality failure, rather than the mandatory use of quality assurance requirements. This position was spelt out in the report on competitive tendering and contracting out:

Agencies should ensure that successful tenderers have in place appropriate quality assurance systems. The systems chosen should be kept as simple and inexpensive as possible. Quality accreditation and quality systems certification should be required only where the risk and cost of quality failure is high. In other cases, a good performance record and/or evidence of appropriate internal management systems will be appropriate. (IC 1996a, p.359)

In some instances where there is low to moderate risk of quality failure, it may be more appropriate for government purchasers to base their judgment of quality on informal quality management systems, or on approvals given by other bodies such as the Therapeutic Goods Administration.<sup>6</sup> However, regardless of which quality assurance measures are adopted, the important consideration is their consistent application to all potential suppliers of equipment being purchased for the same purpose.

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<sup>6</sup> The Queensland Government's Purchasing Guidelines state that the Therapeutic Goods Administration's assessments may be approved for quality assurance purposes for some suppliers.

The Commission notes the issue of a common policy approach to quality standards is within the ambit of the existing Government Procurement Agreement and the National Supply Group.

### **Value for money**

Value for money is the central principle in all government procurement guidelines. Most guidelines contain a list of factors that agencies should take into account when aiming for value for money. They make clear that value for money does not necessarily imply purchasing solely on the basis of the lowest price. Extracts from the guidelines of four governments are presented in Box 5.5.

#### *Participants' views*

Many participants claimed purchasing agencies frequently ignored the value for money objective in making their procurement decisions.

A major complaint from participants was that pressures to contain costs had led public hospitals to make procurement decisions solely on the basis of purchase price, rather than life cycle cost. The MIAA said that health authorities often appeared to buy at the lowest possible price rather than best value for money (sub. 13, p.74). According to the NSW Health Peak Purchasing Council the focus of purchasing decisions was on the price of equipment (sub. 26, p.1). Likewise, Sanitech (sub. 21, p.3) argued that, in some cases, government departments disregarded performance and purchased solely on price.

Another common complaint was that clinical staff dominated purchasing decisions to the exclusion of a comprehensive assessment of the benefits and costs to hospitals. Several participants noted that the preferences of a medical professional usually depend on the brand of equipment to which they were exposed during training — similar concerns were expressed during the Commission's previous inquiry into these industries in 1987. The Victorian ISO commented:

Sometimes the purchasing of an item ... is directly dependent ... on the so-called end-user, not meaning the patient but the doctor or the nurses. They have been trained to use particular types of equipment at maybe the hospital they're in or a previous

#### **Box 5.5 Guidelines for ensuring value for money**

The Commonwealth Government's procurement guidelines contain a list of 61 factors that agencies should consider in order to achieve value for money. These relate to the status of suppliers (for example, their financial and design capability), the nature of the equipment (including quality and whole-of-life costs), delivery, operating costs, product

support, replacement, and longer term strategic factors (such as reliability of supply) (DAS 1989).

The Western Australian Government's procurement policy states:

A 'value for money' approach is aimed at achieving the best overall value for the money spent, which may not necessarily mean choosing the cheapest price. Often it is better to pay a little more for a more durable or better quality product, or one which is supported locally.

... All bids received by public authorities should be assessed on the basis of the total cost of the product (that is: acquisition, ownership, maintenance, operation, downstream cost and fees etc), over its service life. In addition, other factors such as fitness for purpose, assurance of quality, timely delivery and local backup should all be considered, as well as the wider benefits to the State for any contribution the purchase can make to government policy objectives. (Government of Western Australia, 1995)

The Queensland Government's purchasing guidelines state:

The objective of obtaining value for money is that the goods, equipment or services being procured represent the best return and performance for the money spent from a 'total costs of ownership' or 'whole-of-life costs' perspective. The result of using such an evaluation methodology to assess value for money may not necessarily favour the lowest price. (Queensland Government, 1992, p.9)

The ACT Government's purchasing guidelines include a range of potential benefits and costs that agencies should consider in determining value for money. They include fitness for purpose, quality, expertise of the supplier, timely delivery, the purchase price, the administrative costs of purchasing, whole-of-life costs and the risks to the agency. (ACT Government 1994, p.4)

hospital and that's all they know and that's all they care to know. They're not interested in trying to find out what the alternatives are, whether they are better, whether they are worse or whether that's cost effective ... (RT trans, p.163).

A variation of this complaint was that tender specifications were written to effectively self-select predetermined products and suppliers. This issue is treated in the following section.

Some governments disagreed that only purchase price is considered when making procurement decisions. For example, the ACT Government said it takes into account a wide range of benefits and costs other than just the price of equipment (sub. 39, p.3). More technical procurements, or those which are closely associated with the delivery of patient care, typically have a wider range of factors applied to their assessment than straightforward purchase price.

WA Health noted that resources may be inadequate to assess a range of costs and benefits:

... Ideally the costs associated with the use of particular products, clinical techniques or technologies should be a factor in the evaluation of equipment. To undertake such a task

in a systematic manner would require tracking of nearly all inputs to a patient's treatment. However, obtaining and analysing sufficient information to make valid judgements on these costs and benefits may require resources beyond those currently available. (sub. 37, p.5)

### *Commission's comments*

Government procurement guidelines all stress value for money. It is in the translation of that policy into practice where participants' concerns lie.

The Commission considers that achieving value for money in government procurement is more likely when agencies:

- take into account the flow of benefits and costs over time and not just the 'up-front cost' at the time of equipment purchase; and
- are held accountable for justifying that their decisions represent the best the best value for money (that is: the process is transparent).

There are no hard-and-fast rules for achieving value for money in all situations. However, based on other studies, it is possible to distil some general principles to help guide procurement processes and decisions. Such a set of principles was developed by the Commission in its report on *Competitive Tendering and Contracting by Public Sector Agencies* (IC 1996a). Although the principles presented relate to government tendering for services, the Commission considers that, in general, they are equally as relevant to the procurement of goods. These principles are presented in Box 5.4.

The failure of health agencies in particular to pursue value for money observed by participants appears to reflect pressures generated within the broader system in which procurement decisions are made. The organisation, funding or accountability of the public health system, for example, influence the incentives faced by those making purchasing decisions.

Piecemeal reforms will not resolve the failure of procurement agencies to pursue value for money while these systemic influences remain unchanged. This can only occur in the context of a review of the public health system as a whole.

### **Lack of performance specifications**

Many participants commented that contracts are often specified according to the technical attributes of particular equipment, rather than according to performance criteria and outcomes. This has the effect of biasing the purchasing decision towards a particular brand of equipment. This occurs despite government procurement guidelines which clearly reject such a practice.

For example, Biotel claimed that, when a purchasing decision is left to individual hospitals, most tender specifications are heavily biased towards the preferred supplier. The result is that price may not be an important criterion (sub. 12, p.10). Similarly, Baxter Healthcare commented:

... Even when specifications are called, ... a lot of times the clinical part of the decision-making process has already decided in its mind what it wants to buy anyway and the specifications are written so biased that it excludes other companies from tendering on it to start with (RT trans, p.158).

Shimadzu noted a similar problem in the scientific equipment industry. It stated that government tendering is often ineffective in achieving the best price performance ratio, and one reason for this is tenders may be written so only one instrument can comply — so called ‘lock out specifications’ (sub. 56, p.1). Shimadzu considered greater transparency in the process would help to avoid this.

### *Commission's comments*

Discriminatory specifications increase the likelihood that certain suppliers will be awarded contracts despite there being alternative providers who are equally, or more able, to meet the agency's performance requirements (IC 1996a, p.273). The potential for discriminatory specifications would be reduced through consulting with a wider range of stakeholders than just the incumbent supplier, and the use of performance or outcome-based specifications.

As noted earlier, the extra costs of domestic preferences may provide agencies with an incentive to write specifications which exclude domestic products from consideration in tenders (IAC 1987, p.109).

### **Lack of skills in supply management**

Many participants complained about the lack of appropriate skills and experience of supply managers in government, particularly within public hospitals. Faulding attributed the lack of skills to the poor resourcing of purchasing departments in public hospitals (RT trans, p.158).

Some participants noted that the increasing turnover of hospital staff created difficulties for firms supplying to the public hospital system. Malcolm Young and Company noted an increasing turnover of hospital staff and the intrusion of non-medical purchasing officers into a role responsible for purchasing of medical equipment (sub. 5, p.3).

Technological developments can improve supply management. For example, the MIAA (sub. 26, p.84) noted the potential for new technology (for example, electronic data interchange and bar coding) to improve the way medical products

are marketed. To be effective, government supply managers would need to be given appropriate training to take advantage of such technology.

One solution to the deficiency of supply management skills is to provide awareness programs for government purchasing officers, such as those operated by the Victorian Industrial Supplies Office (ISO). The Victorian ISO considers that government purchasers need to be made aware of the advantages of using local competitive companies, and to the benefits of establishing long-term relationships with small and medium enterprises (sub. 10, p.2). Another is to provide additional training to supply managers, and to recruit skills from outside organisations (IC 1996a, pp.372–77).

There is already extensive cooperation in developing competency standards and training. Purchasing Australia's Purchasing Development Centre, for example, delivers training nationally to both Commonwealth and state and territory purchasing officers.

## **5.5 Other issues related to procurement**

Participants also raised several other issues on government procurement of medical and scientific equipment. These are not concerned with the policy and practices of governments but with other aspects of procurement, namely:

- unfair competition by suppliers in the public sector; and
- predatory behaviour by suppliers to government.

### **Competitive neutrality**

Some participants raised concerns about competitive neutrality, between government and non-government suppliers.

The SSAA noted two areas where the industry had to compete with government funded distributors — the New South Wales Government's 'Q Stores' for stocks and services provided by the scientific suppliers specialising in education, and Melbourne University which runs its own chemical supply business (sub. 11, p.7, PH trans, p.55). Gambro also argued that governments have been slow to remove the competitive advantages government agencies enjoy from their exclusion from coverage by the *Trade Practices Act 1974* — the so-called 'Shield of the Crown' (sub. 33).

### ***Commission's comments***

The Commission notes that the *Competition Principles Agreement* (see Appendix F) requires government agencies to compete on an equal footing with

other suppliers of goods and services. Under that agreement each of the Commonwealth, State and Territory Governments is committed to establish a complaints mechanism to deal with issues such as those noted by the SSAA.

In 1995 the Commonwealth implemented legislation to remove Shield of the Crown protection from its businesses. Most of the States and Territories have already legislated to apply the *Trade Practices Act* 1974 to their activities. With these changes, the *Trade Practices Act* 1974 may provide a supplier with a legal course of action in the face of such alleged unfair trading.

### **Supplier behaviour**

Some domestic manufacturers complained about larger overseas suppliers receiving an unfair price advantage from the way the cost of equipment purchases is assessed by government purchasers. For example, they claimed that some multinational companies provide hospitals (at no up-front cost) with computer systems to monitor equipment orders. This has the effect of locking the hospital into buying from the supplier because of the particular codes used. For example, Fairmont Medical linked this practice to possible questions of probity (PH trans, 192).

Similarly, participants claimed that suppliers lend instruments to a hospital or laboratory or sell them at an artificially low price on the proviso that the institution then purchases any related consumables from that supplier. The price for the consumables is usually higher than would normally be the case (sub. 10, p.3). Such practices were described as 'predatory purchasing'. Trace Scientific linked this practice to the reduction in the availability of funds for capital expenditure (sub. 55, p.1). The Australian Diagnostic Manufacturers Association supported this view. It stated:

... Because of the way the public laboratories got their money they were often unable to invest in capital equipment but they had reasonable maintenance budgets. So the deal was that the multinational would loan that instrument to the laboratory on the condition that they bought the reagents for it at agreed figures. Those figures of course were high ... I think it's more a way that capital budgets are set in the public sector that puts these impositions on people. (PH trans, p.269)

The Industrial Supplies Office of Victoria felt that domestic manufacturers are disadvantaged by another practice known as 'bunch selling' by overseas suppliers. This involves selling a single item at maximum price and related items at heavily discounted prices (sub. 10, p.2). Surgi Supplies (sub. 34) and Trace Scientific (sub. 55) considered that, because of the tendency of government agencies to buy a bundle of equipment, domestic manufacturers were disadvantaged because they generally produced a narrow product range.



The Victorian ISO suggested that predatory purchasing and pricing should be monitored and regulated to allow local industry to compete with imports.

### *Commission's comments*

The Commission agrees that predatory behaviour has the potential to create an unfair advantage for particular suppliers and to increase the cost of government purchases. However, it does not believe that there is a need for new regulation. Rather sufficient protection should be provided through the *Trade Practices Act* 1974. Increased transparency of the procurement process would also help.

Some of the problems referred to by participants appear to result from the way in which capital and recurrent funding is allocated to public institutions.

## **5.6 Commission's assessment**

The inquiry received evidence of widespread dissatisfaction with government procurement arrangements among participants from the medical and scientific equipment industries. This dissatisfaction was mostly directed at procurement by health agencies, and related to shortcomings in procurement policy (such as inconsistencies between states and its use as a means of industry assistance) and its implementation by procurement agencies (in particular, the failure to pursue value for money and a lack of transparency surrounding procurement decisions).

A review of Commonwealth, state and territory government policies affecting medical and scientific equipment procurement shows they are generally soundly based and mostly embody the principles endorsed by the Commission in its report on competitive tendering and contracting (see Box 5.4). However, in some areas, information provided to the Commission suggested coordination and cooperation was often lacking on issues of common policy interest to individual governments in the procurement of medical and scientific equipment. Accordingly, a more comprehensive national response may be warranted as requested by the MIAA.

### **Finding 5.1**

There are problems in the procurement of medical and scientific equipment by governments. They involve:

- a lack of transparency of procurement practices;
- inadequate machinery for suppliers to discuss issues and problems with procurement agencies;
- non-compliance by public sector organisations with government purchasing guidelines; and

- insufficient cooperation and coordination between governments on policy issues of common interest. These problems were most pronounced in the public health sector.

### **Recommendation 5.1**

To promote efficiency and transparency in their purchase of medical and scientific equipment, Australian governments should ensure that their procurement guidelines incorporate, as far as practicable, the ‘best practice’ guidelines recommended by the Commission in its 1996 report on *Competitive Tendering and Contracting by Public Sector Agencies*.

### **Recommendation 5.2**

Each Australian Government should examine the adequacy of existing arrangements for ensuring that its public hospitals and agencies comply with its purchasing guidelines.

The Commission notes it is possible to deal on a national basis with many of the issues relating to cooperation raised in this inquiry through the Government Procurement Agreement and the National Supply Group. The National Supply Group is already exploring the scope for greater uniformity in areas of relevance to the medical and scientific equipment industries.

### **Finding 5.2**

The Government Procurement Agreement and the National Supply Group have the potential to address problems in government procurement affecting the medical and scientific equipment industries.

The Government Procurement Agreement and the National Supply Group operate at the highest levels of Commonwealth, state and territory governments. This approach is not inappropriate to assist in delivering procurement policy outcomes consistent with those sought by participants at this inquiry. The MIAA, for example, has recognised that environmental considerations in procurement policy should be developed within general guidelines determined by the highest levels of government.

The Commission is attracted to using these existing arrangements to address the policy concerns of the medical and scientific equipment industries as such issues would be considered in a broad, rather than industry specific, context. Any such policy deliberations should include industry consultation, as provided for in Annexe 4 to the Government Procurement Agreement. While the form of such consultation is not specified, it may involve the formation of working groups designed to reflect the views of the medical and scientific equipment industries.

**Recommendation 5.3**

The National Supply Group should review the different approaches by governments in the procurement of medical and scientific equipment with a view to achieving greater uniformity of policy and practice, including in the use of common use contracts, product and quality standards, environmental requirements and electronic commerce.

The Commission notes that the GPA is currently under review by the National Supply Group. It provided a submission to that review which argued the agreement should reaffirm the core principles of value for money and equal opportunity and treatment among Australian and New Zealand suppliers (IC 1996g). That submission drew attention to the potential of the Government Procurement Agreement to address many of the issues raised in this inquiry and noted that the agreement could be strengthened by reinstating the procedure whereby the National Supply Group reports to a Ministerial Council.

The submission also called for removing industry assistance as an objective from the Government Procurement Agreement. Such an objective is inappropriate because it detracts from the efficiency of government procurement and linking industry assistance to procurement is a particularly inefficient way of providing such assistance. The Commission's reservations about using procurement to provide industry assistance are addressed in its Draft Report on *State, Territory and Local Government Assistance to Industry* (IC 1996e).

**Finding 5.3**

The inclusion of industry assistance as an objective in government procurement compromises the core objective of value for money, and is an inefficient way of providing such assistance.

Many of the shortcomings in the implementation of policy appear to be symptoms of pressures generated within the broader system in which procurement decisions are made. The organisation, management, funding or

accountability of the public health system, for example, inevitably influence the incentives faced by purchasing agencies. Any systemic failures in the implementation of procurement policy can therefore only be fully addressed in this broader context — for example by changes to clinical budgeting, accrual accounting, or funding arrangements that allow for a more neutral choice between recurrent and capital items. Such a task is beyond the scope of this inquiry but is required if any systemic failings are to be addressed.

**Finding 5.4**

The problems in government procurement identified by this inquiry may be due to shortcomings in the organisation, management, funding and accountability of the public health system.



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## 6 LABOUR MARKET ISSUES

*Manufacturing and wholesaling of medical and scientific equipment are generally labour intensive processes. Over 10 000 people are employed in manufacturing alone. As labour costs account for a large share of total costs in the medical and scientific equipment industries, labour market arrangements which facilitate improved labour and total factor productivity will have a significant effect on competitiveness. In addition, effective education and training are required to create the human resources for future productivity increases in these industries.*

The level of education and training undertaken in the medical and scientific equipment industries and the availability of skilled employees are described in Section 6.1. The effect of the industrial relations system on these industries, including awards, enterprise bargaining and rules governing the dismissal of workers, is discussed in Section 6.2. The Commission's assessment is in Section 6.3.

### 6.1 Education and training

The medical and scientific equipment industries (and the economy as a whole) require an appropriately trained and educated workforce. Improving the education and training of the workforce to improve their skills is one avenue by which productivity and incomes may be increased. Training was recognised by several participants as an important factor influencing the future of the medical and scientific equipment industries.

Training can take several forms, including educational and vocational, and off and on-the-job training.

Australian Bureau of Statistics (ABS) data on training are only available for aggregated groups of industries (at the three digit ANZSIC level). The medical and scientific equipment industries are incorporated into two categories at this level:

- Photographic and scientific equipment manufacturing (ANZSIC 283); and
- Machinery and equipment wholesaling (ANZSIC 461).

Although the industries under reference account for 80 per cent of employment in Photographic and scientific equipment manufacturing, they only account for 7 per cent of employment in Machinery and equipment wholesaling. Consequently the Commission has only reported data for Photographic and scientific equipment manufacturing in this chapter.

### Education and training undertaken

Photographic and scientific equipment manufacturing has a relatively highly skilled workforce (see Table 6.1). In 1995 around 46 per cent of employees in this group had trade, degree or higher qualifications, compared with only 15 per cent of employees in all manufacturing and 21 per cent of employees in all industries. Only 32 per cent of employees had no post-school qualifications, compared with over 50 per cent in each of all manufacturing and all industries.

**Table 6.1** Share of employment by educational attainment, percent of employees, May 1995

<i>Type of qualification</i>	<i>Photographic and scientific equipment manufacturing (%)</i>	<i>All manufacturing (%)</i>	<i>All industries (%)</i>
Degree and higher level	12	7	12
Trade	34	8	9
Certificate, diploma and other	22	28	20
Without post-school	32	56	54
Still at school	0	1	5
<b>Total</b>	<b>100</b>	<b>100</b>	<b>100</b>

*Notes:* 'Trade' includes skilled and basic vocational qualifications; 'Certificate, diploma and other' includes undergraduate and associate diplomas.

*Source:* ABS 1995c,e

In 1995, around 70 per cent of employees in photographic and scientific equipment manufacturing were classified as managers and administrators, professionals, para-professionals or trades persons (see Table 6.2). These are the occupations in which more complex skills are required.<sup>1</sup> In the same year, only 46 per cent of all manufacturing employees and 45 per cent of all industry employees fell into the same categories.

<sup>1</sup> The Australian Standard Classification of Occupations (ASCO) system classifies occupations into eight major categories. The categories are in a hierarchy according to the skill level required. Category 1 contains those occupations with the highest skill requirement and Category 8 contains those occupations with the lowest skill requirement.

Table 6.2 Share of employment by occupation, percent of employees, 1995

<i>Major ASCO codes and dominant occupations</i>	<i>Photographic and scientific equipment manufacturing</i>	<i>All manufacturing</i>	<i>All industries</i>
	(%)	(%)	(%)
1. Managers and administrators	5	8	10
2. Professionals	20	7	14
3. Para-professionals	5	3	6
4. Trades persons	41	28	15
5. Clerks	7	11	17
6. Salespersons	0	5	17
7. Plant and machine operators and drivers	3	16	7
8. Labourers and related workers	19	23	15
<b>Total employment</b>	<b>100</b>	<b>100</b>	<b>100</b>

Source: ABS 1995c,d

Results from the Commission's survey of the medical and scientific equipment industry indicated that larger companies generally have a higher proportion of skilled employees in sales/marketing, servicing and management/administration activities than smaller companies. The results showed smaller companies have a higher proportion of skilled labour in research and development (R&D) activities than larger companies. Manufacturing staff are more highly skilled in medium companies than in either of large or small companies.

The results also showed that medical equipment companies have a slightly higher percentage of skilled staff in sales/marketing and R&D activities than scientific equipment companies. However, scientific companies have a higher percentage of skilled staff employed in servicing. A more complete set of survey results is given in Appendix L.

Although the workforce in photographic and scientific equipment manufacturing is highly educated, these industries appeared to undertake relatively little training. ABS data indicated that the hours of training per employee, expenditure on training per employee and the proportion of gross wages and salaries spent on training by the industries are significantly lower than the average for all manufacturing and all industries (see Table 6.3). This may be due to a number of reasons, including:

- the prevalence of small companies in the industry — ABS data show such companies typically spend far less on training than their larger counterparts (ABS 1993a);
- the level of training employees have undertaken before entering the industries is sufficient for the industries; or



- the industries face difficulties in accessing the right kind of training for their employees.

**Table 6.3**      **Average resources devoted to training, July to September 1993**

<i>Training resources</i>	<i>Photographic and scientific equipment manufacturing</i>	<i>All manufacturing</i>	<i>All industries</i>
Per cent of gross wages and salaries	1.4	2.6	2.9
Dollars per employee	86	204	192
Hours per employee	2.9	6.5	5.6

*Sources:*      ABS 1993a,b

The Scientific Suppliers Association of Australia (SSAA) appeared to disagree with the suggestion that the resources devoted to training in the photographic and scientific equipment manufacturing industries was well below the average for all manufacturing. It stated that:

The scientific supply industry as a whole spends considerable sums on training sales, marketing and service staff. The short product life cycle in this industry and the technical nature of the products and the methods of sale use demands the highest level of technical competence by all staff that have customer interface. (sub. 63, p.8)

Results from the Commission's survey indicated that within each of the medical equipment and the scientific equipment industries the percentage of total costs spent on training is between 2–3 per cent. The range is also the same when comparing the training expenditure of small, medium and large companies.

### **Availability of skilled employees**

In general, most participants saw the availability of skilled employees as a major benefit of being located in Australia. Some pointed to specific areas where greater skill development is necessary.

For example, the College of Biomedical Engineers stated that:

Australia has excellent standards in educating staff for work in engineering design and manufacture. The combination of appropriate engineering degree and associate diploma qualified exist in abundance to support far greater manufacturing endeavours in Australia.

There is however a shortage of junior level Biomedical Engineering positions.

Technician staff are not as far down the track with certification in the specialist area of Biomedical Engineering. This primarily affects the Clinical Engineering area of practice within hospitals. There have been some moves towards registration sponsored by both the

IE Australia and the Australian Federation for Medical and Biological Engineering ...  
(sub. 46, p.10)

Similarly, Varian Australia stated:

One of the difficulties that I think we still have in Australia is trying to find appropriate professionals — that is, skilled mechanical, electronics, optics and manufacturing engineering ... we don't seem to have graduates coming out who are really aware of the scientific instrument industry requirements, that is, I would say for fine engineering.  
(RT trans, p.64)

The Commission's survey results suggested that, on average, scientific equipment companies have most difficulty in obtaining staff in sales/marketing followed by servicing. Commenting on the survey results, the SSAA stated that it was not the availability of technically qualified sales staff that was a problem, but the lack of successful and experienced sales staff (sub. 63). Medical equipment respondents indicated that they generally had difficulty in obtaining staff in all areas. In the two industries combined, large companies indicated that they only had difficulty in obtaining sales/marketing staff; medium companies on the whole did not have much difficulty in obtaining any of the staff they required, whereas small companies experienced difficulties in all areas of recruitment.

If appropriate skills are not available in Australia, an alternative is to seek skilled personnel from overseas. However, several participants were critical of the process of obtaining immigration permits for personnel sourced overseas. They claimed that there are significant compliance costs in meeting immigration requirements. They also complained of delays in obtaining work permits for key personnel and the overly short duration of permits. For example, Varian Australia stated:

We haven't brought anybody in in recent times, but typically even to bring in a PhD graduate from the UK can take up to 6 months; one took 9 months ... (RT trans, p.66).

William Cook Australia stated that:

... [It is] particularly difficult to get cooperation from the Immigration and Customs Departments (sub. 62, p.2).

The difficulties in obtaining staff from overseas were supported by the Commission's survey results. The results suggested that about 17 per cent of medical and scientific equipment companies have found it necessary to obtain staff from overseas. The majority of these companies claimed that difficulties with immigration arrangements were the main reason they found it difficult to obtain such staff.

## **Vocational education and training system**

Vocational education and training has been a large and rapidly growing area of government activity. Since the late 1980s, training policies have been developed under the umbrella of the Training Reform Agenda. Implementation of these policies is now the responsibility of the Australian National Training Authority (ANTA).

Major priorities of the Training Reform Agenda include:

- developing a national system of vocational education and training — offering national registration of training providers, accreditation of training courses and national recognition of qualifications;
- introducing competency-based training, national competency standards and national curriculum;
- developing a more diverse and competitive training market; and
- introducing new entry level training arrangements.

Funding for vocational education and training is provided by Commonwealth and State Governments. The allocation of Commonwealth funds is administered through ANTA, and is determined through a consultative process involving input from industry and training authorities.

In its recent inquiry into tourism accommodation and training (IC 1995e), the Commission identified several problems with the Training Reform Agenda that require monitoring. They included:

- the fact that the existence of both government-based accreditation and industry-based recognition for courses has the potential to impose unnecessary costs on training providers;
- the limited involvement of small companies in setting the training agenda;
- inappropriate mixes of job-specific and general content training in publicly funded courses; and
- increasing credentialism (the requirement for formal qualifications not necessary to perform the job).

The College of Biomedical Engineers claimed that the efforts of the National Community Services and Health Industry Training Advisory Board in developing competency standards for biomedical engineering technicians have been of little value. It stated that:

The exercise starts by ignoring the basic training requirements generally accepted for the Biomedical technicians is an appropriate Associate Diploma. Further, the exercise has been largely performed with little or no reference to the employers and supervisor of these staff. (sub. 46, p.10)

The College recommended that:

The National Community Services and Health Industry Training Advisory Board ... project on health industry technicians should either be refocussed, with input from employers and supervisors of these staff and with input from professional organisations such as IE Aust College of Biomedical Engineers, or the project should be ceased (sub. 46, p.3).

In its response to the Draft Report, the Australian TAFE Science Network commented that it supported the concerns of the College of Biomedical Engineers relating to the development of standards which have the confidence of employees. It stated that:

The development of standards which have the confidence of employees, employers and professional bodies is essential and underpins the construction of training curricula (sub. 58, p.1).

In its Draft Report the Commission sought additional information from participants on: the reasons for the relatively low levels of industry training expenditure; the role and adequacy of educational institutions in providing required skills; and whether participants were aware of the reforms introduced under the Training Reform Agenda, and their experience, if any, in developing or using the new training systems. However, minimal response to these issues was received. The National TAFE Science Network stated that:

Because of the diverse nature of enterprises and organisations in the medical and scientific equipment industries (research organisations, universities, hospitals, regulatory bodies, manufactures, importers and retailers), there are no ITABs which are charged with the responsibility of identifying training needs across all aspects of these (sub. 58, p.1).

## **6.2 Industrial relations**

In this section the Commission addresses the industrial relation system as it pertains to the medical and scientific equipment industries. Important elements of this system include awards, enterprise bargaining and rules governing the dismissal of workers.

### **Awards**

Comprehensive data on award coverage are not available for the medical and scientific equipment industries. Data for broader industry groupings show that, in 1990, 72 per cent of employees in photographic and scientific manufacturing were covered by awards, compared to 79 per cent of all manufacturing employees (ABS 1990a,b). The slightly lower figure observed for the industries is likely to be due in part to the prevalence of small companies, in which, on

average, a smaller proportion of employees are normally covered by awards (ABS 1990a).

The Commission's survey results corroborate the above data, with respondents indicating that, on average, 74 per cent of their employees are covered by awards. Award coverage appeared to be greatest amongst R&D employees and least amongst clerical staff.

Employees in the medical and scientific equipment industries are predominantly covered by general, rather than industry specific, awards.<sup>2</sup>

The majority of employees in manufacturing companies are covered by federal awards. The most common are:

- Metal Industry Award 1984 Part I;
- Metal Industry Award 1984 Part II (Draftsmen, Production Planners and Technical Officers);
- Rubber, Plastic and Cablemaking Industry (Consolidated) Award 1983; and
- Rubber, Plastic and Cablemaking Industry Award 1994 Part II (Technical and Supervisory).

Information from participants and the Commission's survey of the medical and scientific equipment industries suggested that employees working in wholesale and distribution operations are more frequently covered by the state award system. Where they are covered by federal awards, the most common appear to be various Storemen and Packers Awards and the Warehousing/NUW Consolidated Award. For sales/marketing employees the common awards are the Commercial Travellers Award and the ASU (Clerical and Administrative Trainees) Award. For administration/management staff the main award is the Administrative and Clerical Officers Award, and for R&D employees the main awards are the CSL Limited Award and the Professional Scientists Award.

Other awards covering employees in the industries include the Manufacturing Chemists Award, various Professional Engineers Awards and Amalgamated Workers Union (AWU) Awards.

### *Award provisions and flexibility*

Workplace flexibility has a number of aspects. These include the ability of companies to:

- increase or decrease the size of their workforce to meet changes in demand (for example, by hiring and firing workers, or using casual workers);

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<sup>2</sup> There are some exceptions, including the (state) Tennis Strings and Sutures Award.

- adjust quantity and timing of labour input without modifying the number of employees (for example, changing the number and span of working hours, overtime and shift working arrangements, and adjustments to leave); and
- redeploy workers quickly and smoothly between activities and tasks (including by multi-skilling and the removal of demarcations).

Awards inevitably reduce flexibility — any instrument that binds parties to a course of behaviour (including individual employment contracts and enterprise agreements) by definition restricts their subsequent choice of action.

A significant number of participants noted the provisions of some awards restricted flexibility and company competitiveness. Examples given included conditions relating to over-time, rostered days off, holiday loading and shift allowances. Respondents to the Commission's survey cited similar provisions as having the greatest effect on business.

Varian noted awards may contain anomalies in relative payments to employees. For example, in commenting at roundtable discussions on the computer allowance for technicians under the Metal Industry Award 1984 Part II, it stated:

We had a commissioner come in several years ago and do a work value study as a result of which he decided that those metals II people who were using computers should be given a computing allowance of \$29 a week and that's still there today. Who in the workforce today does not use a computer? (RT trans, p.62).

Some of the major awards covering employees in the industries are long and complicated. The Metal Industry Award 1984 Part I is 332 pages long, and has been changed by 184 variation orders since its inception. Similarly, the Metal Industry Award 1984 Part II is 124 pages, and has been subject to 64 variation orders. The Rubber, Plastic and Cablemaking Industry Award Parts I and II are 220 pages and 129 pages respectively.

As these awards are complex, both government and business associations have set up various channels through which employers can seek assistance in their interpretation (see Box 6.1).

Some of the provisions contained in the Metal Industry Award which affect workplace flexibility are outlined in Box 6.2. While it is possible to identify various award provisions which affect flexibility, it can be difficult to judge the degree to which they do so and the consequences for productivity.

The Commission asked for comments from participants on this issue in its Draft Report, with regard to not only the Metal Industry Award but any awards which cover employees in the medical and scientific equipment industries. However, no responses were received.

**Box 6.1 Assistance in award interpretation**

The Metal Trades Industry Association provides a hotline service to answer members' award queries, the majority of which are about the Metal Industry Award. The Association also runs training courses on dealing with awards, including a two day course covering all aspects of the Metal Industry Award.

The Australian Chamber of Manufacturers also has an inquiry hotline, and runs 'Know Your Award' courses based on the Metal Industry Award. These courses cover issues including responsency, contract of employment (including termination of employment, the employment of part-time and casual workers), hours of work (including overtime and shift work), leave and union rights of entry.

Similarly, the Victorian Employers Chamber of Commerce and Industry operates a phone room to deal with members queries, including those on awards. Information on awards, including changes in their terms, are included in both general and sectoral newsletters. The Chamber also holds briefings to address members on award changes.

Assistance in award interpretation is also available from government. For example, the Commonwealth Department of Industrial Relations has award inquiry lines in all capital cities and regional centres. The Australian Industrial Relations Commission also has a statutory obligation to provide advice on awards.

Some participants commented that awards are of limited relevance to the operations of their companies as they already provide over-award payments and conditions. For example, while Biotel refers to awards for the conditions under which staff are employed, all staff are paid above award rates. Biotel also operates incentive schemes to boost productivity (sub. 12).

The Commission's survey results also suggested that most employees in medical and scientific equipment companies covered by awards receive

**Box 6.2 Flexibility in the Metal Industry Award 1984 Part I*****Ordinary hours***

Section 18 requires that ordinary hours of work of full time employees are to:

- average 38 hours per week;
- not exceed 8 hours on any day, without the agreement of the majority of employees concerned;
- not exceed 12 hours on any day; and
- fall between 6 am and 6 pm.

An employee may be engaged to work on a part-time basis for a constant number of hours which, having regard to the various ways of arranging ordinary hours, shall average less than 38 hours per week.

#### ***Overtime***

Section 21 sets out the rates and conditions relating to overtime. They are the same for full and part-time employees.

Employees may be required to work reasonable overtime based on specific work requirements.

Employees are to be paid time and a half for the first 3 hours, and double time thereafter.

Employees should be granted a reasonable rest period after working overtime:

- wherever reasonably practicable, employees are to be given at least ten consecutive hours off duty between the work of successive days; and
- where employees are required to resume work without ten consecutive hours off, they will be paid at double rates.

An employee recalled to work overtime after leaving the premises, or required to work overtime on Saturday, shall be paid for a minimum of four hours work.

#### ***Meal breaks***

An employee may not work more than 5 hours without a meal break unless agreed, and not more than 6 hours at ordinary rates of pay.

Except where an alternative is arranged, employees are to be paid time and a half for work done during meal hours and thereafter until a meal break is taken.

Unless over time is less than 1.5 hours, employees are allowed a meal break of 20 minutes (paid for at ordinary rates) before starting overtime.

The award provides scope to vary these requirements under some circumstances. The time scheduled for meal breaks may be altered to meet the requirements for continuity of operations. Meal breaks may also be staggered to meet operational requirements.



**Box 6.2 (continued)*****Rostered days off***

The award provides a number of options for implementing a 38 hour week. One is to roster employees off on various days of the week during a particular work cycle so that each employee has one week day off during that cycle. Where an employee is entitled to a rostered day off, unless there is agreement otherwise, the employer is required to provide at least four weeks notice in advance of the day to be taken off.

An employer may substitute the day an employer is to take off in the case of a breakdown in machinery or to meet the requirements of the business in the event of rush orders or some other emergency situation.

Subject to agreement, rostered days off may be accrued up to a maximum of 5 days off in special circumstances.

***Leave***

The award includes provisions for annual, sick, family, parental and bereavement leave for permanent full-time employees. Leave entitlements for part-time workers are on a pro rata basis. Under the award, employees are entitled to:

- four weeks paid annual leave per year;
- five days sick leave during the first year of employment, then 8 days in subsequent years;
- two days paid bereavement leave; and
- twelve months unpaid parental leave.

The award specifies restrictions on how each type of leave may be taken. In the case of annual leave:

- if no agreement otherwise, leave to be taken in one or two continuous periods — one of which must be at least 21 consecutive days;
- provided employer and employee agree, this may be taken in up to 3 separate periods of any length;
- annual leave must be taken and, with minor exceptions, no payment in lieu of annual leave is permitted;
- annual leave must be taken within 6 months from the date at which the right to annual leave accrued, and after at least 4 weeks notice to the employee; and
- during annual leave employees (day and shift workers) are paid a loading of 17.5 per cent.

*Source:* Metal Industry Award 1984 Part I

over-award payments. On average, across all the employee classifications, medical equipment companies paid over-award payments to about 75 per cent of their staff, and scientific equipment companies to about 90 per cent of their staff.

All the respondents in both industries indicated that 100 per cent of their R&D employees receive over-award payments. The main reasons given by employers for offering above-award payments were the need to reward skills and performance, and that award rates are too low to attract/retain employees.

### **Enterprise bargaining agreements**

Registered enterprise agreements are uncommon in both the medical and scientific equipment industries.<sup>3</sup> The Commission's survey results suggested that 5 per cent of medical equipment companies and 8 per cent of scientific equipment companies have registered enterprise agreements. A search carried out for the Commission by the Australian Centre for Industrial Relations Research and Training (ACIRRT) of all agreements registered in the federal jurisdiction and New South Wales, Queensland, Western Australia and South Australia uncovered only eight registered agreements in the medical and scientific equipment industries. All of the agreements identified were registered at federal level.

The Commission's attention has subsequently been drawn to several other registered agreements. Crown Scientific/Pharmaglass entered into an agreement from 1 January 1995 for a period of two years, and FH Faulding & Co. negotiated two different agreements — one in 1995 and one in 1996. In addition, the Commission is aware that SGE International, Bayer Australia and Varian are moving towards registering agreements.

Several observations can be made from an analysis of the existing registered agreements that the Commission is aware of (see Table 6.4):

- agreements have been registered to cover both manufacturing and distribution operations;
- agreements have all been registered by companies whose employees are unionised. In the federal jurisdiction, no 'non-union' agreements (that is Enterprise Flexibility Agreements) have been identified;
- agreements are more common in large companies (though they do not necessarily cover a lot of employees in these companies);

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<sup>3</sup> A *registered enterprise agreement* is a written collective workplace or enterprise agreement, negotiated between an employer and union(s) or employees which has been formally registered with, or certified or approved by, a State or Federal industrial tribunal.

An *unregistered enterprise agreement* is any written or verbal collective agreement, covering a workplace or enterprise, which has been reached between an employer and union(s) or employees, but which has not been formally registered with, or certified or approved by, a State or Federal industrial tribunal.

Table 6.4 Registered enterprise agreements

<i>Company name</i>	<i>Relevant award</i>	<i>Commencement of agreement</i>	<i>Duration (months)</i>	<i>Employees covered total</i>		<i>Operations covered</i>	<i>Union involvement</i>
<b>ACI Plastics Packaging (Moorabbin)</b>	Rubber, Plastics and Cablemaking Industry (Consolidated) Award 1983	26/6/95	24	na	na	na	yes
<b>Selby Scientific Ltd</b>	National Warehousing and Distribution (NUW) Interim Award 1993	11/9/95	21	4	100	warehousing, distribution	yes
<b>Merck Pty Ltd</b>	Manufacturing Chemists Award 1993	1/4/95	12	11	56	manufacturing	yes
<b>Clyde APAC</b>	Metal Industry Award 1984	22/9/95	34	80	120	manufacturing	yes
<b>CSL Ltd</b>	The CSL Ltd Award 1992	20/10/95	20	1300	1300	manufacturing, distribution	yes
<b>Email Air Handling</b>	Metal Industry Award 1984	1/4/96	24	80	210	manufacturing	yes
<b>Kimberley Clark Aust.</b>							
- Albury Mill	Textile Industry Award 1994	20/9/95	24	na	na	mfg, warehousing	yes
- Warwick Farm Mill	na	29/3/94	24	270	270	mfg, wholesaling	yes
<b>Crown Scientific Pty Ltd / Pharmaglass Pty Ltd</b>	The AWU/FIME Amalgamated Union Award	1/1/95	24	48	140	manufacturing, distribution	yes
<b>FH Faulding &amp; Co. Ltd</b>							
- SA Distribution	na	1/7/94	24	100	100	warehousing,	yes
- Tasmania Distribution	na	20/6/95	30	30	30	distribution	no
- Victoria Distribution	na	25/6/96	24	100	100	(for all three)	yes

*Notes:* na: data not available; mfg: manufacturing

*Sources:* ADAM Database, ACIRRT, University of Sydney, May 1996 and information provided by participants

- all agreements are registered under Commonwealth legislation;
- all agreements pertain to one award only; and
- the duration of agreements ranges from 12 months to 34 months.

The terms of the agreements, possible reasons for the low incidence of registered agreements and experiences with bargaining are discussed below.

### *Terms of agreements*

The comprehensiveness of the agreements listed in Table 6.4 varies greatly. For example, the agreement at Merck introduced a small number of changes to workplace arrangements, with most terms and conditions remaining as specified in the Manufacturing Chemists Award. Changes adopted included:

- the removal of artificial restrictions on the range of tasks that can be performed by different categories of employees;
- the extension of the spread of working hours; and
- the exchange of the Union Picnic Day for a day in lieu.

In contrast, the agreement at Kimberley-Clark Warwick Farm Mill is an extensive document which substantially covers most terms and conditions of employment. Its terms range from shift, overtime and leave arrangements to meal allowances and counselling.

Several workplace arrangements were commonly addressed in the agreements listed in Table 6.4. These included:

- flexibility or spread of starting and finishing times;
- flexibility in allocation of rostered days off;
- dispute settlement procedures;
- demarcation;
- performance indicators and performance based pay; and
- training provisions.

### *Possible reasons for low incidence of registered agreements*

The low incidence of registered enterprise agreements in the medical and scientific equipment industries may be due to a range of factors. In its survey the Commission asked respondents to indicate their main reasons for not registering enterprise agreements. The most common responses were:

- current industrial relations arrangements are satisfactory;
- the potential to involve union(s) in a non-union workplace; and
- insufficient benefits.

Some of these and other factors are discussed below.

### *Prevalence of small companies*

In general, enterprise bargaining has been more common in large companies, which make up a relatively small proportion of companies in the medical and scientific equipment industries (DIR 1994). For example, 90 per cent of establishments in the ANZSIC category of medical and surgical equipment manufacturing have less than 10 employees (ABS 1995b, see Chapter 2).

Enterprise bargaining agreements may be less attractive to small companies than large companies because negotiation and registration costs are spread over fewer employees. For example, Biotel stated that:

With only 12 employees, we are not big enough to consider enterprise bargaining because of the legal and implementation costs (sub. 12, p.11).

### *Informal arrangements*

Another possible reason for the low incidence of registered enterprise agreements is informal working arrangements provide flexibility above that allowed by awards.

Information gathered from visits and submissions suggests informal working arrangements are extensive in the medical and scientific equipment industries in both large and small companies. This is consistent with research conducted by the Commonwealth Department of Industrial Relations, which suggested that around 20 per cent of all Australian workplaces with federal award coverage have 'informal' enterprise agreements (DIR 1994). In the medical and scientific equipment industries these agreements range from comprehensive written agreements to oral agreements covering only a specific aspect of employment or special circumstances.

The Commission's survey suggested that the majority of medical and scientific equipment companies have informal working arrangements of some kind. These arrangements are least common in R&D and servicing activities.

The informality of workplace relations is seen by many in the medical and scientific equipment industries as advantageous. Several human resources managers at a meeting of MIAA representatives stated that if staff presently had a problem then management and staff sat down eye-to-eye and resolved it informally. Enterprise agreements would, they considered, introduce formal industrial relations positions, protocols and possible confrontation not present in the industry now.

*Union involvement*

In general, formal enterprise bargaining (that is leading to registered agreements) is strongly associated with the presence of union members in the workplace (DIR 1994). This is supported by the fact that unions were involved in all registered agreements identified in the medical and scientific equipment industries.

Union coverage appears relatively low in the medical and scientific equipment industries. Though detailed data are unavailable, in 1995 just over 25 per cent of photographic and scientific equipment manufacturing employees were union members (ABS 1995e, 1995f). The SSAA believed that the percentage of employees belonging to unions in the scientific equipment industry alone would be around half this figure (sub. 63). In comparison, the all manufacturing industry average in 1995 was just under 40 per cent (ABS 1995e, 1995f).

The Commission's survey indicated that some 6 per cent of small companies, 17 per cent of medium companies and 28 per cent of large companies have union representation in the workplace. The results also showed that scientific equipment companies have, on average, a slightly higher level of union representation than medical equipment companies.

Merck suggested that the low unionisation of the industries may be due to the fact that the industries do not employ a large number of blue collar workers (pers. comm.).

Several participants suggested that one reason for the low incidence of registered enterprise agreements is the desire of companies to avoid attracting unions to what are currently non-union workplaces. This was also raised as a possible explanation by several human resources managers of member companies of the MIAA.

*Experiences with enterprise bargaining*

While few companies have taken the route of formal enterprise bargaining, the experience of those who have illustrates some of the potential gains and limitations of doing so.

Merck, a manufacturer and importer of fine chemical and measuring instruments, negotiated its second enterprise agreement with employees in 1996. The agreements were negotiated at the request of the National Union of Workers, on behalf of its members, and agreed to by Merck so as to provide a stable working environment.

The agreements introduced a small number of changes to workplace arrangements (see section on terms of agreements). Workers received a 5 per cent

pay rise under the first agreement (covering the 12 months from March 1995), and a further 6 per cent rise under the subsequent agreement (covering the 24 months from April 1996) with a further increase of 2 per cent plus consumer price index adjustment in April 1997.

While the company felt the bargaining process was quite smooth, it had great difficulty gaining any real benefit from the process. The award was used as a basis for the agreements, giving extra benefits to union members with little benefit to the company. The company felt the union was not prepared to discuss any issues which would reduce their member benefits, such as buying out the Show Day holiday.

Email Air Handling entered negotiations for an agreement to pursue continuing workplace improvements and in response to union pressure for wage increases. While the company has benefited from the agreement, it felt most of the changes could have been made without an enterprise agreement.

Biolab have just finished negotiating the company's second (unregistered) enterprise agreement. The company feels the agreements are working well for both employees and employer, and both are broadly happy with the results. However, the company said that it believed enterprise bargaining is only partly successful as companies are still working within a very rigid award system (RT trans). Furthermore, it appears unions may be reluctant to move too far from the award structure for fear of setting precedents elsewhere (sub. 1).

### **Unfair dismissal legislation**

One area seen by many participants as in need of urgent reform was the unfair dismissal legislation. The Technology Industry Exporters Group suggested that the legislation is particularly a problem for small and medium companies (sub. 17).

Several participants pointed to the adverse impact the legislation had on full-time employment and, in turn, the availability of qualified employees. For example, the Scientific Suppliers Association of Australia stated that:

The unfair dismissal laws are as much a problem to this industry as to any other. They make all prudent managements hesitate to employ additional staff on a full time basis. Although our members are not so much concerned about the intent of this legislation they strongly urge some reform in this area. (sub. 11, p.8)

Biolab also urged a review of the legislation. The company has experienced problems with unfair dismissal laws, and is concerned with the focus on procedural correctness (sub. 1). Another company, Biotel, stated that by making it too difficult to terminate unsatisfactory or excess staff, the new laws have

resulted in companies employing fewer trainees and apprenticeships. This in turn was causing a shortage of good trades and technical skills in the industry (sub. 12).

Since the release of the Draft Report, the Commonwealth Government has announced changes to Australia's industrial relations laws, due to come into effect from around February 1997. Included in the changes is a revision of the legislation relating to unfair dismissal. The details of this revision have not yet been released.

### **6.3 Commission's assessment**

Industrial relations and labour market issues were generally not a major focus for many participants to this inquiry. However, some participants did refer to specific issues which restricted the operation of their companies. These included overtime, rostered days off, holiday loading, shift allowances and unfair dismissal provisions. Legislation relating to unfair dismissal generated the most comment. A number of participants noted it imposed additional costs on employers wanting to dismiss workers and so caused a reluctance to take on new workers.

Registered enterprise agreements were relatively uncommon in both the medical and scientific equipment industries. Where they existed they were generally registered by large companies. Instead, informal working arrangements were common, often based on an existing award. Such arrangements were particularly prevalent in smaller companies.

The photographic and scientific equipment manufacturing industries, which include medical equipment manufacturing, have a relatively highly skilled workforce compared to all manufacturing and all industries. However, on the same basis it appeared that the industries undertake relatively little training.



### **Finding 6.1**

In the medical and scientific equipment industries:

- formal enterprise bargaining is uncommon;
- informal agreements appear widespread; and
- although their workforces are relatively highly skilled, companies spend less on workplace training than the average of all manufacturing.

Except for the Commonwealth legislation relating to unfair dismissal, industrial relations and labour market regulation were not major issues for most participants in this inquiry.

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## 7 RESEARCH AND DEVELOPMENT

*The role of innovation, and the contribution of research and development (R&D) in this process, are important to the development and success of many companies in the medical and scientific equipment industries. There are a number of government support measures generally available to assist companies in their R&D endeavours. However, many participants drew attention to the difficulties companies face in gaining access to these measures — particularly small companies.*

The medical and scientific equipment industries are highly reliant upon R&D. In 1992-93, the average proportion of turnover spent on R&D for companies manufacturing medical and surgical equipment in Australia was about 8 per cent. For companies in the professional and scientific equipment industries, the proportion was around 9 per cent (ABS 1996b). These levels are much higher than the all manufacturing industry average of about 1 per cent (ABS 1995a).

These high levels of internal R&D are often attributable to the industries being at the forefront of technological change. For example, Malcolm Young and Company noted that the medical field is renowned for ‘technological breakthroughs’ and that to create and maintain market share an on-going commitment to R&D is needed (sub. 5, p.2). In some cases, R&D has a vital role in a company’s commercial success (see Box 7.1). For example, Nucleus considers high levels of expenditure on R&D are essential to maintain market leadership (sub. 4).

Apart from internally conducted R&D, companies can benefit from links with relevant research conducted by other companies or with publicly funded research bodies like the CSIRO or universities. Such links provide access to a well established research infrastructure, the opportunity to build on the ideas and work of others and avoid duplication of effort. As Johnson and Johnson Research have stated:

The most important reason why Johnson and Johnson set up a worldwide R&D centre in Australia is because Australia has excellent medical institutes and research centres (DIST 1995a, p.14).

The Commonwealth Government has instituted a range of generally available measures to encourage R&D and facilitate linkages between companies and research agencies. The effectiveness of these measures as they relate to the medical and scientific equipment industries is discussed below.

**Box 7.1      Successful innovation in Australia — the case of the Bionic Ear**

The bionic ear developed by Cochlear (part of Nucleus) is an electronic device surgically inserted into the inner ear. Nucleus has commented:

Without R&D expenditure at approximately 15 per cent of sales per annum, it would not have been possible to develop products such as ... cochlear implants which [is] now [one of] the key medical implantable electronic devices on which the company will focus in the future. (sub. 4, p.3)

This product has been successfully commercialised and to date, over 10 000 people in 45 countries have benefited from this invention. Cochlear now holds 85 per cent of the world market in bionic ear implants.

*Sources:* CRC for Cochlear Implant, Speech and Hearing Research 1995; DIST 1995a; sub. 4

## **7.1 Government support for research and development**

Government assistance for R&D encompasses both direct and indirect forms of support. The direct measures include the R&D tax concession (and, until recently, associated syndication arrangements) and competitive grants for R&D. The indirect measures include mechanisms to protect intellectual property and the facilitation of linkages between research bodies. These linkages may sometimes be formalised through entities such as Cooperative Research Centres (CRCs).

Participants in this inquiry have commented favourably on government support for R&D. For instance, Nucleus indicated:

The hundreds of millions of dollars expenditure on R&D which has underpinned Nucleus' growth and internationalisation (approximately \$250 million in the past five years) would not have been possible without Government support in the form of grants, special R&D allocations, access to medical and other research bodies such as universities and the CSIRO and significant levels of tax deductibility through the R&D concessional taxation arrangements (sub. 4, p.3).

While participants acknowledged the value of government support for R&D, many smaller companies argued that current schemes do not adequately address their needs. For example, these companies considered eligibility requirements and compliance costs effectively discriminate against them. The experience of companies in the medical and scientific equipment industries with these programs is reviewed in the following sections.

## 7.2 Direct measures of assistance

The Commonwealth Government provides financial assistance to businesses to undertake R&D in the form of tax concessions and grants. In the latter case the assistance is now provided through two programs: strategic assistance for R&D (START) and competitive grants for R&D.

### Tax concession for research and development

The R&D tax concession scheme is administered jointly by the Australian Tax Office and the Industry Research and Development Board (IRDB). Until August 1996, this program enabled a company with eligible R&D expenditure to deduct 150 per cent of that expenditure in determining its taxable income.<sup>1</sup> However, changes to the scheme announced in the 1996 Budget reduced this level to 125 per cent (see below).

For companies able to take advantage of the scheme, the 150 per cent tax concession has meant an effective subsidy on R&D expenditure of 18 cents in every dollar spent, based on the company tax rate of 36 cents in the dollar. To obtain the full benefits of the scheme, companies were required to have an annual expenditure on R&D of above \$20 000 and a taxable income (before expenditure) of at least 150 per cent of the amount expended. Additional eligibility criteria are detailed in Box 7.2.

Complementing these arrangements was a syndication scheme for companies in a tax loss position, or for projects which were viewed as too big or risky for any one company to undertake. This scheme provided the opportunity for those companies to gain access to the benefits of the tax concession. For instance, a research company with accumulated tax losses was able to exchange them for R&D funds from another company. A minimum expenditure of \$500 000 was required to attract the R&D tax concession (BIE 1994b).

#### Box 7.2 Eligible R&D expenditure for the tax concession

The pre-budget definition of eligible R&D was broad and incorporated any systematic, investigative or experimental activities that were:

- (i) carried out in Australia or an external Territory;
- (ii) involved innovation or levels of technical risk; and

<sup>1</sup> This is in comparison with the ordinary tax treatment of expenditure where 100 per cent of legitimate expenditure incurred in generating income may be deducted.

- (iii) A were carried on for the purpose of —  
acquiring new knowledge (whether or not that knowledge will have a specific practical application); or  
B creating new or improved materials, products, devices, processes or services.

R&D activities must also be carried out on behalf of the applying company, the company must be the owner of the R&D results, the R&D must contain adequate Australian content and any results must be exploited on normal commercial terms and to the benefit of the Australian economy.

*Sources:* AusIndustry 1996a, 1996b

Following the election of the new Government in March 1996, there have been a number of changes to the tax concession arrangements. These changes include:<sup>2</sup>

- companies are now limited to a period of four years in which they can amend their income tax assessments in respect of claims for R&D. Previously companies were allowed to register claims going back to 1985 when the scheme was introduced;
- phasing out of the R&D syndication scheme, starting with those partnerships without advance approval from the IRDB. In the Budget, the Government announced that the strategic assistance for research and development (START) program will take its place;
- the tax concession is to be reduced from 150 per cent to 125 per cent. This will lead to estimated revenue savings of \$1255 million over the next four financial years (Costello and Fahey 1996, p.4.5); and
- the definition of eligible R&D will be tightened. In particular, the definition of eligible R&D activities is to be amended to require 'innovation or high levels of technical risk'. Previously the definition simply required innovation or technical risk.

Before assessing the impact of these changes, it is useful to consider how companies in the medical and scientific equipment industries have made use of the scheme. Participants commenting on the scheme generally viewed it of considerable benefit for the medical and scientific equipment industries. William Cook Australia commented that it is 'a major platform of strength in our R&D efforts' (sub. 62, p.3) while Biotel identified:

The 150 per cent tax deductibility on R&D has generated an enormous incentive ... returns on investment are often substantial ... in our case, over the past three to four years

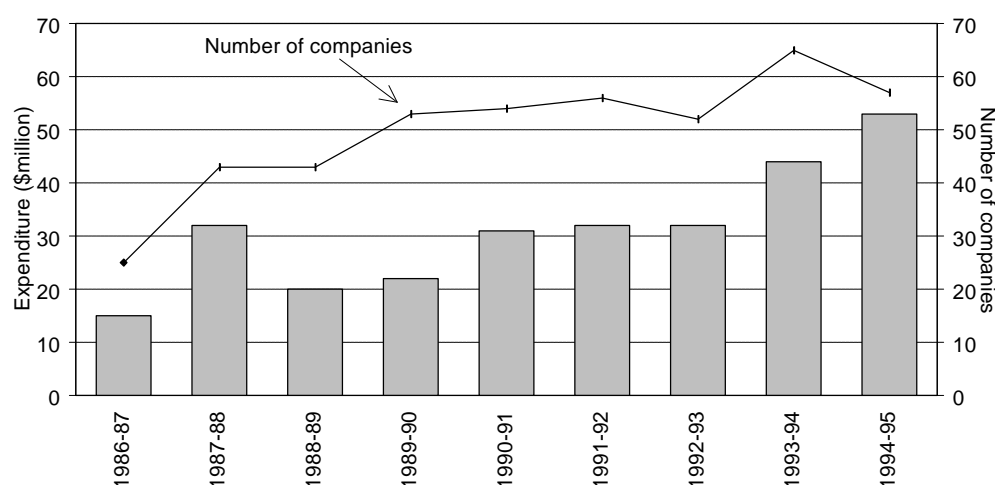
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<sup>2</sup> For other changes, refer the Commonwealth Government's 3 June 1996 R&D statement, 23 July 1996 R&D statement and 20 August 1996 Budget statement.

we have more than doubled our investment in R&D ... and our exports have tripled.  
(sub. 12, p.12)

An indication of the assistance accorded by the scheme is the number of companies and the value of the R&D expenditure claimed through the 150 per cent tax concession from 1992-93 to 1994-95 (see Figure 7.1). The data cover the photographic and scientific equipment manufacturing sector (ANZSIC 283) which incorporates the medical and scientific equipment industries. (Data for medical and scientific equipment industries alone are not available). Within this sector, the medical and scientific equipment industries account for around 80 per cent of turnover.

**Figure 7.1 Photographic and scientific equipment manufacturers who registered for the R&D tax concession: companies and expenditure, 1986-87 to 1994-95**



*Notes:* In 1994-95 dollars. The R&D tax concession during these years was 150 per cent.  
*Source:* DIST 1996a

In general, the number of companies registering under the scheme and the amount of eligible expenditure claimed have increased over time. However, it appears that only a small proportion of total companies in the medical and scientific equipment industries avail themselves of the concession.

Data on the use of the scheme suggest that, in 1994-95, larger companies availed themselves of the scheme in proportionately greater numbers than smaller companies. (DIST 1996a, ABS 1995b)

Data collected by the scheme's administrators did not allow separate identification of the use of the scheme by medical equipment and scientific equipment manufacturers. However, results from the Commission's survey — which indicates 56 per cent of respondents in the medical equipment industry invest in R&D and 30 per cent of respondents in the scientific equipment industry do so — suggests the medical equipment industry has made greater proportionate use of the scheme.

Nevertheless, some participants expressed a range of concerns about the tax concession scheme as it applied to the medical and scientific equipment industries. These concerns focussed on: the effect of minimum expenditure thresholds; the ability of tax loss companies to benefit from the concession; the impact of recent changes to the scheme (especially those announced in the Budget); and perceived more favourable R&D treatment overseas.

### *Minimum expenditure thresholds*

For small companies in particular, minimum expenditure thresholds relating to eligibility for the scheme may present an impediment to their use of the tax concession scheme. Biotel, for example, stated in reference to a number of programs (including the R&D tax concession):

There is an apparent myriad of potential assistance ... however for a small manufacturer, it is difficult or uneconomic to take advantage of most of them because ... [of] minimum thresholds on eligible expenditure. (sub. 12, p.10)

This tendency to exclude small companies is a matter of concern for the medical and scientific equipment industries because of the high proportion of small companies in these industries. However, such concerns are neither unique to the medical and scientific equipment industries nor are they new (see BIE 1994b, IC 1995b and 1995c).

The Commonwealth Government has acknowledged that minimum thresholds present difficulties and introduced measures to address industry concerns. For instance, in 1988 the Government introduced the Registered Research Agency scheme which aimed, among other things, to encourage access by small companies to the tax concession for R&D. As AusIndustry has commented:

The Government introduced [the Registered Research Agency Scheme] as a mechanism to facilitate access by small to medium sized firms to expert R&D without these firms having to invest in the infrastructure to support such activities (AusIndustry 1995b, p.3).

A Registered Research Agency is a body that has been approved by the IRDB Board to perform contract R&D on behalf of eligible companies or groups of companies. Importantly, all contracted expenditure by the companies is eligible for the full R&D tax concession and is not subject to the usual expenditure

threshold (AusIndustry 1995b). Applied Biotechnologies and the Austin Hospital in Victoria are two examples of Registered Research Agencies.

In 1994, the Commonwealth Government lowered the minimum expenditure for the R&D tax concession from \$50 000 to \$20 000, in response to continuing concerns that expenditure thresholds were too high.

Despite these changes, some companies in the medical and scientific equipment industries still consider the current threshold to be too high. However, others disagreed — for instance, the SSAA commented:

It is not considered appropriate to drop the existing R&D tax concession minimum expenditure limit below \$20 000 due to the high cost of administering the program both from a company and government point of view (sub. 63, p.7).

It is not clear to the Commission that further threshold reductions are warranted without compromising the purposes of such measures. These include avoiding situations where the costs of program administration may exceed the value of assistance provided and minimising opportunities for tax avoidance (IC 1995b).

### **Finding 7.1**

There is no compelling case on efficiency grounds to reduce further the minimum expenditure threshold for the tax concession for research and development.

### ***Tax loss companies***

Some participants claimed the R&D tax concession discriminated unfairly against some companies (sub. 17). To receive the benefits of a tax concession, companies must necessarily make a profit on which they pay tax. Therefore, tax loss companies are disadvantaged because they cannot receive the benefit of tax deductions even if expenditure thresholds are met.

This issue of tax loss companies was reviewed at length by the Commission in its report on *Research and Development* (1995b), where it recommended:

A generally available non-taxable grant should be introduced in place of competitive grants for tax loss companies ... (p.33).

In making this recommendation, the Commission was seeking to remove the potential for the benefits of the R&D tax concession to be arbitrarily determined by level of taxable income.

The Commonwealth Government of the day rejected this recommendation. It responded that non-taxable grants would be difficult to administer and would bring pressure for the general introduction of non-taxable grants for other sectors of the economy. The Government also stated that returns on generally available



subsidies for R&D in tax loss companies would be low. It decided that assistance to companies in tax loss would continue under the Competitive Grants Scheme (Cook and Willis 1995).

There were no specific measures announced in the August 1996 Budget regarding the tax concession scheme which addressed this tax loss issue.

### *Impact of changes to the tax concession scheme*

A number of participants considered that the changes introduced by the new Government would adversely affect their companies, particularly smaller companies. For example, Trace Scientific commented:

... reduc[ing] the tax concession to 125 per cent appears to disadvantage small to medium size companies ... [the] impact on companies such as Trace will be significant. (PH trans, p.242)

Also referring to the Budget changes, TIEG stated:

... small and medium sized enterprises cannot put the same level into R&D as they as they have been in the past. Now these companies are spending between 15 and 25 per cent of their revenue on R&D ... For these companies, [the change] means either they cannot afford to exist — if they cannot keep their level of R&D up they will simply go out of business ... or they are going to have to scale back their R&D, which is clearly going to have a commercial impact as well. (PH trans, p.104)

The reduction from 150 per cent to 125 per cent (which effectively halves the tax concession from 18 cents to 9 cents in the dollar at the current company tax rate) and the lower estimated Budget allocation — indicate assistance via the tax concession scheme for all industries will be significantly reduced. The impact of the changes will be greatest in R&D intensive industries which include the medical and scientific equipment industries.

Participants also expressed reservations about the restricting eligible expenditure to *high* levels of technical risk. The Government outlined that the intention of the changed definition was to tighten the eligibility requirements for future R&D and to better focus R&D assistance on 'quality new R&D' as opposed to incremental or product R&D. While this may be the case, TIEG commented that investment uncertainty will increase (PH trans, p.113) as the new definition is highly subjective:

... [It] is open to interpretation as to what high technical risk is ... it is the subjectivity of [the definition] which is the problem ... (PH trans, p.104)

TIEG sought further analysis of the effect of these changes. Some indication of the anticipated effect is provided by recent surveys of a broad range of companies conducted by Deloitte Touche Tohmatsu (1996) and Price Waterhouse and the Australian Industry Research Group (1996). In these surveys, almost half of the

respondents believed the changes would result in a reduction in their R&D, and the cost of compliance as a proportion of available tax benefits would rise by over 100 per cent. (The latter is consistent with the effective after tax subsidy falling from 18 cents to 9 cents in the dollar.)

Deloitte Touche Tohmatsu (1996) noted:

Where even large companies with large claims envisage that the rate reduction will render them less likely to claim the concession, it is reasonable to assume that smaller companies with smaller claims shall be even more significantly affected (p.4).

This assumption would appear valid for the medical and scientific equipment industries. The Commission's survey indicated that small and medium companies on average spend proportionately more of the value of their output on R&D (9 per cent) than do larger companies (4 per cent).<sup>3</sup> Consequently, of those companies within the medical and scientific equipment industries likely to use the scheme, it is probable that smaller companies will face a proportionately greater loss of assistance as a result of the changes.

The changes to the tax concession rate and eligibility requirements are likely to disproportionately affect smaller companies. The Commonwealth Government has announced that the new definitional arrangements will be reviewed in 12 months time (AusIndustry 1996a, p.1). Given the Government's commitment to small business in the recent Budget, any future review of the tax concession could usefully incorporate an analysis of the costs and benefits according to company size.

### **Finding 7.2**

The evidence presented to the inquiry suggests that smaller companies in the medical and scientific equipment industries undertake more research and development as a proportion of their value of output than larger companies.

### **Finding 7.3**

Future reviews of assistance measures for research and development should, among other things, examine their impact according to company size.

<sup>3</sup> This is consistent with OECD research (OECD 1996) which indicates smaller companies are responsible for significantly more R&D and innovation than previously acknowledged.

*Assistance in other countries*

A number of participants claimed that in other countries, R&D tax concession arrangements are more favourable than Australia. TIEG, for example, stated:

One member of ours, Vision Systems, has publicly stated in the media that they will seriously consider looking at taking their R&D over to Malaysia, where they believe that the government is far more friendly towards R&D companies. (PH trans, p.104)

R&D tax incentives available in a number of countries are detailed in Table 7.1. However, as documented in its report on *Research and Development* (1995b), the Commission cautions against comparing Australian rates of assistance with other nations for the following reasons:

- the extent of available support should not be assessed in isolation. For instance, other factors to consider include the available pool of skilled labour and the extent of government research facilities;
- different countries have different industrial policies. Some place a great emphasis on innovation at the expense of other activities; and
- while the concessions in some countries may appear generous, they should be assessed with the company tax rate in mind as this affects the ultimate value of concession received. For instance Australia's company tax rate is currently 36 per cent while Malaysia's and Singapore's are 30 per cent and 27 per cent respectively (CCH 1996).

Furthermore, the Commonwealth Government has noted with respect to the tax concession arrangements in Malaysia and Singapore:

Whilst Malaysia and Singapore have attractive headline deductions (at 200 per cent) for expenditure on R&D, the concessions in these countries are far more restrictive than those available in Australia. Many research projects which qualify for the R&D tax concession in Australia would not qualify for the concession in those countries. Most expenditure claimed under the Australian R&D tax concession would receive far *less* concessionary treatment in Singapore and Malaysia. (Costello and Fahey 1996, p.4.68)

In its recent inquiry into R&D (1995b), the Commission did not support increasing the R&D tax concession in Australia to match rates applying in other countries.

Table 7.1      Research and development tax incentives in other countries

<i>Country</i>	<i>Concession</i>
Canada	Companies receive a 20 per cent credit on total qualified R&D. Carry-forward and backward provisions exist, as does a preferential rate (35 per cent on the first C\$200 000 of research and experimental development of refundable credit for small and medium-sized enterprises. <sup>a</sup>
France	Firms can receive a tax credit equal to 50 per cent of the increase in qualified R&D over average R&D expenditure in the previous two years, with an upper limit of FF40 million. Unused credits can be refunded. There are special incentives for new (generally small) companies.
Japan	Companies receive a tax credit equal to 20 per cent of the increase in qualified R&D over the highest previous year's R&D expenditure, up to a maximum of 10 per cent of the company's tax liabilities. There are special incentives for smaller enterprises for expenditures on special R&D activities (including joint research with national laboratories, cooperation with foreign research laboratories, the efficient use of energy and the use of recycled resources).
US	Until 1 July 1995, companies received a tax credit equal to 20 per cent of the increase in qualified research and experimental development over a defined base amount (average of the 1984–88 period). There are provisions for carrying forward credits not used in the current fiscal year. Start-up companies that do not yet have tax liabilities are offered a special tax-credit if they spend more than 3 per cent of their turnover on R&D.
Singapore	Manufacturing and some services companies are allowed to deduct 200 per cent of the cost of their R&D activities from their taxable income. Eligible R&D must have the approval of the Minister who may at his discretion, specify the amount of expenditure and period for which the deduction is allowed. <sup>b</sup>
Malaysia	Companies are allowed to deduct 200 per cent of eligible R&D from their taxable income. R&D must have the approval of the relevant Minister. <sup>b, c</sup>
a	Several provinces in Canada (Quebec, Manitoba, Ontario, Nova Scotia and New Brunswick) have their own tax credit scheme.
b	See Costello and Fahey (1996) for additional information.
c	This scheme has a tighter definition of R&D than Australia.
Source:	Costello and Fahey (1996) and Guinet and Kamata (1996)

### **Strategic assistance for research and development**

In the August 1996 Budget, the Government also announced the formation of new selective assistance program — the Strategic Assistance for R&D (START) program. This scheme aims to encourage a new contestable R&D replacement program for R&D syndication for large projects. It involves the provision of direct government grants for R&D — similar in nature to the Competitive Grants Scheme (discussed below).

The Government has decided that companies with large R&D projects with clear economic spillover effects and which would otherwise not proceed due to lack of finance, are eligible for assistance within this program. Assistance is in the form of grants, loans and interest subsidies. Projects which cost in excess of \$2 million are eligible for funding. AusIndustry has commented:

The degree of total support will depend on the level of additional R&D and commercialisation which is likely to be induced by Government support, together with the national economic benefits likely to flow from the project. Commercialisation elements of approved projects will generally be provided with interest rate subsidies or loans rather than grants in order to maximise private sector financing. (AusIndustry 1996e, p.2)

The program is to be administered by AusIndustry with the IRDB responsible for funding approval. The Government will provide a total of \$520 million over the next four years, including \$340 million of which has been provided in the 1996-97 Budget (Costello and Fahey 1996).

TIEG expressed concern that the program's eligible expenditure was at too high a level to be of use for the smaller companies which predominate in the medical and scientific equipment industries (PH trans, p.106). Participants (for instance TIEG) also commented that a degree of uncertainty existed given that details of this program have not yet been finalised (PH trans, p.106).

### **Competitive grants scheme**

The Competitive Grants for R&D scheme was created in May 1994 from five existing R&D schemes. It is administered by the IRDB. Grants are provided on a competitive basis for:

- market driven R&D for companies unable to use the R&D tax concession;
- collaborative R&D activities which are high risk but could provide extensive benefit to Australia; and
- trial and demonstration activities between technology developers and potential customers (DIST 1996c).

The grants provide selective assistance to particular research projects based on an assessment of their relative merits. Applications for grants are made to the IRDB for assessment against a set of eligibility criteria. Companies are not precluded from receiving grants if they are in tax-loss or have not satisfied expenditure thresholds.

In the August 1996 Budget, the Government announced the IRDB will be given greater flexibility in determining the size of grants. Approximately \$24 million has been allocated to this program in 1996-97, and the Government has stated that funding will increase to \$41 million in 1998-99 (Costello and Fahey 1996).

The SSAA commented favourably on this increase:

The increase in funding to the Competitive Grants Scheme for the current year is encouraging with this program being of great benefit ... (sub. 63, p.8).

Information on grants to medical and scientific equipment companies is not available in order to assess the impact of this program on the scientific and medical equipment industries. However, more general information is available on grants to companies in the photographic and scientific equipment manufacturing sector (ANZSIC 283) — of which medical and scientific equipment manufacturers constitute about 80 per cent of turnover. This is shown in Table 7.2.

**Table 7.2** Grants to photographic and scientific equipment manufacturing companies<sup>a</sup>: 1991–92 to 1995–96

<i>Financial Year</i>	<i>Grants (\$'000)</i>	<i>Companies (No.)</i>
1991-92	3 695	7
1992-93	2 541	7
1993-94	1 284	3
1994-95	4 309	9
1995-96	894	3

a Companies within Photographic and Scientific Equipment Manufacturing Group (ANZSIC 283).

Source: DIST 1996a

### **Accessibility of direct assistance**

Evidence presented to this inquiry suggests small companies are disadvantaged in gaining access to direct assistance for R&D. The significance of this for the medical and scientific equipment industries is emphasised by the preponderance of small companies in the industries and the Commission's survey which found small companies spend more on R&D as a proportion of the value of their output than do larger companies.

As noted above, tax loss companies are disadvantaged in gaining assistance from the tax concession scheme. Because many medical and scientific equipment companies are commonly small companies in the start-up and early development stages and not making a profit, this feature of the tax concession means they are less likely to benefit from this scheme than larger companies.

Small companies are also disadvantaged in gaining access to grants for R&D. For example, the Australian Society for Biomaterials commented:

The [Competitive Grants for Research and Development Scheme] has the potential to generate and deliver successful research outcomes to companies. However, as many small to medium enterprises have limited resources to invest ... small firms appear less able to take full advantage of these schemes. (sub. 7, p.4)

Similar concerns have been expressed during previous Commission inquiries. For example, in a submission to the Commission's inquiry on the computer and

related industries (IC 1995c), the Canberra Region Advanced Technology Manufacturing Association stated:

The smaller company seems to be disadvantaged regarding access to R&D grants as the IRDB is less interested in smaller proposals (say less than \$0.5 m) ... (p.140).

Nevertheless, some small to medium companies in the medical and scientific equipment industries have been successful in obtaining grants. One such case is that of Jakab Industries, outlined in Box 7.3.

To gain access to Government R&D programs is not costless to companies. For example, companies face costs in obtaining program information, understanding often complex legislative requirements, and collecting the detailed information required to meet the eligibility criteria.

### **Box 7.3      Jakab Industries**

Jakab Industries, using a Competitive Grant and with support from the Queensland Ambulance Service, built and trialed a modular-bodied ambulance capable of meeting 90 per cent of all emergencies. The basis of the vehicle was a Holden Commodore Utility, stretched by Jakab to provide the requisite length.

The Jakab ambulance cuts capital costs and operating costs by 50 and 70 per cent respectively, while offering a superior performance and ride. It has been endorsed by Ambulance Services in all states with over 200 being sold domestically. In addition, export revenue from the project has amounted to \$0.9 million, with units operating in Indonesia, Thailand and Brunei. The project commenced in June 1992 with a grant of approximately \$150 000 and was completed in April 1993.

*Source:*                IRDB 1995a

With regard to compliance costs, Baldwin Medical and Veterinary Devices (Australia) noted:

We are constantly involved in R&D of some kind but we do not find that we have the adequate resources to collate and record the information required by the Act (sub. 24, p.2).

Murphy Furniture also indicated that:

... [the] administrative burden (cost) of submitting claims on the R&D tax concession ... is relatively high compared to benefits to small firms (sub. 27, p.1).

### **Commission's assessment of direct assistance**

The Commission examined the R&D tax concession in depth in its report on *Research and Development* (1995b). In that report, the Commission commented that one of the attractions of the R&D tax concession is that it is a generally available form of assistance. The only form of discretion in the scheme involves

the administrative arrangements — in deciding whether the eligibility criteria (for example technical risk) have been met. In commenting more broadly on the pre-existing eligibility criteria, the Commission believed that those definitions within section 73B of the *Income Tax Assessment Act* 1936 were appropriate.

That report considered the exclusion of tax loss companies a weakness in the tax concession for R&D. It also considered there was no reason to recommend changing the level of the tax concession and found that at its earlier level of 150 per cent, the concession had brought net benefits to the Australian economy. In particular, the Commission noted:

On balance, the Commission favours continuation of the assistance in the form of a tax concession ... it has widespread acceptance among businesses and there would be undesirable impacts on incentives to perform R&D if uncertainty is created by changes in the form of assistance. (IC 1995b, p.654)

#### **Finding 7.4**

The recent changes to the tax concession for research and development appear to have increased the uncertainty associated with investing in research and development. This is likely to have an adverse impact on research and development in the medical and scientific equipment industries.

The changes introduced by the Commonwealth Government — placing a greater emphasis on selective forms of assistance and a move away from more generally available taxation measures — are intended to increase the effectiveness of R&D (Costello and Fahey 1996, p.4.66). However, the Commission has cautioned against this approach in its report into *Research and Development* (1995b):

... the ability of a selective scheme to perform better than generally available assistance [for example the tax concession scheme] is greatly constrained by the difficulty of knowing in advance how different R&D projects will turn out and the great uncertainty that thus surrounds judgements about the relative (social) benefits of alternative claimants for support. (IC 1995b, p.31)

That report detailed some of the inherent problems with selective subsidy schemes for R&D. These included:

- the potential for support to become focused on picking likely successful firms and industries rather than addressing market failure in R&D;
- assistance tends to be concentrated on a relatively small number of companies, with the majority of applicants with eligible R&D receiving no assistance; and



- the costs of running selective assistance schemes are many times higher than for non-discretionary R&D support. For instance, the Commission estimated that the costs of running the Competitive Grants Scheme relative to disbursements, may be at least ten times higher than the tax concession scheme (IC 1995b, p.31).

The Commission also notes that, of the estimated revenue savings of \$1255 million from reducing the tax concession level, approximately \$520 million will be allocated to the START program. As the START initiative is focused primarily on the funding of large scale risky projects, this will further disadvantage smaller companies in the medical and scientific equipment industries as they are not eligible for this program.

**Finding 7.5**

Overall, smaller companies in the medical and scientific equipment industries will be disadvantaged by redirecting savings from recent changes to the tax concession for research and development to the START program.

If the objectives of the government assistance programs are to be achieved, programs need to be designed so as to reduce unnecessary administration and compliance costs to companies. These costs can be minimised, consistent with adequate accountability, by ensuring that procedures are easy to follow, advice is readily available, and information requirements are kept to a minimum.

In a report on the *Stocktake of progress in microeconomic reform* (PC 1996), the Commission recommended budgetary support for industry should be retained only where a clear rationale for government support is established. The principle underlying this recommendation is that industry support programs should be reviewed for their appropriateness, effectiveness and efficiency. It is in the context of such a review that any issues of compliance costs, administration and access should be addressed.

### **7.3 Indirect measures of government assistance**

The Commonwealth provides non-financial forms of assistance to businesses to undertake R&D. These include patent protection and facilitating linkages between public and private research bodies.

## Patent protection

A patent provides owners with a legal right to prevent others from making or using their invention for a fixed period of time.<sup>4</sup> Patents are designed to facilitate investment in R&D by providing investors with the opportunity to appropriate the benefits of their research as well as providing a secure 'asset' which may be used as collateral to obtain finance. In return, patent applicants must share their know-how by providing a full description of how their invention works.

Australian patents provide protection within Australia — to obtain similar protection overseas separate applications generally need to be made in each country. Such protection involves costs and, with reference to this, Biotel commented:

Like most legal services, the costs of protecting intellectual property are relatively high — particularly overseas (eg: a simple renewal of our Trade mark in Singapore recently cost us A\$525) (sub. 12, p.21).

Other participants commented on the complexity of the patent arrangements. For instance, Tuta Laboratories (Australia) noted:

Intellectual Property considerations are complex and require the direct involvement of professionals in this field ... government recognition of these sometimes large up front financial requirements, needs to be realistic to allow for the passage of time, to generate funding ... (sub. 15, p.10)

Despite the complexities and costs, patents may in some instances be a useful way to enable investors in R&D to appropriate the benefits of their research. However, patents are not always appropriate and may have limited applicability for the medical and scientific equipment industries. This arises because of the difficulty in specifying designs and applications, and the constant and rapid change in technology. Even if a patent application is successful, there is a high probability that the equipment will quickly become obsolete through technological developments long before the patent expires. Under such circumstances, it may not be worthwhile incurring the costs of obtaining patent protection. As Kahn (1991) commented:

In instrumentation products, patenting the design of the instrument itself is a futile exercise because it is not difficult to design another instrument in a different way that performs in exactly the same manner (p.90).

## Industry linkages

Linkage mechanisms between, for example, industry and research institutions have an important role in the innovation process relating to medical and scientific

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<sup>4</sup> As a result of the GATT Uruguay Round Agreement, the Australian Government has extended the term of existing and new patents from 16 to 20 years.

equipment. Linkages may be formal or informal and provide a means of gaining access to existing sources of technological knowledge and avoiding duplication of effort.

Linkages may be established between companies within an industry, between private companies and public institutions such as the CSIRO or universities, as well as through more formal institutional arrangements such as CRCs. Informal linkages may occur through personal communication with colleagues in other companies, at conferences or through contact within professional societies. Linkages can also be with overseas participants.

The Australian Society for Biomaterials commented on the importance of establishing linkages:

A strong network of interactions exist between many of the laboratories and with certain industrial partners ... and this has led to substantial collaborations and coordination of effort in many areas of research ... Another area for considerable interactions is with Europe. Australia has signed a memorandum which enables our researchers to be participants in European Union 4th framework programs ... Leading research groups in Europe have already sought interaction with Australian groups ... such interactions are seen as very beneficial for emerging Australian industry. (sub. 7, p.4)

Similarly, Trace Scientific commented on their importance by noting:

The resources available to firms such as Trace to carry out R&D on a scale comparable to that of its major competitors is simply not available. However, Trace is of the opinion that this gap can be reduced somewhat by establishing strong links with public sector R&D institutes throughout Australia. (sub. 55, p.4)

Inadequate linkages in the innovation process between institutions and the users of research, or in the diffusion of research, can reduce national returns to R&D. With respect to cooperative arrangements in the medical and scientific industries, the Bureau of Industry Economics (BIE 1995a) found:

The industry experiencing the most 'major' problems in its cooperative arrangements is scientific/medical. A high 21 per cent of firms complain about time as a major burden. The proportion of firms having 'major' problems with financial costs, disclosing commercial secrets and loss of control are also relatively high compared with other industries. (p.184)

Results from the Commission's survey of the medical and scientific equipment industries indicate the importance of formal cooperative arrangements — especially for small to medium companies. The results show that 12.5 per cent of large companies have formal cooperative arrangements, compared with 26 per cent and 11 per cent of medium and small companies respectively.

The survey also indicated that R&D and marketing overseas were the most important reasons for cooperation. Additionally, companies in the scientific

equipment industry are more likely to have formal cooperative arrangements than companies in the medical equipment industry.

The most important formal linkage mechanisms identified by inquiry participants were within CRCs and links between private companies and public institutions like the CSIRO and universities. These linkages are considered below along with linkages with the international community.

### *Cooperative research centres*

CRCs were developed to link public research organisations and private companies and to encourage them to share ideas and infrastructure. Sixty-two have been established since 1990, covering many areas of natural science and engineering. There are eight medical CRCs, which are listed in Table 7.3.<sup>5</sup>

CRCs were established in response to a report by the Australian Science and Technology Council (ASTEC) in 1989 on *The Core Capacity of Australian Science and Technology*. ASTEC considered many of the R&D oriented programs targeted at the manufacturing industry lacked ‘focus.’ It believed policies to encourage linkages would improve the situation. ASTEC noted that improved linkages required, among other things, a critical mass of people and facilities, and the collaboration of researchers across conventional disciplines.

The CRC program was considered only briefly by the Commission in its R&D report (IC 1995b). At the time of reporting, a review into the CRC Program was being undertaken by the CRC Program Evaluation Steering Committee (CRCPESC 1995). This review concluded that the CRC program was making a valuable contribution to Australia’s education, training, and R&D efforts.

Table 7.3      Medical cooperative research centres, 1996

<sup>5</sup> Other science-oriented CRCs are classified under Manufacturing Technology and Information and Communications Technology (see DIST 1995b for details).

<i>Starting date</i>	<i>Name of CRC</i>	<i>Steady state funding per year<sup>a</sup></i> <i>(\$m)</i>	<i>Total grant</i> <i>(\$m)</i>
1991	CRC for Tissue Growth and Repair	1.8	11.1
1991	CRC for Cellular Growth Factors	2.3	14.5
1991	CRC for Eye Research and Technology	2.3	14.5
1992	CRC for Bio-pharmaceutical Research	2.2	13.3
1992	CRC for Cochlear Implant, Speech and Hearing Research	2.2	13.3
1992	CRC for Cardiac Technology	2.2	13.3
1993	CRC for Vaccine Technology	2.1	13.5
1994	CRC for Diagnostic Technologies	2.2	14.5

a Steady state funding and total grants for all centres are in 1995-96 dollars.

Sources: DIST 1995b and 1996d

In 1995-96, Commonwealth funding for the CRC program was about \$133 million (McGauran 1996, p.5.68). The Government announced in the August 1996 Budget that Commonwealth funding for the CRC program will be maintained at \$145 million in 1996-97, rising to \$148 million in 1998-99 (Costello and Fahey 1996, p.3.63).

The Government has also agreed to implement the recommendations of the CRC Evaluation Committee and to provide funding for two additional CRCs. No specified areas have been targeted for this funding and applications have been received from 36 interested parties. Of these, eight are from the general area of medical, science and technology.<sup>6</sup>

The Government has agreed to fund each CRC for no more than seven years and will contribute a maximum of 50 per cent of the total cost of establishing and operating each centre. Business contributions since 1990 have totalled over \$400 million (DIST 1995b).

The emphasis of the CRC program is on high quality applied research of national significance. A key objective of the program is to capture the benefits of research and to strengthen the links between research and commercialisation. As the Department of Industry, Science and Technology commented:

A primary focus of the Program is the enhancement of cooperative linkages between researchers, and between researchers and the users of the research. The Program is intended to bring together researchers and research groups from universities, government research laboratories (both Federal and State) and the private sector, into long-term cooperative relationships. (DIST 1995b, p.13)

Similarly, Nucleus commented:

<sup>6</sup> Of these eight applications, three are from already existing CRCs which were established in the first-round of funding arrangements.

In Australia the CRC scheme is one of the major mechanisms provided by Government specifically to encourage corporations to participate in strategic and applied research and to aid in the commercial capture of the research (sub. 4, p.19).

### *Access of small companies to CRCs*

One area identified for improvement by the Evaluation Steering Committee was access to CRCs for small companies. Against the recognition that small companies would have problems contributing the required staff or cash to centres, the Committee recommended:

The CRC Committee and the CRC Association need to develop a coordinated publicity strategy for the CRC Program to increase general understanding of its role and potential benefits, particularly targeting information that is directly relevant to small and medium sizes enterprises.

CRCs note the range of different models for providing small to medium enterprises access to CRCs in further developing their own approaches, and that the CRC association provide support for identifying and achieving best practice among CRCs in providing access to small to medium enterprises. (CRCPESC 1995, pp.14, 34)

Participants in this inquiry also consider that many CRCs are oriented to the needs of larger companies at the expense of smaller ones. For instance, State and Regional Development (NSW) observed that CRCs have not attracted investment from the smaller companies (sub. 28, p.6), while Biotel indicated:

It appears that [CRCs] much prefer projects and sponsorship from large corporations ... small companies would have limited opportunity, if not prohibited by the cost. (sub. 12, p.12)

The SSAA commented:

The lack of involvement of smaller companies in the CRC program is due to three reasons: firstly, they are highly internally focussed by economic necessity, they lack resources to put into the CRC and are doubtful about their ability to afford to commercialise products that result from the research. We suspect that there is a degree of ignorance about the CRC program itself. (sub. 63, p.9)

As outlined in the *Cooperative Research Centres Program Guidelines* (DIST 1995b), CRCs have an obligation to ensure that they interact effectively with small and medium companies in their sector. Centres are encouraged to develop strategies to ensure that smaller companies have access to their research and training activities. In particular, the guidelines state:

In developing their own strategy, Centres could take note of various approaches that have been used successfully, including industry associates programs, industries associations as core participants ... use of CRCs as demonstrator sites, sponsorship of postgraduate students and assisting small to medium enterprise employees to work in a Centre on temporary secondment. (p.12)

The CRC for Diagnostic Technologies provides an example of a CRC with an extensive established network between a range of different companies (including small to medium companies) and publicly funded institutions (see Box 7.4). However, it is unclear if these linkages are directly attributable to the CRC program — extensive and sometimes longstanding relationships may have existed before the CRC was established.

### *Impediments to industry linkages*

Some inquiry participants commented on the difficulties experienced when public and private organisations collaborate on projects. In particular, Nucleus stated:

There is often a clash of cultures between commercial and public research institutions. For public researchers to operate effectively in the commercially oriented CRC projects they often require new skills in project management, and an understanding of commercial cost factors and risk. (sub. 4, p.20)

The BIE also commented:

Most academic research, and a substantial portion of R&D in government agencies, is driven by curiosity and a desire to increase the community's store of knowledge ... By contrast, business R&D is usually motivated by a desire to generate income or profits, and research results are often kept secret ... to maintain a commercial advantage. Collaboration with industry may require public research to accommodate the business approach. (1996a, p.45)

The Evaluation Steering Committee commented that the tasks of developing effective cooperation had been challenging. In particular, the review noted that differing research organisations have differing cultures and objectives and that much commitment and effort is required from program participants to reconcile and benefit from these differences. The Committee also considered there was room for further improvement in CRC management (CRCPESC 1995). Given

### Box 7.4 CRC for Diagnostic Technologies

This CRC is based at the Queensland University of Technology (QUT) and began operation on 1 July, 1995. It aims to develop innovative generic diagnostic technologies, and specific diagnostic products and processes that are highly competitive in the international market.

The CRC's membership consists of a number of public and private enterprises. The public organisations are the School of Life Science (QUT), the Division of Biomolecular Engineering (CSIRO), the Schools of Biochemistry and Electronic Engineering (La Trobe University) and the Kolling Institute of Medical Research (NSW). The private organisations are all members of the Australian Diagnostics Manufacturers Association (ADMA) and are as follows:

*AGEN Biomedical* — this company originated as a research group working on monoclonal antibody-based diagnostics within QUT. It was floated in 1986 and since then, has grown at 30–40 per cent per annum. It currently has an annual turnover of approximately \$10 million and spends approximately \$2.5 million per annum on R&D. The company maintains research collaborations with the CSIRO Division of Biomolecular Engineering (for antibody engineering) and with QUT/GeneCo (for DNA diagnostics). GeneCo is jointly owned by QUT, AGEN and the Queensland Industry Development Corporation;

*Panbio* — this is a private company owned by a group of scientists with extensive experience in all aspects of commercialisation of diagnostics. The company was formed in 1987 and has a staff of 15. It specialises in R&D and global marketing of niche ELISA kits for infectious diseases. The company has collaborative interests with QUT, the Queensland Institute of Medical Research and the Sir Albert Saksewski Viral Research Laboratory. PanBio invests over \$300 000 a year on R&D. In 1995, PanBio was awarded the Telstra Australian Small Business Award for companies with less than 30 employees;

*Silenus Laboratories* (part of ICI Australia Operations) — this company manufactures and markets immuno-diagnostic products. It works closely with institutions such as the Flinders Medical Centre (Adelaide), the Westmead and Royal Prince Alfred Hospitals (Sydney), the Austin Hospital (Melbourne) and the Peter McCallum Institute (Melbourne); and

*Bioclone Australia* — is a private company with investments from the Commonwealth Development Bank and Hambro-Grantham Investments. The company manufactures a range of monoclonal and polyclonal antibodies and a range of diagnostic kits. Bioclone has a number of agreements or affiliations with international diagnostic companies. These include Serono Diagnostics, Kodak Clinical Diagnostics, Wako Pure Chemicals (Japan's largest manufacturer of clinical chemistry products) and Hitachi Chemicals.

*Sources:* CRC for Diagnostic Technologies 1996; DIST 1995b, 1996d and 1996e



the extent of public funding resources involved, there is also a need for the government to ensure that the centres are managed for the benefit of Australia.

*Impediments due to product liability*

The CRC for Cardiac Technology drew the Commission's attention to an impediment it encountered in bridging the gap from R&D to commercialisation. It noted that commercialisation of the technology it was working on requires testing through clinical trialing before local or international capital can be found to develop the idea (sub. 49, p.1). Product liability insurance is an essential pre-requisite for that clinical trialing.

The CRC noted that its commercial partner in this exercise — Amlab — was effectively unable to obtain product liability insurance to cover the necessary clinical trialing. Amlab had approached major suppliers of insurance in Australia and the US and only one company was prepared to offer a quote: an apparently exorbitant 'go away' price of several hundred thousand dollars (sub. 49, p.1).

The submission from the CRC for Cardiac Technology and its evidence at public hearings provided some reasons why this occurred. It noted:

- Australia does not have the history that the US has in manufacturing medical devices, so local insurers are extremely averse in this high risk area;
- there has never been a clinical trial case tried in Australia so for all involved, the magnitude of the risk is unknown; and
- that the apportionment of liability to individual CRC partners, while being necessary to obtain liability insurance, is an inherently difficult task. (sub. 47, pp.1-2; PH trans, pp.125–35)

Similar problems are expected for another product the CRC is developing (a novel polyurethane for use in implantable medical devices). Without access to reasonably priced product liability insurance the CRC claimed the commercialisation of its technology would be forced offshore. It considered this represented a fundamental flaw in the way government supported R&D:

... any government over a period of time will be spending substantial amounts of money supporting a CRC in its early formative years. The CRCs will, as the Cardiac CRC has, develop an extensive range and list of intellectual property which is world class technology and then at the end of the day that technology will not be able to remain in Australia and the benefits to the Australian economy will be negligible compared to the potential benefits if that technology were in Australia (PH trans, p.136).

The Commission approached the agency in DIST that administers the CRC program to determine if other CRCs had encountered this impediment. The response from DIST indicated they were not aware of similar cases, although the

CRC for Cardiac Technology claimed it was a common problem with other medical CRCs (PH trans, p.140).

The Commission also contacted a number of insurers seeking information about whether there is any reluctance to provide product liability cover to entities conducting clinical trials. AMP General Insurance Limited documented that insurance premiums are based on an assessment of the risk and the potential payout. For medical research, AMP argued that the potential of claims for damages is not clear and that claims may arise many years after the product is developed — and may also involve class actions and cost millions of dollars. Commenting on the case which the CRC for Cardiac Technology presented, AMP stated that:

The costs of product liability insurance for medical research will be very expensive, however, [AMP does not] believe the cost in Australia will be any dearer than what a research group in Europe or the US will have to pay as payments in Australia are not likely to be as large, based on current court determinations. (AMP 1996, p.2)

AMP commented further:

The [submission from the CRC for Cardiac Technology] only addresses the issue of products liability insurance which relates solely to injury or damage to property resulting from a faulty product. [AMP] would have thought that professional indemnity or medical practice insurance would be more relevant to a research team which provides protection against breach of professional duty. (AMP 1996, p.2)

The CRC for Cardiac Technology offered possible solutions to the problem it had identified. It suggested that the Government could provide a pool of insurance funds available at reasonable cost to medical institutions wishing to conduct trials; insurance cover for clinical trials could be underwritten by Government to keep costs down and risk apportioned; and the introduction of legislation to protect materials and components suppliers from product liability for end-use devices (similar legislation has been proposed in the US). Some of these issues were also raised by Dow Corning (sub 59, p.2) in the context of regulation applying to medical devices (see Chapter 4).

The experience of the CRC for Cardiac Technology raises issues regarding the operation of the CRC program (eg the selection of projects, CRC guidelines and the allocation of CRC funding). The Commission notes that it is not a requirement of the CRC program that commercialisation of research occurs; indeed, many CRCs are involved in research which will never reach the commercialisation stage. Nevertheless, the Commission questions the wisdom of continuing to support research when there is a clear impediment to its conduct and its successful conclusion (the issue of gaining product liability insurance). For instance, funding may have been better allocated to another project which may not have faced similar impediments.

This experience also impinges on the broader issue of the allocation of funding for R&D, and the Government's approach to product liability and the operation of the market for product liability insurance. These issues extend well beyond the scope of this inquiry and it is thus inappropriate for the Commission, in this report, to make recommendations in this area.

*The Commission draws the Government's attention to the difficulties faced by the CRC for Cardiac Technology in obtaining product liability insurance for their implications for the operation and funding of the CRC program.*

### **Linkages with CSIRO**

The CSIRO is Australia's largest research institution. Public funding of CSIRO totalled \$462 million dollars in 1994-95, accounting for nearly half of Commonwealth budget outlays to its research agencies (Cook 1995). The Government recently announced in its August 1996 Budget that CSIRO's funding base will be 'restored' and an extra \$115 million has been allocated over the next four years. Funding for CSIRO in 1996-97 is estimated to be \$444 million rising to \$509 million in 1999-2000. (Costello and Fahey 1996)

CSIRO's role is broadly defined through legislation and Ministerial Directions. It is required to emphasise research of significance to national economic development, including research in support of industries and the interests of the Australian community generally. The dissemination of results is seen as central to its role. While CSIRO is to give 'due regard to the industry and research priorities of the Government', there is very little guidance about the exact focus of research (IC 1995b). One influencing factor is the decision of the Government to set an external earnings target for CSIRO equivalent to 30 per cent of its total funds expended.

Participants in this inquiry commented on the importance of forming strategic links with organisations like CSIRO, and many useful linkages have been formed in the past (see Box 7.5). Biotel commented:

We're increasingly looking at alliances on a project by project basis, joint ventures with other organisations, be it government or private ... we were investigating ... a manufacturer of tissue culture plastic, surface treatment of the plastic to give it particular properties. We just happened to stumble across a guy at ... CSIRO in Clayton who were doing exactly that same thing for the manufacture of contact lenses ... I think for the small companies that are not going to be able to employ the specialist skills in-house, there needs to be a mechanism whereby we can form some form of joint venture or tap in with them. (RT trans, p.55)

#### **Box 7.5      Metal Manufactures collaboration with CSIRO**

The CSIRO Division of Applied Physics, in collaboration with Metal Manufactures and the University of Wollongong have been working together to develop a high temperature

superconductor wire. This technology can be used in existing power equipment applications such as motors, generators and cables. It can also be used for new applications like magnetic resonance imaging in the medical industry. It has other energy storage uses and forecasts have indicated that superconducting products will generate global business of around \$150 billion within about 20 years.

Much of the research work has been supported through the receipt of a \$500 000 competitive research and development grant.

*Source:* McGauran 1996

In its report on *Research and Development* (IC 1995b), the Commission found the 30 per cent external funding requirement had caused CSIRO to increasingly respond to the needs of industry. However, that requirement appeared to have shifted CSIRO's industry orientation towards contractual arrangements with larger private companies. In particular, CSIRO was criticised by participants in that inquiry for not catering enough for the needs of smaller companies.

Participants in this inquiry had similar concerns. TIEG, for example, noted:

Historically, the CSIRO has interacted well with small to medium enterprises. It was possible to telephone scientists and obtain quick and succinct advice from specialists in a relevant field. However, with the advent of the 30 per cent funding requirement, the situation has changed ... scientists are reluctant to talk on a casual basis as they had done in the past. The 'meter' would often go on almost immediately and companies were required to pay consulting fees. (sub. 17, attachment 1, p.6)

As part of the 1994–97 triennium funding arrangements, additional funds have been allocated to CSIRO for it to develop linkages with smaller companies. In particular, small to medium companies are able to access expertise in areas such as quality improvement, instrumentation and electronic systems, irrespective of the industry sector to which they belong. Technical advice and short-term consulting services from CSIRO are now directed at smaller companies.

The merits of encouraging smaller companies to develop links with CSIRO should not be understated. However, any specific linkages that are developed need to be consistent with the wider objectives for CSIRO. As the Commission found in its report on *Research and Development* (1995b), while the dissemination of results beneficial to the wider community is a central objective of CSIRO, this has to be weighed against the merits of CSIRO becoming involved in company-specific research.

### *Linkages with universities*

Universities occupy a central position in the innovation process. The benefits of university research through the knowledge it generates for the wider community are well recognised. These wider benefits arise, not just from research directly

associated with teaching and training, but also through independent work undertaken by academics and post-graduates.

In recent years, higher education institutions in Australia (and overseas) have been increasingly required to undertake more 'relevant' research and to earn more by commercialising results. There is a plethora of programs which aim to develop the necessary linkages between industry and higher education institutions. There appear to be considerable overlaps in these programs, which detailed in Table 7.4.

**Table 7.4 Major linkage programs with higher education institutions**

<i>Program</i>	<i>Linkage</i>	<i>Funding (\$m)</i>
Special Research Centres (1995)	University-user links developing through applied research activities and postgraduate training	13
Key Centres of Teaching and Research (1995)	University-user links effected through research and teaching activities	6
Collaborative Research Grants (1995)	University-user links effected through collaborative projects with university researchers	16
Advanced Engineering Centres Program (1995)	University-user links effected through advanced education courses and consultancies	2
Australian Postgraduate Awards (Industry) (1995)	University-user links effected through research and training at masters and doctorate levels	8
National Priority (Reserve) Fund (1995)	Projects focused on improving links between higher education, industry and other sectors	2
National Teaching Company Scheme (1993-96)	University-business links effected through graduates working on company R&D projects	1

*Source:* IC 1995b, p.41

Some participants were positive about the development of linkages with universities. For instance, the Australian Society for Biomaterials commented:

Australia has a recognised, international excellence in research in biomaterials ... these research activities are multi-disciplinary and primarily located in Government Laboratories ... and in Universities. A strong network of interactions exist ... and this has led to substantial collaborations and coordination of effort in many areas of research. (sub. 7, p.4)

One such collaboration involves the participation of the Magnetic Resonance Institute (University of Sydney) and General Electric Medical Systems Australia (General Electric). The Magnetic Resonance Institute is primarily involved in the research, development and commercialisation of technologies associated with magnetic resonance. This technology is used for the detection, diagnosis and treatment of human diseases. General Electric has agreed to provide funding of

\$16 million over six years for research leading to commercialisation of any hardware and software products related to this research.

Trace Scientific also commented favourably on the establishment of linkages with universities. It has formed links with Monash University, Wollongong University (through AusIndustry funding), and joint projects were also due to commence with La Trobe University and the University of Melbourne. (sub. 55, p.5)

However, recent work by the BIE (1996a) indicates the extent of collaboration between Australian higher education institutions and businesses in science and technology R&D is generally limited. The BIE cites a number of impediments which may account for poor levels of collaboration. These include:

- R&D intensive companies usually have stronger knowledge in their areas of specialisation than outside academics. Companies will be reluctant to embark on collaborative R&D with a public institution unless they can acquire R&D inputs at subsidised prices and only if they can obtain guarantees against the leakage of information to competitors;
- academics have little incentive to embark on confidential research projects with industry. For instance, traditional criteria for academic promotion depend on open publications and effective teaching rather than R&D projects shrouded in secrecy;
- a combined teaching-research workload may pose problems for academics or university administrators; and
- administrative difficulties on the university side — including difficulties in costing research projects and avoiding cross-subsidisation of collaborative projects from other R&D funds or teaching funds.

Trace Scientific commented that many of the government programs facilitating linkages were very much project driven, and this inhibited the process for smaller companies. It suggested ‘visiting scholarships’ and the placement of industry scientists in public sector institutes were ways around this problem. (sub. 55, p.5)

Collaborative programs have proliferated recently and there appears to be considerable overlap in their objectives. This suggests an examination of these programs is warranted. As the Commission commented in its report on *Research and Development* (IC 1995b), any such examination should consider the extent of benefits from the government support relative to the opportunities forgone in funding linkage programs rather than other research needs.

### *International linkages*

The Commonwealth Government is increasingly recognising the importance of stimulating international linkage relationships through science and technology. For instance, the Commonwealth Government have noted:

Most of the science and technology vital to the future competitiveness of Australian industry is developed overseas. Collaboration with leading international researchers and access to overseas facilities is a very cost effective way to maintain expertise in key areas, to allow specialised commercial research problems to be studied and to build relationships which can advance Australia's interests in trade and investment. (Costello and Fahey 1996, p.86)

Such linkages may be encouraged through informal measures such as joint-country workshops or alternatively, through more formal mechanisms such as government sponsored programs.

For instance, in late 1995, the Department of Health and Family Services and the National Health and Medical Research Council (NHMRC) supported a workshop in cancer research between Australia and Japan. In 1996, the NHMRC will provide support for a similar workshop on cardiovascular (hypertension) research. It is hoped that these collaborative endeavours will foster increased research linkages with Japan (McGauran 1996).

The international science and technology program (ISTP) and the bilateral science and technology program (BSTP) are two particular government endeavours which aim to develop and strengthen international linkages (see Box 7.6). The details of these programs and use by the medical and scientific equipment industries are outlined in greater detail in Appendix H.

## **7.4 National Health and Medical Research Council**

The National Health and Medical Research Council (NHMRC) — an independent statutory authority — is Australia's peak group advising governments on public health, health care, health and health ethics. One of its principal functions is to make recommendations to the Commonwealth Government concerning expenditure on public health and medical research. This research funding is administered by two committees:

- the Medical Research Committee (MRC); and
- the Public Health Research and Development Committee (PHRDC).

<b>Box 7.6</b>	<b>Government programs supporting international linkages</b>
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The ISTP aims to enhance international science and technology linkages through collaboration between research teams in Australia and overseas on projects of significance to Australian industry and national research interests. The program is administered by DIST and the Government has indicated that in 1996-97 particular funding emphasis will be placed on collaborative arrangements with the European Union, ASEAN, India and North Asia. The BSTP is administered by DIST and provides support for collaborative research between scientists in Australia and other countries for fundamental and industrial applications. Support is available for research visits by individual scientists and for joint seminars and technical workshops.

Source: DIST 1996

Most of the research for which funding is provided is of a basic nature which is not easily commercialised. In 1993, basic research accounted for approximately 65 per cent of total funding — see Table 7.5. Reflecting this, the majority of the research funding is allocated to universities, research institutes and hospitals.

Table 7.5 Allocation of NHMRC research in 1993

	<i>Basic</i>	<i>Clinical</i>	<i>Preventive</i>	<i>Health services</i>	<i>Public health</i>	<i>Total</i>
	<i>(\$m)</i>	<i>(\$m)</i>	<i>(\$m)</i>	<i>(\$m)</i>	<i>(\$m)</i>	<i>(\$m)</i>
Allocation	49.8	20.0	2.8	1.5	2.5	<b>76.7</b>

Notes: Data does not include block grants or training awards.  
More up-to-date information is not available.

Source: Bienenstock 1993, p.73

In the August 1996 Budget, the Government announced that 1996-97 funding for health and medical research through the NHMRC will be \$150 million (McGauran 1996, p.5.58). This represents an increase of \$8.6 million from the previous financial year.

Some participants commented that the level of funding provided to the NHMRC is deficient. For instance, the SSAA commented that, despite the increased funding:

NHMRC funding ... appears inadequate relevant to the significant gains that are available to the health care system by the implementation and /or commercialisation of the many successful research projects. (PH trans, p.47)

The Commission in its report on *Research and Development* (1995b) commented that approximately one quarter of Australia's total expenditure on health and medical research is allocated through the NHMRC. While the Commission considers that funding may appear small compared to the gains achieved through



successfully commercialised research, any assessment of funding should be considered in its wider context. Companies in the medical industry are able to access other forms of government support — such as the tax concession for R&D and the CRC programs.

Other participants considered that the NHMRC could better fulfil its role if it consulted more with industry. For instance, State and Regional Development (NSW) commented that an improvement in communication with industry was desirable (sub. 28, p.4), while the MIAA drew attention to the findings of the Bienenstock review of the role and operation of the NHMRC.

The Bienenstock report was presented to the Minister of Health in December 1993. One of its recommendations was that an advisory committee from industry be established to promote interaction between the NHMRC and the commercial sector. Bienenstock (1993) commented:

The primary purpose of research funded by the NHMRC is to improve health rather than to further economic objectives. It would not be appropriate to direct a significant proportion of NHMRC funds away from basic research into research that is deemed more commercially relevant ... However, it is reasonable to expect that the NHMRC should do what it can to enable the commercial development of NHMRC-funded research ... it is in the best interests of both researchers and developing stand-alone health-related industries for this to happen; better cooperation and collaboration between the sectors must occur ... (p.33)

The *National Health and Medical Research Council Act 1993* requires the NHMRC to consult in the development of its research recommendations and guidelines, and for its Strategic Plan. Notwithstanding these requirement, the Bienenstock report noted that there was still an important gap in the flow of expert advice from the commercial sector — ‘industry is represented by one person on Council, and patchily if at all on Principal Committees and their working parties’ (Bienenstock 1993, p.49). The report recommended that an advisory body be established to promote interaction between the NHMRC and the commercial sector.

The MIAA requested that this recommendation should be implemented. It stated:

The value of such an advisory group would not be confined simply to the benefits that might flow from having commercial possibilities taken more fully into account in the consideration of research proposals that come before the NHMRC. The group would also provide a means for industry to readily bring to the Council’s notice any relevant problems that the Council might be able to assist with. (sub. 13, p.105)

The Commission supports the notion of effective consultation as advocated by the Bienenstock report. However, it is not in a position to evaluate the relative merits of implementing this recommendation. As far as the Commission can ascertain, there has been no substantive response by either the Commonwealth

Government or the NHMRC to the Bienenstock report. Indeed the only formal reaction has been an acknowledgment of the report in the NHMRC's recent Strategic Plan with no indication as to what action, if any, was to be taken on it (NHMRC 1996).

*The Commission draws the attention of the Commonwealth Government to the Bienenstock report on the role and operation of the NHMRC and to the MIAA request regarding its recommendations.*

## **7.5 Conclusions**

The commercial success of companies in the medical and scientific equipment industries is, in many cases, dependent on an on-going commitment to invest in R&D. Government support for R&D plays an important role in this.

Information from participants suggested that companies in the medical and scientific equipment industries have difficulty gaining access to this support. For instance, many small to medium companies are in non-profit situations and are unable to derive benefits from the R&D tax concession, at least in the short term. Minimum expenditure thresholds can exclude smaller companies, while the administration and compliance costs of applying for grants are also seen as significant impediments for smaller companies in applying for R&D assistance.

This problem appears to have been exacerbated by recent changes to the tax concession scheme. The Commission considers that the lowering of the level of assistance is likely to adversely affect smaller companies more than larger ones. Additionally, participants commented that the new definition of technical risk for eligible expenditure under the R&D tax concession is highly subjective and will add to investment uncertainty.

In commenting more generally on the impact of the Budget changes, the Commission reiterates the findings of its *Research and Development* report (1995b) about the inherent disadvantages of selective forms of assistance compared to generally available assistance to support R&D.

The Commission also concludes that smaller companies will fare relatively worse than larger companies as a result of the recent changes to R&D assistance because a significant proportion of the savings from the tax concession arrangements will go to a program (START) from which smaller companies are effectively excluded.

Concerns expressed by some participants in this inquiry about the effectiveness of linkages between research institutions and industry, especially with smaller

companies, suggests changes are still required to enhance the development of such linkages.

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## 8 FINANCE, EXPORT AND MANAGEMENT ASSISTANCE

*Australian producers of medical and scientific equipment are characterised by a high proportion of small companies and a heavy dependence on exports. For those producers, these characteristics mean issues relating to access to finance, export markets and business management are important. Where Government has initiated measures to assist companies in these areas, the effectiveness and accessibility of those measures to those in the medical and scientific equipment industries are similarly important.*

Issues relating to availability and access to finance for companies in the medical and scientific equipment industries are discussed in Section 8.1. Government measures to assist companies obtain finance and the Commission's assessment of these matters are also contained in that section. Measures aimed at assisting companies to export and improve their business management performance are outlined in Section 8.2. Participants' views on those measures and the Commission's assessment are also contained in Section 8.2.

### 8.1 Availability and access to finance

The ability of companies in the medical and scientific equipment industries to obtain finance is determined by both the availability of finance and companies access to that finance.

#### Availability

Companies require finance for starting a business, expanding an existing one, researching and developing new products or for entering and developing new markets for their products. Depending on their stage of development, companies may seek debt financing (borrowing with or without collateral) or equity finance (capital injected in exchange for a share of ownership). Once big enough, companies may get equity finance through listing on a stock exchange — as Cochlear has done recently.

The Commission obtained unpublished data from the Australian Bureau of Statistics (ABS) on the source of funds for capital expenditure for medical and

scientific equipment manufacturers. In 1992-93 — the latest year for which data are available — the two most important sources of funds for medical equipment manufacturers were retained profits (7 per cent of the total) and bank loans (20 per cent). For scientific equipment manufacturers, retained profits and bank loans (35 per cent and 15 per cent) were also the two most important sources of funds. More detail on sources of funds for companies in the industries is contained in Appendix H.

Results from the Commission's survey of the medical and scientific equipment industries confirm the importance of retained profits and commercial loans as sources of capital for the industries (see Table 8.1).

**Table 8.1** Main sources of capital for companies in the MSE industries (percentages of respondents by company size)

<i>Main source of capital</i>	<i>Large (%)</i>	<i>Medium (%)</i>	<i>Small (%)</i>
Private borrowings	6	9	34
Commercial borrowings	31	13	23
Venture capital		4	3
Retained earnings/shareholder funds	46	57	43
Parent company loans/investments	41	30	18
Government loans/grants	3	9	2

*Source:* Industry Commission survey of medical and scientific equipment industries, 1996

However, the SSAA commented that for some companies, it is difficult to adequately fund business growth by retained profits:

There are a number of local importer/distributor type companies with sales in the \$4 to \$20 million region who supply mainly capital equipment who have very successful businesses which offer very high returns on capital employed (>30 per cent). On the other end of the scale are the smaller businesses, particularly with a manufacturing capacity that struggle to survive let alone grow. Many of these companies ... need nurturing and assistance with capital raising. (sub. 63, p.7)

Many participants in both industries referred to difficulties in getting finance at various stages of their company's development. These difficulties were most pressing for small producers. Companies engaged in importing and distribution had much lower capital requirements and getting finance was not generally an issue (sub. 11, p.8).

A common theme for some participants was such difficulties retarded producers' prospects for growth and are a brake on the industries' potential for development.

For instance, New South Wales State and Regional Development (sub. 28, p.7) noted significant funds are available in Australia for research, but venture capital for product development was limited. It cited the example of Resmed — a local company of developers and manufacturers of a sleep apnoea device — raising capital on the US market and establishing a marketing and manufacturing facility in Northern America. In comparison, the CRC for Cardiac Technology commented:

The venture capital industry in Australia is dead. It doesn't really exist. (PH trans, p.137)

In short, participants suggested capital markets are not working for companies in the medical and scientific equipment industries — and, especially so for small, high-tech start-up companies.

This issue is not new nor is it confined to companies in the medical and scientific equipment industries. It has been reviewed by the Commission in other reports, for example, in the context of the economy at large (IC 1991b), funding for research and development (IC 1995b) and industry development references (IC 1995c, 1995e).

Previous work by the Commission has found there is in general no shortage of capital for investment. Available capital has if anything increased with the deregulation of Australia's capital market and the internationalisation of capital markets. An active capital market appears to exist for development capital — that is, patient capital seeking a return through dividends and ultimately capital gain (ADCAL 1995, p.3).

Information on funds under management by Australian development capital providers is provided in Appendix H.

## **Access**

Even where finance is *available* participants claimed companies in the medical and scientific equipment industries have trouble getting *access* to it. The Technology Industries Exporters Group (TIEG), for example, noted in its submission and at public hearings that access to patient capital is still the major hurdle for small, innovative companies trying to get off the ground (sub. 17, p.7, PH trans, p.113). Diffraction Technology (sub. 6, p.1) — commenting on the difficulty in getting access to patient capital — argued it could be three to five times its present size if it could get a relatively small injection of capital, while Weber Consulting noted '... our biggest weakness as small Australian suppliers is access to capital. It's just killing us' (RT trans, p.195).

There are two factors of importance which affect issues concerning access — the risk attached to investing in those companies and the ‘investment readiness’ of companies seeking finance.

For medical and scientific equipment producers at the start up stage for example, there is generally a high level of technical and commercial risk attached to the venture. There may not be an established market for the product and any new or innovative technology faces uncertainties (including potential regulatory impediments and obsolescence). It is thus very difficult for venture capital companies to value intellectual property embodied in proposals from medical and scientific equipment companies seeking capital to start up or develop a product. This has a major influence on investors’ willingness to loan or invest in a company and the amount they may commit. In addition, a relatively long period is likely before investors receive a payback on their initial investment. All of these factors increase the risk of investing in such a project.

Participants acknowledged the highly risky nature of investing in unproven technologies. While companies pursuing such technologies may prove to be profitable investments — Biota, which developed a successful flu vaccine, was given as an example — many more fail, giving investors good cause for caution:

But for that one [Biota] success there are dozens and dozens where a lot of people have lost money (RT trans, p.86).

Some participants — for instance, the SSAA claimed medical and scientific equipment companies cannot get access to finance because local investment companies are too risk averse (sub. 63, p.7). TIEG also made this point in its submission (sub. 17, pp.4–5) and at public hearings commented:

I think that people do perceive [the Medical and Scientific Equipment Industries] to be a higher risk than is correct. Certainly if you talk to someone like Graham Little of Greenchip and the investments they have made and the clear successes they have had, I think they can demonstrate to most people that the risk is less high than perceived by the general community. I don’t think there is much analysis done on the risk to be honest. I think [investors] just look at it and go, “Oh, no thanks”, and run away. (PH trans, p.116)

A similar claim was made in the Commission’s recent computer industries inquiry — industries whose companies share many of the characteristics of companies in the medical and scientific equipment industries. However, during that inquiry the Australian Information Industry Association noted:

You certainly can’t say the Australian capital markets are risk averse, because they have put money into fairly risky mining ventures and all sorts of things from time to time (trans, p.459).

TIEG suggested a revision to capital gains tax was needed to make investing in high risk start-up companies more rewarding. TIEG noted that a similar scheme operates in the US where capital gains tax is halved if investment in companies

under a certain size occurs — ‘so there is an inducement to invest in smaller high-tech companies’ (PH trans, p.114). Similarly, the SSAA suggested that greater incentive needs to be given to the superannuation investment community, in the form of tax incentives to invest in the small technology based manufacturing industry (sub. 63, p.7). However, given the specific focus of this inquiry, it is inappropriate for the Commission to recommend changes to the tax system which would have economy wide implications.

The other crucial factor affecting companies’ access to the finance available is whether those companies are ‘investment ready’. That is whether they have the management structure or financial control and reporting systems to give them the necessary business focus required by investors.

In 1983, the High Technology Financing Committee of the Australian Academy of Technological Sciences released a report (Espie 1983) on venture capital in Australia. That report found that poor management and commercial skills within companies was one of two factors which most inhibit the growth of high technology companies.

Evidence suggests these deficiencies are still a major obstacle generally, as well as for companies in the medical and scientific equipment industries. In 1995, for example, a National Investment Council report found small and medium companies are often not ‘finance ready’ and this could be one reason why Pooled Development Funds, and other venture and development capital funds, have not invested greater amounts in them (NIC 1995, pp.19–20). The report noted this was because they are either not willing, or do not know how, to meet the requirements of external investors.

The Commission’s report on computer industries found evidence that information technology companies have the same problem (IC 1995c, p.209). That report also found the problem widespread. It noted a survey of Australian exporters undertaken by LEK Partnership (1994) which found:

Survey data repeatedly indicated that too many firms seeking finance were clearly ill-prepared, poorly organised and in some cases, not well administered. (pp.74–75)

In discussions with the Commission during the inquiry, venture capital providers ATG and Hambro-Grantham also noted companies seeking capital have not organised themselves sufficiently to attract the confidence of investors.

However, some participants disagreed that a lack of professionalism or investment readiness was behind companies’ inability to access finance. For example, TIEG commented:

When we have got companies that are selling 50 to 90 per cent of what they have made overseas, even though they are small companies ... I don’t think they’re terribly unprofessional ... (PH trans, p.119)



That notwithstanding, TIEG is taking steps to directly address these concerns. It is in the process of developing an 'investment readiness program' for its members, 'to overcome the excuses and smokescreens that the development capital people are putting up about the lack of professionalism and the lack of investment readiness.' (PH trans, p.119)

### **Government measures of assistance**

In response to widespread concerns by industry about the workings of the capital market, the Government has instituted a range of programs and other measures to assist small and medium companies or technology based ventures gain access to finance. A number of these are described below, together with participants comments on specific programs and comments on their use by the medical and scientific equipment industries.

As well as these measures, other government programs can reduce a company's need for external finance or assist companies in obtaining finance (eg by protecting an intellectual asset so it may be used for collateral). Various forms of assistance for research and development (R&D) and export marketing are in this category. Government measures to assist companies with their R&D are discussed in Chapter 7. The main Government measures available to assist companies in the medical and scientific equipment industries with exporting are discussed in Section 8.2 of this chapter.

#### *Pooled Development Funds*

The Pooled Development Funds (PDF) program, introduced in 1992, aims to encourage the provision of patient equity capital to small and medium sized Australian companies. Registered PDFs may invest in Australian companies with assets up to \$50 million. A concessional rate of taxation applies to dividends issued to its shareholders (PDF Registration Board 1995). As at November 1995, PDFs had raised about \$100 million and made investments of around \$40 million (Costello 1996a).

TIEG (sub. 17, p.11) stated the PDF scheme is not having the desired effect in improving the supply of venture capital, because most PDFs are interested in providing development capital and had no interest in companies at a start up stage. It concluded the PDFs are merely replicating other venture and development capital funds not registered as a PDF.

Until recently the PDF Registration Board did not record the destination of PDF funds on the basis of industry classification. To determine the use of the PDF by the medical and scientific equipment industries the Commission wrote to over 20 PDFs requesting information on where their funds were invested. However, the limited responses have not allowed the Commission to report on this matter.

In the August 1996 Budget, the Government announced there will be no change to the Pooled Development Funds Program. However, the program is to be reviewed by the Department of Industry, Science and Tourism (DIST) in late 1996-97.

*Concessional loans for commercialisation of technological innovation*

In the *Working Nation* White Paper in 1994 the Government allocated \$48 million over four years for concessional loans to technology-oriented small companies seeking to commercialise their technological innovations. Loan amounts are typically between \$500 000 and \$600 000, with interest at 40 per cent of the Commonwealth Bank loan reference rate. The scheme operates as a lender of last resort and requires companies to show they have been unable to get funds through normal commercial sources. It is administered by AusIndustry, with loans made through the Commonwealth Development Bank.

Information provided by DIST (1996a) about use of the concessional loans scheme by firms in the medical and scientific equipment industries indicated that no loans had been identified to firms falling within ANZSIC 283 — the division encompassing most medical and scientific equipment manufacturers. However, TIEG noted in correspondence with the Commission that a Queensland based manufacturer of scientific equipment (Greenspan) had used the scheme in the past. In the apparent absence of a comprehensive database, the Commission is unable to comment on usage of the scheme by the industries.

TIEG further commented that a ‘gap’ in potential assistance exists, as the concessional loans program does not adequately meet the costs of setting up production; one of the crucial stages of the commercialisation process (sub. 17, p.11).

The Commission reviewed the scheme in its *Research and Development* (1995b) report. That report expressed doubts about the scheme’s rationale of subsidising loans for commercialisation but considered it should have a period of operation to judge its success. That report also recommended the scheme be reviewed within four years. The Government accepted this recommendation and announced in the 1995 Budget the program would be reviewed 18 months after commencement and a year prior to the end of the four year funding. How well the program is meeting its objectives should be assessed in those reviews.

The Government announced in the August 1996 Budget that funding for this program will increase from \$10 million in 1995-96 to \$13 million in 1996-97 (Costello and Fahey 1996, p.4.71).

### *Australian Technology Group*

In 1991, as part of measures announced in the *One Nation* White Paper, the Commonwealth Government established the Australian Technology Group (ATG) as a source of start up finance. ATG was given a one-off capital base of \$30 million by the Government and is meant to become self-financing through fee and investment income. There have been no funding changes to the Australian Technology Group which have been initiated through the Budget.

ATG has received queries for capital injection from companies in the medical and scientific equipment industries. Up to May 1996, none of those proposals it had investigated had sufficient commercial appeal for it to invest in them.

### *Other measures*

The Government's *Innovation Statement* in December 1995 announced a number of measures to facilitate additional funding for small and medium companies (Keating 1995). These measures would be expected to assist companies in the medical and scientific equipment industries. They included:

- banks be allowed more flexibility to invest equity in small and medium companies;
- further consideration be given to reviewing the Corporations Law to relax the provisions concerning fund raising without a prospectus. Currently, private fund raising is restricted to no more than 20 investors;
- a Business Equity Information Scheme to link investors with small and medium companies;
- a program to help bring small and medium companies to 'finance ready' status;
- funding for a study into the feasibility of alternative equity exchanges; and
- funding to improve the understanding of superannuation funds about the investment opportunities provided by small and medium companies.

As a result of the change of Government in March 1996 not all of these measures have been implemented. A relaxation of guidelines for bank equity investments was announced by the Reserve Bank in December 1995 and the Government has implicitly acknowledged the difficulties that small to medium companies have in raising venture capital:

Access to capital, particularly equity capital, is a major problem for small to medium enterprises. This may be partly due to the fact that small to medium enterprises have limited access to a formal market for the buying and selling of stocks or shares to raise equity capital. (Moore 1996, p.1)

The feasibility of alternative equity exchanges is being reviewed by the Australian Securities Commission and the Government has confirmed additional funding for research into the viability of an alternative equity market to cater for smaller companies — including start up-companies. The August 1996 Budget committed \$1.4 million for research in 1996-97, and \$1.12 million dedicated over the following two financial years. (Moore 1996b, p.1)

The scheme linking investors and small to medium companies, which was to finish at the end of June, has had its pilot funding extended and its future will depend on a review now underway.

It is too early to know if changed prudential guidelines have increased banks' willingness to invest in small and medium companies or if this has had any consequences for companies in the medical and scientific equipment industries.

### **Commission's assessment**

Some companies in the medical and scientific equipment industries have difficulty in getting finance to start, develop and expand their business. Information from participants indicated that this was most pronounced for small, high technology companies requiring start-up capital. The difficulties small companies face in getting government support for their R&D (see Chapter 7) exacerbates this as an obstacle to development.

Why companies experience such difficulty in getting finance and what governments may do about this has been reviewed elsewhere. The Commission's report on *Availability of Capital* (IC 1991b), for example, found problems faced by small companies usually reflect the risk preferences of investors rather than institutional barriers or market failures. It concluded direct government intervention to expand institutional funds available to smaller companies would not improve the efficiency of the capital market or the economy.

More recently — in its report on *Research and Development* (IC 1995b, p.631) — the Commission did not find evidence of any market failure in the provision of venture capital. That notwithstanding, the National Investment Council (NIC 1995, pp.32, 49) has identified a gap between the upper threshold that so-called 'business angels' are willing to provide (around \$0.5 million) and the minimum investment preferred by venture and development capital funds (around \$2 million).

The Commission notes measures announced in the *Innovation Statement* in December 1995 to facilitate access to additional funding for small and medium companies were intended to address concerns in this area. Some of these measures have since been implemented although it is too soon to see their effect on availability or access to finance for companies in the medical and scientific

equipment industries. The program intended to assist small and medium companies become 'finance ready' — and hence more likely to attract investors — has not been implemented. This impediment to medical and scientific equipment companies obtaining finance appears likely to continue although it is an area which the companies themselves have scope to address. TIEG for example notes it has for a long time been working on a program to assist smaller companies in this area (sub. 17, p.5, PH trans, pp.119–20).

The Commission also notes the terms of reference for the Wallis inquiry, which is reviewing the results arising from the financial deregulation of the Australian financial system in the 1980s, address many of the issues raised by inquiry participants. The inquiry has flagged it will be examining '... how to improve the environment for raising funds, especially for small business ...' (Financial Systems Inquiry 1996) and has recently released its draft report. In its final report (due 31 March 1997), the inquiry will make recommendations concerning the regulatory arrangements for the financial system — and in particular, ensure:

... there are no regulatory impediments to the further development of equity and debt securities markets in meeting the financial needs of businesses, including small and medium sized enterprises (including rural enterprises) (Wallis 1996, p.xviii).

### **Finding 8.1**

Access to seed and venture capital continues to be a significant obstacle to the development of the smaller, high technology companies within the medical and scientific equipment industries, notwithstanding recent government initiatives in this area.

## **8.2 Export and business management assistance**

With about 80 per cent of the domestic market supplied by imports and about 60 per cent of local production sold on export markets, the Australian medical and scientific equipment industries are highly integrated with world markets. Under these circumstances, export and management capabilities of local companies are important determinants of their future. Companies in the medical and scientific equipment industries have access to a range of generally available government measures designed to enhance export and business management performance.

Preliminary results from the Commission's survey of the Australian medical and scientific equipment industries indicate that approximately 30 per cent of respondents in both industries' have applied for some form of government

assistance (other than tariff assistance) over the last five years. Survey results also indicate that applications for assistance varies according to company size — with approximately 23 and 28 per cent of large and small companies respectively having applied for assistance.

These measures and participants' comments on them are discussed below.

## Export assistance

Export assistance for companies in the medical and scientific equipment industries has been provided through a variety of programs (see Box 8.1). A description of some of these and information on their use by the industries is provided in Appendix H. The majority of these programs are administered by the Australian Trade Commission (Austrade).

In addition to these programs, Austrade itself provides a number of services to companies in the medical and scientific equipment industries wishing to develop international business. These include identifying export opportunities through market research, promoting Australian exports through trade fairs and the operation of a specialist Health Business Unit which aims to assist companies identified as having excellent export potential. The Health Business Unit is primarily involved in developing exports of health services and medical equipment to Asian markets (sub. 22, pp.2–3). However, some of Austrade's activities are currently being restructured and specific industry-based Business Units will not be included in the new organisational structure (sub. 61, p.3).

In the August 1996 Budget, the Government announced changes to these programs, including the abolition of the Asia Pacific Fellowship Program, Asia

### **Box 8.1 Government assistance programs for exporters<sup>1</sup>**

*Export Market Development Grants (EMDG)* — offers partial reimbursement of marketing expenses as taxable grants to exporters of goods, specified services, industrial property rights or know-how which are of substantially Australian origin;

*The Asia Pacific Fellowship Program* — funds 'fellowships' by way of financial assistance of between 50 and 75 per cent of costs to encourage exporters to develop the practical language, commercial and cultural skills for executive staff doing business with Asia;

*Asia Business Links* — partly finances costs incurred by Australian exporters hosting key overseas business contacts, enabling the visitor to gain knowledge and skills therefore enhancing international business opportunities for Australian companies;

<sup>1</sup> EFIC and DIFF are not administered by Austrade.

*The International Trade Enhancement Scheme (ITES)* — was set up to enhance the international business prospects for Australian companies, joint ventures, consortia and industry associations, which may generate substantial foreign exchange earnings for Australia;

*Export Access* — is a program designed to assist smaller companies to become involved in exporting on a sustainable basis. The program is funded by Austrade but is delivered by a network of industry associations;

*The Export Finance and Insurance Corporation (EFIC)* — is an export credit agency which provides a range of insurance and financial services to Australian exporters; and

*The Development Import Finance Facility (DIFF)* — assists Australian exporters of capital goods and services by allowing aid funds to be combined with loans provided through EFIC. To be eligible for DIFF support, the equipment or service being supplied must be wholly or mainly of Australian origin.

Sources: AusIndustry (1995a, 1996b) and Austrade (1995c)

Business Links, ITES and DIFF. Austrade trade promotion and facilitation services will also be rationalised and preliminary estimates indicate Government funding of Austrade activities is to decrease by \$15.2 million in 1996-97. (Costello 1996b, p.45)

## **Business management assistance**

As with export assistance, there are a variety of generally available measures to improve business management performance which the medical and scientific equipment industries can access (see Box 8.2). More details of these particular programs are outlined in Appendix H.

### **Box 8.2      Programs to improve business management capabilities**

*The Enterprise Improvement Scheme (EIS)*<sup>2</sup> — is a joint Commonwealth, State and Territory network of business information, referral and advisory services for small to medium companies. EIS helps companies identify and respond to opportunities for improving the way they do business;

*The Business Networks Program (BNP)* — is a four year program and assists groups of at least three businesses to undertake joint business activities in order to increase their capabilities. Activities can include targeting export or domestic markets, sharing production facilities and product development costs, or grouping together to win large contracts;

*BizLink* — BizLink aims to improve access to business information for small and medium companies and their advisers, by using appropriate information technologies to deliver relevant, accurate and comprehensive information products; and

*BizHelp* — contains information on all Commonwealth, State and Territory Government business assistance programs. Updates are issued quarterly.

*Sources:* AusIndustry (1995a and 1996f) and DIST (1995c)

These programs fall within the operation of AusIndustry — a Commonwealth, State and Territory Government initiative which, amongst other things aims to help business become more internationally competitive. The Office of AusIndustry was established in 1995 within the (then) Department of Industry, Science and Industry as a result of the previous Commonwealth Government's *Working Nation* White Paper (1994).

AusIndustry was formed to provide more effective coordination and delivery of industry assistance programs, both within particular spheres of government and between levels of government. It is broadly responsible for advice and assistance in the following areas:

- Industry Innovation — for instance, R&D and commercialisation;
- Business Improvement Services; and
- Marketing and Business Information.

Participants in this inquiry did not comment specifically on the performance of AusIndustry, but in a R&D Tax Concession survey by Price Waterhouse and AIRG (1996), comment was sought from a number of industry sectors on the

<sup>2</sup> This program was formerly the National Industry Extension Scheme (NIES). The name was changed in 1995 when AusIndustry became responsible for its administration.



performance of AusIndustry.<sup>3</sup> On a scale of 1 to 5 (1 being not satisfied, 5 being satisfied), 90 per cent of survey respondents nominated a rating of 3 or below for performance in communication and technical advice and service.<sup>4</sup>

The Government has forecast that in 1996-97 and 1997-98 Government funding of AusIndustry will be reduced by approximately \$17 million in each financial year (Costello 1996b, p.63).

In the August 1996 Budget the Government also announced that the EIS, BNP, BizLink and BizHelp will continue although some savings will be achieved through the EIS scheme.

## Participants views

### *Austrade services*

Some participants questioned the value of services provided by Austrade itself to the medical and scientific equipment industries. George Weber and Associates believed that support for small medical and scientific equipment manufacturers has been of little value (trans, p.28), Crown Scientific argued that Austrade should be made 'more accessible' (sub. 57, p.3) while the TIEG stated:

Austrade is not vitally useful to the scientific and medical industries. They have no Business Development Unit (BDU) looking after scientific firms and the medical BDU is specifically looking at the export of services — for example, aged care. (sub. 17, p.3)

Austrade disagreed with this comment and responded:

The Health Business Unit has worked with exporters of both health services and medical equipment. A major focus of the Unit has been to encourage participation by Australian suppliers in health infrastructure projects offshore which require provision of medical equipment as well as health services. The Health Business Unit has also assisted exporters of medical equipment, both individually and in networks, with market intelligence, inclusion in trade promotions and assistance with strategic advice. (sub. 61, p.3)

Austrade's Health Business Unit emphasises exports of health *services*. In particular, Japan is targeted for aged care services. According to Austrade, the Health Business Unit is also facilitating the export of medical equipment. For

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<sup>3</sup> This survey was sent to 250 companies from a number of industry sectors including: mining and resources, high technology, communications, building, food, chemical, pharmaceutical and manufacturing.

<sup>4</sup> Price Waterhouse and AIRG (1996) caution about excessive reliance on these results as there is no available benchmark against which to compare AusIndustry. In particular, Price Waterhouse and AIRG comment that 'the raw results must be regarded as less than satisfactory.' (p.11)

instance, Austrade organised three health related promotions in 1995 in Thailand, Malaysia and Germany. As Austrade commented:

The promotions in Bangkok [Thailand] and Kuala Lumpur [Malaysia] featured Australian providers of services such as health planning, architecture, hospital management and staff training in addition to medical equipment. Participants in [Germany] were all manufacturers of medical equipment and diagnostic re-agents. (sub. 22, p.3)

Some participants confirmed the importance of these promotions for their businesses. Nascor, for example, commented:

We do our own marketing and have found the most successful approach for overseas marketing is ... the Australian Health and Medical Industry Directory put out by Austrade Offices and Overseas Trade Fairs ... It is the Trade Fairs that are making all the difference to this company. (sub. 3, pp.1–2)

### *Government programs*

Information from visits and submissions clearly indicated companies in the industries have made effective use of the programs. For instance companies such as La Mont Medical Systems, Starkeys Products and Relpar successfully developed export programs through support measures provided by the NIES, Export Access Program and EFIC (see Box 8.3).

In general, participants viewed the EMDG program as the most important, particularly for small organisations exporting for the first time. As New South Wales State and Regional Development noted:

Many of the small high tech Australian companies must establish export markets early in their evolution as in many cases the local market is very small. Growth through exports, especially for small companies, is difficult and expensive and support such as that offered by the EMDG scheme is vital for success of many of these start-up companies. (sub. 28, p.5)

TIEG also indicated the EMDG program had been vital to the export success of many Australian exporters of scientific and medical equipment. In particular, it noted small exporters find it too expensive to set up their export business without assistance from the EMDG scheme (sub. 17, p.3).

Preliminary results from the Commission's survey of the medical and scientific equipment industries have indicated that EMDG support is particularly valuable

<b>Box 8.3</b>	<b>Successful use of assistance measures by medical and scientific equipment companies</b>
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*La Mont Medical Systems* was established in 1984 by Peter Montgomery, a biomedical engineer. The company concentrated on developing one product, a video patient monitoring system for export markets. The company approached NIES in 1988, for assistance to expand its existing domestic and export markets. The findings of a NIES subsidised market research and business plan indicated that substantial design modifications were needed to better address clinical needs. The product was redesigned and NIES then assisted La Mont to introduce a Quality Assurance program to ensure the product met international standards. La Mont then agreed in 1991 to undertake a NIES-assisted export and sales marketing plan to expose company products to international markets.

By 1994, the La Mont video electro encephalograph gram (EEG) system had captured 50 per cent of the EEG market in Australia and made strong in-roads into South-East Asian markets.

*Starkeys Products* joined the Export Access Program in February 1994 and is a manufacturer of a range of electrical products with environmental health protection applications. One of their key products is the Ultra Violet Sterile Storage Cabinet designed for the sterile storage of various medical and dental instruments.

As a participant in the Export Access Program, Starkeys undertook a market visit to South East Asia in early 1994 to liaise with prospective agents and distributors. Starkeys identified positive prospects for its product in the region and has negotiated distributors in Indonesia, Malaysia, Sri Lanka and Thailand.

*Relpar* is an Australian wholesaler of home health care products and rehabilitation equipment. This company secured its first export contract for a development project in Indonesia with EFIC support. Relpar won a \$13 million contract to provide training and equipment for the education of handicapped children. EFIC provided part of the finance package on aid (DIFF) terms, together with an 'unsecured' performance bond and insurance to manage the exporter's exposure to payment risks.

*Sources:* sub. 13, attachment 21; EFIC 1994

for small companies. For instance, in 1994-95, the average support for small companies from the EMDG program approximated \$41 000, while for large companies, average support totalled \$44 000. The average support for all companies in the medical industries and the scientific industries totalled \$35 000 and \$66 000 respectively.

However, while participants welcomed programs designed to improve their export and business management performance they also noted there were difficulties associated with them. These fell broadly into three areas:

- awareness of relevant programs;
- eligibility conditions/criteria (for instance minimum thresholds); and

- administrative requirements.

### *Awareness*

A number of participants commented about the extensive range of assistance programs available. For instance, the Scientific Suppliers Association of Australia noted it is often difficult to keep up to date about the range of programs offered (sub. 11, p.6). Similarly, Biolab Scientific said:

There is undoubtedly a number of worthwhile assistance schemes available, however, it is a difficult maze to work through. It is important that there is an opportunity for small to medium companies to keep abreast of what is available in an administratively simple manner. (sub. 1, p.2)

Leo Barnes and Associates stated that many of the small medical device manufacturers in Australia are:

... 'one-man bands' and have absolutely no idea that any government assistance schemes exist let alone how to access them ... The services and schemes are generally misunderstood or even viewed with some suspicion by more than a few small [medical device manufacturers] businesses. (sub. 14, p.4)

### *Eligibility*

Participants claimed eligibility requirements for programs presented difficulties. For the EIS for example, Biotel commented:

The conditions and/or criteria for eligibility are too onerous. Some of the conditions for NIES subsidies are:

- (a) only available for certain types of export business development;
- (b) only provide consultancy assistance;
- (c) we must use one of a few consultants 'selected' by NIES;
- (d) in our experience, the quoted fees by the selected consultants are significantly higher than other consultants (probably because they know we are subsidised). (sub. 12, p.10)

Similarly for the EMDG scheme, Nascor stated:

The EMD Grants ... plays a major part in offsetting some of the expenses for overseas marketing and advertising. However, for small companies ... cash flow is a major issues and the criteria for obtaining EMDG grants are too rigorous. (sub. 3, p.2)

In other instances the eligibility criteria of most concern related to the minimum expenditure thresholds. For smaller companies this may present a major barrier. Biotel and Surgi Supplies for example, claimed the \$30 000 minimum threshold on eligible expenditure for the EMDG scheme means most small exporters are unable to take advantage of it (sub. 12, sub. 34).

However, as announced in the August 1996 Budget, these concerns have been addressed. Small business access to the scheme will be improved by reducing the eligible expenditure threshold from \$30 000 to \$20 000. Larger firms with a turnover of more than \$50 million a year will no longer be eligible.

### *Administrative requirements*

Participants considered administrative requirements for some programs had increased significantly over recent years. GBC Scientific Equipment, for example, stated:

In general I would have to say that the way it used to be was quite simple and if you did something you got some cash back on it. That was simple. You did what you wanted, did what was needed and it came back. There was very little admin in it. You put in a claim once a year. The accountant could do it over the space of ... a couple of cups of coffee and it was simple, whereas now you have got huge teams of people ... going through the stuff. It's very complex. (RT trans, p.48).

In particular, the EMDG was singled out for comment by some companies in the medical and scientific equipment industries. Murphy Furniture believed that the administrative burden for smaller companies is high compared to the benefits received (sub. 27, p.1). George Weber and Associates, while recognising the value of the EMDG program also noted the administration burden companies faced (PH trans, p.29). The Australian Health Industry Development Forum commented similarly:

A number of sector players are recipients of EMDG grants ... Many are small companies and the grants ... (although administrative requirements are complex and unwieldy) provide essential funds to assist them in entering or developing new overseas markets ... (sub. 30, p.5).

Biotel further identified that for the EMDG:

The documentation is so onerous you literally need a consultant to apply for and maintain the funding (there are many consultants to choose from, and they all charge a significant percentage of the assistance granted) (sub. 12, p.10).

Changes have been announced in the August 1996 Budget to address this. In particular, the EMDG has been simplified and better targeted to small and medium sized companies (sub. 61, p.2). Austrade believes the administrative requirements of the EMDG are set at an appropriate level to provide accountability for the spending of public funds. Additionally, Austrade is implementing a number of initiatives to make it easier for applicants to comply with these requirements (sub. 61, p.3).

## Commission's assessment

Companies in the medical and scientific equipment industries have access to an extensive range of generally available government support measures aimed at enhancing export and business management performance. While participants indicated that those programs have proved valuable for companies in their industries, they also pointed to difficulties in getting access to them.

Information provided by participants suggests companies are generally not aware of some government programs. In this, companies in the medical and scientific equipment industries are not alone. To address this matter, the Office of AusIndustry was created in 1995 with the objective of making it easier for all companies to gain access to information about government programs. As AusIndustry has only been in existence for a short while, it is difficult for the Commission to comment on its success in tackling this concern. However, DIST (1994, p.80) has commented that:

The more focused delivery of the Department's enterprise improvement programs and the framework being established under AusIndustry will make it easier for Australian enterprises, particularly small to medium enterprises, to access and benefit from government business improvement programs.

Information from participants also suggests that the eligibility criteria of some programs limit their usefulness for many small and medium sized companies. In particular, minimum expenditure thresholds present significant difficulties. As noted in Chapter 7, minimum thresholds have a legitimate purpose. For example, some level of base expenditure is necessary to avoid administration costs exceeding the benefits of any assistance provided. Similarly, the administrative burden on applicant companies must be balanced against the needs of government to be accountable for the taxpayers dollars it spends.

That notwithstanding, changes announced in the August 1996 Budget (such as lower threshold expenditure for the EMDG and simplifying that scheme) appears to address some of the participants concerns.

Although participants have drawn attention to shortcomings of programs aimed at improving exporting and business management capabilities, the Commission has refrained from making recommendations on those programs in this report. It has done so because these programs apply well beyond the medical and scientific equipment industries. Any assessment of these programs would thus only be sensible in an economy-wide review, which is beyond the scope of this inquiry.

The Government should ensure that any Government programs of industry assistance remain appropriate in a changing environment and are administered in an efficient and effective manner. The Productivity Commission — in its *Stocktake of progress in microeconomic reform* (PC 1996) — recommended

budgetary support for industry should be retained only where a clear rationale for government support is established and where it enhances national income. It is in this context that the difficulties raised by participants would most usefully be addressed. The Commission also notes that as many companies receive support through a number of programs (such as the EIS and the EMDG scheme) it would be difficult to isolate the value of any one program. In such a case, the Commission considers any review of export and business management assistance should occur as a 'package'.

**Finding 8.2**

Although there is an extensive range of government support programs aimed at export and business management performance, companies in the medical and scientific equipment industries are generally unaware of or have difficulties obtaining information about them.

**Finding 8.3**

The difficulties the Commission has identified with government programs aimed at export and business management performance are most appropriately addressed in a comprehensive, rather than industry specific, review.

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## 9 TARIFFS AND RELATED ARRANGEMENTS

*The vast majority of medical and scientific equipment imports enter under Chapter 90 of the Customs Tariff Schedule. Most of these goods have a tariff rate of zero. Of the balance, almost all are subject to concessional tariff rates of either zero or 3 per cent because the imports do not compete with local production. Taking these factors into consideration, there appears little justification to retain tariffs on Chapter 90 imports of medical and scientific equipment.*

Tariffs and concessional tariff arrangements applying to imports of medical and scientific equipment are discussed in Sections 9.1 and 9.2 respectively. The economic effects of tariffs and of possible changes to them are discussed in Section 9.3. Participants' comments on tariffs and concessional arrangements are in Section 9.4, with the Commission's assessment in Section 9.5. Finally, anti-dumping procedures are discussed in Section 9.6.

### 9.1 Tariffs on medical and scientific equipment

Judgement is often needed to determine the tariffs which are relevant to an industry, as tariffs are defined for products not industries. This explains why the information collected by the ABS on the *industries* in Chapters 2 and 3 appears to paint a different picture from that inferred from the ABS information about their *products*. Any industry which produces a wide range of diverse products may find them spread across different parts of the Customs Tariff Schedule — as is the case for the medical and scientific equipment industries.

Given the large number of diverse products produced by these industries the Commission has confined its examination to those products covered by subheadings 9011 to 9033 of Chapter 90 of the Tariff Schedule. These subheadings represented the largest concentration of readily identifiable medical and scientific equipment in the Tariff Schedule and covered the vast majority of the equipment of interest to the inquiry.<sup>1</sup> They included measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof (see Appendix I).

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<sup>1</sup> Some 85 per cent of imports corresponding to ASIC code 3343 (measuring and scientific equipment not elsewhere classified) entered under subheadings 9011 to 9033 in 1994-95.



Within subheadings 9011 to 9033 are tariff items which clearly cover instruments and components used in motor vehicles. Examples include revolution counters, tachometers, speed indicators and pressure gauges. These were omitted from the discussion in this report, although they are being considered in the Commission's inquiry into *The Automotive Industry* (Appendix I includes a full list of the relevant items).

The SSAA considered there were many other items in Chapter 90 which neither met its definition of scientific equipment nor, it believed, were medical equipment. (The SSAA position derives from its view, noted in Chapters 1 and 3, that the Commission's definition of the scientific equipment industry is too broad.)

Medical and scientific equipment items are also found in other chapters of the Tariff Schedule. For example, surgical rubber gloves in Chapter 40 and centrifuges, sterilisers and laboratory furnaces in Chapter 84. The Commission invited participants to bring to its attention any tariff items outside Chapter 90 which they felt it should address in the Final Report. Only a few participants did so. Trace Scientific, for instance, drew the Commission's attention to diagnostic and chemical reagents — item 3822 within Chapter 38 (Miscellaneous Chemical Products) (PH trans, p.243).

However, the items identified in other chapters represent both a relatively small proportion of total imports of medical and scientific equipment and a small proportion of imports within that chapter.<sup>2</sup>

In the absence of other readily identifiable concentrations of medical and scientific equipment, Chapter 90 has remained the focus for discussing issues relating to tariffs and other arrangements.

### **Tariff rates on equipment**

On 1 July 1996, most tariff rates above 5 per cent (including those on medical and scientific equipment items in Chapter 90) were reduced to 5 per cent in line with the Government's policy of general tariff reductions (see Box 9.1) — the exceptions were tariffs on passenger motor vehicles and textiles, clothing and footwear.

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<b>Box 9.1      Tariff reductions in Australia</b>
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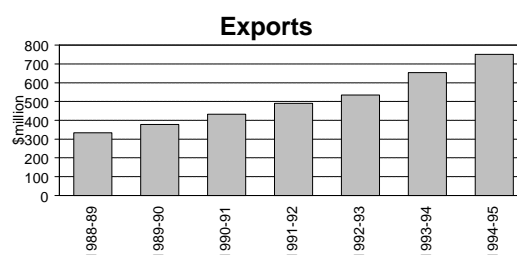
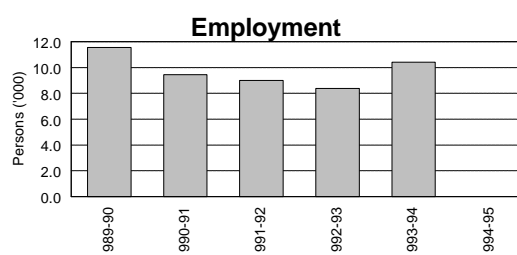
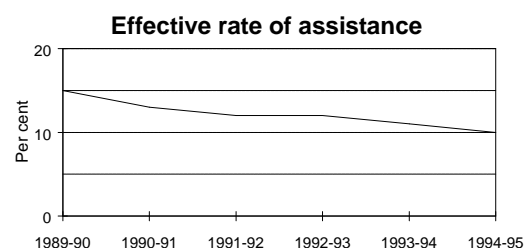
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<sup>2</sup> The concentration of medical and scientific equipment items within a tariff chapter is an important consideration in analysing the effects of tariff changes as it is necessary to confine the effect of any such changes only to the industries under reference and to exclude, as far as is possible, those outside the scope of the inquiry.

In 1987, when the industries were last reviewed by the IAC, tariffs within Chapter 90 ranged from 30 per cent (eg on electro cardiographs) to zero, although about 90 per cent of imports paid duty at rates of 2 per cent or zero. Since then, tariffs on Chapter 90 items have been progressively reduced — to 10 per cent in July 1994, 8 per cent in July 1995 and on 1 July 1996 any still above 5 per cent were reduced to 5 per cent.

While tariffs have been reduced, the industry in aggregate has continued to grow in terms of exports, while employment has declined only slightly (see figures below).

For a few items, the Commonwealth Government has legislated further tariff reductions. Tariffs on certain instruments and appliances used in medical, dental and veterinary sciences (9018) will be reduced from 5 per cent to zero in 1999 under the GATT Uruguay Round Agreement.



*Notes:* Figures are for ASIC 3343, and exclude exports relevant to passenger motor vehicles; ABS employment data are not available for 1994-95; the effective rate of assistance seeks to measure the net impact of all interventions affecting an industry (including tariffs) and relates it to the net contribution the industry makes to the economy (see IC 1992 for a full discussion).

*Source:* ABS unpublished data

Overall Chapter 90 has 33 sub-headings, of which 23 cover medical and scientific equipment. The sub-headings for medical and scientific equipment are divided into 215 tariff items, each with its own tariff rate. In some sub-headings, all the items are duty free. Examples include:

- orthopaedic appliances (9021);
- instruments designed for demonstrational purposes (9023); and
- microscopes (9011 and 9012).

In other sub-headings, different items have different tariff rates. For example:

- non-electrical spectrometers enter duty free, while electrical ones attract a 5 per cent tariff (9027); and
- parts and accessories for programmable controlling instruments enter duty free, while parts for other controlling instruments attract a 5 per cent tariff (9032).

In many sub-headings, the specified items have a tariff of 5 per cent while other items are classified in a residual category (ie 'other') and enter duty free. For example, in the case of navigational instruments, a 5 per cent duty only applies to instruments incorporating, or designed to incorporate, lasers.

### **Imports of equipment**

Imports of medical and scientific equipment under Chapter 90 totalled \$1.8 billion in 1994-95, representing over 85 per cent of all medical and scientific equipment imports for that year. Just under half of these imports were in the following categories:

- instruments and appliances used in medical, surgical, dental or veterinary sciences;
- automatic regulating or controlling instruments and apparatus; and
- instruments and apparatus for physical or chemical analysis.

Other common imports were orthopaedic appliances and X-ray apparatus.

Three-quarters of these medical and scientific equipment imports were not dutiable (see Table 9.1). Although the rest had scheduled rates of either 8 per cent or 10 per cent in 1994-95, almost 80 per cent of dutiable equipment and 94 per cent of all medical and scientific equipment was imported duty free under concessional arrangements (see Table 9.2).

The Commission's survey results indicated that in 1994-95, for medical equipment companies, large companies paid an average of about \$64 000 duty, medium companies an average of about \$19 000 and small companies an average of about \$4000. For scientific equipment companies, large companies paid an average of about \$20 000 duty, medium companies an average of \$10 000 and small companies an average of about \$3000.

Table 9.1 Medical and scientific equipment imports, by tariff rate, 1994-95<sup>a</sup>

<i>Scheduled tariff rate (%)</i>	<i>Value of MSE imports (\$m)<sup>b</sup></i>	<i>Share of total MSE imports (%)</i>
0	1 346	75
8	104	6
10	350	19
<b>Total</b>	<b>1 799</b>	<b>100</b>

*Note:* MSE denotes medical and scientific equipment.

a Sub-headings 9011 to 9033, less passenger motor vehicle tariff items are set out in Appendix I.

b 1994-95 data are the most recent import data available in the required format. In 1996-97 all tariffs are 5 per cent or zero.

*Source:* ABS Foreign Trade Tailored Statistics

Table 9.2 Medical and scientific equipment imports, by import concession, 1994-95<sup>a</sup>

	<i>Value of MSE imports (\$m)<sup>b</sup></i>	<i>Share of total MSE imports (%)</i>
Total imports	1 799	100
Dutiable imports	454	25
Total concessional entry	360	20
Tariff Concession System	288	16
Policy by-laws	72	4
Imports on which full duty paid	94	5

*Note:* MSE denotes medical and scientific equipment.

a Sub-headings 9011 to 9033, less passenger motor vehicle tariff items, are set out in Appendix I.

b 1994-95 data are the most recent import data available in the required format.

*Source:* ABS Foreign Trade Tailored Statistics

Assuming the composition of imports does not change, around 25 per cent of equipment would be subject to a scheduled 5 per cent tariff in 1996-97. However, most will be imported either duty free or at a reduced tariff, under concessional tariff arrangements (see below). Had these arrangements not been recently changed, all equipment eligible for concessional tariff arrangements would have been imported duty free.

The share of imports scheduled as duty free will increase further with the legislated reduction of most tariffs on instruments and appliances used in medical, dental and veterinary sciences (9018) to zero in 1999. Such equipment accounted for 6 per cent of medical and scientific equipment imports in 1994-95.

## 9.2 Concessional tariff arrangements

This section describes the concessional tariff arrangements for importers and exporters and the recent changes made to those arrangements. The effects of these changes are assessed in Section 9.3.

### Concessions for importers

There are two main forms of tariff concession for importers in Australia — policy by-laws and the Tariff Concession System (TCS).

Policy by-laws allow automatic duty free entry of otherwise dutiable imports for reasons of government policy. The by-law may be a standing by-law, which already exists, or an importer can apply to obtain a new by-law. Automatic duty free entry is subject to the Australian Customs Service's (ACS) normal audit and verification procedures.

The TCS involves the granting of Tariff Concession Orders (TCOs) for the concessional entry of goods which are not locally manufactured. Once granted, a TCO can be used for all relevant imports by all importers. Until recently, as well as being issued where there are no locally produced substitutes for the imports (the substitute test), TCOs could also be issued where there were substitutes but importation would have had little effect on local production (the market test).

In May 1996, the Minister for Industry, Science and Tourism announced the following changes to concessional tariff arrangements to be effective from 15 July 1996:<sup>3</sup>

- increasing the TCO tariff from zero to 3 per cent for business inputs (duty free entry remains for consumer goods);<sup>4</sup>
- removing the market test for TCOs;
- making existing TCOs subject to the new arrangements; those granted under the market test will eventually disappear, although this may take several years (ACS 1996a); and
- revoking certain policy by-law concessions and requiring them to be reassessed against new criteria (ACS 1996b).

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<sup>3</sup> Prior to these changes, the Government had announced its intention to abolish the TCS. In the light of negative reactions by industry to that proposal, a revised system was retained.

<sup>4</sup> Orthopaedic appliances, hearing aids and implantables under subheading 9021 are now defined as consumption goods under the *Customs Tariff Amendment Act 1996* (Australian Customs Notice No. 96/28). However, as their tariff rates are already zero, this change will have no impact.

The changes will effectively reduce the ability of importers of medical and scientific equipment to achieve concessional entry, as well as reducing the rate of concession available. The net result will be to increase the duty paid on medical and scientific equipment imports. This is discussed further in Section 9.3.

Before the changes took effect, a TCO application was gazetted and unless a local manufacturer lodged an objection, or the ACS identified a local manufacturer of substitutes, a concession was granted. In theory, the applicant was supposed to establish a case for the import of the product for which the application was lodged by showing there were no local manufacturers of substitutes. In practice, it was the ACS which determined the existence of local manufacturers of substitutes.

Since the changes have taken effect, companies applying for a TCO must establish that they have been unable to find Australian-made substitutes after all reasonable inquiry. The ACS now has the power to reject a TCO application if it believes such a case has not been satisfactorily established — it also retains the power to reject an application if it knows of a local substitute. To facilitate the process for TCO applicants, the ACS will amend its customs regulations to designate Industrial Supplies Offices (ISOs) as one group of a number of bodies that companies can approach to establish whether Australian substitutes exist.

In 1994-95, only 25 per cent of medical and scientific equipment imports under Chapter 90 were dutiable. Of this, 20 percentage points entered under policy by-laws and TCOs, with TCOs accounting for 16 percentage points of that 20 per cent (see Table 9.2).

### **Concessions for exporters**

In addition to the above scheme, there are two tariff concession schemes which provide relief solely to exporters.

Duty drawback enables exporters to claim a refund of tariffs, excise or sales tax paid on imported goods subsequently exported or incorporated into exported goods. The Tariff Export Concession Scheme (TEXCO) permits duty free entry of goods imported for industrial processing and intended for export.

Both mechanisms enable exporters to reduce their tariff burden, and provide them with the potential to offset the increase in duty paid resulting from the changes to the TCS. However, the usefulness of the TEXCO System may be limited because the importer may not be the exporter of the finished product. In such a case neither the importer nor exporter is eligible for a concession under this scheme.

Comprehensive information on the use of duty drawback by the medical and scientific equipment industries is unavailable. The ACS estimated 43 companies

used the TEXCO System to import some \$52 million of equipment duty free under Chapter 90 in 1995-96 (unpublished ACS estimates).<sup>5</sup>

In the Draft Report the Commission requested further information from participants on their use of the TEXCO System and duty drawback, and the costs of using these schemes. However, no responses were received beyond those provided to its survey.

In the Commission's survey, 16 per cent of scientific equipment companies and 8 per cent of medical equipment companies used the TEXCO System or claimed duty drawback in 1994-95. On average, medical equipment respondents imported about \$6575 of equipment under the TEXCO System and received about \$1543 duty drawback in 1994-95. For the scientific equipment companies the average figures were \$2961 and \$1425 respectively. Just over half of the survey respondents described the duty drawback process as 'difficult' or 'very difficult'. Their explanations for the difficulties were that it is costly, time-consuming and 'not worth the effort to get small amounts of duty repaid'.

The Government has listed both schemes for review in 1996-97 (Costello 1996a).

### **9.3 Economic effects of tariffs**

Tariffs artificially increase the ability of local producers to compete in the domestic market by raising the prices of competing imports. This has the effect of favouring resource flows into the production of protected goods at the expense of those resources flowing into less protected industries. However, the effects of tariffs go far beyond this. For example:

- tariffs raise the price paid by consumers for final goods;
- where the protected goods are used to produce others, tariffs reduce the competitiveness of the downstream industries;
- by pressuring the exchange rate to appreciate, tariffs erode the competitiveness of all exporting and import-competing businesses;
- under disparate tariff rates resources may be applied to disputing the classification of goods under tariff;
- different tariff rates can increase business uncertainty; and
- tariffs involve administrative costs for government and compliance costs for industry.

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<sup>5</sup> As already noted, Chapter 90 includes many products outside the medical and scientific equipment industries, including equipment used in motor vehicles. Data are not available at a disaggregated level to enable the exclusion of these products.

Due to these effects, tariffs and other assistance mechanisms generally reduce productivity and overall efficiency in the economy. For this reason the Commonwealth Government legislated for a tariff reduction program to begin in March 1991 — most tariffs are now at 5 per cent, with the exception of those on passenger motor vehicles and textiles, clothing and footwear.

The Commission considers a broadly based program of tariff reductions is the best way to reduce the costs which tariffs impose. Such an approach improves resource allocation with greater certainty and uniformity over time, and minimises inconsistencies and arguments for special pleading.

In its *Stocktake of progress in microeconomic reform* (PC 1996) the Commission recommended a continuation of reductions in all tariffs, which would see tariffs reduced to 3 per cent in 1997 and to zero in 1998 (with the exception of passenger motor vehicles, and textiles, clothing and footwear which are subject to separate reviews). Acceptance of this recommendation would remove the need for the Government to consider specific tariff changes to medical and scientific equipment.

Nevertheless, this inquiry considered whether reducing tariffs to the medical and scientific equipment industries would be justified ahead of further general reductions in tariffs. This examination involved a number of factors, including the effects of any reductions on the level of assistance, the dispersion of assistance and administrative and compliance costs associated with tariffs. It is to these issues the discussion now turns.

### **Effect on the level of assistance**

Around 75 per cent of imported medical and scientific equipment and parts is already subject to a zero tariff. A further 20 per cent of such imports is imported under concessional arrangements which, until the changes to the TCS introduced from 15 July 1996, meant it also came in duty free. The majority of concessional items enter under Tariff Concession Orders (as opposed to policy by-laws) and so by definition they do not compete with locally manufactured goods. Only the remaining 5 per cent of medical and scientific equipment imports is subject to full tariffs, and so the proportion of domestic production sheltered by remaining tariffs is likely to be small.

The changes to the TCS will have little effect on the level of protection to domestic production, as by definition they will only apply to the importation of goods for which there are no local substitutes. However, the increase in the concessional tariff rate to 3 per cent will disadvantage manufacturers who use imported equipment, parts and components to make their own products, as the higher prices for such items will erode their competitiveness.



In addition, the fact that about 65 per cent of aggregate local production is exported suggests most Australian producers are internationally competitive without tariff protection.

As a result, the Commission considers reducing scheduled tariffs on the relevant items to zero would be likely to have a small positive impact on the two industries.

### **Effect on the dispersion of assistance**

Tariff reform aims to reduce the average level of tariffs and create more uniform rates of assistance throughout the economy. Both changes help promote productivity and economic efficiency, which raise living standards. Reducing some tariffs but not others lowers the average rate of assistance, but may increase the dispersion of rates. In such cases there can be no presumption the overall effect will be an increase in economic efficiency — this can only be established by a case-by-case assessment of each tariff reduction.

Disparities in tariff rates bias production and consumption decisions in ways that reduce economic efficiency. On the production side, land, capital and labour may be attracted into (or retained in) more highly protected activities. These resources could be more productively used elsewhere in the economy. For example, electrical spectrophotometers have a tariff of 5 per cent while other spectrophotometers are duty free. In such cases, companies are encouraged to invest, or continue to invest, in producing the former rather than the latter. This would be so even if higher returns were associated with non-electrical spectrophotometers were there no tariffs on either equipment.

On the consumption side, where tariffs inflate the price of one type of equipment, users may purchase less of it in favour of other broadly comparable equipment. The latter only represents better value for money because of the tariff. For example, a hospital requiring diagnostic imaging equipment may purchase duty free equipment rather than other equipment for which the price is inflated by tariffs, even though it would have preferred the latter were there no tariffs.

Disparities in tariff rates often exist both within and between chapters of the Tariff Schedule. Such disparities are likely to have a greater adverse effect on resource allocation where they exist between close substitutes in production and consumption. Close substitutes are often classified within the same chapter of the Tariff, for example Chapter 90, and so it is generally the case that ensuring a consistent tariff level within a chapter is more important in terms of efficiency than ensuring consistency between chapters. However, this depends on a case-by-case examination of the substitutes in production and consumption.

Reducing tariffs on medical and scientific equipment in Chapter 90 to zero would potentially affect economic efficiency in two ways. It would reduce the disparities in rates of assistance between products within Chapter 90, thereby increasing economic efficiency. However, it could either increase or decrease disparities in the assistance rates between Chapter 90 items and products classified elsewhere in the Tariff Schedule — this would depend on whether these other activities are protected by tariffs.

Where it would decrease disparities, this would increase economic efficiency. Where it would increase disparities, economic efficiency would be reduced. However, in the latter case, given that only about 15 per cent of medical and scientific equipment is classified outside Chapter 90, it is unlikely that there are strong substitutes between Chapter 90 items and products classified elsewhere. This suggests that any negative efficiency effects would not be strong.

Furthermore, as discussed in the previous sub-section, available evidence suggests that in recent years the production of virtually all medical and scientific equipment has been unprotected by tariffs, and so any change to tariff levels would necessarily have a small impact on the industries. The recent changes to the TCS are unlikely to alter this situation.

In its recent report on the *Stocktake of progress in microeconomic reform* (PC 1996), the Commission recommended that most tariffs be reduced to zero by 1998. If this recommendation is adopted by the Government, then any negative effects that might arise (from any increased disparities between tariffs between Chapter 90 items and items classified elsewhere) will be short term.

For these reasons the elimination of the remaining tariffs on medical and scientific equipment is unlikely to reduce economic efficiency.

### **Administrative and compliance costs**

The ACS incurs costs in administering both tariffs and tariff concessions. Companies incur compliance costs in meeting the paper work and other administrative requirements imposed by tariffs and the concessional schemes. These compliance costs also include costs incurred voluntarily by companies in attempts to influence the tariffs applicable to equipment, such as through classification disputes with the ACS.

The levels of administrative and compliance costs associated with tariffs and concessional arrangements are hard to determine — detailed estimates are not available. Evidence from the ACS suggests compliance costs at least are significant (see Box 9.2). Furthermore, administrative and compliance costs assume increasing relative importance as tariff rates are reduced — that is, these

costs do not proportionally decline with the level of assistance. However, the exact relationship is not clear.

**Box 9.2 Tariff Concession System — compliance costs**

*Compliance costs* are incurred by both importers and local producers in dealing with the Tariff Concession System. These were documented by the Department of Industry, Science and Technology in its recent evaluation of the system.

Importers' costs include the costs of finding any local manufacturers of the good plus completion of the application form. One company estimated Tariff Concession Orders cost it about \$5000 per year, while another estimated the cost at between \$15 000 and \$20 000 per year.

Local producers also incur costs in defending their level of tariff assistance against Concessional Orders. These costs include scrutiny of the Tariff Concession gazette, lodging objections, making cases to the Customs Internal Review, and on occasions, taking cases to the Administrative Appeals Tribunal. A survey by the Metal Trades Industry Association showed, on average, local producers spent between 2 and 35 hours per month examining gazettes and lodging objections. The costs of defending an appeal ranged from \$7000 to \$20 000 per case. Other non-quantifiable costs include the cost of distraction from core business, often by senior executives.

*Source:* DIST/ACS 1995

If tariffs on medical and scientific equipment in Chapter 90 were reduced to zero, some administrative costs, such as those incurred in collecting duties from importers, would disappear. However, there would be little effect on other administrative costs — for example, imports would still need to be inspected to confirm their duty free status and to assess their liability for sales and excise taxes.

The effect on compliance costs is similarly uncertain. While companies would no longer need to process the paperwork associated with import duties, they would still incur costs in establishing that the equipment they are importing is eligible to enter duty free.

The effect on the costs incurred in disputing tariff classifications is also unclear. Reducing tariffs on equipment in Chapter 90 to zero would end classification disputes within the chapter. However, there may be a greater incentive for importers of medical and scientific equipment falling outside Chapter 90 to have this equipment re-classified to within that chapter.

In summary, the elimination of tariffs on Chapter 90 items would clearly remove the administrative and compliance costs associated with concessional arrangements, as the arrangements would no longer be relevant. However, the costs of administering the tariff system and establishing the duty free status or otherwise of imported equipment may be little affected, as may the compliance costs incurred by companies in the same process.

Based on these considerations, the Commission believes the elimination of tariffs on Chapter 90 items is likely to result in a net reduction in administrative and compliance costs. However, the extent of the reduction is difficult to estimate.

In the Draft Report, the Commission sought further information from participants on the administrative and compliance costs of tariffs and concessional arrangements. No comments were forthcoming in submissions. However, some respondents to the Commission's survey expressed concerns about the duty drawback process.

### **Revenue implications**

In 1994-95 importers of medical and scientific equipment under Chapter 90 paid duties totalling \$9.3 million. However, tariff revenue is likely to be affected by recent changes to tariffs and concessional arrangements. Whilst revenue will increase as a result of the extra duty to be paid on concessional imports from July 1996, at the same time it will decrease as a result of the move to reduce to 5 per cent all tariffs above that level. Assuming the composition of imports remains the same as in 1994-95, the former will increase revenue by \$8.6 million, while the latter will reduce it by about \$4.6 million, giving a net increase of about \$4 million.<sup>6</sup> Therefore, total tariff revenue from medical and scientific equipment would be in the order of \$13.3 million a year.

If the remaining tariffs in Chapter 90 were reduced to zero, the Government would forego this annual revenue of around \$13.3 million. However, as governments are the major provider of funds to public hospitals, research bodies and educational institutions, which are the main purchasers of equipment covered in Chapter 90, much of tariff revenue is currently paid for indirectly by Commonwealth, State and Territory governments.

## **9.4 Participants' comments**

In the Draft Report the Commission asked for further evidence relating to the issues of tariffs and the TCS, but there was little response from participants. Where they did respond, the comments were varied, partly reflecting the differing interest of companies which import components or finished products. The main comments are presented below.

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<sup>6</sup> The increase was calculated by applying a 3 per cent tariff to the value of imports which entered under the Tariff Concession System in 1994-95 (ie \$288 million); the decrease was calculated by taking the value of imports that paid duty in 1994-94 and dividing it by the aggregated tariff revenue to get the average tariff paid (which was just under 10 per cent) and then calculating the cost of reducing that average rate to 5 per cent.

### *Tariffs*

A number of participants who commented on the level of tariffs in Australia believed there should be a 'level playing field' between Australia and overseas countries. That is, they believed the level of tariff assistance should be the same in both Australia and overseas countries for similar products.

A few participants argued tariffs should not be reduced, because reductions make it difficult for Australian companies to compete with overseas companies. For example, the TIEG stated that:

... anything that assists overseas companies to sell their products in here when they make it very difficult for us to sell our products into their countries, goes against the development of the Australian industry (PH trans, pp.122–23).

On the other hand, some participants suggested that the inequality between the zero or low levels of tariffs in Australia and higher levels in other countries should not be addressed by increasing tariffs in Australia to the levels of our trading partners. For example, Terumo Corporation stated that:

... we need to encourage local companies and local manufacture but if those companies become so reliant on support locally for survival the moment they step foot overseas they will collapse. It is a big hard world out there. If Australian manufacture can't mix it internationally in that world without ultimately the support of government or local tariffs and things then in the long term we won't be competitive and we shouldn't be in the game. (PH trans, p.62)

Other participants held the view tariffs on imported components add to the price of Australian products made with such components, thus reducing their competitiveness. As a result the MIAA noted:

As far as tariffs are concerned, the members of MIAA, with one exception, support the recommendation that the remaining tariffs in Chapter 90 be eliminated (PH trans, p.196).

Trace Scientific agreed that the increased cost of imported raw materials reduces its competitiveness. However, it also believed tariffs on imported products which compete with locally manufactured products should not be reduced. It stated that:

Not only have they [the Government] applied a duty for us to pay on raw material, but they have also reduced the tariff that our competitors needed to pay on imported product. The net competitive effect for our manufacturing industry was in excess of 7 per cent unfavourable ... (sub. 57, p.2)

Some participants thought the problem should be addressed by encouraging the reduction of tariffs in those countries with high tariff barriers, such as Asia. The SSAA stated that 'a significant reduction in Asian tariffs are necessary to restore the balance' (PH trans, p.48).

### *Tariff Concession System*

Most participants expressed concern over the changes to the TCS announced in May 1996. Several complained about the lack of consultation by the Government in reaching its decision to alter the system.

The SSAA (sub. 11) and the MIAA (sub. 13) opposed the initial proposition by the Government to abolish the system, which would have meant items eligible for tariff concession would carry the full tariff rate. They considered the changes would likely add to local costs and prices. The Australian Health Industry Development Forum (sub. 30) and Tuta Laboratories (sub. 15) also objected to the proposed changes. However, the Technology Industry Exporters Group (sub. 17) felt any effect on exporters would be diluted by greater use of duty drawback or the TEXCO System.

In response to industry concerns, the Government decided, instead of abolishing the system, to increase the concessional tariff rate from zero to 3 per cent. Following this announcement, and the release of the Draft Report, the MIAA surveyed its members on the effects of the changes to the TCS. On the basis of its survey results it still believes the changes are a disadvantage to companies, stating:

... most companies, to varying degrees, have been disadvantaged by the Government's recent changes to the Tariff Concession System (sub. 51, p.2).

## **9.5 Commission's assessment**

The Commission is directed by its Act to take an economy-wide perspective when developing its policy advice. This approach has been applied in the assessment of tariffs and the TCS affecting the medical and scientific equipment industries.

### *Tariffs*

The Commission has focused on the level of domestic tariffs in assessing the effects of tariffs on medical and scientific equipment in Australia. Whilst it is true that Australia's tariff rates are lower than those of some of its trading partners, Australia is unlikely to bring about a reduction of foreign tariff rates through the threat of raising or maintaining its own tariff rates. Given that, Australia must choose domestic tariff rates that maximise net benefits to the Australian economy.

Unilateral tariff reductions reduce the imbalances in the treatment of different industries, and of different entities within the same industry, created by tariffs. In doing so, they reduce the inefficiencies arising from biased production and

consumption decisions. Therefore, there are economy-wide gains to Australia from unilaterally reducing tariffs, and these gains are unrelated to the level of tariffs in overseas countries.

With regard to the medical and scientific equipment industries, it was noted that most of the companies competing with imported products have already been doing so on a zero tariff basis for some time. Furthermore, the majority of imported medical and scientific equipment either enters the country duty free or, if not, is eligible for some form of tariff concession because it is not considered to compete with locally produced equipment.

Based on the information available to it, the Commission expects that reducing tariffs on the relevant items of Chapter 90 would be likely to have a small positive impact on the industries under reference, and on the economy as a whole. It is also anticipated that:

- the elimination of scheduled tariffs would merely formalise the situation that existed prior to the recently implemented changes to the concessional tariff arrangements — that virtually all imports are duty free and no domestic production appears to be protected by tariffs;
- the increase in tariffs due to the concessional tariff changes is unlikely to promote any appreciable domestic activity in the medical and scientific industries;
- overall the concessional tariff changes have decreased the competitiveness of the two industries;
- eliminating the remaining tariffs would have little adverse effect on the efficiency of resource use within the rest of the economy;
- the costs of administration and compliance would be reduced; and
- the cost of some equipment to Australian users would be reduced.

### **Recommendation 9.1**

The Commonwealth Government should reduce to zero the remaining tariffs on medical and scientific equipment in Chapter 90 of the Customs Tariff. The relevant sub-headings of the Customs Tariff are 9011 to 9033 inclusive (with the exception of items used in passenger motor vehicles).

Regarding the level of tariffs in overseas countries, the Commission has noted in Chapters 2 and 3 the recent world wide tariff reductions achieved in the GATT Uruguay Round Agreement. The GATT and its objectives have since been absorbed by the World Trade Organisation (WTO), which was established at the

beginning of 1995 after the conclusion of the GATT Uruguay Round. Australia has been an active participant in the GATT, and will continue to address issues of inequality in tariff levels between countries through the WTO.

### *Tariff Concession System*

The TCS has been thoroughly reviewed at different stages of its development — in recent years by the Industry Commission (IC 1991a) and by the then Department of Industry Science and Technology (DIST 1995).

The Commission recommended the retention of the system but noted that, as tariffs fell, at some point the total costs of the system would outweigh the benefits. DIST concluded the removal of the TCS would conflict with the need to remove unnecessary imposts on industry in moving towards an internationally competitive environment. It also considered abolition of the system would disrupt business planning and recommended that it be retained, but modified to narrow its use.

It would be inappropriate to propose wholesale changes to the TCS in this inquiry. An industry specific review does not allow a comprehensive review of all the implications for all the industries and parties who would be affected by such changes.

This inquiry has recommended that tariffs under subheadings 9011 to 9033 of Chapter 90 be reduced to zero (with the exception of items used in passenger motor vehicles). If the Government accepts this recommendation the TCS would no longer be relevant to medical and scientific equipment under Chapter 90. However, tariff concessions may still be relevant to medical and scientific equipment outside Chapter 90 and to various inputs used in production.

In its *Stocktake of progress in microeconomic reform* (PC 1996), the Commission proposed that most industry tariffs should be reduced to zero by 1998. This would render the TCS irrelevant to the medical and scientific equipment industries.

It is estimated that the additional duty paid by importers of medical and scientific equipment from raising the concessional tariff rate to 3 per cent will be about \$8.6 million. In addition, the revocation of the TCOs applying to certain imports will increase the actual tariff rate on the imports in question to 5 per cent.

The impact of these changes may be partly offset by importers making greater use of policy by-laws. However, the scope to do so may be limited by the tightening of by-laws, and the extra costs to importers in applying for them, such as lodging security or identifying end-use. Domestic producers will face higher prices for production inputs and parts. To the extent they pass them on, the changes to the system will make equipment more expensive to end-users.



In its *Stocktake of progress in microeconomic reform* (1996) the Commission stated that:

In terms of resource allocation effects, the announced changes to the TCS are a step in the wrong direction. Much of the revenue raised will be a tax on imported business inputs for which there are no domestically produced alternatives. Taxing business inputs is costly to the economy. (PC 1996)

Overall, it is expected that the changes to the TCS introduced by the Government will impose an additional burden on producers, importers and users of medical and scientific equipment. However, the system applies not only to medical and scientific equipment but to all imported products subject to tariffs, and any changes to it will have economy wide effects. For this reason the Commission considers any future changes to the TCS should be based on a full assessment of its impact on the whole economy.

## 9.6 Anti-dumping

Australia's anti-dumping system allows action to be taken against goods imported into Australia at a price below their 'normal' value in their country of origin. This action may only be taken if the Australian industry producing 'like goods' has suffered, or is threatened with, material injury.

The simplest form of anti-dumping action is the imposition of a duty on the dumped good. Once imposed, anti-dumping duties can remain in force for up to five years without review — they may be extended, after this time, subject to a review. As an alternative, to avoid the imposition of a duty, an exporter to Australia may make a 'price undertaking' — an undertaking to sell at a price which matches or exceeds a 'non-injurious' price.

A company seeking anti-dumping action can complain to the ACS. If the ACS finds *prima facie* evidence of dumping, it will arrange for the provisional relief from dumping for the industry and refer the matter to the Anti-Dumping Authority (ADA) for a full inquiry. The final decision on the action to be taken is determined by the Minister for Small Business and Consumer Affairs in the light of the recommendations of the ADA (ADA 1995).

While the rationale for Australia's anti-dumping regime is to protect certain producers, anti-dumping actions have a broader impact. By increasing the price of imported goods, anti-dumping actions also increase the cost of equipment to end users.<sup>7</sup> There can be no presumption the benefits generated by anti-dumping

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<sup>7</sup> Anti-dumping action will also injure the importing party, which may be an Australian company. However, in the following discussion the Commission has focused on the interests of firms producing in Australia.

action will outweigh the costs associated with increased prices and reduced competition.<sup>8</sup>

In addition to the direct costs of anti-dumping action, the anti-dumping system generates substantial indirect costs which are less visible and which may be greater than the direct costs.

First, the anti-dumping system encourages restraint from exporters to Australia via price undertakings.

Second, the dumping inquiry process can generate a climate of uncertainty and threat which may discourage exporters to Australia from competing too vigorously for fear of incurring anti-dumping action. Provisional anti-dumping measures, such as cash securities and provisional duties, can be imposed on importers by the ACS pending an ADA inquiry. The inquiry may then conclude the goods in question were not injuriously dumped and thus should not be subject to measures at all or that measures only apply to some of the overseas exporters. While provisional cash securities and duties are refunded, their cost must be borne for the duration of the investigation. Thus they increase the cost and risk borne by foreign exporters and hence Australian users.

However, the imposition of provisional measures provides the exporters to Australia (or importers of their product) with the incentive to raise their prices to avoid paying cash securities and provisional duties. Therefore, provisional and final duties are not always collected since the overseas exporter can avoid paying the duty by charging the 'non-injurious' price.

Australia's current anti-dumping system does not formally involve weighing the competing interests of producers and users to reach a judgement based on the public interest. Once the facts of dumping and injury to an industry have been established, the minister can impose anti-dumping action.

The Commission was informally advised, during its recent inquiry into the packaging and labelling industries (IC 1996b), the inclusion of public interest considerations *may* be possible under current legislation. However, there is no obligation for these interests to be considered.

A number of companies in the medical and scientific equipment industries have lodged complaints of dumping since 1990. These are summarised in Table 9.3. In the majority of these cases, the ADA found there was insufficient evidence that dumping was causing the industry material injury.

In its *Stocktake on the progress of microeconomic reform*, the Productivity Commission indicated the national competition policy package (agreed to by the

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<sup>8</sup> For a more detailed discussion of the affect on users, see the Industry Commission's *Annual Report 1994-95*.

COAG in 1995) included an undertaking to introduce of a program of review of anti-competitive regulations. As part of this program, the Commission is currently examining both the determinants of anti-dumping petitions in Australia and their effects on trade and competition. This report is due mid-1997.

**Table 9.3 Anti-Dumping Authority inquiries, medical and scientific equipment**

<i>Year</i>	<i>Report No.</i>	<i>Product</i>	<i>Finding</i>
1990	20	Wound dressings from the USA	No material injury
1990	25	Vibrating wire piezometers and pressure transducers from the USA	ADA could find no causal link between dumping and the injury experienced
1991	28, 51	Diagnostic reagent strips from the UK and USA	Anti-dumping action taken against one exporter to Australia
1991	46	Plaster of Paris bandages from the Federal Republic of Germany	Anti-dumping action duties imposed
1994	130	Blood collection packs from Japan	Insufficient grounds for action
1994	136	Blood collection packs from the USA	Recommendation that the price undertakings offered by exporters be accepted by the Minister
1996	151	Re-enforced wound closure strips from the USA	ADA could find no causal link between dumping and the injury experienced

*Sources:* ADA various reports

### Participants comments

Several participants complained about the length of time it took to seek redress through the anti-dumping system, and the lack of adequate compensation where successful. For example, William Green Pty Ltd (sub. 19) stated that it learned from a 1988 case companies are better off not instigating anti-dumping actions as they are time consuming, costly, a distraction from core business objectives and offer no effective solution to the problem.

In response to these statements, the ADA pointed out since this case there have been substantial changes to the administration of anti-dumping inquiries in Australia, with no fewer than three major reviews having taken place (sub. 42).

The ACS did not accept Australia's anti-dumping system provided no effective solution to dumping. It stated that:

Such a claim does not have regard to the cases where measures have been imposed and the continuing applications for action. ... it should be noted that Australia has the fastest investigation time of any of the major, credible users of the anti-dumping process. In terms of cost, Australia has managed to maintain a system which, unlike the US system, does not revolve around legal representation. Thus the costs associated with the process are greatly reduced. (sub. 45, p.6)

Tuta Laboratories (sub. 15) once lodged a dumping complaint against importers of blood collection packs. As a result of the experience it felt the anti-dumping process was drawn out and the results inadequate. In this case, the Minister

accepted price undertakings from the companies involved, which were designed to stop the injury to Tuta, but the undertakings were not implemented by the relevant companies. After Tuta lodged several further complaints with the Minister, a dumping duty was finally imposed.

The ADA noted that it was unable to respond to Tuta's comments, as the role of the ADA essentially ends when it reports to the Minister on what action, if any, should be taken (sub. 42). For its part, the ACS commented that the prime issue was whether price undertakings were a suitable measure at the outset. It also noted that amendments to the law since this case should strengthen its ability to monitor future undertakings and rapidly impose duties where the undertakings are found to be ineffective (sub. 45).

Surgi Supplies (sub. 34) expressed concern at the inconsistencies between the ACS and the ADA in calculating dumping margins and deciding material injury. The company also commented on the lack of information available from the ADA regarding the criteria used to make its decisions, and how far it goes to verify supplied information.

In response to Surgi Supplies, the ACS noted that the anti-dumping process involved an assessment of many factors where subjective judgements are made. This was a consequence of the international rules on dumping. As a result it said it was not surprising that when a case is assessed by two separate bodies there will be instances where the findings differ.

The ADA also responded to the concerns expressed by Surgi Supplies. The ADA indicated in its response there had been no inconsistencies in the case of Surgi Supplies. It said it repeatedly stated the same conclusion in its report (No. 151) on the case as that reached by the ACS — that is, that Surgi had suffered material injury. The ADA also stated that it concluded dumping had occurred. However, it did not believe the dumping had caused the material injury. It said:

It does not automatically follow that, because there is dumping and material injury, one was brought about by the other (sub. 42, p.2).

### *Other sanctions on dumped products*

Several participants raised the issue of whether other measures should be implemented to limit the purchase of products identified as dumped. For example, Tuta considered public monies should not be spent on dumped products, and recommended that:

... companies proven to be dumping products into Australia to eliminate the competitive ability of Australian manufacturers be excluded from tenders for such products for the five year life of the dumping measures (sub. 15, p.13).

With respect to the purchase of products subject to dumping duties, the Health Department of Western Australia (WA) stated that:

... except with the approval of the [WA] State Supply Commission, no goods which have been declared to be dumped are purchased and provisions are included in contracts to terminate existing contracts if a dumping declaration is made (sub. 37, p.2).

The ACS did not support Tuta's suggestion to exclude companies from Government tenders for the duration of any dumping measures imposed on them. It stated that:

... the Government has a system to investigate alleged cases of dumping and subsidisation, and to impose measures to counter such situations ... It is not, and should not be, the Government's policy to do other than ensure that a situation of fair competition is in place. An effective ban on the products would not be an appropriate outcome.

In order to provide support for domestic industry, it may be appropriate for Government agencies to ensure that the prices of such tenders in these situations reflect the non-dumped or non-injurious levels prior to finalising any contract from suppliers (sub. 45, p.5).

The ACS also noted that, in certain circumstances, purchasing agencies should ensure any contracts include a provision to transfer the liability for any anti-dumping or countervailing duty to the party exporting to Australia.

### **Commission's assessment**

The Government has undertaken to improve existing anti-dumping and countervailing procedures in response to broader concerns. It has expressed its intention to, among other things:

- reduce the inquiry period to 155 days (compared with 245–265 days);
- ensure material injury tests do not require the virtual decimation of the local industry before remedial action is taken; and
- simplify the informational requirements imposed on local complainants.

An independent review on how best to implement these measures was commissioned by the Minister for Small Business and Consumer Affairs in June 1996. The review was also to examine the roles of the ACS and the ADA in the investigation process (sub. 45). The report was completed in August of this year, and has been sent to the Minister.

The Commission does not believe it would be appropriate to propose changes to the anti-dumping system in this inquiry into the medical and scientific equipment industries. An industry specific review does not allow a comprehensive review of the implications for all the industries and parties who would be affected by such a

proposal. The Government has scheduled a review of anti-dumping legislation for 1997-98 (Costello 1996a).

*Other sanctions on dumped products*

The Commission agrees with the response of the ACS that it should not be the Government's policy to do other than ensure a situation of fair competition is in place. Furthermore, the GATT (now WTO) rules concerning the treatment of dumping do not allow for the type of action suggested by Tuta. The rules only allow for the imposition of a duty (which may provisionally take the form of either a duty or a cash or bond security) which must 'not exceed the margin of dumping' (GATT 1994, Part I Article 7). They state that:

No specific action against dumping of exports from another Member can be taken except in accordance with the provisions of the GATT 1994 ... (GATT 1994, Part III Article 18).

The Commission considers that care should be taken in the imposition of further penalties on exporters to Australia of dumped products. As noted above, while this would be beneficial to domestic producers of medical and scientific equipment, there can be no presumption that this benefit would outweigh the extra costs borne by the users of equipment.

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## 10 FUTURE PROSPECTS

*Australia offers producers of medical and scientific equipment a number of advantages. However the future is one where competition for market share — on local and export markets — is likely to increase. As well, governments in other countries are competing to host investment in the medical and scientific equipment industries.*

*Australia must continue to provide a competitive business environment for producers if its industries are to retain or increase their share of future markets and if it is to attract future investment in these industries.*

*Government can help by providing a stable institutional and regulatory framework for the medical and scientific equipment industries and by removing impediments to better performance.*

The objective of this chapter is to identify the main strengths and weaknesses of Australia as a location for producing medical and scientific equipment (Section 10.1). In doing so, it reflects the advantages and disadvantages of Australia as a location for investment. In the light of these strengths and weaknesses, the chapter then considers the opportunities and challenges facing the industries in Australia — from both a global and Australian context (Section 10.2). Finally, the chapter provides some concluding comments on the role of government in creating an environment in which Australia's medical and scientific equipment industries may better meet the challenges of the future (Section 10.3).

### 10.1 Strengths and weaknesses

Australia has both strengths and weaknesses as a location for the production of medical and scientific equipment. Some of these apply to all industries and relate to the country's resources and political and economic circumstances. Others are more specific to the medical and scientific equipment industries. A summary of participants' perceptions of Australia's strengths and weaknesses is contained in Box 10.1.

In addition, responses to the Commission's survey indicated that on average Australia's manufacturing labour costs, transport and distribution costs, and



**Box 10.1 Perceptions of Australia's main strengths and weaknesses**

Participants identified the following main strengths and weaknesses of Australia as a place to produce medical and scientific equipment:

*Strengths*

- well developed research and development infrastructure;
- well educated and trained workforce with a substantial skills and knowledge base, and a highly regarded international reputation;
- the low cost of skilled employees, especially engineers, relative to other advanced economies;
- internationally credible system for regulating medical equipment;
- a mature, sophisticated market, providing 'leading edge' customers;
- proximity to, and experience in dealing with, growing markets in Asia;
- well developed transport and communications infrastructure;
- low cost of living, construction costs and office rentals compared with corporate headquarter sites in Hong Kong, Singapore and Japan; and
- political and economic stability.

*Weaknesses*

- a small domestic market;
- distance from the large markets of the US and Europe;
- inadequate government procurement arrangements, particularly in public health agencies;
- for medical device suppliers, the lack of harmonisation of standards with major overseas markets and high cost of regulatory fees for small companies;
- restrictive labour practices such as the unfair dismissal laws;
- difficulties in obtaining venture and development finance;
- difficulties for small companies in gaining access to government programs; and
- lack of management skills in the industries, particularly in small companies.

taxation system detracted from Australia's appeal as a location to invest in the medical and scientific equipment industries. The responses particularly emphasised Australia's strength in the availability of quality labour and in research and development (R&D). Details of the survey results are contained in Appendix L.

## Research and development

Participants generally consider Australia is strong in R&D. It has the infrastructure needed to support their industries and skilled people to conduct R&D. A recent report by the Bureau of Industry Economics (BIE 1996) looking at availability of R&D personnel, their employment costs and productivity supports the view that Australia is well endowed with relatively low-cost and efficient R&D personnel. This strength was also acknowledged by participants to the Commission's recent inquiry into the pharmaceutical industry (IC 1996c).

Another related strength is in the clinical trialing of medical devices. The advantages of conducting clinical trials in Australia include the high standard of health care at moderate cost and the high standards of medical research (IC 1996c, p.157). A submission from Flinders Medical Centre, for example, noted:

Large medical manufacturing companies require research departments and clinical testing facilities in the development of new products. Australian health units and schools can provide this as well as anywhere in the world and because of considerations such as lesser regulatory requirements than overseas (FDA for example), Australia may even have advantages. (sub. 2, p.2)

The CRC for Cardiac Technology drew attention to its inability to get liability insurance to cover clinical trials essential for the commercialising its R&D (sub. 49). However, their experience does not reflect a failure in the market for product liability insurance nor threaten Australia's advantage in clinical trialing.

Some participants noted though that Australia did not get the maximum benefit from its strength in R&D. Despite progress in improving links between companies and research institutions like CSIRO and universities, there was still considerable scope for improving those links (see Chapter 7). In addition, Australia's record in converting R&D into marketable products (ie commercialisation) was held to be poor, despite government initiatives to address this issue. In part this was attributed to difficulties small companies faced in obtaining adequate venture finance (see Chapter 8).

## Government programs

Government programs which support the activities of the industries represent both a strength and a weakness. The Commonwealth Government has actively intervened to assist companies in their R&D effort, in obtaining finance, and in improving their exporting and business management performance. Information in Chapters 7 and 8 showed the value of these Government measures to companies in the medical and scientific equipment industries. However, concerns remain about the awareness within the industries of the programs available and the

difficulties small companies face in gaining access to them. The uncertainty about the future of some of the programs (eg the R&D tax concession, syndication, EMDG, DIFF) was also viewed as a weakness (sub. 30, pp.2 and 5–6).

The announcement of the Government's position on these programs in the August 1996 Budget removed some of the uncertainty. At the same time the Government has reduced assistance and terminated some programs. These changes have introduced new concerns. For example, the SSAA stated the cutbacks in DIFF and other foreign aid schemes will make it more difficult for Australian companies to share in opportunities in the Asian Pacific Rim (sub. 63, p.5). Participants also considered the changes to R&D assistance had introduced uncertainty to R&D investment decisions and discriminated against smaller companies.

If the industries in Australia are to make best use of programs designed to support their activities, governments must make sure those programs remain appropriate to changing circumstances and are delivered in an efficient and effective manner.

## **Regulation**

One of the strengths Australia offers producers of medical equipment is a credible and internationally respected system of regulation (see Chapter 4). This has enhanced Australia's reputation for quality manufacturing (sub. 46) and helped Australian suppliers penetrate export markets. The Commonwealth Department of Health and Family Services, for example, noted:

Australian exports are facilitated by the standing given to products through having an internationally recognised regulatory system. Countries such as Thailand, which does not yet have a comprehensive system of device regulation, rely on certification issued by the Australian Government attesting to the free availability of a device in the Australian market and the acceptability of the quality system of the Australian manufacturer. (sub. 16, p.6)

Australia's system of regulation is, however, not yet fully integrated into the emerging international system and to that extent can hinder local producers' access to global markets.

In addition, participants claimed the efficiency of the Therapeutic Goods Administration needed improving, citing areas such as the cost and time taken for product assessments. Current changes to the Therapeutic Goods Administration should improve the service it provides, although concerns remain that the move to cost recovery will mean a greater burden falling on manufacturers (sub. 46).

## **Labour market**

Participants claimed one of Australia's strengths for their industries is a well educated, skilled and productive labour force. This was clearly reflected in responses to the Commission's survey. The significance of this as a strength will depend on the nature of industrial relations arrangements. Arrangements that promote industrial stability, allow flexible use of labour and provide incentives for productivity improvements will help Australia capitalise on its inherent strengths.

While provisions in the awards covering employees in the medical and scientific equipment industries restrict workplace flexibility, it is difficult to determine the degree to which they do and any consequences for workplace productivity. Participants viewed some aspects of those arrangements as a hindrance to their industries and in need of reform — the legislation dealing with unfair dismissal was one such area. Recent changes to the legislation governing unfair dismissal were intended to address such concerns.

## **Australian market size and composition**

The Australian market for most medical and scientific equipment products is generally a mature one, with sophisticated end-user demand and leading edge customers. It is, however, a small market and largely depends on government funding which is increasingly under expenditure restraint.

Some participants viewed the small size of the domestic market and its likely low growth rate as a constraint to the development of the medical and scientific equipment industries. These participants (eg the Australian Dental Industry Association, sub. 47) considered it imposed a limit on the size a company could reach and this disadvantaged such companies in competing with overseas producers. Not all participants shared this view. Diffraction Technology (sub. 6, p.1) stated that being small and 'fleet of foot' gave it a competitive advantage over big 'monolithic' companies. Similarly, Denyers International stated:

... the much lamented problem of the scale of manufacture ... is in fact in many instances an advantage. I recently assisted a small bed manufacturer in getting quite a large contract for a hospital bed and he was up against an American company.

The fact that his tooling costs and changeover to a specific design requirement of this customer could be done effectively and efficiently, as opposed to the American who was tooled up to turn out 100 000 beds a month, as opposed to this guy turning out 100 a month, they couldn't move. They couldn't make an alteration for what was a 400-bed order. To this man ... these minor adjustments were simple. (RT trans, p.204).

Other participants also noted the small Australian market did not necessarily limit the industries’ potential for development. These participants viewed the world as their market and by exporting could grow beyond the limits imposed by the size of local demand. Already around 65 per cent of the Australian industries’ total value of production is exported.

Within the Australian market, governments are the major source of funding (see Chapters 2 and 3). In view of that, shortcomings in government procurement policies and practices represent a potential weakness in the environment facing the medical and scientific equipment industries (see Chapter 5). Some examples of these shortcomings involve problems with ‘common use’ contracts and the use of technical–based rather than performance–based specifications in tenders. Many of these shortcomings appear to reflect pressures generated within the public health system, and may only be fully addressed by a review of the system as a whole.

**10.2 Emerging threats and opportunities**

Australia’s medical and scientific equipment industries are highly integrated with global markets — around 65 per cent of total Australian production is exported and imports supply about 80 per cent of all domestic sales. The future of the industries is therefore dependent on trends both in Australia and globally. The main threats and opportunities facing Australia’s medical and scientific equipment industries are summarised in Box 10.2. Particularly important for their future are the opportunities and threats in domestic and global markets posed by the global rationalisation of activity in the industries.

**Global threats and opportunities**

*Health cost containment in major markets*

In most OECD countries, governments are under continuing pressure to contain health care budgets (HIMA 1994). As a result of these pressures, the medical equipment markets in the major economies are expected to experience low growth.

<b>Box 10.2 Potential threats and opportunities for Australia</b>		
	<b>Opportunities</b>	<b>Threats</b>
<b>Global</b>	Growing markets in Asia	Health cost containment in major markets
	Reducing barriers to trade	

	Global harmonisation of regulation	
	Technological change and new product markets	Technological change and new product markets
	Global rationalisation of activity	Global rationalisation of activity
<b>Australian</b>	Increased effectiveness of R&D	Government expenditure restraint
	Reforms to Australia's business environment	Government procurement arrangements
		Product liability

As well, since the 1980s, such cost containment has intensified price competition among manufacturers and importers in the global medical equipment market. In response, suppliers have sought lower costs by, for example, consolidating production and distribution operations and moving some manufacturing offshore to more competitive locations (see below).

As these cost containment pressures are expected to continue in the immediate future, Australian suppliers will face greater competition for a share of domestic and export markets.

### *Growing markets in Asia*

In the face of a relatively small Australian market, exports represent the main source of future growth for the industries.

For medical equipment, growth in the large markets of the US, EU and Japan is expected to be relatively low — the result of maturing markets and government efforts in those countries to reign in health care costs. However, the growing economies of Asia — coupled with their increasing adoption of 'Western' health care — represent rapidly expanding markets. Australian medical equipment producers are well placed to take advantage of Australia's proximity to these countries — see Sheehan *et al* (1995). This is especially so as almost 50 per cent of their exports are now sold in Asian markets (see Chapter 2). Growth prospects in Asia also mean Australia has the opportunity to attract investment from international companies seeking a regional manufacturing base to supply these markets (sub. 13, Attachment 14).

The majority of scientific equipment exports are to US and EU markets, which have grown slowly in recent years. In contrast, the economies of the ASEAN countries, Hong Kong and Korea have grown strongly, as have the industry's exports to those markets (see Chapter 3). The proximity and existing presence of

Australian producers in these markets suggest they are also well placed to take advantage of future growth in the region. The Pacific Islands, New Zealand and Papua New Guinea also present opportunities for scientific equipment suppliers from Australia (sub. 57, p.3).

### *Reducing barriers to trade*

In addition to the opportunity for the growth of Australia's industries presented by the expansion in export markets noted above, is the opportunity they face as a result of these markets becoming *more accessible*. While tariff and non-tariff barriers can prohibit Australian producers from expanding into these growing markets (sub. 15, p.3, sub. 13, Attachment 9) the global trend has been for these barriers to fall.

Scientific equipment producers already face relatively few regulatory or tariff barriers to export markets. The signing of the 'Florence Agreement' overcame many of the barriers that used to exist (sub. 17, p.2).

Recent years have seen major reductions in barriers to trade in most countries. As noted in Chapters 2 and 3, the Uruguay Round of the General Agreement on Tariffs and Trade resulted in the biggest tariff reductions package ever achieved in such negotiations. In general, tariffs on products of interest to Australia will be cut on average by about 50 per cent (sub. 8, p.1). For example, for Australian medical equipment, the Uruguay Round resulted in duty free entry for 82 per cent of exports (a rise from 17 per cent). For scientific equipment it resulted in duty free access for one-third of Australia's exports (about double the pre-Uruguay Round incidence).

Trade in medical and scientific equipment will continue to be liberalised through the efforts of the World Trade Organisation (sub. 8, p.1).

The significance of export markets for Australian producers and the ongoing trend to freer world trade reinforce how important it is that Government measures aimed at facilitating companies' access to export markets operate as efficiently and effectively as possible (see Chapter 8).

### *Harmonisation of regulation*

The growing move internationally to adopt the EU system of regulating medical devices will also serve to facilitate trade by reducing non-tariff barriers for these industries in the near future (sub. 17, p.2).

Australia too is moving to harmonise with the EU system (see Chapter 4). The first steps in this direction have already been taken with the Commonwealth Government signing a draft Mutual Recognition Agreement on conformance assessment. As the Department of Health and Family Services stated:

Moves in this direction will mean Australian manufacturers can have the conformity assessment of their devices intended for the European market carried out in Australia, conveniently and at lower cost, and thereby gain more rapid access to the whole of the EU market (sub. 16, p.7).

Participants such as the Australian Dental Industry Association generally considered the move to align Australia with the European system is a move in the right direction (sub. 47, p.10).

Participants noted the importance of Australia having an internationally credible system of medical device regulation if its medical device industry is to have ready access to export markets. Australian Surgical Design, for example, noted:

It is essential that the regulatory standard applied by the TGA [Therapeutic Goods Administration] is world class so that the shift to exporting is as simple as possible ...

and that it be consistent with international requirements:

Mutual recognition between the TGA [Therapeutic Goods Administration] and other regulatory authorities is a key step (sub. 20, p.1).

If the medical equipment industry in Australia is to take advantage of the international trend to adopt the EU model, Australia needs to do more than pursue the Mutual Recognition Agreement. Australia needs to move as quickly as possible to harmonise more fully with the EU system of device regulation (see Chapter 4).

### *Technological change and new product markets*

Markets are constantly emerging for new and innovative medical and scientific equipment. To remain competitive, companies must not only pay attention to their costs but must also rely on innovation to differentiate themselves in the market and maintain a competitive edge (sub. 17, p.3). Chapters 2 and 3 indicated the importance companies in the industries place on R&D as a means of achieving this.

Technological change represents both a threat and an opportunity for companies in the industries. SGE International, for example, noted:

Someone finds [a new] technology and puts you straight out of business. That's a major threat and always has been (RT trans, p.79).

Emerging product markets driven by innovative use of technologies also offer new opportunities for Australian medical and scientific equipment companies. Australian companies have the ability to successfully enter and, in some cases, to dominate emerging new product markets. Cochlear, for example, now supplies around 85 per cent of the global market for bionic ear implants.



Computer technology is playing an increasingly large role in these new markets. For example, a small Melbourne-based computer company recently entered the lucrative US sleep disorder market, signing an agreement worth A\$15 million a year to export monitoring computers to up to 1500 US sleep centres (*The Age*, 18 June 1996). The growth of telemedicine — which combines computer and communications technology — is another example. Australia has a strong telecommunications industry and well developed infrastructure, as well as high quality medical skills. Not only is there the opportunity to develop telemedicine in Australia, but also to export services to our Asian neighbours. Binary Image, for example, considered Australia had the chance to become a regional leader in telemedicine (sub. 53, p.2). Australia has thus far been slow to capitalise on this opportunity.

Participants universally acknowledged Australia was well placed to take advantage of new opportunities because of its strengths in R&D. GBC, for example, noted:

... research and marketing costs are very big parts of the pie in this industry [scientific equipment] because it is a knowledge-based industry and ... those things are in fact reasonable deals here in this country, especially the research one. ... I think knowledge-based industries are a positive for this country. ... We have got far more knowledge infrastructure than any of the people in our region right at the moment, so it's a window of opportunity. In 50 years we won't have that ... we need to take advantage of our knowledge-based industries while we have this window of opportunity (RT trans, pp.86-7).

However, as noted in Chapter 7, Australia still has some way to go in making full use of its strengths in R&D.

### *Global rationalisation of activity*

A feature of the medical and scientific equipment industries has been a move to global rationalisation of activity (in research, production and distribution). Much of this has occurred through mergers, acquisitions and the forming of strategic alliances (see Chapters 2 and 3). A host of factors lie behind this move. Among them are the lessening of barriers to trade, health cost containment by governments in major economies, international deregulation of capital markets and a growing acceptance by governments of the benefits of foreign direct investment (BIE 1993, EPAC 1995). Global rationalisation means activity is increasingly moving to the most competitive locations. Australia has the opportunity to benefit from this trend or to suffer from it.

The added emphasis on lower production costs inherent in the trend means Australian industries face increasing competition from the rest of the world for market share. The trend also means that, in a world where production is

increasingly mobile, Australia is competing with other locations for investment in the medical and scientific equipment industries (sub. 13, pp.50–51).

Participants acknowledged the pressure this placed on them to be world competitive in price or face closure. For example, Baxters (a subsidiary of a foreign-owned parent) stated:

I guess we do fight heavily against our own organisation on why ... we should be here ... I think that we will still see companies disappearing offshore. ... Baxter [the parent body] will decide whether we stay here or not or move offshore and just import. ... if we didn't ... give them world price parity ... we would be closed down eventually by our own corporation and move offshore and lose a central part of manufacturing and ... lose a lot of jobs for Australians ... (RT trans, p.206).

In recent years, Australia has experienced both success and failure in attracting and sustaining overseas investment in the medical and scientific equipment industries. Shimadzu, one of the world's leading manufacturers of medical and scientific equipment, chose to locate its Asia–Pacific manufacturing plant in Melbourne, over competing locations such as Taiwan and Singapore (see Box 10.3). SGE International noted:

... Shimadzu wandered around in the countries they went into and they did very strong studies in Malaysia, Taiwan, Singapore and the Philippines. They looked real close at that and said, 'Where do all these countries stack up for us as a manufacturer?' (RT trans, 90)

However, for Terumo Corporation, a Japanese medical device manufacturer, investing in Australia did not produce the benefits initially expected. After several years of manufacturing in Australia, the company decided to close down its manufacturing plant in Melbourne and transfer operations to the US and Japan (see Box 10.4).

**Box 10.3 Case study: Shimadzu Australia Manufacturing P/L**

Shimadzu Australia Manufacturing Pty Ltd began operations in Melbourne in May 1995. Its parent, Shimadzu Corporation, is located in, Japan. Shimadzu Corporation is one of the largest manufacturers of medical and analytical instruments, and has offices around the world: including Europe, North America and Asia. In 1995, total instrument sales were around A\$1 billion.

Shimadzu Australia Manufacturing is Shimadzu's second largest manufacturing centre. It produces scientific and process instruments, and medical systems and equipment. Most production is shipped to Japan and the US.

Shimadzu chose Australia over other Asian countries and the US because of its well developed infrastructure, the cost and supply of utilities, the cost and availability of land and the supply of skilled labour. Within Australia, Melbourne was chosen over Sydney because of its more efficient air transport facilities, and the higher level of supporting industries such as sheet metal manufacturers. The Federal Government's Investment Promotion and Facilitation Program played a significant role in Shimadzu's decision to invest in Australia.

Although too early for Shimadzu Australia to know in detail how well the company is going, so far management have experienced few problems. An indication though, is that construction is currently underway on a second, larger plant adjacent to the first. The new plant will more than double the company's manufacturing capabilities and will contribute to planned exports of over \$100 million.

*Sources:* SDi (1996); industry visits; information from Austrade; and sub. 56

**Australian threats and opportunities**

In addition to external threats and opportunities, the medical and scientific equipment industries are also subject to pressures within Australia.

***Government expenditure***

The general climate of budgetary restraint at all levels of government in Australia is likely to continue in the immediate future. Restraint is likely to continue across all sectors, including health, science and education. The health sector, for example, will be particularly affected by the ageing of the Australian population and the development of new technologies which suggests ongoing pressure on healthcare costs. As government funding is the main source of domestic demand for Australia's medical and scientific equipment industries, this represents a considerable threat to their future development.

Ongoing restraint will place added pressure on all companies in the industries to become more productive if they are to reduce their costs and prices. Australian

### Box 10.4 Case study: Terumo Corporation Pty Ltd

Terumo Corporation is a major Japanese manufacturer of medical devices; such as syringes, artificial organs and medical electronics. The company has sales offices in 19 countries and manufacturing operations in Japan, the US and Europe.

Until 1992, Terumo Corporation had a manufacturing plant in Melbourne, Victoria, called Terumo Australia Pty Ltd. Terumo Australia was Australia's only manufacturer of syringes and needles, and also produced catheters, wound irrigation sets and regional anaesthesia sets. In 1990, sales by Terumo Australia were around A\$26 million and it employed 220 people. Exports — mainly to New Zealand, South East Asia, Russia and the US — accounted for about 12 per cent of sales.

Despite a A\$40 million investment program in 1989 aimed primarily at local and export business expansion, Terumo announced the closure of its Victorian plant in June 1992 and the transfer of its manufacturing operations to Japan and the US.

A number of factors contributed to Terumo's decision, some relating to the company itself, and some to the Australian operating environment. The main factors included:

- price cutting by a major competitor which began manufacturing in South East Asia in 1989;
- rapidly reducing tariffs;
- high interest rates;
- increasing trend to buy on price because of cost containment in health care funding in Australia and New Zealand;
- difficulty in penetrating overseas markets;
- overly optimistic view by the Japanese parent of likely returns from the investment in the expansion of Australian manufacturing; and
- the parent company had its own financial problems and could not continue to underwrite losses in Australia.

Other factors affecting the decision were:

- a lack of commitment by local purchasers to the 'Australian made' campaign;
- difficulties in establishing new technology in the Australian plant; and
- the limited size of the Australasian market.

*Source:* Information supplied by Terumo Corporation Australian Branch

companies will need to respond to these added pressures or lose out to overseas suppliers. The recent history of the medical equipment industry suggests Australia has already lost a significant number of manufacturing companies (sub. 13, sub. 41).

Within this climate of expenditure restraint, government concerns about new medical technology as a source of upward pressure on health costs will continue. As the Department of Health and Family Services noted:

With rapid technological development and finite health resources, a critical issue the Government faces is defining the place of new health care technologies ... in the Australian health care systems so that those with proven benefits and costs are promoted (sub. 16, p.17).

US and EU experience shows that the way in which government decides on the cost effectiveness of medical technologies has a major influence on the industry's development (see Gelijns & Halm 1991 and TWG 1995). Those decisions affect incentives to invest in new medical equipment technology. The success of Australia's medical equipment industry in responding to changing market demands in part depends on the future operation of Australia's system for controlling the adoption of new technology (see Chapter 5).

### *Government procurement arrangements*

Government bodies or government funded bodies are the major customers for both industries so any continuing deficiencies in procurement arrangements have the potential to frustrate their future development. Some deficiencies in current procurement arrangements were examined in Chapter 5 and have been the subject of recent reviews.

Despite those reviews, some participants in both industries believed government procurement arrangements were still inimical to local manufacturing — at times adding unwarranted costs for suppliers and exhibiting a bias to imported equipment. Moves to the use of prime suppliers may also put a barrier between suppliers and users. Where users are 'leading edge' customers whose demands stimulate suppliers to innovate and improve quality, these barriers may adversely affect development of new medical and scientific equipment (sub. 9).

Some shortcomings appear to result from a lack of effective coordination and cooperation between government procurement agencies. A nation-wide review aimed at achieving more uniform policies and practices seems warranted and could be undertaken by the (existing) National Supply Group.

As noted in Chapter 5, other shortcomings in procurement arrangements may be symptoms of a much broader issue — such as the organisation, management and accountability of the public health system. As such, these shortcomings are only likely to be fully addressed in the context of a system-wide review.

### *Product liability*

Product liability litigation could be a major threat to the future development of the medical equipment industry in Australia (see Chapter 4).

In the US, litigation has led some companies (such as Dow Corning) to stop production of certain products and withdraw biomaterials from medical devices

manufacture (sub. 18). Australian producers have been affected through the restricted supply of certain biomaterials and components or an increase in their costs. However, the consequences of the operation of the US legal system apply to the medical equipment industry worldwide and do not disadvantage Australia relative to other countries. As well, the restrictions on the supply of material from the US may provide the opportunity for the local development and supply of substitute products.

The threat of litigation in the US has also led to huge increases in product liability insurance for that market (sub. 13). Some participants claimed this is a barrier to trade with the US — threatening their potential to export and their industry's development. As such insurance appears to reflect the cost of selling into the US market and applies to all those wishing to do so — including US companies — it is not a barrier to trade. Whether Australian companies sell into the US remains a commercial decision.

The high cost of product liability insurance for the US market led to calls for the Government to consider assisting Australian exporters to get such insurance at 'reasonable cost'. Such assistance does not seem warranted. No evidence was provided to the Commission to suggest insurance markets are failing to accurately reflect the risk of selling into that market.

Dow Corning noted that increasing litigation in Australia would adversely affect parts of the industry by, for example, increasing insurance costs for commercialising new materials or increasing the difficulty in finding investors for R&D in 'high risk' product areas (sub. 59, p.2). It is not clear, however, that these consequences do not just accurately reflect the costs involved in pursuing that commercial activity.

### *Increasing effectiveness of research and development*

Almost universally, participants noted Australia's strength in R&D skills and infrastructure. There is scope to build on this strength. The Flinders Medical Centre, for example, claimed:

Medical research conducted in higher education institutions such as Flinders University is as good as anywhere in the world. The transfer of research to industry is however poor. (Sub. 2, p.2)

Improving the links between public research institutions and industry would allow Australia to better grasp the opportunity afforded by more accessible global markets, by emerging markets and new products. It would also improve the attractiveness of Australia as a location for new investment in the medical and scientific equipment industries.

Australia cannot afford to be complacent about its strengths in R&D. William A Cook Australia, for example, noted that our advantage is gradually being lost due to the acceleration of medical research overseas (sub. 62, p.2).

Having a strong R&D base alone is not sufficient to ensure Australia will be viewed as an attractive location for investment. The ability to convert any R&D output to marketable products is also important. As the College of Biomedical Engineers noted:

Australia has a fine tradition of significant R&D in the areas of medical technology and ... Our difficulty remains in commercialisation. (sub. 46, p.8)

The Government has put in place a range of measures to improve links between public research bodies and industry and improve Australia's commercialisation performance (see Chapters 7 and 5).<sup>1</sup> In view of the advantage afforded to Australia by its existing R&D base and the potential to build on that strength, it is important such measures work as they are intended. This implies those programs should be subject to regular review to ensure they remain appropriate and effective in the face of changing circumstances.

### *Reform of Australia's business environment*

Since the 1980s, Australian governments have introduced substantial reforms to improve Australia's productivity performance. These reforms have occurred across a broad front — for example; covering tariffs, capital markets, economic and social infrastructure and labour markets (see Box 10.5). These reforms have, by improving Australia's business climate, also increased Australia's attractiveness as an investment location (see BIE 1994a, 1995b).

These reforms have also meant Australia's medical and scientific equipment industries are better placed today to seize the opportunities of the future. However, the scope for improving the general climate for business has not been exhausted. As well, other countries are instituting similar or additional reforms.

#### **Box 10.5 Major microeconomic reforms**

- Tariffs have been reduced. A major initiative was the phased reductions introduced in 1988 and 1991, which have seen most tariffs reduced to a ceiling of 5 per cent. While tariffs for textiles, clothing and footwear and passenger motor vehicles remain higher, they have been reduced substantially over the last decade.

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<sup>1</sup> The Commission has examined the issue of impediments to the commercialisation of Australian R&D more generally in its report on *Research and Development* (IC 1995, pp.609-32).

- Financial markets were deregulated, interest rate and exchange controls abolished, and banking opened to new entry in the early 1980s.
- In infrastructure, significant steps have been taken by the Commonwealth, States and Territories to improve telecommunications, transport and energy infrastructure, including in electricity (particularly through the establishment of the national electricity market), airlines (abolition of the Two Airline policy), telecommunications (with the introduction of domestic competition), coastal shipping and the waterfront.
- New standards of performance and accountability for government business enterprises have been introduced and efficiency improvements sought in the general government sector (including in government purchasing).
- Company taxation has been substantially reduced and full dividend imputation and capital gains tax introduced.
- Steps have been taken to rationalise business regulation through mutual recognition of regulation between the Commonwealth, States and Territories and to strengthen regulatory review processes.
- Efforts have been made to reduce overlap and promote cooperation among levels of government. Crucial were the Special Premiers' Conferences and subsequent establishment of the Council of Australian Governments in 1992.
- Labour market reforms have been introduced by the States and Commonwealth to restructure awards, support a move towards enterprise-based agreements, and to improve the flexibility and skills of the workforce, including through immigration.

Source: PC (1996)

If Australia is to improve the relative competitiveness of its industries and its attractiveness as a location for investment, it must continue with the reform process. The case for doing so has recently been spelt out in the Productivity Commission's *Stocktake of progress in microeconomic reform* (PC 1996).

### 10.3 Concluding comments

Australia has both strengths and weaknesses as a location for investment in the these industries and from which companies may face the future.

That future will be a challenging one. The increased globalisation of activity has intensified competition between companies for market share and pressure on companies to seek the most commercially attractive locations for their activities. It has also promoted keener competition between governments to improve the attractiveness of their economies to domestic and foreign companies alike.



To help these industries to successfully meet the challenges of the future, governments in Australia must continue their efforts to improve the general climate for business. Ongoing reforms in areas like infrastructure, the labour market, competition policy and tariffs will help the industries lower business costs and respond flexibly to changing circumstances. As Yetton, Davis and Swan (1992, p.72) observe: 'Our task is not to pick winners but rather create an environment in which (enough) winners pick Australia.'

It is also important that Government ensures that its various programs (such as those facilitating R&D, access to finance and export marketing) are operating efficiently and effectively and remain appropriate in the face of changing circumstances. (This should also include ensuring they do not unnecessarily discriminate against smaller companies). These programs, while generally available, are particularly important for the future development of the medical and scientific equipment industries.

To allow the industries to face their future with confidence will also require changes in areas of more specific interest to them. The Commission's recommendations for improving the national system of regulation of medical devices, to address concerns with government procurement and reducing tariffs on imports of medical and scientific equipment are intended to achieve this.

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## A TERMS OF REFERENCE

I, GEORGE GEAR, Assistant Treasurer, in pursuance of Part 2 of the *Industry Commission Act 1989*, hereby:

1. refer, as an Industry Development Reference, the medical and scientific equipment industries to the Industry Commission for inquiry and report within twelve months of receiving this reference;
2. specify that, in making its recommendations, the Commission aim to improve the overall economic performance of the Australian economy;
3. request that the Commission report on:
  - (a) emerging trends in local and global markets for the industries;
  - (b) the international marketing environment, including tariff and non-tariff barriers to Australian exports, and the effectiveness of Government efforts to improve market access for the industries;
  - (c) the current structure and competitiveness of the industries, including an identification of strengths and weaknesses, drawing international comparisons where appropriate;
  - (d) the role of research and development programs, universities and other training and research institutions and linkages with the domestic and international scientific community;
  - (e) the advantages and disadvantages of Australia as an investment location for all phases of medical and scientific equipment activity, from research and development through to manufacturing and export. In doing so, the Commission should report on programs in other countries designed to create a favourable environment for the industries;
  - (f) the potential for further development of the industries, including the scope for further value adding, exports and import replacement;
  - (g) the impact of the current institutional and regulatory measures, including the Therapeutic Goods Administration regime, on industry structure, performance, international competitiveness, resource allocation and growth prospects;
  - (h) any measures which could be undertaken to remove impediments or otherwise contribute to the efficiency, growth or export development of the industries;
  - (i) the identification of groups which would benefit from, or be disadvantaged by, any measures flowing from 3(h) above, and implementation strategies for proposed measures; and
  - (j) the effects on the industries, and the economy in general, of any measures recommended by the Commission;
4. specify that the Commission:
  - (a) report, where appropriate and without disclosing material provided in confidence, on examples of past success and failure in the industries, both in Australia and elsewhere, by way of case studies or other means; and
  - (b) have regard to the established economic, social and environmental objectives of governments.

GEORGE GEAR

24 January 1996

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## B MINISTERIAL CORRESPONDENCE

When the Assistant Treasurer forwarded the terms of reference for this inquiry to the Industry Commission, he attached copies of letters from the (then) Ministers for Industry, Science and Technology and Human Services, and Health commenting on those terms of reference. These letters emphasised the need for the Industry Commission to distinguish between the medical equipment and scientific equipment industries in its report.

The text of these letters is reproduced below.

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13 Oct 1995

The Hon George Gear MP  
Assistant Treasurer  
Parliament House  
CANBERRA ACT 2600

Dear George,

Thank you for your letter of 5 September 1995 concerning terms of reference for an Industry Commission inquiry into Medical and Scientific Equipment.

I approve the terms of reference for this inquiry.

Although there are commonalities between the medical equipment industry and the scientific equipment industry, the two industries are dissimilar in many respects. I therefore suggest that you instruct the Industry Commission to explicitly note these differences and provide separate sections of its report to cover the two industries.

Yours fraternally

Peter Cook

24 Jan 1996

The Hon G. Gear MP  
Assistant Treasurer  
PO Box 96  
GOSNELLS WA 6110

Dear Assistant Treasurer

Thank you for your letter of 5 September 1995 regarding the Terms of Reference for the inquiry into the Medical and Scientific Equipment Industries. I apologise for the delay in replying.

The Terms of Reference are generally satisfactory from my perspective. There are some concerns which I would like to raise. Firstly, I would seek your agreement that the report distinguish sufficiently between the industries in its recommendations. This will enable the report findings to be better targeted and capable of implementation.

Secondly, my Department has a major interest in health care technology including medical and scientific equipment. Rapidly changing technologies are altering the way in which health care is practised and delivered and increasing the possibilities for diagnosis and treatment. However, technological developments have their benefits and costs. Increasingly, health technology assessments and evaluations are becoming important policy and planning tools.

My Department provides innovation in health industry and technology in a number of ways:

- Research to develop new and improved ways to prevent, diagnose and treat illness and disease is promoted through the National Health and Medical Research Council (NHMRC) and other funding bodies.
- Through the universal health subsidies program of Medicare, the Government seeks to provide Australians with access to quality, appropriate and cost effective health care technologies and other health modalities.
- With rapid technological development and finite health resources, a critical issue the Government faces is defining the place of new health care technologies and other innovations in the Australian health care system so that those with proven benefits and costs are promoted.
- This requires looking at how industry's needs to develop new health care technologies and other health innovations can be best aligned with the Government's health care funding, needs to have evidence on clinical and economic benefits through technology assessments and evaluations, and with research activity and programs of NHMRC and other funding bodies.

Yours sincerely

Dr Carmen Lawrence



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## C SUBMISSIONS AND PARTICIPANTS

As part of the inquiry process, the Commission visited a number of organisations and individuals to seek their views. Interested parties also participated in the inquiry by attending the roundtables and public hearings, and by providing submissions to the inquiry.

### C.1 Visits

#### New South Wales

Activon Scientific Products Company Pty Ltd  
Ajax Chemicals  
Australian Dental Industry Association Inc  
Australian Health Industry Development Forum (now Australian Business Ltd)  
Australian Mezzanine Investments Pty Ltd  
Australian Society for Medical Research  
Australian Technology Group Limited  
Baxter Healthcare  
Boots Company (Australia) Pty Ltd  
CHK Engineering  
Cochlear Ltd  
Coopers & Lybrand  
Dobbie Instruments  
ETP Pty Ltd  
ETP Semra Pty Ltd  
GE Medical Systems Australia Pty Ltd  
George Weber and Associates Pty Ltd  
Halas Dental Limited  
Hambro-Grantham Management Limited  
HD Scientific Supplies Pty Ltd  
Indoplas Pty Ltd  
Leica Instruments Pty Ltd  
Medical Industry Association of Australia Inc  
Medical Innovations Ltd  
NSW Industrial Supplies Office Ltd  
PWV Medical  
Scientific Suppliers Association of Australia Inc  
Shimadzu Oceania Pty Ltd  
Standards Association of Australia

State and Regional Development (NSW)  
Synthes Australia Pty Ltd  
Technology Industries Exporters Group  
Testing and Certification Australia  
Tuta Laboratories (Australia) Pty Ltd  
University of NSW, National Pulsed Magnet Laboratory

## **Victoria**

Australian Diagnostic Manufacturers Association  
Australian Health Industry Development Forum (now Australian  
Business Ltd)  
Australian Medical and Services Export Group Ltd  
B & L Tetlow Pty Ltd  
Biolab Scientific Pty Ltd  
Business Victoria, Department of Business & Employment  
Coopers & Lybrand Consultants  
CSIRO Australia  
Denyers Pty Ltd  
DePuy Australia Pty Ltd  
Dr Stephanie Burns, Dow Corning Australia Pty Ltd  
GBC Scientific Equipment Pty Ltd  
Hewlett-Packard Australia Ltd  
Industrial Supplies Office (Victoria) Ltd  
Monash University, Department of Chemistry  
Royal Melbourne Institute of Technology, Seismology Research Centre  
SGE International Pty Ltd  
Shimadzu Australia Manufacturing Pty Ltd  
Victorian Hospitals Association Trading Company  
Varian Australia Pty Ltd  
Dr Geoffrey Vaughan

## **South Australia**

Biomedical Engineering Services, Woden Valley Hospital  
Dynek Pty Ltd  
Faulding Distribution Pty Ltd  
Flinders Medical Centre  
Flinders University, School of Engineering  
Flinders University, Office of Research  
Hospital and Health Services Association Purchasing Agency  
Lyell McEwin Health Service  
Magnacare Pty Ltd



Norseld Pty Ltd  
Queen Elizabeth Hospital  
Royal Adelaide Hospital  
South Australian Health Commission (Health Plus Program)  
Supply South Australia  
University of Adelaide, Department of Dentistry

### **Australian Capital Territory**

ACT Department of Health and Community Care  
Australian Hospitals Association  
Australian Private Hospitals Association  
Commonwealth Department of Health and Family Services, Therapeutic Goods Administration  
Department of Industry, Science and Technology (now Department of Industry, Science and Tourism)  
Diffraction Technologies

## **C.2 Roundtable participants**

### *Scientific equipment industry — Melbourne 29 May 1996*

Mike Churchin	Industrial Supplies Office (Victoria) Limited
Richard Eyre	SGE International Pty Ltd
Ron Grey	GBC Scientific Equipment Pty Ltd
John Jew	Scientific Suppliers Association of Australia
Heinz Regel	HD Scientific Supplies Pty Ltd
Tony Revell	Biolab Scientific Pty Ltd
Philip Thomas	Varian Australia Pty Ltd

### *Medical equipment industry — Melbourne 30 May 1996*

Harry Engel	Industrial Supplies Office (Victoria) Ltd
Leonie Hunt	Faulding Distribution Pty Ltd
Roger James	VHA Trading Co
Brian Lee	Baxter Health Care Pty Ltd
Richard Morris	Denyers International P/L (also a member of Australian Medical and Export Services Ltd)
George Neale	Australian Private Hospitals Association
Armin Roth	Halas Dental Ltd (also a member of the Australian Dental Industry Association Inc)
David Thompson	Medical Innovations Ltd (also a member of Australian Diagnostic Manufacturers of Australia and the Medical Industry)

	Association of Australia)
Sheriff Vallance	Medical Industry Association of Australia
Geoffery Vaughan	(immediate former head of the Therapeutic Goods Administration)
George Weber	George Weber & Associates Pty Ltd
Ross Wraight	Standards Australia

### **C.3 Public hearing participants**

#### *Sydney—16 and 17 October 1996*

CRC for Cardiac Technology  
George Weber and Associates Pty Ltd  
Medical Industry Association of Australia  
NSW Industrial Supplies Office Ltd  
Scientific Suppliers Association of Australia  
Technology Industries Exporters Group  
Therapeutic Goods Administration

#### *Melbourne—21st and 28th October 1996*

Binary Image Pty Ltd  
Diagnostic Manufacturers Association  
Fairmont Medical Products  
Fisher and Paykel Healthcare  
Medical Industry Association of Australia  
Relpar Pty Ltd  
Trace Scientific Ltd  
TUTA Laboratories

## C.4 Submissions

Organisations and individuals who made submissions to the inquiry are listed below.

Organisation or individual's name	Submission No.
ACT Government (Chief Minister's Department)	23, 39
Anti-Dumping Authority	42
Austrade	22, 61
Australian Health Industry Development Forum (now Australian Business Ltd)	30
Australian Customs Service	45
Australian Dental Industry Association Inc	47
Australian Hospital Association	67
Australian Law Reform Commission	78
Australian Society for Biomaterials Inc	7, 68
Australian Surgical Design & Manufacture	20
Baldwin Medical & Veterinary Devices (Australia) Pty Ltd	24
Biolab Scientific Pty Ltd	1
Biotel Pty Ltd	12
Binary Image Pty Ltd	53
Cardiac Nurses Group (NSW Diagnostic and Interventional)	74
Commonwealth Department of Health and Family Services (including the Therapeutic Goods Administration)	16
College of Biomedical Engineers	46, 60
Co-operative Research Centre for Cardiac Technology	49
Crown Scientific Pty Ltd	57
Department of Foreign Affairs and Trade	8
Department of Treasury & Finance (Tasmania)(State Purchasing and Sales)	44
Diffraction Technology	6
Douglas Bean (Australia) Pty Ltd	64
Dow Corning Australia Pty Ltd	18, 59
Flinders Medical Centre	2
Galeshka Pty Ltd	31
Gambro Pty Ltd	33
George Weber & Associates Pty Ltd	50
Go Medical Industries Pty Ltd	41
Hall, Dr W.L.	40, 71
Health Department of Western Australia	37
Organisation or individual's name	Submission No.

Industrial Supplies Office (Victoria) Limited	10
Kerr, Dr P.G., Australian and New Zealand Society of Nephrology	76
Leo Barnes & Assoc	14, 25
Malcolm Young & Company	5
Marceau, Professor Jane (Australian National University)	9
Medical Industry Association of Australia	13, 43, 51, 72
Morris, Ms S., Central Sterile Supply Department, Women's and Children's Hospital	70
Murphy Furniture Pty Ltd	27
Nascor Pty Ltd	3
National TAFE Science Network	58
Newton, Merle	75
New Zealand Ministry of Commerce (Business Policy Division)	81
NSW Health Peak Purchasing Council	26
NSW Industrial Supplies Office Ltd	35
NSW State & Regional Development	28
Nucleus Limited	4
Nursing the Environment (Australian Nursing Federation)	36, 69
Private Hospitals Association of Queensland	32
Private Hospitals Association of Victoria	38
Queensland Health	66
Relpar Pty Ltd	54
Ross, Dr D., Department of Cardiology, Westmead Hospital	73
Sanitech Victoria	21
Scientific Suppliers Association of Australia Inc	11, 63
Shimadzu Oceana Pty Ltd	56
South Australian Health Commission	48
Surgi Supplies International Pty Ltd	34
Sydlore Pty Ltd	29
Technology Industries Exporters Group	17
Taylor, Dr P., Prince of Wales Hospital (NSW)	79
Testing & Certification Australia, Electromedical Laboratory	65
Therapeutic Goods Administration	52, 77, 80
Trace Scientific Ltd	55
Tuta Laboratories (Australia) Pty Ltd	15
William A. Cook Australia Pty Ltd	62
William Green Pty Ltd	19

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## D REGULATION OF MEDICAL DEVICES IN AUSTRALIA

Medical devices greatly benefit many individuals by assisting with the diagnosis and treatment of disease and injury, and by supplementing, replacing or restoring bodily function.

Where medical devices deliver drugs or blood products, are physically invasive, or where they seek to modify bodily functions, special care is required in their design, manufacture and use to minimise the potential for adverse effects.

To achieve this, Australian governments have agreed on a national system of preventative regulation to ensure the quality, safety, efficacy and timely availability of therapeutic goods. This Appendix describes the regulation of medical devices as part of this national system.

### D.1 Legislation covering medical devices

Like most products, medical equipment is subject to general commercial law and regulation. The more important general legislation includes the:

- Commonwealth *Trade Practices Act* 1974 — which covers most business activities and has as its objective to enhance the welfare of Australians through the promotion of competition and fair trading and by providing for consumer protection; and
- various State and Territory Acts which seek to mirror and complement the *Trade Practices Act* 1974.<sup>1</sup>

Medical and scientific equipment and other products are treated alike by this legislation, hence, a detailed review of such legislation falls beyond the scope of this inquiry.

However, there is specific legislation that applies to certain medical equipment described as therapeutic (or medical) devices — the Commonwealth *Therapeutic Goods Act* 1989. The next section explores the rationale for this ancillary regulatory control. The rest of the appendix outlines how the Act is administered to control medical devices.

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<sup>1</sup> For the rest of the appendix State refers to State and Territory.

**Box D.1 History of medical device regulation**

Last century and early this century, a number of products which were claimed to be 'therapeutic' proved to be dangerous or ineffective. Many individuals were defrauded, and many others became ill or died as a result of purchasing 'patent medicines'. The resulting community pressures in developed countries led to the introduction of preventative regulatory controls of therapeutic goods — including medical devices.

In most countries, the regulation of medical devices lagged behind the regulation of food and pharmaceuticals. For example, in the US medical devices were not regulated until the *Federal Food, Drug and Cosmetic Act* 1938 despite the regulation of food and drugs from the turn of the century. Against opposition from industry and advertising interests, this Act took five years in the American congress before it was passed. It only became law on 30 June 1938, after an incident in which more than 100 people died from a poisonous 'Elixir of Sulphanilamide'.

Amendments increasing the Act's coverage of medical devices were made in:

- 1976, after deaths related to defective pacemakers and heart valves. Medical Device amendments were enacted to insure the safety and effectiveness of medical devices by subjecting 'critical' devices to controls similar to those for pharmaceuticals; and
- 1990, to (amongst other changes) correct problems noted with the implementation and enforcement of the 1976 amendments.

Since 1976, medical devices made or sold in the US have been subject to a comprehensive system of pre-market testing, auditing of manufacture and post-marketing surveillance.

In Australia, medical device regulation also trailed the development of pharmaceutical regulation. Not until August 1984 did the Commonwealth Government begin a Medical Device Program, by establishing a national register of medical devices sold in Australia. Initially, registration did not involve evaluation or approval for sale. In February 1987, the Medical Devices and Dental Products Branch of the Department of Health began to require pre-market evaluation for a small number of 'critical' devices.

The Commonwealth Government introduced a comprehensive framework for the regulation of medical devices by passing the *Therapeutic Goods Act* 1989 (which repealed the *Therapeutic Goods Act* 1966). This legislation provides for pre-market testing and evaluation of registerable devices and approval of listed devices, as well as monitoring and auditing of manufacture, and post-marketing tracking and investigation of reported problems.

Sources: FDA 1992, sub. 16 and IAC 1987

**D.2 Rationale for regulating medical devices**

In the United States (US), medical devices have been subject to increasing regulatory control over the last fifty years. In Australia, medical device regulation is more recent (see Box D.1).

The danger to health and safety from poor design or manufacture, or inappropriate use of potentially dangerous goods, such as medical devices, forms the main rationale for subjecting these types of goods to preventative regulation.

The high level of risk associated with some medical devices distinguishes them from many other products which have little or negligible risk associated with them. New products from these low risk product groups are also expected to be safe. The benefits gained, in terms of timeliness and lower product costs, of allowing low risk products to be marketed without a pre-market approval process or without monitoring of their manufacture, far outweigh the costs imposed by an occasional dangerous or defective product. Moreover, for most manufacturers, common law remedies, the *Trade Practices Act* and a desire to maintain a good business reputation provide powerful incentives against knowingly marketing dangerous or defective products.

In some developed countries, tragedies related to dangerous products (including tragedies related to medical devices) have contributed to public demand for comprehensive controls of such products.

Widespread demand for regulatory control, whether rationally based or not, is another rationale for regulation. Unsatisfied public demand for regulation can limit the development of a market. Confidence in, and knowledge about, a product may be increased when a credible system of regulation is instituted. Such a system — whether supplied by a government or non-government body — can increase a product's economic value.<sup>2</sup>

### **D.3 The approach to medical device regulation**

The Commonwealth's *Therapeutic Goods Act 1989* (the Act) provides for regulatory control of therapeutic goods. The Act's intent is:

... to provide, so far as the Constitution permits, for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia, whether the goods are produced in Australia or elsewhere (*Therapeutic Goods Act 1989*, s4).

In this context, the four goals of quality, safety, efficacy and timely availability are centred around balancing the risk of allowing a dangerous product (or at least one that fails to offer a net benefit) on to the market against the risk of preventing or delaying a beneficial product from being marketed.<sup>3</sup>

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<sup>2</sup> Certification by a government or non-government regulatory authority can increase the willingness of potential customers to buy therapeutic devices.

<sup>3</sup> The goal of timely availability was added to the Act following the Baume Report (1991) on the future of drug evaluation in Australia. The Report also recommended, in relation

Therapeutic goods are divided by the Act into drugs and medical devices (see Box D.2). Most of the Act applies equally to drugs and devices. The definition of therapeutic goods also includes goods for animal use. However, the Act provides for no controls over therapeutic goods for animal use, except for compliance with relevant standards to ensure quality. Elsewhere in this appendix, where therapeutic goods are referred to, they refer only to therapeutic goods for human use.

**Box D.2     Defining medical devices**

Therapeutic goods are defined broadly in the Act as anything used for the prevention, diagnosis or treatment of diseases and other bodily conditions, such as pregnancy, in humans (or animals). These goods are divided into two classes — drugs and medical devices (TGA 1992).

For the purposes of the Act, medical devices are:

... therapeutic goods consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with software required for proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in its function by such means ... (*Therapeutic Goods Act 1989*, s3).

Medical devices include: implants (such as heart valves, intra-ocular lenses, hip joints, dental materials and intra-uterine contraceptive devices); anaesthetic equipment; X-ray equipment; magnetic resonance imaging equipment; drug infusion pumps; syringes; bandages; catheters; examination gloves; in-vitro diagnostic kits; condoms; contraceptive diaphragms; stethoscopes, and so on.

The Act is administered by a division of the Department of Health and Family Services (DHFS) — the Therapeutic Goods Administration (TGA). The TGA takes as its objective:

To ensure the safety, quality, and efficacy of therapeutic goods available in Australia at a standard equal to that of comparable countries, and that pre-market assessment of therapeutic goods is conducted within a reasonable time (sub. 16, p.1).

There are seven branches of the TGA, each of which undertakes a number of activities in pursuit of these objectives. Table D.1 provides a description of each branch and the activities it undertakes.

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to the evaluation of new chemical entities: that the TGA should guarantee evaluation fees; that fees should be increased by 20 per cent to enable it to do so; and that manufacturers should gain a 25 per cent fee reduction where there was a failure to meet the guaranteed time.



The TGA's system of regulatory control involves:

- *pre-market evaluation or assessment of medical devices* — the evaluation and assessment of medical devices is coordinated by the Conformity Assessment Branch with testing undertaken by the TGA Laboratories Branch and outside laboratories (see Table D.1);
- *periodic monitoring of the quality and consistency of manufacturing processes and the commercial products* — this is undertaken by the Conformity Assessment Branch which also uses the services of the TGA Laboratories Branch and outside laboratories;
- *monitoring compliance with advertising, labelling and presentation standards*;
- *post-marketing surveillance and the investigation of therapeutic goods problems* — the monitoring of compliance with the Act is conducted by the Surveillance section of the Business and Services Branch;
- *disseminating information about drug and device problems through 'alerts', facilitating corrective actions and recalls* — the TGA has a computer tracking system for devices and coordinates with State Departments of Health to monitor corrective actions and recalls as necessary; and
- *investigation of offences and the preparation of cases for prosecution under the Act* — this is carried out by the Surveillance section of the Business and Services Branch.

Before therapeutic goods are manufactured or supplied within Australia, they must be either registered or listed on the Australian Register of Therapeutic Goods (ARTG).<sup>4</sup> The system of exemptions is explained in Box D.3.

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<sup>4</sup> Except for exempt persons or, for exempt or excluded goods, a 'registerable' therapeutic good or a 'listable' drug must appear on the ARTG, or it is an offence to 'knowingly or recklessly supply' the good.

Table D.1 Organisational structure of the Therapeutic Goods Administration

BUSINESS & SERVICES BRANCH	CHEMICAL & NON PRESCRIPTION DRUG BRANCH	TGA LABORATORIES BRANCH	CONFORMITY ASSESSMENT BRANCH	DRUG EVALUATION & SAFETY BRANCH
<b>Legal</b> Provides legal advice. <b>Business Management Unit</b> Financial management & control. <b>Executive Support</b> Provides corporate services to TGA <b>Information Technology &amp; Services</b> Coordinates TGA IT activities, library and consumer information services. <b>Surveillance</b> Monitors compliance with TGA legislation, prepares cases for prosecution.	<b>Non prescription Drugs</b> Export control of drugs. Registers non prescription drugs. <b>National Drugs and Poisons Schedule</b> Technical and administrative support to NDPSC and maintains the Standard for Uniform Scheduling of Drugs and Poisons. <b>Chemical Product Assessment</b> Manages AgVet chemical registration processes, provides toxicological assessments and maintains publications on Standards and label directions <b>Chemical Review and International Harmonisation</b> Provides policy advice on national/international chemicals regulation and provides toxicological assessments and advice	<b>Administration/Workshop</b> Receipt and storage of sampling. Provides branch administrative support. <b>Animal Services</b> Supplies animals for laboratory testing program. <b>Microbiology</b> Tests vaccines, medicines, biologicals & medical devices for microbiological/sterility quality Evaluates new vaccines & sterile goods applications. <b>Chemistry</b> Quality and safety testing of antibiotics, evaluates new antibiotics & tests & evaluates pharmaceutical products. <b>Molecular biology</b> Tests & evaluates biological products. Tests viral vaccines. <b>Immunobiology</b> Tests and evaluates vaccines and immunobiological. Tests and evaluates endotoxin content. <b>Biomaterials &amp; Engineering</b> Operates problem reporting scheme. Develops and validates test methods and standards. <b>Workshop</b> Repairs, maintains and constructs lab equipment and facilities.	<b>Registration &amp; International Liaison</b> General enquires and information provision. Prepares legislation & regulatory guidelines. Secretariat to Therapeutic Device Evaluation Committee (TDEC). Standards Australia / TGA coordination. Provides administrative and systems support. <b>Secretariat &amp; Recalls</b> Coordinates recalls and investigates problem reports for drugs. Implements advertising controls and provides NCCTG secretariat support. Secretariat support for TGC and its subcommittees. <b>Medical devices</b> Reviews and coordinates applications for registration and listing and approves supply. Carries out technical evaluations. <b>GMP Audit &amp; Licensing</b> Carries out GMP audits and licensing of manufacturers. <b>Clinical</b> Operates clinical trial and special access schemes. Evaluates and advises on clinical aspects of devices.	<b>Evaluation Units (4 separate sections)</b> Approvals for new drugs and variations of registered drugs. Product information review. Approvals of Special Access Scheme (SAS) drugs <b>Pharmaceutical Chemistry Evaluation</b> Evaluates pharmaceutical chemistry data (including bioavailability) for registration of new drugs, variations to registered drugs and clinical trial use. <b>Drug Toxicology Evaluation</b> Evaluates toxicology data for registration of new drugs, etc. <b>Coordination Unit</b> Administrative & systems support. Maintains a drug information tracking system. Receives & logs applications for registration, variation, notification and clinical trial use of drugs. Performs budgeting & personnel functions <b>Adverse Drug Reactions</b> Processes reports of adverse drug reactions. Secretariat support to Adverse Drug Reactions Committee (ADRAC). Contributes data to WHO collaborating centre. <b>ADEC Secretariat</b> Secretariat support to Australian Drug Evaluation Committee (ADEC) and its subcommittees.

Source

TGA news, Issue 22, October 1996

Medical devices are divided by regulations into several ‘groups’. These groups are arranged into one of two divisions to allow devices to be placed on the Australian Register of Therapeutic Goods (ARTG) as either ‘registered’ or ‘listed’. ‘Registered’ devices are more risky and include, for example, heart valves. ‘Listed’ devices are less risky and include, for example, ultrasonic devices. If a medical device of new technology does not belong to a registered group it is automatically classed as listable unless the legislation is amended.

**Box D.3      Exempt medical devices**

Goods, that might otherwise be considered therapeutic goods, can be declared not to be therapeutic goods under Section 7 of the *Therapeutic Goods Act* 1989. The Secretary of the Department of Health and Family Services can declare whether goods are or are not therapeutic goods, or that goods are or are not therapeutic goods when they are used or labelled in a particular way. These declarations are published in the Commonwealth Gazette.

Medical devices that have not been declared exempt may be given exemptions for special and experimental uses, either by the Secretary, under the *Therapeutic Goods Regulations*, or through an approval process. These uses include personal imports (covered by Schedule 5 of the *Regulations*), products on a Clinical Trial Notification scheme (CTN) (Schedule 5A) or on a Clinical Trial Exemption scheme (CTE), products that have Authorised User Access (AUA) and products for individual patient use (which are all covered by Section 19 of the Act and Section 12B(4) of the *Regulations*).

Under the provisions of the Act, the *Therapeutic Goods Regulations* and *Therapeutic Goods Orders* that are provided for by the Act, the TGA uses a system of licensing, registration, auditing, testing and pre-market evaluation to ensure that therapeutic goods:

- have appropriate sponsors (see Box D.4);
- are either listed or registered on the ARTG;
- comply with advertising controls;
- comply with relevant standards or Therapeutic Goods Orders;
- are manufactured according to the Good Manufacturing Practice (GMP); and
- have been manufactured by those licensed to do so, where the relevant goods are manufactured in Australia (see Box D.4).

**Box D.4 Sponsors and licensing**

Under the *Therapeutic Goods Act* 1989, if a person is (or intends to be) responsible for a therapeutic good (or device) being imported, manufactured, exported or modified for supply then person is called the ‘sponsor’ of the therapeutic good. Unless exempted, before a therapeutic good may be legally supplied in Australia or exported from Australia it must be listed or registered on the Australian Register of Therapeutic Goods. The sponsor is responsible for listing or registering the product on the ARTG.

Except for exempt persons and exempt or excluded goods, therapeutic goods manufactured in Australia can only be manufactured by a licence holder in licenced premises. The sponsor and licence holder need not be the same person. Manufacture, in this context, includes processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for sale, of the goods or of any component or ingredient of the goods as part of that process.

Licensing is a means of ensuring that therapeutic goods are manufactured to high standards of quality to avoid the harm likely to occur if they are ineffective or unsafe. To obtain and keep a licence to manufacture a therapeutic good, it is necessary to permit regular factory audits conducted by the TGA which assesses compliance with manufacturing principles.<sup>5</sup> If therapeutic goods are produced overseas, the sponsor must provide evidence that the goods were produced in accordance with appropriate codes of Good Manufacturing Practice or have the overseas factory submit to regular audits by the Conformity Assessment Branch.

In addition, the regulatory framework provides for:

- export certification of export-only products when importing countries require this certification; and
- approvals for individual patient’s or specialist’s use of products, not included on the ARTG but otherwise not exempt from the Act’s provisions.

On the basis of past experience, therapeutic goods (including devices) are divided into high risk and low risk products, and products exempt from the ARTG. Low risk products (which include medical devices in Schedule 4) are assessed (but not evaluated) for quality and safety, and when approved, are listed on the ARTG.<sup>6</sup> High risk products (which include medical devices in Schedule 3) having been categorised as potentially dangerous, are evaluated for quality, safety and efficacy and, if approved, are registered on the ARTG (see Figure D.1).

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<sup>5</sup> Manufacturing principles are determined by the Minister of Health and Family Services according to Section 36 of the Act and differ according to the type of product being produced.

<sup>6</sup> The assessment does not involve testing of a therapeutic device. Instead, it involves checking of documentation — for example, to ensure that it has been produced in accordance with appropriate Codes of Good Manufacturing Practice.

Essentially, this means that low risk products are expected to be produced to a certain standard of quality which will assure their safety. They are also expected to satisfy their therapeutic claims. The assessment procedure for listed medical devices is relatively limited. The sponsor has to provide the TGA with product and manufacturing information, but the products do not have to undergo pre-market evaluation before supply. In addition to checking quality of manufacture and assessing therapeutic claims, a high risk product is evaluated to ensure that the risks or side-effects associated with the product are more than offset by therapeutic benefits.

#### **D.4 The national system of controls**

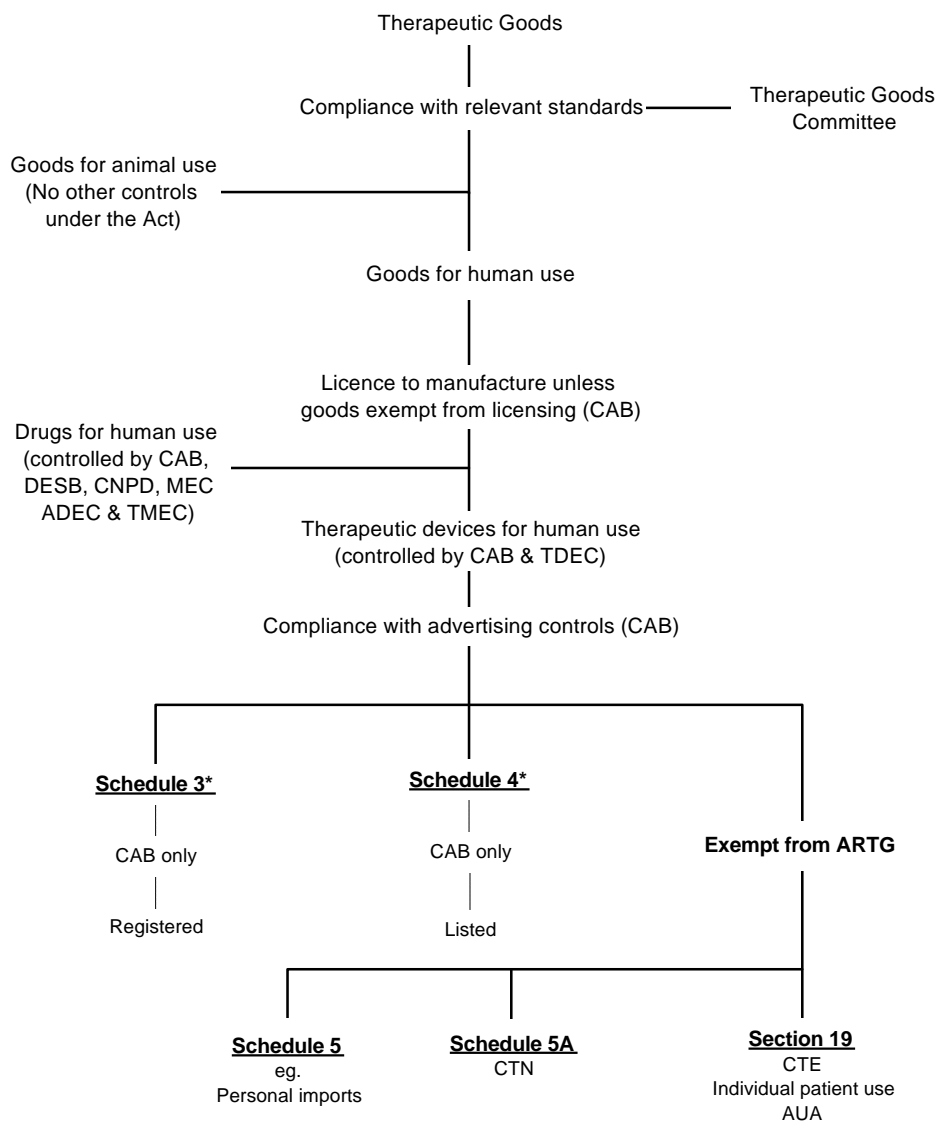
The Commonwealth's *Therapeutic Goods Act* 1989 was intended to provide for a uniform national system of controls over therapeutic goods — so far as the Constitution permits. The coverage is limited by the Commonwealth's constitutional powers which extend to corporations, and interstate and international trade and commerce, but do not extend to individuals or unincorporated enterprises operating solely within a state.

To allow for a fully comprehensive national system of control, the States and Territories agreed in 1992 to pass legislation complementary to the Commonwealth Act (IC 1996c). As of December 1996, only Victoria and New South Wales (NSW) have implemented this agreement.

In its report on the Pharmaceutical Industry (IC 1996c), the Commission endorsed the approach of the NSW legislation which adopts the Commonwealth's *Therapeutic Goods Act* 1989 by reference.

This approach is a simple and most efficient means of providing for the intended cooperative, national and uniform system of regulation of therapeutic goods. This approach was also favoured by the former Commonwealth Department of Human Services and Health (now the DHFS) because it avoids delays in adopting future amendments of the Commonwealth Act.

**Figure D.1 Main categories of control of medical devices under the *Therapeutic Goods Act 1989***



**Abbreviations**

ADEC = Australian Drug Evaluation Committee	CTE = Clinical Trial Exemption Scheme (Devices)
ARTG = Australian Register of Therapeutic Goods	DESB = Drug Evaluation & Safety Branch
AUA = Authorised User Access	MEC = Medicines Evaluation Committee
CAB = Conformity Assessment Branch	TDEC = Therapeutic Devices Evaluation Committee
CTN = Clinical Trial Notification Scheme	TMEC = Traditional Medicines Evaluation Committee
CNPD = Chemicals and Non Prescription Drugs Branch	

\* Also Schedule 6 registerable or listable devices.

Source: sub. 16

## Policy coordination and standard setting

The TGA uses a number of instruments to regulate therapeutic goods in Australia (see Box D.5).

### Box D.5 Commonwealth regulatory instruments

Therapeutic goods are regulated by a range of Commonwealth instruments.

- The *Therapeutic Goods Act* 1989 provides for Commonwealth licensing of individual manufacturing premises, the production of data demonstrating efficacy and safety of human use and introduced compulsory listing of all except exempt or exempted medical devices.
- The ARTG, established under the Act, comprises an inventory of all therapeutic goods (not otherwise exempt or excluded) that are imported, exported, manufactured or supplied within Australia.
- *Therapeutic Goods Regulations* are authorised by the Act. Current regulations include references to advertisements, patient information, establishing committees and fees, costs and charges. Schedules to the Regulations divide medical devices into those which must be listed and those which must be registered in the ARTG.
- *Therapeutic Goods Orders* may be made by the Minister under Section 10 of the Act. Matters specified in an Order constitute a standard for therapeutic goods.
- Various Australian Standards and Pharmacopoeia monographs are given status, by reference, in *Therapeutic Goods Orders*.
- The TGA has issued *Guidelines for the Registration of Therapeutic Devices* (DR3).
- The TGA also issues the *Australian Device Groups* — a list of names for medical devices which standardises the terminology for data entry.
- The Proprietary Medicines Association of Australia (PMAA) Code of Practice for marketing therapeutic goods to medical practitioners and other health professionals, is approved by the Australian Competition and Consumer Council. The PMAA is a delegate of the DHFS for the purposes of approving certain broadcast advertisements under this Code.

Source: sub. 16

Therapeutic goods which must appear on the ARTG (if they are to be supplied in Australia) are first categorised according to schedules established under the *Therapeutic Goods Regulations*. Therapeutic goods are subject to various controls on advertising, labelling and ‘presentation’ (described in Section D.5) including the Therapeutic Goods Advertising Code and a code that governs the

manner in which they are marketed to health professionals — the Proprietary Medicines Association of Australia (PMAA) Code of Practice.<sup>7</sup>

According to their grouping, therapeutic goods must also comply with appropriate standards before they are included in the ARTG. The primary instrument for setting these standards is *Therapeutic Goods Orders* (TGOs). TGOs are made by the Commonwealth Minister for Health and Family Services under Section 10 of the Act. TGOs usually make reference, and give legal status to, an Australian or international standard — for example, a British Pharmacopoeia monograph, or a standard developed by Standards Australia, the International Standards Organisation (ISO) or by Institutional Ethics Committees. An agreed goal of Commonwealth and State governments, wherever possible, is to harmonise standards with suitable overseas standards.

In developing appropriate Australian standards for therapeutic goods, the Minister is advised by a number of health committees and councils which coordinate the views of independent specialist experts, the Commonwealth and State health departments, health professionals, the health industry and consumers (see Box D.6).

The Therapeutic Devices Evaluation Committee (TDEC) is the principal committee for advising the Minister on issues related to medical devices. This committee — which includes professional, consumer and industry representatives, and has a number of specialist sub-committees — also provides advice on medical device policy.

Another important advisory committee, which meets two times a year to review issues relating to controls over therapeutic goods, is the National Coordinating Committee on Therapeutic Goods. This committee is comprised of representatives of State and Commonwealth health departments and reports to the Australian Health Minister's Advisory Council.

## **D.5 Stages of device regulation**

Medical devices, whether manufactured locally or imported, are regulated in four stages. When they are:

- *first introduced into Australia* — pre-market evaluation and assessment;

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<sup>7</sup> 'Presentation' means the manner in which therapeutic goods are packaged and made available for sale or supply.



### **Box D.6 Policy oversight, coordinating and regulating organisations and committees**

The **Department of Health and Family Services** (DHFS) is the Commonwealth department primarily responsible for the national system of therapeutic goods regulation. DHFS also acts as secretariat to various committees and councils that participate in coordinating and developing this system, including the following six.

The **Australian Health Ministers' Advisory Council** is made up of officials from Commonwealth, State and New Zealand Health Departments. The purpose of the Council is to advise health ministers on appropriate coordinated health policies.

The **National Coordinating Committee on Therapeutic Goods** comprises representatives from Commonwealth and State health authorities and makes recommendations to the Australian Health Ministers' Advisory Council. An observer from New Zealand also participates on the Committee.

The **Therapeutic Goods Committee** is a committee established under the *Therapeutic Goods Regulations*. It comprises an independent body of experts who advise the Commonwealth Minister of Health and Family Services on standards for therapeutic goods including labelling, packaging and appropriate manufacturing principles.

The **Therapeutic Devices Evaluation Committee** (TDEC) is a committee established under the *Therapeutic Goods Regulations*. The Committee advises the Minister and the Secretary of Health and Family Services on policies and priorities related to the safety, quality, efficacy and timely availability of medical devices, and develops guidelines to maximise the effectiveness and efficiency of the devices program.

The **Australian Health Technology Advisory Committee** is a standing committee of the National Health and Medical Research Council and evaluates health technologies and highly specialised services looking at safety, effectiveness, efficacy, cost, equity, access and impact.

The **Industry–Government Consultative Committee** comprises representatives from industry, one from the Department of Finance, one from the Department of Industry, Science and Tourism and two representatives from the TGA. It reports to the Commonwealth Minister of Health and Family Services, reviews the financial outlays and performance indicators of the TGA, and comments on the size of the TGA's budget and pattern of fees and charges.

Other relevant bodies include:

The **Therapeutic Goods Administration** (TGA) is a division of the DHFS and acts as the national therapeutic goods control authority.

The **Conformity Assessment Branch** is a branch of the TGA and part of its responsibilities is to act as a secretariat to the TDEC.

**Institutional Ethics Committees** approve the conduct of clinical trials by their institution or organisation (which operate in accordance with guidelines issued by the National Health and Medical Research Council).

- *manufactured* — verifying compliance with appropriate manufacturing principles;
- *marketed* — compliance with *Therapeutic Goods Orders* and codes governing advertising, labelling and presentation; and
- *used and problems occur* — post-market monitoring and recall procedures.

### **Pre-market evaluation and assessment**

Sponsors wishing to have a device included in the ARTG have to pay an application fee. If the device is registrable they also must pay an evaluation fee. In addition, an annual fee is charged for a device to remain on the ARTG (see Box D.7).

#### **Box D.7 Fees for registration and listing**

Application fees for a new registrable device to be registered on the ARTG vary from between \$380 to \$1300 per device.

The evaluation fee for a new high level registrable device varies from between \$23 800 to \$28 800. For low level registrable devices, the pre-market evaluation is not as detailed and the fee is \$2200. The fees are also lower for new devices which are a variation of a device already registered. They range from between \$2900 to \$17 000 for high level registrable devices and are \$500 for a low level registrable device.

The application fee for a listable device is \$200 and there is no additional fee for the assessment.

In addition, there are annual fees to keep a product on the ARTG — they are \$350 for registered devices and \$200 for listed devices.

Most medical devices introduced into Australia are listable devices and are placed on the ARTG with a brief assessment of quality and safety (for most devices, efficacy is not assessed). Only a small number of medical devices are registrable devices and must sustain a detailed pre-market evaluation for quality, safety and efficacy before being placed on the ARTG.

At 18 December 1996, there were 423 registration entries for 1253 registered device products, and 7901 listing entries for 20 929 device products. However, the number of individual items represented by these entries is considerably higher (sub. 16).

To have a device included in the ARTG, sponsors of listable devices have to provide the TGA with product information. The product must also comply with

TGO 37 (which covers labelling of medical devices), other applicable TGOs and relevant sections of the Therapeutic Goods Advertising Code.

If a product is a registerable device, in addition to the requirements for a listable device, the product undergoes a pre-market evaluation. Registrable devices are further categorised as 'high or low level registerable', according to the extent of evaluation required before they can be put on the ARTG. These categories are also broadly correlated with level of risk. Typically, high level registered devices, for example pacemakers, are based on insufficiently proven or new technology. Low level registered devices include products of proven technology, like disinfectants or barrier contraceptives.<sup>8</sup>

Evaluating a registrable device can involve examining data the sponsor has supplied on the device's:

- design, materials and testing;
- manufacture and quality control;
- bio-compatibility and pre-clinical tests; and
- human clinical trials.

In cases where some aspects of a device or its manufacture are the same as a device that is already on the register, only partial evaluation may be considered necessary. This process is expedited by the TGA's recognition of various decisions by overseas regulatory authorities. The DHFS stated that:

Some formal and informal GMP agreements, and agreements for exchange of evaluation reports, exist with other regulatory agencies and independent certification bodies. (sub. 16, p.12)

and that:

... the principles of the European Directives are being adopted as far as permitted under existing legislation. In the longer term, and following appropriate consultation, it is hoped to align Australia's existing legislation with the European system ... (p.8)

Furthermore:

It is anticipated that most devices will eventually enter Australia with the conformity assessment having already been undertaken in Europe or USA. (p.13).

Where a device is registerable and clinical data is not available clinical trials may be necessary (see Box D.8).

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<sup>8</sup> Disinfectants and barrier contraceptives, which are used to prevent the spread of viruses and bacteria are registrable because of the risk involved if they fail in use.

**Box D.8 Clinical Trial Exemption**

Clinical trials for medical devices may be approved under the Clinical Trial Exemption (CTE) and Clinical Trial Notification (CTN) schemes. Exemption from registration on the ARTG may be granted by the Secretary of the DHFS so a device may be supplied for experimental use in humans.

Under the CTE scheme, the comprehensive information that must be submitted to the TGA for an exemption includes: the name and details of the sponsor; extensive details of the device including its intended purpose and the principles of its operation; and the major processes of its manufacture and the extent of compliance of manufacture with GMP. Thorough details of the planned trial also need to be provided, such as, detailed descriptions of each proposed test with appropriate references and a detailed clinical plan of investigation.

Devices subject to the CTN scheme do not require the Secretary's approval but must meet certain conditions to qualify for exemption. The device must be approved by an Institutional Ethics Committee and the TGA must be notified. The Secretary has the power to stop a trial under the CTN scheme should there be a safety concern.

**Ensuring the quality and consistency of manufacture**

The principal way that the TGA ensures the quality and safety of many critical devices is by 'auditing' manufacturers for compliance with appropriate manufacturing principles. If there is compliance with these principles an Australian manufacturer may be issued a licence on payment of a fee (see Box D.9).

**Box D.9 Fees and charges for licences and audits**

The current charge for an audit of a local manufacturer of 'single step' devices, or ingredients or components, is \$1400 for the first four hours and \$450 every two hours thereafter. These local manufacturers also pay a licence fee of \$2400 a year.

The majority of manufacturers carry out more than one of the above activities and are charged at higher rates. Audits of these manufacturing sites cost \$2700 for the first four hours and \$800 for every two hours thereafter. The licence fee for these local manufacturers is \$4700 a year.

In the absence of suitable evidence of compliance an overseas manufacturer is audited. For overseas manufacturers of 'single step' devices, or ingredients or components, the audit fee is \$1800 for the first four hours and \$600 for every two hours thereafter. Other overseas manufacturers are charged \$3400 for the first four hours and \$1100 for every two hours thereafter. In addition, the sponsor of any overseas manufactured device must pay transport, accommodation, salary, on-costs and other expenses for the TGA staff involved in travelling to the overseas manufacturing site.

Except for exempt persons, Australian manufacturers must be licenced to produce any medical device other than those exempted by Schedule 7 of the

*Regulations* (see Box D.10 for the exceptions). The licence relates to specific manufacturing premises and defines the sub-categories of goods, or manufacturing activities, to which it applies. It is an offence to manufacture medical devices (for human use) without a licence unless the manufacturer or goods are exempt.

**Box D.10 Classes of persons exempt from licensing**

Several classes of individuals are exempt from licensing:

- medical practitioners, dentists and other health care workers registered under state or territory legislation making goods for their own patients;
- pharmacists, biomedical engineers and radio-chemists within public hospital systems manufacturing goods for use within the hospitals in the same state or territory;
- pharmacists in their own retail shops, Friendly Society dispensaries and private hospitals, provided the goods are not sold by wholesale, but supplied from their premises; and
- alternative therapy practitioners making goods for private supply to their own clients; and persons who are adding a supplementary label to show their name and address or a product registration or listing number.

*Source:* *Therapeutic Goods Regulations*, Schedule 8

To obtain a licence, manufacturing premises are audited for compliance with ‘manufacturing principles’ specified in Therapeutic Goods (Manufacturing Principles) Determinations (TGDs). The Minister of Health and Family Services, on the advice of the Therapeutic Goods Committee, determines the manufacturing principles specified in the TGDs.

These ‘manufacturing principles’ mainly relate to:

- the manufacturing site’s building design, location and construction;
- methods of manufacture;
- qualifications and experience of staff employed;
- quality assurance and quality control used;
- documentation; and
- complaint handling.

Currently, the TGDs specify Codes of Good Manufacturing Practice. The manufacturing principles for therapeutic devices currently specify a single European standard for all devices (EN 46001 – *Application of EN29001 (BS5750: Part 1) to the manufacture of medical devices*). This standard is becoming the harmonised GMP requirement in all developed countries (sub. 16).

A licence is granted when the manufacturer's factory is audited and the audit confirms compliance with manufacturing principles. The manufacturer retains the licence while periodic on-site audits confirm continued compliance. Each audit involves a detailed evaluation of the factory's operations and procedures, and systems of quality control testing. After each audit the TGA issues a report to the manufacturer advising the assessment of the level of compliance and listing any deficiencies.<sup>9</sup>

The timing of audits is decided using a risk-based approach. Most are surveillance audits with the period between them varying from two months to one year (or longer in the case of high compliance). However, if the device is high risk and previous levels of conformance have been low, audits are conducted every two months until conformance improves. Full audits must take place every three years.

**Box D.11    Use of other countries' Good Manufacturing Practice audits**

For therapeutic goods (or components) imported into Australia, the TGA recognises suitable certification resulting from other countries Good Manufacturing Practice audits as equivalent to TGA certification. For medical devices, such certification is acceptable from:

- countries of the European Union;
- Japan;
- Sweden; and
- Switzerland.

Evidence of an acceptable US Food and Drug Administration (FDA) audit is also recognised.

Overseas manufacturers are not licenced but are subject to equivalent manufacturing requirements. If evidence of suitable compliance is provided the overseas manufacturer is neither audited nor charged (see Box D.11). When suitable evidence is not provided, the overseas manufacturer is audited by the TGA (at the sponsor's expense).

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<sup>9</sup> After the report is issued, there is an opportunity to correct misunderstandings, present data not available at the audit or debate interpretations.

## Advertising and labelling

Advertising of therapeutic goods, and goods in general, is covered by the *Trade Practices Act 1974* which states:

A corporation shall not, in trade or commerce, engage in conduct which is misleading or deceptive. (s52, Part V Consumer Requirements)

Advertising is also covered by some relevant State Acts, such as the NSW *Fair Trading Act* and the NSW *Therapeutic Goods and Cosmetics Act*.

In addition to these Acts, all therapeutic goods must comply with the *Therapeutic Goods Regulations* and the *Therapeutic Goods Advertising Code* of the Media Council of Australia which specify advertising, labelling and presentation requirements.<sup>10</sup>

Advertising restrictions include that:

- products supplied under the Special Access Scheme, devices under the Individual Patient Use scheme, therapeutic goods exempted subject to special conditions or otherwise granted approval by the Secretary of Health and Family Services for special or experimental purposes may not be advertised; and
- prescription-only therapeutic goods, or therapeutic goods that are 'restricted' to supply by pharmacists or medical, dental or veterinary practitioners, may not be advertised to the general public (this is prohibited by Commonwealth and State laws). Currently, there are only three 'restricted' medical devices — injectable silicones, injectable collagens and, injectable hyaluronic acid preparations or derivatives.

Most medical devices must have labels that comply with TGO No. 37, *General requirements for labels for therapeutic devices*.<sup>11</sup>

Restrictions are also placed on the 'presentation' of (most) therapeutic goods.<sup>12</sup> The way goods are presented is unacceptable if:

- it is stated or suggested that the goods have ingredients, components or characteristics which they do not have;

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<sup>10</sup> The *Therapeutic Goods Regulations* allow for a penalty of \$1000 for various failures to comply. The Therapeutic Goods Advertising Code of the Media Council of Australia has been authorised by the Trade Practices Commission and is also referred to by the *Therapeutic Goods Regulations*.

<sup>11</sup> Most drugs must comply with TGO No. 32, *General requirements for labels for therapeutic goods*.

<sup>12</sup> 'Presentation' means the manner in which therapeutic goods are presented for supply and includes the name of the goods and any advertising and other informational material associated with the goods (TGA 1992, p.31).

- the name applied to the goods is the same as a name applied to other therapeutic goods supplied in Australia and those other goods contain additional or different therapeutically active ingredients;
- the label of the goods does not declare the presence of all therapeutically active ingredients (devices do not generally have therapeutically active ingredients); or
- a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to supply of the goods in Australia.

The Therapeutic Goods Advertising Code which explains the process by which advertisements may be approved before publication may be obtained from the Advertising Section of the TGA's Compliance Branch.<sup>13</sup>

### **Post-marketing monitoring**

To ensure that problems with therapeutic goods are quickly identified and corrected, the TGA:

- conducts routine and targeted testing of products;
- monitors reports of adverse reactions and problems with devices; and
- coordinates the recall of unsafe products.

#### *Testing and monitoring problem reports*

Goods are selected for testing on the basis of history, therapeutic importance, consumer complaints and advice from the TGA's GMP auditors. Samples may be obtained from manufacturers, sponsors, or distributors or from retailers' premises. If a sample fails to meet official standards (but the failure is not serious enough to justify immediate recall) the sponsor is notified and given 21 days to respond. If the sponsor disagrees with the TGA's assessment an independent analyst may be appointed to re-test the sample.

Sponsors must report all adverse reactions, serious injuries or deaths that arise from, or are related to, the use of their registered or listed goods. Also, if an overseas authority initiates a regulatory action, such as a recall, against a good which is also used in Australia then the sponsor must immediately notify the TGA.

Sponsors and others — for example, doctors or patients — can report problems with medical devices by using the Therapeutic Device Problem Reporting

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<sup>13</sup> Also, the *Broadcasting Act* 1942 requires that advertisements relating to medicine have to be approved by the Secretary of Health and Family Services or his/her delegate.



Scheme's hotline. Problems with devices are reported in the Problem Reporting/Safety Alert section of the Therapeutic Devices Bulletin.

### *Recalls and non-recall actions*

In the event of a problem with a therapeutic good, the good may need to be recalled. This action is designated as either a:

- *Recall* — permanent removal of the good from supply or use; or
- *Recall for Product Correction* — temporary removal for repair, modification, adjustment or relabelling.

Recalls and recalls for product correction are also categorised as either urgent — where the hazard is significant — or routine.

In the past, goods subject to urgent recall have included:

- goods contaminated by toxic substances;
- non-sterile injections; and
- devices which did not perform correctly or which significantly deviated from specifications.

Reasons for routine recalls have included:

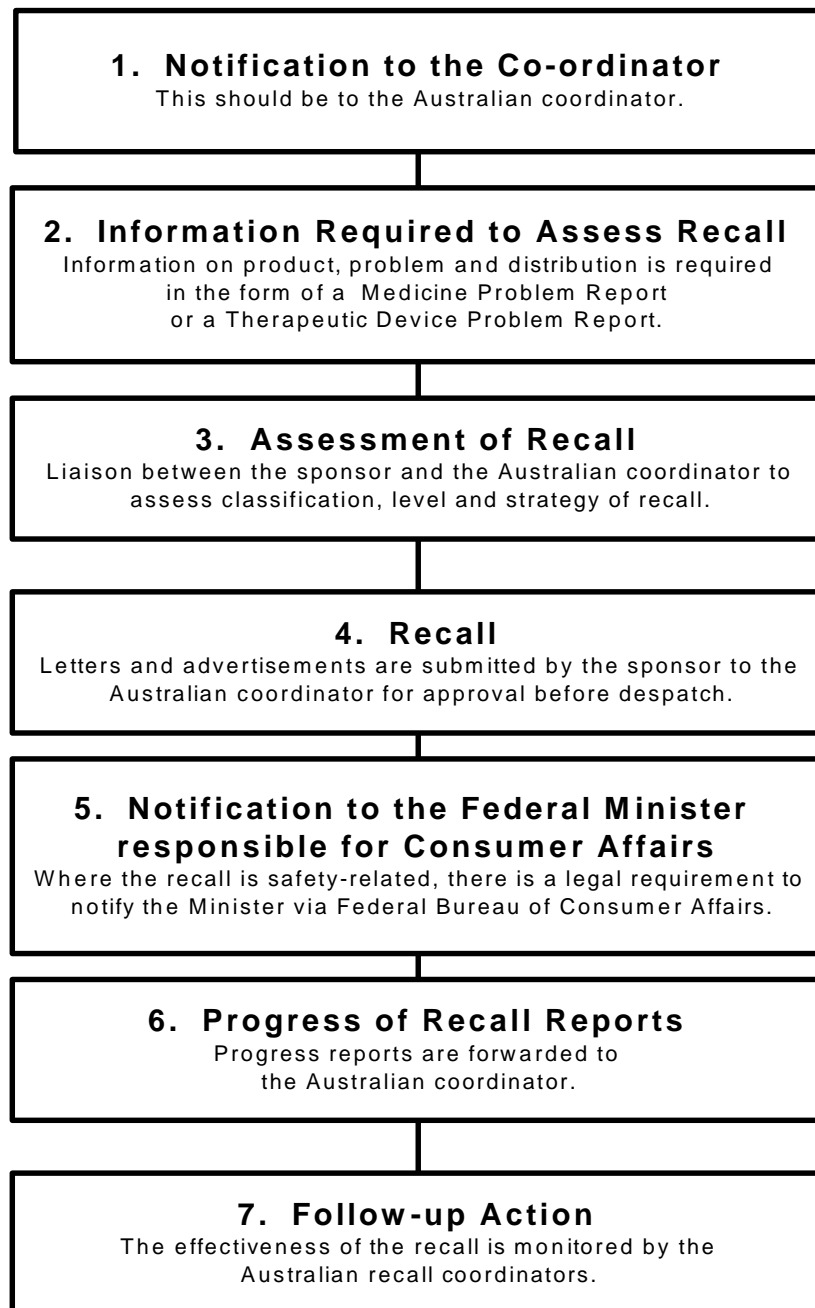
- minor labelling deficiencies;
- device corrections where minimal patient hazard existed; and
- contamination of goods with non-toxic substances.

Recalls (and recalls for product correction) may be initiated:

- as a result of reports from manufacturers, wholesalers, pharmacists, medical practitioners, biomedical engineers, dentists and patients;

**Figure D.2 The stages of the Uniform Recall Procedure for Therapeutic Goods**

## Recall Stages



Source: TGA 1994 p.4

- following analysis and testing of samples;
- on the advice of an Australian advisory committee — for example, the TDEC; or
- following a report from an overseas regulatory body —for example, the FDA.

The procedure used for recalls was developed by the Commonwealth and State government health authorities in agreement with the therapeutic goods industry and is called the Uniform Recall Procedure for Therapeutic Goods. The procedure specifies the actions to be taken by health authorities and sponsors when therapeutic goods need to be recalled (see Figure D.2). For other reasons a sponsor may initiate a non-recall action (see Box D.12).

### **Box D.12 Non-recall actions**

The four non-recall actions are:

- *Safety Alert*, which is intended to provide information on safe use and sponsors are encouraged to distribute alerts with the minimum of delay. A safety alert relates to advice regarding *a specific situation* where the therapeutic good (which continues to perform to all specifications and therapeutic indications) might present an unreasonable risk of substantial harm if certain specified precautions, in regard to its use, are not observed;
- *Product Notification*, which involves the issue of precautionary information about a device in a situation that is unlikely to involve significant adverse health consequences;
- *Withdrawal*, which involves a sponsor's removal of a therapeutic good from supply or use for reasons unrelated to its quality, safety or efficacy; and
- *Recovery*, which involves a sponsor's removal of therapeutic goods that have not left the direct control of the sponsor.

Source: TGA 1994

When a need for recall is established, the sponsor is responsible for recovery of the goods, or for the corrective action. The Commonwealth coordinator (TGA) assists by advising the sponsor of the procedure, notifying third parties and monitoring the overall action. Under 1986 amendments to the *Trade Practices Act 1974*, the Minister for Small Business and Consumer Affairs is empowered to take action where notification of safety-related recalls is not made, or where the safety-related recall has not been satisfactorily completed.<sup>14</sup>

<sup>14</sup> Where a recall is safety-related, a sponsor is legally required under Section 65R of the *Trade Practices Act 1974* to notify the Minister for Consumer Affairs within two days of

The Federal Bureau of Consumer Affairs (in consultation with the TGA), may conduct product recall audits in order to advise the Minister of Consumer Affairs that recalls have been satisfactorily completed.

When a recall is completed follow-up action is taken. The follow-up consists of a check on the effectiveness of the recall and remedial action to prevent recurrence of the problem. Remedial action may involve Good Manufacturing Practice audits of the manufacturer and a review of the product (TGA 1994).

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taking recall action. Under Section 65F of this Act they are also required to notify in writing, as soon as is practicable, overseas recipients of the recalled stock (with a copy of the notification going to the Minister within 10 days of sending).

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## **E IMPLICATIONS OF THE COMPETITION PRINCIPLES AGREEMENT**

A national approach to competition policy was approved by the Commonwealth, State and Territory governments in April 1995 following the Hilmer Report (1993).<sup>1</sup> The approach was designed to extend both the coverage and depth of the *Trade Practices Act* 1974 and establish a process to identify and remove impediments to competition throughout the economy. The Competition Principles Agreement is a key element of the reform package. This Agreement seeks to remove impediments to competition that would not be dealt with by the extended coverage of the *Trade Practices Act*.

An implication of the Competition Principles Agreement is that a review of the structure and functions of the Therapeutic Goods Administration (TGA) may be required:

- as a result of Australia's Mutual Recognition Agreement on conformance assessment with the European Union (EU); or
- in order to implement the Commission's recommendations to restructure the TGA and to introduce competition in the provisions of assessment services.

This is because the TGA is currently a public monopoly supplier of conformance assessment services.

### **E.1 Provisions of the Competition Principles Agreement**

The Agreement lists reforms necessary to put commercial activities of governments on equal terms with private businesses. These commercial activities are mostly undertaken by organisations referred to as Government Trading Enterprises (GTEs). Under the Agreement, to ensure equal terms for private businesses (which is known as 'competitive neutrality'), governments are required to:

- corporatise GTEs 'where appropriate';
- apply tax equivalent systems and debt guarantee fees;

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<sup>1</sup> The Hilmer Report was the report of the Independent Committee of Inquiry into National Competition Policy which was established in October 1992 to make recommendations on a national approach to competition policy.

- subject GTEs and core business activities of government agencies to the same environmental, planning and approval regulations as those which apply to private enterprises;<sup>2</sup> and
- review legislation that restricts competition.

In addition, the Agreement covers structural reform and prices oversight of GTEs, and the non-discriminatory access to essential infrastructure facilities.

## **E.2 Application of the Agreement to government–provided assessment services**

The issues that would need to be covered in a review of the TGA under the Competition Principles Agreement are detailed in Box E.1.

### **Box E.1 Structural reform elements of the Competition Principles Agreement**

Before any government privatises a public monopoly or introduces competition to a market traditionally supplied by a public monopoly, it must first undertake a review into the appropriate structure for the effected enterprise. Such a review must examine a number of issues, including the:

- merits of separating any natural monopoly elements from potentially competitive elements of the public monopoly;
- merits of separating potentially competitive elements of the public monopoly;
- most effective means of separating regulatory and commercial functions of the enterprise;
- appropriate commercial objectives for the enterprise;
- most effective means of implementing competitive neutrality principles;
- merits and most appropriate means of funding and delivering any mandated community service obligations;
- price and service regulations to be applied to the industry; and
- appropriate financial relationships between the owner of the public monopoly and the public monopoly, including the rate of return targets, dividends and capital structure.

*Sources:* Inter-governmental Agreement on Competition Principles, April 1995 and IC 1996d.

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<sup>2</sup> In its most basic form, corporatisation involves subjecting GTEs to corporations law. However, in practice it is usually accompanied by a range of initiatives such as providing management with greater autonomy, clear commercial objectives, and performance monitoring.

An aspect that may need further consideration in the review is the recent restructuring of the TGA. Part of the restructured organisation is planning to provide conformance assessment services (to the EU requirements) through a new business arm. However, it is not clear whether this restructuring will fully satisfy the requirements of the Competition Principles Agreement. For example, the commercial conformance assessment services have not been fully separated from the other activities of the TGA. The Competition Principles Agreement requires that such a structural separation must be considered.





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## **F MEDICAL DEVICE REGULATION IN THE EUROPEAN UNION**

Manufacturers of medical devices are selling in increasingly global markets. To gain entry to these markets their products must comply with many differing regulatory regimes. These regimes frequently create barriers to trade which delay the timely availability of medical devices and increase their cost.

Nevertheless, regulation of medical devices in all developed countries involves the same essential elements — pre-market evaluation, compliance by manufacturers with suitable manufacturing codes or practices, and post-market surveillance with procedures for alerts and recalls when problems arise.

To overcome unnecessary barriers, regulatory authorities in many countries are pursuing policies to harmonise their regimes to enable them to confidently endorse each others' decisions. The European Union's system of medical device regulation is the cornerstone of moves toward global harmonisation.

### **F.1 Global harmonisation**

In 1992 the European Union (EU) began sponsoring annual conferences on global harmonisation of medical device regulations. These conferences are now well attended by nations from all over the world (sub. 16, p.8).

One outcome of conference discussions is that many developed countries are in the process of harmonising their regulation of medical devices by moving toward the EU's system. As the Commonwealth Department of Health and Family Services (DHFS) noted:

... nations such as Canada, New Zealand, Israel, Japan and South Africa have all signalled their intention to move towards adoption of the European model.

In mid-1995, the United States FDA [Food and Drug Administration] announced that responsibility for decision making on low risk devices (Class I and II) would be delegated outside the Food and Drug Administration, and commenced setting up pilots. This will move the US, previously the nation with the most extensive system of device regulation based on pre-market control, towards the EU system. (sub. 16, p.8)

The DHFS also advised that Australia is harmonising its approach to medical device regulation more closely with the EU regulatory system to ensure consistency with most other developed countries. The department indicated that:

... initially the principles of the European Directives are being adopted as far as permitted under existing legislation. In the longer term, and following appropriate consultation, it is hoped to align Australia's existing legislation with the European system.<sup>1</sup> (sub. 16, p.8)

Harmonisation with the EU regulatory system will enable mutual recognition agreements to be signed without compromising product safety (see Box F.1).

### **Box F.1     Harmonisation and mutual recognition**

*Harmonisation* is the process of aligning two or more countries' regulatory systems so that they are more alike. Changes do not need to occur in both countries. A single country may harmonise with another simply by adopting the other country's standards and styles of regulatory control.

*Mutual recognition* is where two or more countries recognise a correspondence between certain types of regulatory decisions made by each other and formally agree to treat corresponding decisions as being equivalent to their own decisions. For example, decisions and certification (whether by competent government or private regulatory authorities), in regard to a manufacturer's compliance with an appropriate Code of Good Manufacturing Practice (GMP), are often mutually (or unilaterally) recognised within another country.

*Mutual Recognition Agreements* and unilateral recognition can eliminate a regulatory obligation for manufacturers and products to be re-assessed when manufacturers can provide documentation that they or their products have already met essentially the same requirements in another country.

Harmonisation, based around a mutually agreed regime, facilitates mutual recognition because it makes it easier for different regulatory authorities to determine that a decision made in another country is essentially equivalent to a decision made in their own jurisdiction.

A global system of mutual recognition agreements — which endorse regulatory decisions by a number of competent organisations in many countries — will foster international trade in medical devices and conformance assessment services.

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<sup>1</sup> In the October 1995 issue of the *Australian Therapeutic Device Bulletin* the Therapeutic Goods Administration indicated that 'Australia is looking to adopt the EU requirements into legislation ... Discussions are underway with all interested parties to try to achieve this within two years'. (pp.4–5)

## F.2 Regulation of medical devices in the European Union

A primary reason for the creation of the European Community and the EU was to facilitate free trade between member states (see Box F.2).<sup>2</sup>

### Box F.2 History and role of the European Union

The European Community was formalised by the *Treaty of Rome* 1957 to consolidate a Western European trading bloc. It comprised three different groupings: the European Economic Community (EEC); the European Coal and Steel Community — established earlier under the *Treaty of Paris* 1951; and EURATOM, the atomic power management, development and control community.

The *Single European Act* 1986 paved the way for the *Treaty of Maastricht* 1992, which replaced the three communities with a single EU.

In 1992, the EU and the European Free Trade Association signed a bilateral agreement to create a larger trading block.

The principles of the EU (and the EEC before it) include that there should be no barriers to the free movement of goods within the community. To eliminate non-tariff trade barriers, unified standards and assessment procedures were needed to certify the safety and quality of some products. The European Commission has achieved this by encouraging mutual recognition of some national standards, and by issuing Directives, Regulations and European Standards.<sup>3</sup>

The system of regulation for consumer protection, popularly known as the ‘CE mark’ has been developed by the European Commission as a means of aiding the free movement of goods within the EU. The system is known as the ‘CE mark’ after the mark affixed to conforming products. The CE mark indicates goods conform to mutually-agreed norms outlined in the European Commission Directives.

One way this has been achieved is by the reduction of tariff and non-tariff trade barriers. Non-tariff trade barriers — created by technical and regulatory differences — have been reduced by the introduction of the ‘CE mark’. This

<sup>2</sup> The EU is comprised of Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Denmark, Ireland, the United Kingdom, Greece, Portugal, Spain, Austria, Finland and Sweden.

<sup>3</sup> The European Commission is the executive branch of the EU and has 22 directorates to carry out EU legislation which has been approved by the EU Council of Ministers or the European Parliament. A Directive is a piece of legislation approved by a majority of a Council of Ministers of the EU and can be interpreted into existing national laws by passing necessary statutes and decrees. Directives usually involve a transition period. A Regulation is a piece of legislation which has been unanimously approved by a Council of Ministers and is binding on member states. Member states must put the terms of a Regulation in place immediately — repealing existing legislation if necessary.

system of certification assures the quality and safety of a wide range of products — including medical devices. CE marked products may be freely marketed in all EU member states. CE marked products are also automatically accepted by the European Free Trade Association countries.

### **Regulation of medical devices under the CE mark**

Before the creation of the CE mark, medical devices within the EU were subject to many different regulatory regimes.<sup>4</sup> Implementation of the CE mark for medical devices reduces compliance costs and facilitates EU-wide trade because a device is approved in single review process (see Box F.3).

#### **Box F.3 The CE mark**

The CE mark, or more properly EU Conformity Marking, is based on a range of procedures to ensure the conformity of a product to ‘essential requirements’. Medical devices are but one product covered by the CE mark. Compliance with relevant European Commission Directives is assessed by ‘Notified Bodies’ based on one or more of eight procedures:

- internal production control;
- EU type examination;
- conformity of type;
- production quality assurance;
- product quality assurance;
- product verification;
- unit (or batch) verification; and
- full quality assurance.

If compliance is satisfactory, a Declaration of Conformity is established and verified by a Notified Body, and a CE mark may be affixed to the product. Directives affect the design, manufacture, placing on the market, entry into service or use of a product with the purpose of ensuring consumer safety, protection and public health.

The European Commission issues Directives as a means of coordinating the implementation of the CE mark. At the EU level, the Directorate General for Industry is responsible for implementing the medical device Directives. The Directives specify that a member state may not create obstacles to the marketing of a CE marked device within its territory.

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<sup>4</sup> In some countries, medical devices were not regulated at all.

## Directives

The European Commission's Directives are issued to ensure that products are sufficiently well designed and built so that they will be fit for the purpose for which they are sold, and to ensure that reasonable precautions have been taken to protect the user against injury while the product is being used.

The first specific 'Medical Devices' Directive was the Active Implantable Medical Devices Directive which covers all powered medical devices implanted and left in the human body (a draft was released in 1991). The second of the Medical Devices Directives, which was simply (but confusingly) called the Medical Devices Directive, was released in 1993. This Directive regulates most other medical devices — from bandages to diagnostic X-ray machines. The latest Medical Devices Directive is the draft In-Vitro Diagnostic Medical

### Box F.4 Medical Device and other relevant Directives

The Medical Device and related Directives that have been issued by the European Commission to achieve the aims stated above are:

- 90/385 **Active Implantable Medical Devices Directive (AIMDD)** for all powered implants or partial implants that are left in the human body, including essential non-powered components, software and ancillary hardware;
- 93/42 **Medical Devices Directive** for most other devices ranging from bandages, tongue depressors and insertion thermometers through to bone replacements and prostheses;
- *draft In-Vitro Diagnostic Medical Devices Directive* for any medical device, reagent, reagent product, kit, instrument, apparatus or system which will be used in-vitro for examining samples from the human body;
- 89/336 *Electromedical Compatibility Directive* incorporating *Electromedical Devices Directive* 84/539;
- 93/86 *CE Marking Directive* ;
- 92/59 *General Product Safety Directive*;
- 93/39 amending Directive 65/65 for human medicines — potential involvement if a medicinal product is included in a device; and
- 93/41 replacing Directive 87/22 for 'high-tech biotech' products — potential involvement if a biotechnology product is included in a device.

Source: sub. 16

Devices Directive. It covers any item to be used for the examination of substances derived from the human body. This Directive is expected to come into effect in 1997 and be fully implemented by 1998.

*Medical devices classified according to risk*

The Medical Devices Directive, which covers most medical devices, establishes four categories of devices. No pre-determined lists are published. Manufacturers classify their devices — on the basis of the intended use — into these risk classes by following the decision rules published in Annex IX of the Medical Devices Directive.

**Box F.5      Risked based categories of medical devices**

There are four classes of medical devices under the Medical Devices Directive.

- **Class I** devices are generally regarded as low risk and include most non invasive products, certain invasive products, and reusable surgical instruments.
- **Class IIa** devices are generally regarded as medium risk and include both invasive and non invasive products, generally for short-term use. This class includes some wound dressings; certain products that channel and store blood for administration into the body; surgically invasive devices for transient or short-term use; most active therapeutic devices that administer or exchange energy; and active diagnostic devices that supply energy (other than for illumination) absorbed by the body, such as ultrasonic imagers.
- **Class IIb** devices are also regarded as medium risk, but this class covers active products therapeutically delivering energy or substances at potentially hazardous levels. Devices placed in this class include blood bags, chemicals that clean or disinfect contact lenses, surgically invasive devices for long-term use, radiological equipment, and condoms and other contraceptive devices (except for intra-uterine devices, which are in Class III).
- **Class III** devices are generally regarded as high risk and include products that are used to diagnose or monitor or that come in contact with the circulatory or central nervous system, such as vascular grafts. This category also includes devices that incorporate medicinal products, such as bone-cement containing an antibiotic.

Source:                      GAO 1996a, p.31

The classes are based on a device's:

- riskiness;
- degree of invasiveness; and
- length of time the device is likely to be in contact with the body.

In ascending order of risk, the medical device classes are: Class I, Class IIa, Class IIb and Class III (see Box F.5).

### **Box F.6      Competent Authorities and Notified Bodies**

Under the EU's system of medical device regulation, a Competent Authority in each country is responsible for the regulatory oversight of medical devices within that country.

The Competent Authority ensures that all Medical Device Directives are incorporated into national law, approves clinical investigations of devices, operates the country's reporting system for adverse incidents and, designates, certifies and monitors the conformity assessment bodies (also known as Notified Bodies) within that country.

Conformity assessment bodies may only offer the services for which they are designated. They can be designated to offer any of the services set out in one or more of the relevant annexes to the Directives. Some essential requirements a Notified Body must satisfy relate to: independence; impartiality; technical competence; appropriate facilities; confidentiality; liability insurance; ensuring the conformance of subcontractors to essential requirements; and the use of quality systems.

The Competent Authority (or an appointed agent) subjects a prospective Notified Body to an assessment audit to determine whether it satisfies criteria in relevant Directives.

The Notified Body may expect to be monitored through surveillance audits at intervals determined by the Competent Authority. If the Notified Body fails to meet the criteria the Competent Authority is compelled to withdraw designation .

Once a good has a Certificate of Conformance from a Notified Body it may be marketed in each member country of the EU — except where a country invokes the 'safety clause'.<sup>5</sup>

Sources:                      GAO 1996a, p.35 and sub. 16, attach. 7

### ***Essential requirements rather than standards***

The Directives do not specify mandatory standards — it is the essential requirements of the Directives which are mandatory. Manufacturers have a choice of a number of ways by which essential requirements may be met. A number of 'harmonised standards' that are deemed to comply with essential requirements may be used. Alternatively, manufacturers can choose to conform

<sup>5</sup> The EU's Medical Device Directives requires each Competent Authority to withdraw CE-marked devices from the market if it finds that the device may compromise patients' health or safety. The authority must immediately inform the European Commission of the action and reasons for withdrawal. The Commission informs other member states that the device has been withdrawn if it agrees the action was justified. Otherwise it informs the Competent Authority that made the decision and the device manufacturer that it believes the withdrawal unjustified. If a Competent Authority continues to ban the CE-marked product, despite the European Commission's decision, the Commission may bring a legal proceeding in the European Court of Justice. European officials envisage the safeguard clause will not and should not be invoked routinely. If it is, the objective of facilitating EU-wide trade will be undermined.

with essential requirements by, for example, undergoing a full quality assurance system review of their operations.

The Medical Devices Directives provide ‘model legislation’ for adoption by member states. They also form the technical basis for mutual recognition agreements between the EU and non-EU countries.

### *Regulation by Competent Authorities and Notified Bodies*

Each EU member state is obliged to enact the EU Directives into law. National laws and regulations that implement the Directives are enforced by that government’s Competent Authority (see Box F.6). The Competent Authority for medical devices is usually a Department of Health.

Within their own country, Competent Authorities designate and certify conformity assessment bodies (which are also known as Notified Bodies).

These Notified Bodies perform conformity assessments of medium and high risk medical devices. Manufacturers can choose which Notified Body they wish to use — as long as the Notified Body has been designated to perform the required task.

### *Different assessment routes for manufacturers to ensure conformity*

To evaluate whether a device conforms to the essential requirements of the appropriate Directive, a Notified Body performs a conformity assessment. In most cases, the manufacturer may choose from a variety of conformity assessment routes dependent on the device classification.

Conformity to the essential requirements of Medical Devices Directives can be assessed on the basis of a:

- full quality assurance system review;
- type examination (which can involve product verification or assessment of production quality assurance); and
- self-assessment for Class I non-sterile–non-measuring devices. The self-assessing manufacturer makes a Declaration of Conformity .
- partial self-assessment for Class I sterile or measuring devices, and for Class IIa design and construction assessment by a notified body of the quality assurance system (see Box F.7).



**Box F.7      Conformity assessment routes in the European Union Medical Devices Directive**

The conformity assessment routes that manufacturers can choose are summarised in the United States Government's General Accounting Office (GAO 1996a) comparative review of the European and American regulatory systems (see also Figure F.1). The routes to conformity assessment are found in the Annexes to the EU's First Medical Devices Directive. They are:

- **Full Quality Assurance System Review (Annex II)** which examines every aspect of the manufacturer's quality assurance system, covering every phase of the manufacture of a device, from design through to shipping. The phases involved in producing a new device for the market include a feasibility phase; a design phase, which results in a written definition of the device; design verification, which involves creating prototypes of the device; mass production; and full market release. At each of these phases the manufacturer must ensure that it has defined the requirements for completing that phase and that the 'deliverable' for that phase, such as a product design or a packaged device, is verified by qualified staff.

A manufacturer choosing the full Quality Assurance system route for a Class III device is also required to submit a design dossier for the Notified Body's review. The dossier may include specifications and performance data of the product as claimed; an explanation of how the product meets the essential requirements for safety; risk analysis, including risk control methods; electrical/mechanical/chemical constructional data, including drawings; design verification documents; and, when relevant, clinical investigation data. After certifying a manufacturer's Quality Assurance system, the Notified Body must carry out periodic inspections to ensure that the manufacturer is continuing to implement the Quality Assurance system. Additionally, the Notified Body may pay unannounced visits to the manufacturer to check that the quality system is working properly.

Under the full Quality Assurance assessment route, the Notified Body does not need to conduct individual reviews of related devices that are produced under the same Quality Assurance system. If the Notified Body certifies the manufacturer's Quality Assurance system, that certification covers the related devices. This practice allows the manufacturer to place a CE mark on, and market all of, the related devices without going through an additional conformity assessment review.

- **Type Examination (Annex III)** is a procedure in which the Notified Body ascertains and certifies that a representative sample of the device being reviewed conforms to the essential requirements. The Notified Body reviews documentation on the device that the manufacturer provides and conducts a product test of the device. The Notified Body physically tests a prototype of the device to determine whether it meets certain standards. The documentation reviewed might include documentation of other product tests. Type examination is always linked with a

**Box F.7 (continued)**

Quality Assurance review limited to the production phase of manufacture. The Quality Assurance review is intended to ensure the consistency of product quality. There are three types of limited Quality Assurance reviews, as follows.

*Product Verification (Annex IV)* — the Notified Body must individually test every device produced or test a random sample from every production batch. Few companies choose this approach because it is very expensive.

*Production Quality Assurance (Annex V)* — the Notified Body reviews the manufacturer's Quality Assurance system for the production stage of manufacturing devices, including inspection and Quality Assurance techniques. The Notified Body must carry out periodic inspections after certifying the production Quality Assurance system and can pay unannounced visits to the manufacturer. The GAO (1996a) review of the EU system found that this is the type of production phase quality review that manufacturers select most often to complement type examination.

*Product Quality Assurance (Annex VI)* — the Notified Body reviews and certifies the manufacturer's system for inspecting and testing final products. The Notified Body must carry out periodic inspections and can pay unannounced visits to the manufacturer.

- **Declaration of Conformity (Annex VII)** is a procedure which is available only for devices in Classes I and IIa. A manufacturer 'declares' that a device conforms to the essential requirements (Note: the declaration does not have to be furnished to anybody) and maintains technical documentation that would permit review of the device. The Notified Body reviews only aspects of the devices relating to sterility or measuring function.

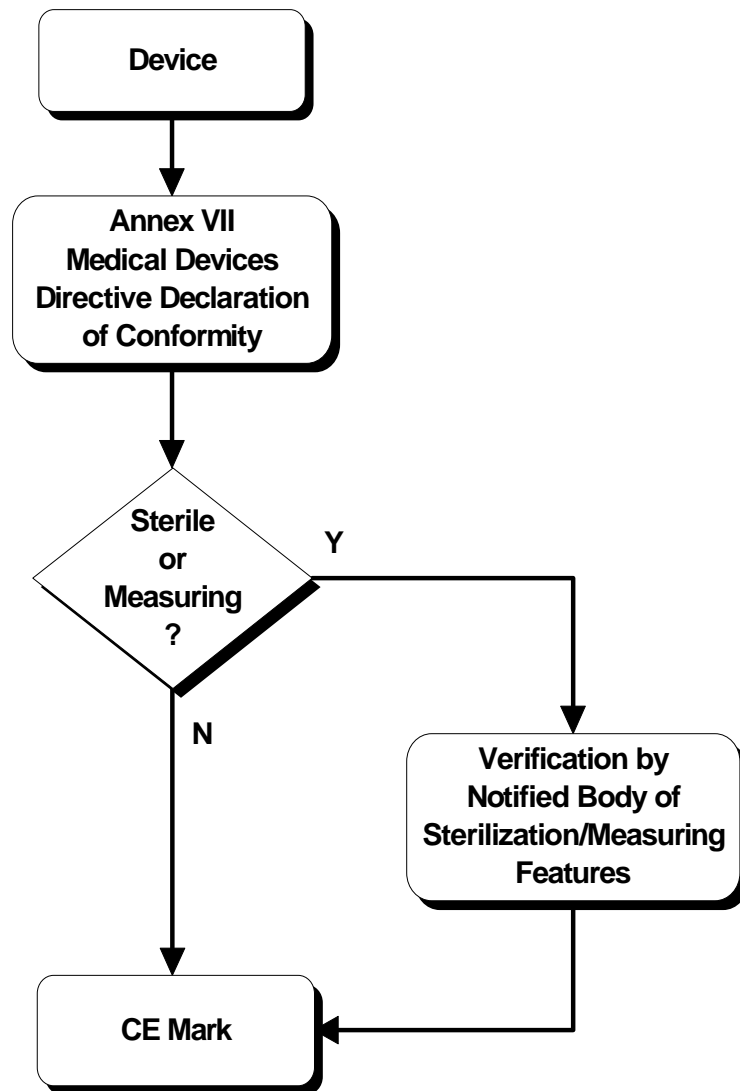
Source: GAO 1996a, pp.32–3

The different conformity assessment paths available to a manufacturer are related to the class of device being manufactured (see Figures F.1 to F.4). If the device is sterile or has a measuring function then a Notified Body *must* be involved in the assessment of aspects relating to the sterility or measuring function (sub. 16 and MDD 93/42/EEC Annex VII, Section 5).

Some 25 countries in and bordering Europe — representing nearly 500 million people — have adopted the Medical Device Directives into legislation or have stated their intention to do so (sub. 16, p.7).

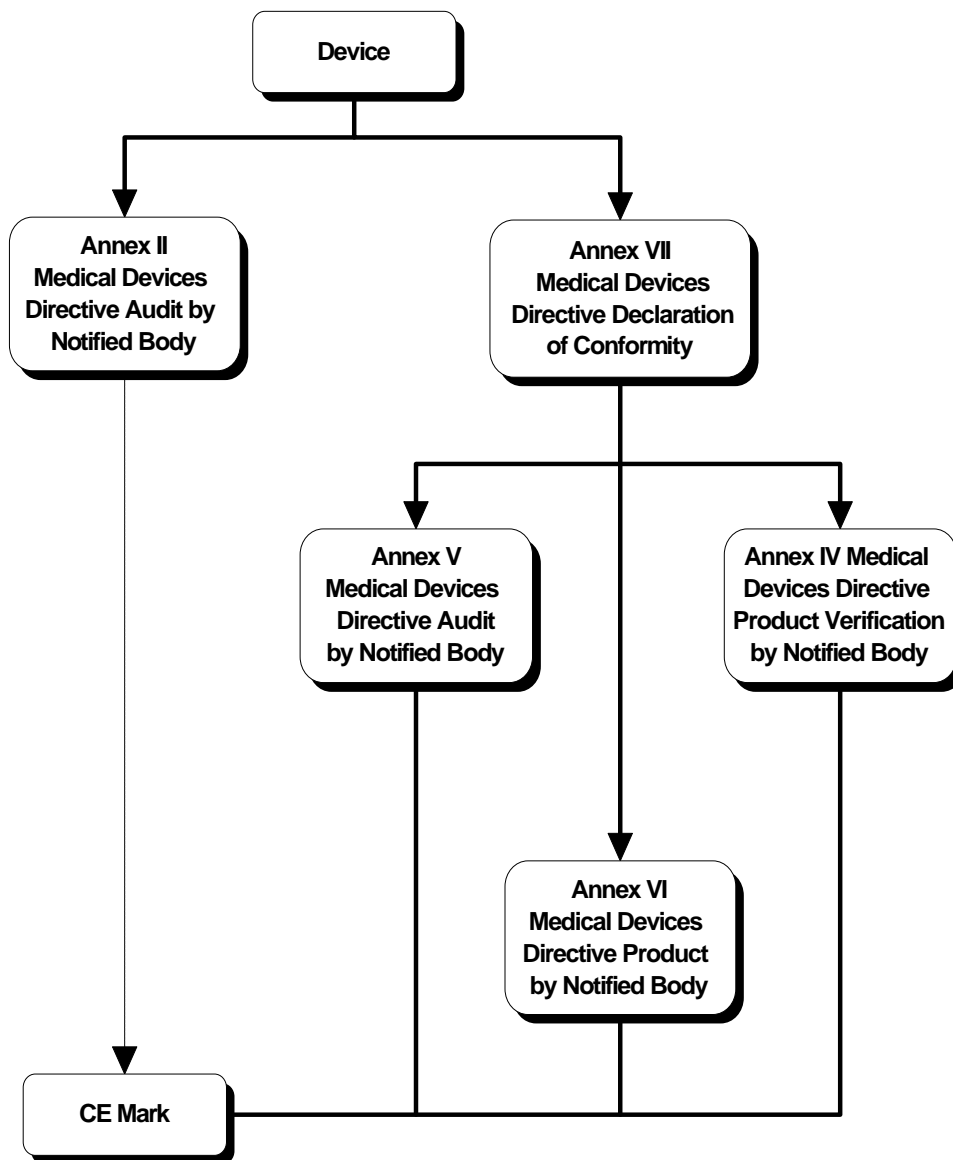
In the EU, most countries are well advanced toward implementing CE marking of medical devices — only Belgium has not yet incorporated the Medical Device Directives into legislation. CE marking of medical devices in the EU will be mandatory from 14 June 1998. Many customers are insisting that medical devices they purchase be CE marked by June 1997.

**Figure F.1 Conformity assessment under the European Union Medical Devices Directive, Class I devices**



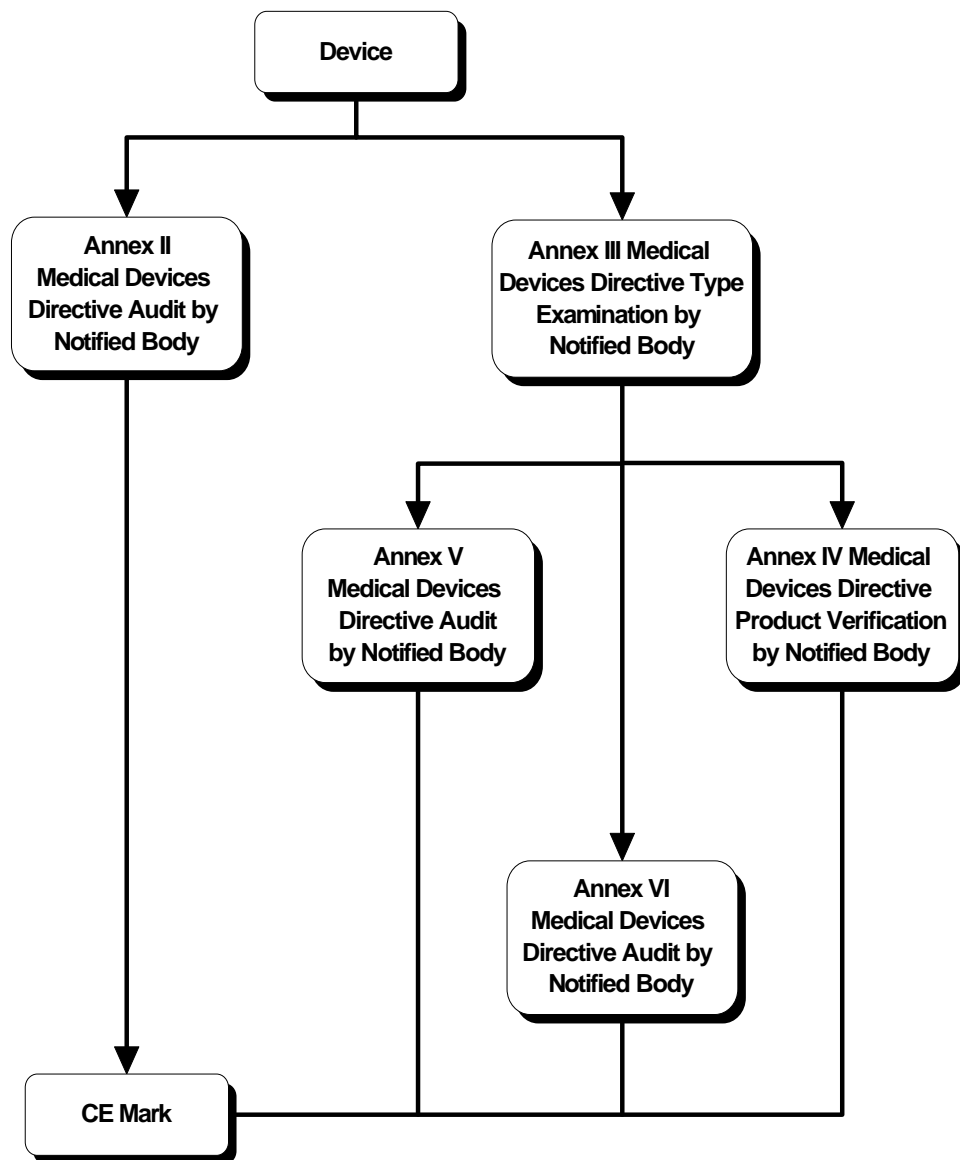
Source: GAO 1996a, p.34

**Figure F.2 Conformity assessment under the European Union Medical Devices Directive, Class IIa devices**



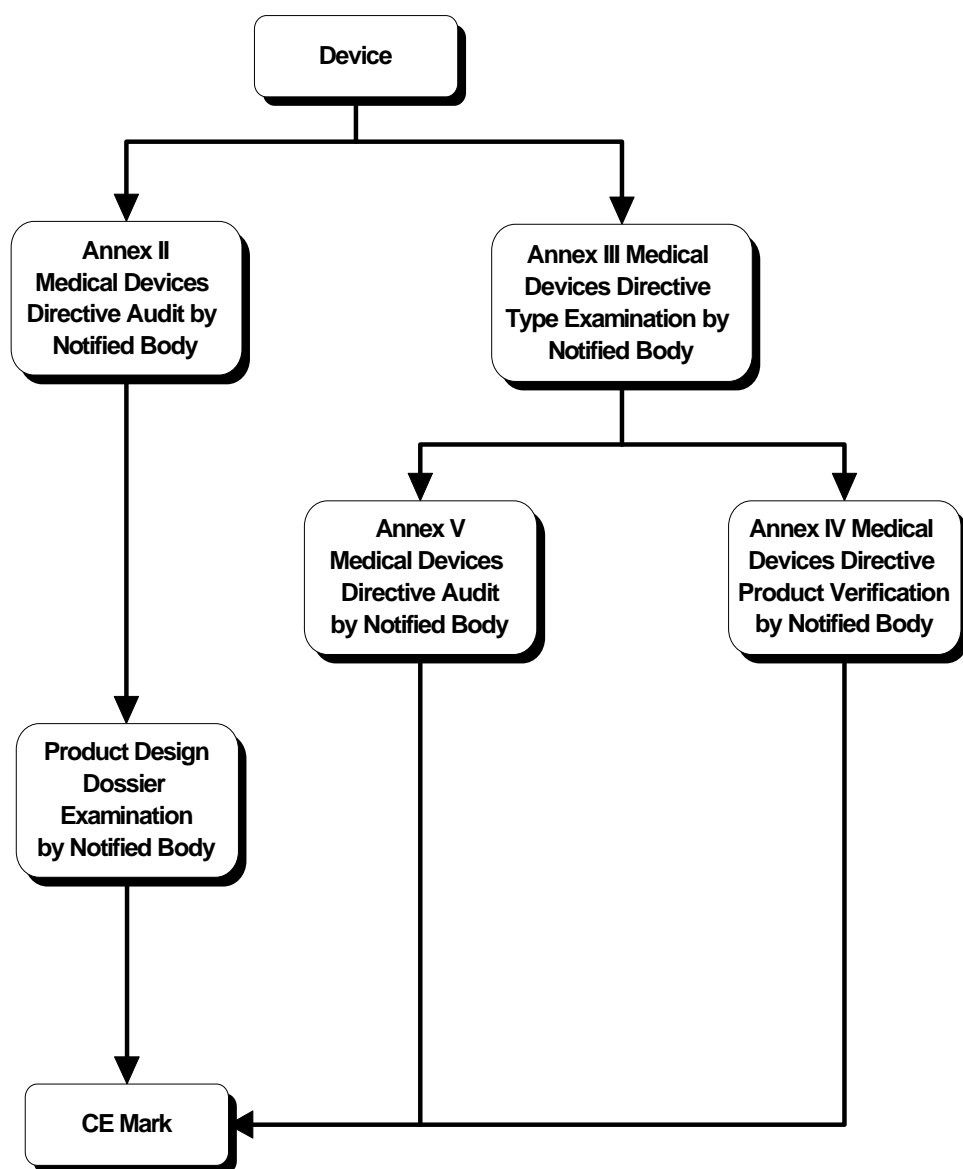
Source: GAO 1996a, p.34

**Figure F.3 Conformity assessment under the European Union Medical Devices Directive, Class IIb devices**



Source: GAO 1996a, p.34

**Figure F.4 Conformity assessment under the European Union Medical Devices Directive, Class III devices**



Source: GAO 1996a, p.34

## **Medical device regulation in a European Union country — The United Kingdom**

The agency primarily responsible for medical device regulation in the United Kingdom (UK) is the Medical Devices Agency (MDA) — which is an Executive Agency of the UK Department of Health.<sup>6</sup> The MDA is also the UK's Competent Authority for medical devices. With implementation of the CE mark, the MDA is in the midst of a transition.

### *Current regulatory activities*

At present, the MDA has six main activities:

- auditing the quality assurance systems of medical device manufacturers supplying the UK market, and publishing a register of approved companies;
- investigating adverse incidents associated with medical devices;
- managing an on-going program to evaluate medical devices, and publishing reports;
- offering advice to Ministers, the Department of Health, the National Health Service and other healthcare providers, manufacturers and customers;
- setting safety and performance standards for medical devices through the British Standards Institution (BSI); and
- introducing and enforcing statutory controls on medical devices throughout the UK. (MDA 1996)

The MDA has about 170 staff. Some testing and evaluation is conducted in the MDA's own laboratories. Other testing is contracted out to independent specialists in hospitals and universities.

The agency also operates a voluntary Manufacturers Registration Scheme (MRS) which involves the auditing of quality assurance systems and the register of approved companies. Some 582 companies representing 834 approved manufacturing sites in approximately 30 countries are registered. Registration requirements under the MRS are substantially similar to those under the Therapeutic Goods Association's (TGA) GMP requirements (and certification under the MRS is recognised by the TGA as equivalent to their own GMP audits). The MRS will be phased out by 14 June 1998 when the Medical Device Directives transition period ends.

The MDA also has a Medical Devices Adverse Incident Centre, responsible for receiving and coordinating all adverse incident reports, and for initiating investigations. More than 3500 incidents were reported during 1993.

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<sup>6</sup> The Head of the agency is directly accountable to the UK Minister of Health.

Investigation of incidents can result in the issue of a Hazard or Safety Notice, or a Device Bulletin to alert users to potential problems. The Agency can recommend that a product be withdrawn where there is serious risk.

In addition, the Agency's product evaluation program looks at the safety, performance and user acceptance of technical products used by the UK's National Health Service. To do this they fund about 35 centres to make technical and user assessments.

### *The Agency's role under the CE mark*

Within the CE mark regulatory model, the MDA as the Competent Authority for medical devices is responsible for implementing Directives on (or the parts related to) medical devices. During the transition period, the MRS will continue to run in parallel with the new European system. For most products, new statutory requirements — enacting the Directives — will replace the MRS by 1998.

After 1998, the MDA will continue to have responsibility for quality and safety of devices although it will be the Notified Bodies which will check that devices meet the standards required in the Directives.

As a Competent Authority for Medical Devices the MDA will have five main functions:

- enforcing the regulations which implement the Directives;
- providing advice on the Directives;
- operating the 'vigilance system' for adverse incident reporting by manufacturers, supplementing the work of the Adverse Incident Centre;
- assessing applications from manufacturers for clinical investigations with new devices; and
- approving and monitoring Notified Bodies.

Already there are several Notified Bodies operating in the UK. They include the BSI, Bureau Veritas and SGS Yarsley. BSI, for example, is an Notified Body for active implantable medical devices.

## **F.3 The Australian Mutual Recognition Agreement on Conformity Assessment with the European Union**

Preliminary steps have already been taken to better integrate Australia's approach with that of the EU. These steps are in the form of a Mutual Recognition Agreement on conformance assessment (MRA) that has been signed and is being



concluded between Australia and the EU.<sup>7</sup> In addition to medical devices, the MRA covers simple pressure equipment, machinery, low voltage electrical equipment, telecommunications terminal equipment, electromagnetic compatibility, automotive products and Good Manufacturing Practice for pharmaceuticals. The MRA will also allow other sectors to be added later.

### **Changes that are taking place**

With respect to medical devices, the MRA provides for designated independent bodies (known as ‘conformity assessment bodies’) in the EU to assess devices manufactured in the EU against the requirements of the Australian therapeutic goods legislation. Likewise it provides for the TGA (and any other body designated by the Commonwealth Government) to assess devices manufactured in Australia for conformance with EU requirements. The Australian body named in the MRA, to designate additional ‘conformity assessment bodies’, is the DHFS.

When a device manufactured in the EU has been assessed as conforming to Australian requirements, a certificate of conformance will be issued. On presentation of that certificate to the TGA in Australia the device will be put on the Australian Register of Therapeutic Goods without further evaluation.

Similarly when an Australian device is assessed by the TGA as complying with EU requirements, a Certificate of Conformance is issued and a CE mark may be affixed. The device may then be marketed within all member states of the EU.

The MRA will ease the compliance burdens of manufacturers in Europe wishing to market in Australia and of Australian manufacturers wishing to market in Europe. There are clear benefits from implementing the MRA as soon as practical.

Negotiations on the part of the MRA relating to medical devices began in early 1994. There was essential agreement on the technical content of this part of the MRA by the end of 1994 — since then only minor procedural details have been changed. Progress on the MRA has been delayed by negotiations over annexes related to the other sectors noted above. As the Technology Industry Exporters Group stated:

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<sup>7</sup> New Zealand is also negotiating its own Mutual Recognition Agreement on conformance assessment with the EU. In addition, under the Trans-Tasman Mutual Recognition Arrangement between Australia and New Zealand the medical device regulators of both countries are working cooperatively toward addressing differences in each others regulatory approach. This cooperative program may provide added impetus for each country to adopt the EU approach. (sub. 81)

... it would be of great benefit to Australian manufacturers to be able to obtain CE marking here in Australia. However, negotiations have been hampered by the need to sign up several sectors at once. A firm date for signing the MRA is still not forthcoming. (sub. 17, p.2)

The MRA text was finalised and initialled on 23 July 1996. However, this is only the first of a number of steps that need to be completed before the MRA, which has international treaty status, can come into force.

The TGA outlined that:

... before the treaty can be implemented, legislative action and changes to regulations and administrative procedures to give effect to the treaty must be completed.

The Department of Industry, Science and Tourism (DIST) has responsibility for the consultation with States and Territories in accordance with Council of Australian Governments (COAG) principles. The Minister for Industry Science and Tourism, Mr John Moore has written to all State premiers/Territory chief ministers departments.

The steps to be taken before the MRA can take effect include:

- (i) National interest analysis.
- (ii) A memorandum of understanding (MOU) must be completed between the Commonwealth, States and Territories on co-operation in relation to the MRA.
- (iii) Some Commonwealth, State and Territory legislation will require amendment.
- (iii) An MRA must be completed between the National Association of Testing Authorities (Australia) and the Joint Accreditation System of Australia and New Zealand in their role as designating authorities under the MRA in certain sectors.
- (iv) The MRA must be tabled in both Houses of Federal Parliament at least 15 days before taking treaty action.
- (v) Effecting final treaty through exchange of notes between Australia and the EU. The agreement will enter into force 'on the first day of the second month following the date on which the Parties have exchanged notes confirming the completion of their respective procedures for the entry into force of this agreement'.

Amendments are required to the *Therapeutic Goods Act* 1989 to enable the acceptance of medical device approvals from European Union notified bodies. It is proposed that these changes be considered in the Autumn Sittings 1997 to facilitate implementation by mid 1997. (sub. 52, p.3)

As at 18 December 1996, there was agreement at the level of officials on the draft memorandum of understanding between the Commonwealth and States and Territories in relation to the MRA. There was also an agreement in principle in relation to the memorandums of understanding between the Commonwealth and National Association of Testing Authorities (Australia), and the Joint Accreditation System of Australia and New Zealand.

## Longer term plans to harmonise with the CE mark

The DHFS submitted that Australia is moving to harmonise with the CE mark approach because:

... the European system of device regulation which has emerged as the globally preferred model. [The system also offers] considerable scope for mutual recognition agreements ... (sub. 16, p.12)

The Department believes that there are a number of benefits to Australia from harmonisation. It stated that these are:

... both in community protection and cost efficiency for industry. The proposed system will provide:

- improved scrutiny of all medical devices at a level commensurate with the risk to the user thus greater protection for the community;
- ongoing review (five yearly) of devices being supplied;
- avoidance of duplication of work by recognising overseas approvals;
- with mutual recognition agreements — easier entry to Europe and other markets for Australian manufactured devices;
- facilitation of availability of new technology;
- mandatory post market surveillance;
- self assessment of low risk devices;
- alignment with New Zealand's stated intentions for regulation; and
- facilitation of exports to markets with similar regulation. (sub. 16, p.9).

Presently, only some elements of the European system are fully met within the legislative framework established by the *Therapeutic Goods Act* 1989. The Department's longer term plan is that, following appropriate consultation, Australia's medical device legislation will be amended to align it with the European system (sub. 16).



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## **G PROCUREMENT ARRANGEMENTS FOR MEDICAL AND SCIENTIFIC EQUIPMENT**

This appendix describes some of the main arrangements affecting government procurement of medical and scientific equipment for most states and territories and the Commonwealth.

### **G.1 New South Wales**

In New South Wales, the Department of Public Works and Housing is responsible for procuring major capital items (usually over \$50 000). Regional area health services and individual hospitals generally let contracts for smaller amounts. The New South Wales Health Peak Purchasing Council was established to review policy and practices in NSW Health (sub. 28, p.3).

The Commission received information which indicated that in the near future, for tenders over \$100 000, tenderers will be required to provide an Economic Impact Statement. These statements will require tenderers to detail their activities, sales, market share, and future industry intentions (NSW Health Peak Purchasing Council, sub. 26, p.1). NSW Health will not pay a premium for goods in exchange for industry development. However, where Australian and New Zealand companies are competitive, NSW Health and the Department of State and Regional Development work together to help realise investment opportunities (sub. 28, p.3).

A Networking Committee has been created within New South Wales Health to promote microeconomic reform within the health system infrastructure. A Logistics Working Party is conducting a review of procurement arrangements in the State.

### **G.2 Victoria**

Regional health care networks and public hospitals in Victoria are corporate entities. They enter into contracts for the purchase of medical and scientific equipment separately from the Department of Human Services. However, they are required to follow the Victorian Government's asset management and evaluation guidelines.

The trading arm of the Victorian Healthcare Association (VHA Trading) — formerly the Victorian Hospitals Association — purchases and distributes some

equipment as an agent of public hospitals in Victoria, usually for items of up to \$20 000 (RT trans. p.153). These purchases are not subject to general Victorian Government purchasing guidelines. However, public hospitals are not compelled to make use of the VHA trading system, and may make their own purchases. Some private hospitals may also elect to meet their equipment needs through the VHA system.

In some instances, the Department of Human Services undertakes group purchasing negotiations on behalf of public hospitals to achieve savings on bulk purchases for common upgrades of specific types of major medical equipment.

### **G.3 Western Australia**

The State Supply Commission is the central procurement agency in Western Australia. Management of the purchase of goods and services by Western Australian Health is the responsibility of the Government Health Supply Council (WA Health Supply Services acts as its secretariat). Public tenders must be called for amounts over \$50 000.

Public hospitals may make their own purchases up to a value of \$20 000. Royal Perth Hospital is allowed to distribute some products to regional hospitals which do not have their own purchasing departments. Public benevolent institutions may also be authorised by the State Supply Commission to purchase equipment through state government contracts.

A 10 per cent preferential price margin may be applied to domestically produced equipment. For whole of health arrangements, or where the anticipated value exceeds \$1 million, a procurement plan is developed including identifying industry impacts of the proposed procurement.

### **G.4 South Australia**

Supply South Australia (Supply SA) is the central procurement agency, and is involved in the purchase of common-use medical and scientific equipment. For purchases above \$10 million, approval of the State Supply Board is required.

The Hospitals and Health Services Association of South Australia purchasing agency was established following a review by Coopers & Lybrand. The aim of the Association is to reduce the costs of medical equipment in South Australia. Supply SA has authorised the Association to call and let tenders for specialised technical and surgical products in hospitals, and other products as agreed by Supply SA. Some private hospitals are permitted to use Supply SA's common use contracts, warehousing and purchasing facilities.

Individual agencies including public hospitals can purchase against common use contracts (consumables in the case of hospitals), and can process one-off equipment needs less than \$10 000 in value. One-off acquisitions by agencies exceeding \$500 000 require the approval of the State Supply Board.

## **G.5 Tasmania**

State Purchasing and Sales is the purchasing authority for the Tasmanian Government. It is responsible for the procurement of medical and scientific equipment valued at \$50 000, or higher in the case of inner budget agencies (sub. 44, p.1). Tenders are required for purchases above \$50 000. A 10 per cent preferential price margin may be provided to domestically produced equipment.

Tasmania's public hospitals are independent statutory authorities. They tend to purchase their own equipment up to the \$50 000 limit. For larger amounts, the Department of Community and Health Services funds the majority of purchases, but will require tenders to be let through State Purchasing and Sales. Equipment needs are generally determined by the three health regions in Tasmania in consultation with the Department of Community and Health Services.

State Purchasing and Sales also arranges government supply contracts on behalf of hospitals for items such as medical gases, oxygen concentrators and pharmaceuticals. Not-for-profit private hospitals are able to use the State Government's procurement system.

## **G.6 Australian Capital Territory**

The ACT Department of Health and Community Care procures medical and scientific equipment for the public health sector. Procurement in the public health sector is conducted in accordance with the ACT Government Purchasing Policy. Some other agencies also procure medical and scientific equipment, including ACT Electricity and Works and the ACT Department of Urban Services.

Public tenders are usually invited for purchases over \$50 000 (ACT Government, sub. 23, p.2). For purchases of over \$1 million, tenderers are required to submit a Canberra Regional Industry Plan.

## **G.7 Commonwealth Government**

The Department of Administrative Services is the Commonwealth Government's procurement agency. According to the Medical Industry Association of Australia, the Commonwealth Government is not a major purchaser of medical products

overall but for some products (such as Stoma products) it is the only significant purchaser (sub. 26, p.75).

The National Procurement Development Program, which is a joint program involving Commonwealth and state governments, provides funding for agencies to develop a partnership with industry to develop solutions to government purchasing needs.

The Partnerships for Development program has been introduced for the information technology sector. This program is mainly used by the information technology industry.

In 1995, the Commonwealth Government introduced a number of additional measures to encourage Government purchasers to make use of local suppliers. These included a requirement for industry impact statements for contracts over \$10 million, and a 'two envelope' tendering arrangement with one envelope covering proposals for industry development.



## **Attachment 1**

### **ANNEX 4**

#### *MEMORANDUM OF UNDERSTANDING*

1. The Parties, in entering into the Government Procurement Agreement, are committed to the pursuit of the following objectives in conjunction with the implementation of the Agreement:
  - (a) Discussions will be entered into with a view to all Parties reaching greater commonality in contractual, technical and performance standards and specifications.
  - (b) The Parties shall work through their various procurement authorities, other relevant bodies and industry to examine specific measures and guidelines designed to achieve greater simplicity and uniformity in procurement policies, practices and procedures. Areas which could be examined include:
    - a unified approach to procurement of goods subject to dumping action or alleged to be dumped;
    - procurement arrangements, including both public and confined tendering;
    - procurement evaluation methodologies and criteria;
    - general conditions of contract;
    - contract administration;
    - wider use of functional specifications;
    - quality assurance;
    - exchange of procurement information;
    - public sector forward procurement plans;
    - cooperation and reciprocal procurement arrangements aimed at creating opportunities for local industry to supply government needs;
    - development of a national supply language; and
    - abolition of monetary preference margins.
  - (c) In pursuit of these functions the National Supply Group will consult with industry bodies.

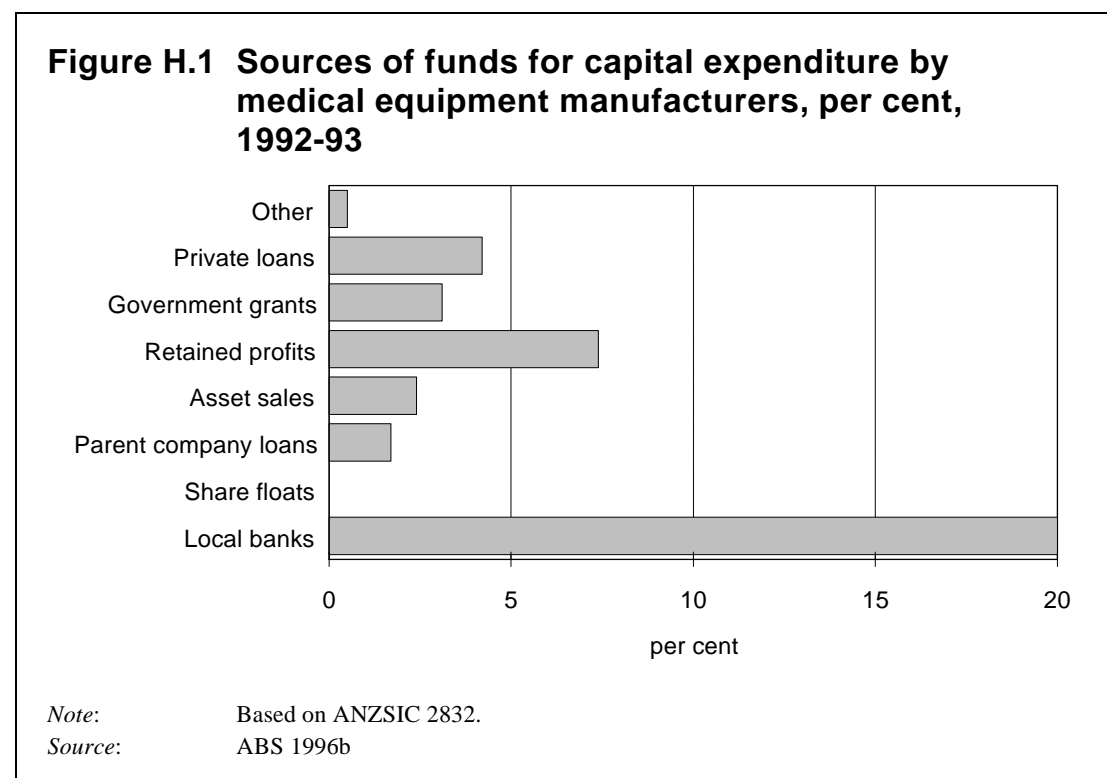
2. The parties accept the following interpretations in relation to the provisions of the Government Procurement Agreement:
  - (a) Nothing in the Agreement precludes the Parties from new developments in purchasing policy, or the use of that policy to implement other policies, provided that in doing so there is no discrimination on the basis of State of origin.
  - (b) Under the provisions of Paragraph 5 [of the Government Procurement Agreement], the Ministerial Council on Common Service Provision will consider exemptions in respect of purchasing brought forward to stimulate depressed industries.
  - (c) Requests for interim or permanent exemptions under Paragraph 5 which were not notified in Annexe 2 [of the Government Procurement Agreement] for approval prior to the implementation of the Agreement may be submitted to the Ministerial Council on Common Service Provision for approval and incorporation into the Agreement.

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## H FINANCE, EXPORT, BUSINESS MANAGEMENT AND INTERNATIONAL LINKAGE MEASURES

### H.1 Sources of finance for medical and scientific equipment manufacturers

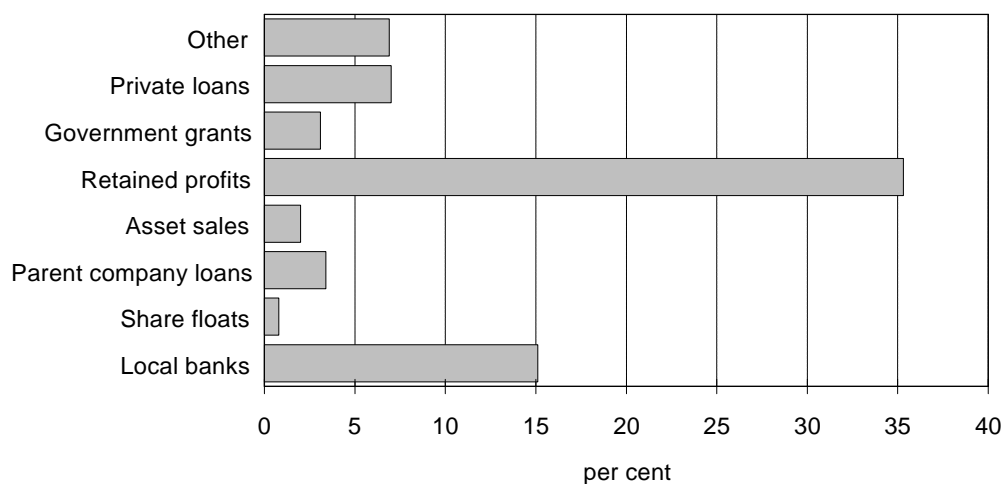
The main sources of finance for capital expenditure for medical and scientific equipment manufacturers are shown in Figures H.1 and H.2, respectively.<sup>1</sup> In 1992-93 (the latest ABS data available) the two most important sources were retained profits and bank loans. These were especially important for scientific equipment manufacturers — constituting around 50 per cent of total funds.



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<sup>1</sup> Capital expenditure includes all costs incurred in the acquisition of items of a capital nature. This includes expenses for the acquisition of: dwellings; other building and structures; plant, machinery and equipment; and other capital expenditure — including land and intangible assets (ABS 1996a, p.81).

**Figure H.2 Source of funds for capital expenditure by scientific equipment manufacturers, 1992-93 (per cent)**



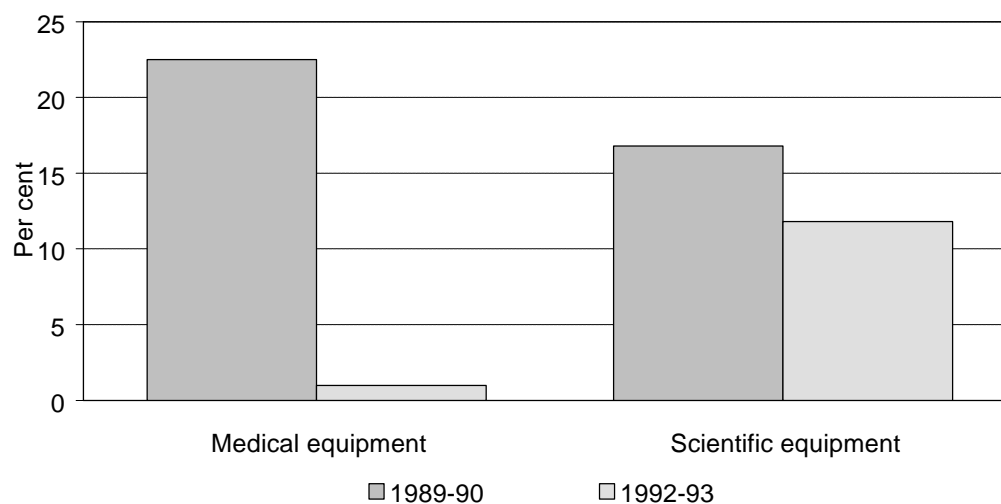
*Note:* Based on ANZSIC 2839.

*Source:* ABS 1996b

While comparable data for sources of funds are not available for earlier years, ABS data on the return on assets in both industries suggests the proportion of expenditure funded from retained profits in 1992-93 is less than in 1989-90, and the proportion funded from debt is greater.

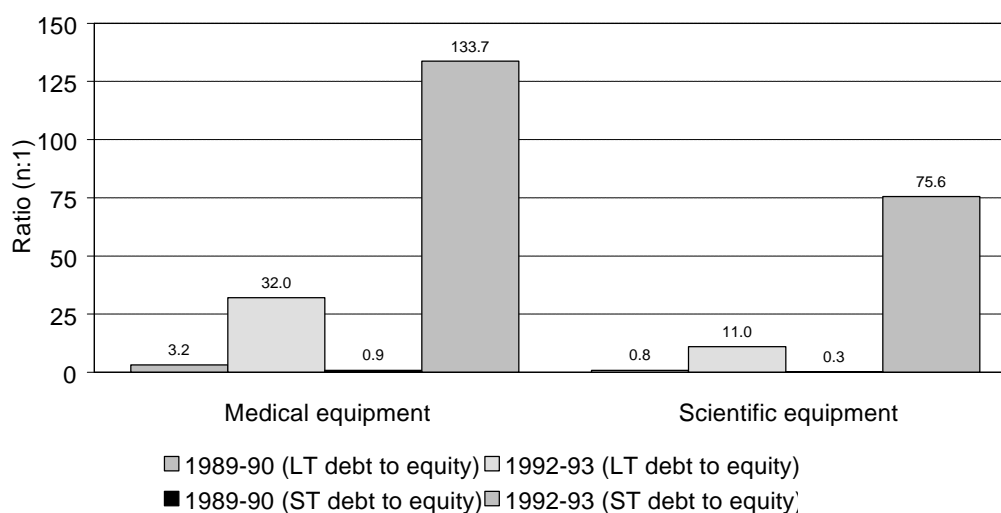
Compared with 1989-90, the return on assets in 1992-93 was lower in both industries (see Figure H.3). The difference was particularly large in the medical equipment industry. At the same time, the ratio of debt to equity in both industries was considerably more in 1992-93 than in 1989-90 (see Figure H.4).

**Figure H.3 Return on assets for medical equipment and scientific equipment manufacturing, 1989-90 and 1992-93**



Source: ABS 1996b

**Figure H.4 Debt to equity ratios in medical equipment and scientific equipment manufacturing, 1989-90 and 1992-93**



Source: ABS 1996b

## H.2 Private finance markets

In 1993, the Australian Development Capital Association Limited (ADCAL) began a series of annual surveys of Australian development capital providers. 1995 survey returns were completed by 17 of ADCAL's 23 investor members. Total funds under management from the 14 members who have limited their activities to direct investments largely in small to medium enterprises are shown in Table H.1.

Table H.1 ADCAL funds under management

	30 June 1994		30 June 1995	
	<i>Investees</i> (No.)	<i>Funds</i> (\$m)	<i>Investees</i> (No.)	<i>Funds</i> (\$m)
Total capital invested	296	445	329	541
Total capital committed	15	23	14	42
Total uncommitted capital		270		286
<b>Total</b>	<b>311</b>	<b>737</b>	<b>343</b>	<b>868</b>

*Note:* Figures may not add due to rounding.

*Source:* ADCAL 1995

Not all capital available is invested as development capital as fund managers retain some liquidity for new and additional investments. The companies raised \$148 million in 1993-94 and \$137 million in 1994-95.

During 1994-95, the members of ADCAL surveyed:

- invested \$103 million in 57 new investee companies; and
- invested an additional \$49 million in existing investees.

Of the 57 new investments, 61 per cent were for expansion of an existing business, 15 per cent for management buy-outs or buy-ins, and 24 per cent for start-ups.

Information on activities in which the companies invested is only available for investee companies with annual turnover of less than \$100 million. That information indicates that in 1994-95, ADCAL companies had investments in nine medical/health related activities — representing some 8 per cent of investee companies identified in the survey (ADCAL 1995). About half of the investments by ADCAL companies were in computer related, industrial products, manufacturing, communications and service industries, which generally have the potential for high value-added and significant export growth.

A number of funds target small companies. Allen Consulting Group (1996) considered the reason for the growth of these funds is that fund managers have

found it possible to achieve above average returns over the medium and longer term by investing in a range of small to medium sized companies.

For smaller enterprises with a good track record and potential for growth, there is an informal 'business angels' network for amounts usually less than \$500 000. A business angel is typically a wealthy individual with a business background who is willing to make equity investments which are too small for a venture or development capital fund (NIC 1995). Business angels currently represent a limited source of funds. As the CRC for Cardiac Technology commented:

... in real terms there are only a small band of those wealthy investors. There are many, many companies in Australia that are chasing these investors. (PH trans, p.137)

However, capital from this source is predicted to increase in Australia as 'business angels' from Asia demonstrate an increased willingness to invest in innovative or expanding firms. These business angels traditionally expect a minimum 30 per cent return on their investment and are unlikely to retain their equity for more than five years. (*Financial Review*, 22 October 1996, p.43)

Some industry associations operate informal business networking systems, that aim to link these business angels with owners of small and medium enterprises. The Victorian Employers' Chamber of Commerce and Industry, and Australian Business (formerly the New South Wales Chamber of Manufacturers) also operates a networking facility. Similarly, the South Australian Employers' Chamber of Commerce and Industry recently established an 'Ideas and the Investor' program aimed at linking investors with innovative companies with growth potential. (Limited funding for both programs was provided under the Business Equity Information Scheme in the *Innovation Statement* in December 1995.) In the case of the latter program it is too early to judge its success (NIC 1995).

### **H.3 Government assistance for export, business management and developing international linkages**

#### **Export assistance programs**

A number of assistance programs are available for exporters, many of which are administered by Austrade.

### *Export Market Development Grants Scheme*

The Export Market Development Grants (EMDG) scheme provides financial support to promote the development of exports by Australian companies. The scheme is intended to fund export marketing and sales promotional activities such as overseas market research, trade fairs and preparation of tenders.

The EMDG scheme provides taxable cash grants mainly to eligible small to medium companies. Up to \$200 000 per year is available to subsidise overseas marketing costs. Eligible goods must contain Australian content of at least 50 per cent of free on board value and be manufactured, produced, processed, or assembled in Australia.

In the August 1996 Budget, the Government announced that the EMDG scheme will continue but will be simplified and made more efficient. It will also be subject to tighter eligibility criteria and expenditure by the scheme capped at \$150 million. An expenditure cap will be introduced from the 1996-97 grant year. Grants are being further targeted at small-to-medium enterprises by reducing the minimum expenditure threshold from \$30 000 to \$20 000. Larger firms, with a turnover of more than \$50 million a year, will no longer be eligible for funding. Additionally, improved administration processes will see an estimated total savings of \$62.3 million over the next three years.

In 1993-94, a total of 3071 recipients received grants under the EMDG scheme totalling \$199.7 million. Of this, about 3.3 per cent were allocated to medical and scientific equipment industries (see Table H.2).



Table H.2 Export Market Development Grant recipients in the medical and scientific equipment industries, 1993-94

ANZSIC		Recipients (No.)	Grants (\$m)
2832	Medical and surgical equipment manufacturing	42	2.8
2389	Professional and scientific equipment manufacturing	53	3.5
4612	Professional equipment wholesaling	5	0.3
<i>Note:</i> The most recent available data is for the 1993-94 financial year.			
<i>Source:</i> sub. 22, p.4			

In 1993, the EMDG scheme was reviewed by both Austrade and the Australian National Audit Office (ANAO). The Austrade Review noted the scheme was meeting its objective of encouraging companies to seek out and develop export markets and recommended that the scheme be extended for another five years (Austrade 1994). In comparison, the ANAO review concluded the information kept by Austrade concerning the EMDG scheme made it difficult to judge the overall effectiveness of the scheme. ANAO recommended better information be kept and outlined measures on how this could be achieved (ANAO 1994a).

Since this time, Austrade has undertaken a series of measures to address some of these claims. For instance, a program is being implemented to make the rules of the EMDG scheme easier to understand and administer, and for the scheme to be more responsive to the needs of the market place.

### *Export Access Program*

This program provides a comprehensive package of training and practical assistance to small and medium companies requiring specialist assistance for their export activities. It does not provide cash grants. The programs assists small to medium companies to identify export opportunities, training, and the preparation and evaluation of overseas visits.

The program is available, in all industries, to:

- any manufacturer with an annual turnover below \$20 million or less than 200 employees;
- any service provider with an annual turnover below \$20 million or less than 50 employees; and
- any company in the agricultural sector with an annual turnover below \$8 million or less than 20 employees.

Although administered by Austrade, the program is delivered by project managers located in the Australian Chambers of Manufactures, the Metal Trades

Industry Association of Australia, and state affiliates of the Australian Chamber of Commerce and Industry. Entry into the program is based on a company's commitment to exporting, export potential and financial viability. In 1995-96, approximately 24 firms from the medical and scientific equipment industries are estimated to have participated in this scheme.<sup>2</sup> In comparison, a total of 500 companies received assistance under the Export Access Program in 1995-96 (Export Access 1996). An example of a medical equipment supplier — Starkeys Products — which was involved in the program is documented in Box 8.3 in Chapter 8.

In the August 1996 Budget, the Government announced the Export Access Program will be maintained — however, program funding is forecast to be cut by approximately 22 per cent over the next three years.

### *Export Finance and Insurance Corporation*

The Export Finance and Insurance Corporation (EFIC) is an export credit agency which provides a range of insurance and financial services to Australian exporters. It provides competitive export finance and helps manage payment risk for exports sold on credit. The services provided include:

- insurance against risks of non-payment by overseas buyers;
- guarantees to financial institutions for finance they provide to support Australian export transactions (including working capital guarantees);
- finance to overseas buyers of Australian exports of capital goods and related services on commercial, concessional, or mixed credit terms;
- performance bonds and indemnities to banks and insurance companies which provide such bonds; and
- insurance for Australian investors in offshore enterprises.

Eligibility is determined on a case by case basis and the majority of clients are small exporters. As EFIC outlined:

The predominance of small exporters among EFIC's clients was confirmed in 1993-94. More than three-quarters of our clients insured with us less than \$2 million of exports. Nearly a third of the indications of finance we provided to assist companies negotiating for capital goods and services contracts were for deals less than \$3 million. (EFIC 1994, p.8)

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<sup>2</sup> The Export Access Program does not collect data on the basis of ANZSIC and ASIC classifications. Data were provided from the pharmaceutical and medicinal category, the surgical and medical equipment category and the medical and health services category. The surgical and medical equipment category also includes data from the medical checking and photographic sector.

In 1994-95, EFIC provided credit insurance for exports worth approximately \$5.7 billion and lending for the export of capital goods and services of nearly \$600 million (EFIC 1995, p.4). In the past, EFIC has provided part of the finance package in conjunction with other government programs, for instance, through the Development Import Finance Facility (DIFF). The use of EFIC's programs by the medical and scientific equipment industries are documented in Table H.3.

**Table H.3** EFIC supported export value: MSE and other industries, 1991-92 to 1995-96

	1991-92		1992-93		1993-94		1994-95		1995-96	
	<i>Funds</i> (\$m)	<i>Firms</i> (No.)	<i>Funds</i> (\$m)	<i>Firms</i> (No.)	<i>Funds</i> (\$m)	<i>Firms</i> (No.)	<i>Funds</i> (\$m)	<i>Firms</i> (No.)	<i>Funds</i> (\$m)	<i>Firms</i> (No.)
All industries	5109	na	5149	na	5853	na	6364	874	7457	1020
MSE industries	11	8	8	7	9	8	5	7	8	10

*Note:* Data is classified according to the Australian Harmonised Export Commodity Classification system. For this analysis, equipment from peripheral industries (for example, meteorological equipment, prosthetics and, Occupational, Health and Safety projects) have been excluded.

This data details the support provided through EFIC financing and insurance schemes.

na not available.

*Source:* EFIC 1996

### *Development Import Finance Facility*

The Development Import Finance Facility (DIFF) was a 'tied aid mixed credit' scheme. Financing for DIFF projects came from two sources — the DIFF grant provided by AusAid (part of the Department of Foreign Affairs and Trade), and export credit financing provided by EFIC. The combination of aid and export credits meant that DIFF could be used for large development activities beyond the scope of grant funds available through country programs by providing a concessional, mixed-credit finance package to developing countries for the purchase of Australian equipment. (AusAid 1996)

In the August 1996 Budget the Government announced that the DIFF program would be terminated, except for some small outlays in 1996-97 to meet pre-existing formal offers of DIFF support.

Some participants raised concerns about the abolition of the program. For example, the Australian Health Industry Development Forum commented that 'the elimination of DIFF funding has the potential to limit the success of the medical equipment industry in supplying to any health infrastructure projects in recipient countries' (sub. 30, p.6). The SSAA commented similarly, documenting

that the abolition of DIFF would reduce opportunities for Australian companies in the Asia Pacific rim (sub. 63, p.5, PH trans, p.43) while Relpar (a former recipient of the program) claimed:

The cancellation of the DIFF soft loan scheme will have a serious effect on potential exports of Australian scientific and medical equipment to developing countries ... since its inception, the DIFF scheme has generated A\$140 million in contracts in Indonesia alone for scientific and medical equipment. (sub. 54, p.1)

In 1992, the National Institute of Economic and Industry Research (NIEIR) examined and reported on various aspects of the DIFF scheme. This study concluded that there were substantial benefits from the scheme — mostly through trade creation and ‘internationalisation’ effects. With respect to internationalisation, the NIEIR commented:

The interesting feature ... is the impact that the use of DIFF of funds has had on certain firms. In a number of cases ... the Australian companies involved have changed from being primarily domestically oriented in their business outlook to being internationally oriented companies. (Maxwell in ADAB 1992, p.67)

However, the NIEIR further concluded that it was unable to determine whether this would have occurred in the absence of DIFF support.

The DIFF program was also recently reviewed by AusAid (1996). As part of this review, an assessment about the extent of commercial and other trade benefits to Australia was made. It found that the program had generated substantial commercial benefits for Australia. However, it also concluded that more ex-post evaluations should be conducted of DIFF programs so that future performance could be enhanced (AusAid 1996).

## **AusIndustry programs**

### *The Enterprise Improvement Scheme*

The Enterprise Improvement Scheme (EIS) is a joint Commonwealth, State and Territory network of business information, referral and advisory services for small to medium enterprises. This program was formerly the National Industry Extension Scheme (NIES) — the name was changed in 1995 when AusIndustry became responsible for its administration. In 1995-96, Commonwealth and State budget allocations to this program totalled \$39.2 million.

EIS helps companies identify and respond to opportunities for improving how they do business. In particular, EIS can help enterprises to:

- assess their effectiveness and market positioning;
- identify problem areas affecting cost competitiveness; and

- develop a new business operation plan.

EIS also provides a subsidy of 50 per cent of the cost of engaging specialist consultants who assist in identifying and facilitating change. Subsidies are available for a range of business improvement activities. These include export marketing and financial planning, technology and environment audits, as well as human resource and manufacturing development.

Data concerning the medical and scientific equipment industries' use of this program are available on a state and territory basis (see Table H.4).

**Table H.4** Use of EIS scheme by MSE industries, by State: a comparison with total EIS assistance, 1995-96

<i>State<sup>a,b,c</sup></i>	<i>Total government assistance to MSE sector (\$'000)</i>	<i>Total MSE companies receiving assistance (No.)</i>	<i>Total government assistance (all industries) (\$'000)</i>	<i>Total companies (all industries) receiving assistance (No.)</i>
New South Wales	31	6	3 907	369
Victoria	73	9	6 000	673
South Australia	13	4	2 700	260
Queensland	186	4	6 255	677
Western Australia	55	10	1 897	247
Tasmania	42	2	1 140	86
ACT	0	0	650	60

a NT excluded as no assistance provided to the industries through the EIS over the past five years.

b NSW and Qld data classified according to ANZSIC 283 (Photographic and scientific equipment manufacturing); Vic, WA, Tas and ACT data classified according to ANZSIC 2832 (Medical and surgical equipment manufacturing) and ANZSIC 2839 (Professional and surgical equipment manufacturing); and SA data classified according to ASIC 334 (Photographic, professional and scientific equipment manufacturing).

c Although no assistance was provided in the ACT to the MSE in 1995-96, assistance in 1994-95 was about \$11 200.

*Sources:* State and Regional Development (NSW) 1996; AusIndustry (VIC) 1996; Department of Manufacturing Industry, Small Business and Regional Development (SA) 1996; Department of Tourism, Small Business and Industry (QLD) 1996; Department of Commerce and Trade (WA) 1996; AusIndustry (Tas) 1996; and AusIndustry (ACT) 1996

The Bureau of Industry Economics (BIE) reviewed the NIES in 1992. Among other things, the BIE found there appeared to be some overlap with programs of other government departments and the program could be further improved by better dissemination of information. The BIE commented:

There may still, however, be a need for more specialised information for firms about where to obtain advice about technologies and what sort of issues are involved in adopting best practice techniques. (BIE 1992, p.ii)

The program was also reviewed by Australian National Audit Office (ANAO) in 1994. The ANAO considered that greater priority should be given to clearly establishing the effectiveness of the program in achieving its aim of making companies more internationally competitive. It also concluded that there was some evidence of duplication between this scheme and others (ANAO 1994b).

In the August 1996 Budget, the Government announced the EIS will be rationalised and savings will be made by reducing payments to the States and Territories through the AusIndustry Commonwealth/State Bilateral Agreements. Over the next two years these savings are estimated to amount to \$34 million.<sup>3</sup> (Costello 1996b, p.63)

### *The Business Networks Program*

The Business Networks Program originated from the Government's *Working Nation* statement in 1994. It is a four year program and assists groups of at least three businesses to undertake joint activities to increase their capabilities. Activities can include targeting export or domestic markets, sharing production facilities and product development costs, or grouping together to win large contracts.

The basis of the Business Networks Program is a three-stage network formation process, in which network brokers facilitate cooperation among the participants. Financial assistance is provided to engage the services of an accredited network broker. The broker's role is to do a feasibility study of the proposed business network, develop a business plan, and act as a facilitator throughout the process.

The Government funds the program through AusIndustry, and it is being implemented in conjunction with a range of industry associations, federal and state government agencies, local governments, regional development authorities and private consultants. The Commonwealth Government has allocated \$38 million since 1994 to support the creation of networks, with most going to the Business Networks Program (BIE 1995a). Funding for the program in 1996-97 is \$8 million (AusIndustry 1996f, p.3).

Participants in this inquiry have commented favourably on the program. For instance, George Weber and Associates identified:

The AusIndustry business network program ... doesn't deliver a lot of money but it delivers a lot of support and a lot of fostering of getting SMEs together to do things ... It's an excellent one. (PH trans, p.29)

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<sup>3</sup> These savings affect funding for the selection Enterprise Development Programs of which the EIS is a part.

Information from the Department of Industry, Science and Tourism (DIST) identifies that in the 18 months to September 1996 a total of 170 networks have been created through this program. As program data are not collected on an ASIC or ANZSIC basis, it is not possible to identify the use of the program by companies in the medical and scientific equipment industries. However, in the Health Services Sector, 12 networks have been formed since the program's inception. Additionally, a total of 77 companies in the Health and Education Services Sector are currently involved in network formation. (DIST 1996a)

In a report assessing business linkages and networks in Australia, the BIE found many companies were sceptical about governments providing specialist brokers to help form networks (BIE 1995a).<sup>4</sup> The BIE believed the reliance on network brokers might result in some resistance to the formation of new networks. It suggested AusIndustry supplement its Business Networks information material and recommended:

... AusIndustry should supplement its information material about the program with new data highlighting the many benefits of networks. The role of network facilitators need to be marketed if they are to become acceptable to a wider range of firms. (BIE 1995a, p.258)

In the August 1996 Budget, the Government did not to introduce any changes to the Business Networks Program.

### *BizLink, BizHelp and BizAccess*

BizLink aims to improve access to government program information for small and medium companies and their advisers by forming an integrated easily accessible business information source. The August 1996 Budget provided for the BizLink, BizHelp and BizAccess programs to be maintained and Commonwealth funding for the program in 1996-97 is \$0.55 million. (AusIndustry 1996f, p.2)

BizHelp is an electronic guide to business assistance programs and services. It is distributed on computer diskette and updated every three months. Over 500 Commonwealth, State and Territory government programs are available on the BizHelp module. A twelve month subscription costs \$200.

In comparison, BizAccess was developed for AusIndustry by the Australian Chamber of Commerce and Industry. This companion product to BizHelp lists more than 260 forms of assistance provided by the various industry associations and chambers of commerce — ranging from business start-up advice to training and trade facilitation. (AusIndustry 1996b and 1996d)

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<sup>4</sup> These comments were not restricted to firms in the medical and scientific equipment industries.

Data is not collected by AusIndustry on use of this program by industry sector.

### **International linkage programs**

The International Science and Technology Program (ISTP) and the Bilateral Science and Technology Program (BSTP) are two particular government endeavours which aim to develop and strengthen international linkages. These programs are outlined below.

#### *International science and technology program*

The ISTP was established in 1989 and aims to enhance international science and technology linkages through collaboration between research teams in Australia and overseas on projects of significance to Australian industry and national research interests. An example of an ISTP grant for Photonics/laser research is documented in Box H.1.

#### **Box H.1     Photonics/laser research**

In 1992-93, an ISTP grant of \$35 000 was given to the Photonics Cooperative Research Centre (CRC). This CRC is particularly interested in developing links with major transnational companies involved in fibre optics technology. This grant was to be used for developing collaboration between Korea and the centre — it was initially proposed to facilitate this through the conduct of a workshop in Korea to identify areas for collaborative research. However, the funds have been used to develop linkages through a series of researcher visits to Korea. As Peter Kearns and Associates (1995) document:

The Korean interaction has involved visits to Korea to address Korean researchers at their annual photonics meetings; visits to the CRC by delegates to the first APEC Information Superhighway Forum held in Sydney from which links with a major Korean company were initiated ... the project has focused on establishing linkages with industry. (p.29)

*Source:*                      Peter Kearns and Associates, 1995

This program is administered through DIST with applications for funding considered by the International Science and Technology Advisory Committee. The Commonwealth Government allocated approximately \$4.8 million to this program in 1996-97.

Funding is available for a period of one to three years and is not available for small scale activities such as visits by individual researchers or single visits. All organisations (local and overseas) that are involved in the collaboration are expected to contribute towards the cost of the program.

Australian research groups or consortia in universities, government research institutions and industry are eligible for funding. Where projects are of relevance to industry — the collaborative activities and how they will benefit the firms in



question need to be detailed. In particular, a significant share of commercial benefits must accrue to Australian firms.

Data from DIST indicates that in the past three financial years, a number of collaborative activities involving the medical and scientific equipment industries were organised within the context of this scheme. Data are not collected separately for this scheme and incorporate the BSTP (see Table H.5).

An independent review of the ISTP was completed in 1995 by Peter Kearns and Associates. This review found that the program has been effective in stimulating and supporting longer-term collaboration in R&D with other countries; and that the program has generated new ideas and stimulated innovation. The review was supportive of the program and its management but recommended that the program provide a clearer focus on national priorities and on maximising returns in stimulating industry innovation. (Peter Kearns and Associates 1995)

**Table H.5 Assistance provided to the MSE industries through the ISTP and the BSTP: 1993-94 to 1995-96 (current dollars)**

	<i>1993-94</i>		<i>1994-95</i>		<i>1995-96</i>	
	<i>Recipients (No.)</i>	<i>Amount (\$'000)</i>	<i>Recipients (No.)</i>	<i>Amount (\$'000)</i>	<i>Recipients (No.)</i>	<i>Amount (\$'000)</i>
Companies <sup>a</sup>	nil		nil		nil	
Other organisations <sup>b</sup>	16	107	17	111	20	186
<b>Total grants provided (across all industries)</b>		<b>2630</b>		<b>2870</b>		<b>3590</b>

a Two applications were received from companies in the period 1993 to 1996. Both failed to meet the required eligibility criteria.

b Other organisations include government funded research institutions (for example, universities) and private not-for-profit organisations (for example, the Florey Institute).

Source: DIST 1996

### *Bilateral science and technology program*

The BSTP is administered by DIST and provides support for collaborative research between scientists in Australia and other countries for basic research and more applied industrial endeavours. Support is available for research visits by individual scientists and for joint seminars and technical workshops. Funding within the Program covers or contributes to travel and living expenses. Research resources, salaries and equipment are the responsibility of the various participating institutions.

In 1995-96, a total of \$1.2 million was allocated to this program and in 1996-1997 this will increase to \$1.5 million. Information from DIST suggests that the ISTP and the BSTP have been used by those within the medical and scientific equipment industries (see Table H.5).



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# **I CHAPTER 90 TARIFF ITEMS**

## **I.1 Customs Tariff, Schedule 3**

### **Section XVIII, Chapter 90**

Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof.

- 9011 Compound optical microscopes, including those for photomicrography, cinephotomicrography or microprojection.
- 9012 Microscopes other than optical microscopes; diffraction apparatus.
- 9013 Liquid crystal devices not constituting articles provided for more specifically in other headings; lasers, other than laser diodes; other optical appliances and instruments, not specified or included elsewhere in this Chapter.
- 9014 Direction finding compasses; other navigational instruments and appliances.
- 9015 Surveying (including photogrammetrical surveying), hydrographic, oceanographic, hydrological meteorological or geophysical instruments and appliances, excluding compasses; rangefinders.
- 9016 Balances of a sensitivity of 5 cg or better, with or without weights.
- 9017 Drawing, marking-out or mathematical calculating instruments (for example, drafting machines, pantographs, protractors, drawing sets, slide rules, disc calculators); instruments for measuring length, for use in the hand (for example, measuring rods and tapes, micrometers, callipers), not specified or included elsewhere in this Chapter.
- 9018 Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments.
- 9019 Mechano-therapy appliances; massage apparatus; psychological aptitude-testing apparatus; ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus.
- 9020 Other breathing appliances and gas masks, excluding protective masks having neither mechanical parts nor replaceable filters.

- 9021 Orthopaedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability.
- 9022 Apparatus based on the use of X-rays or of alpha, beta or gamma radiations, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus, X-ray tubes and other X-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like.
- 9023 Instruments, apparatus and models, designed for demonstrational purposes (for example, in education or exhibitions), unsuitable for other uses.
- 9024 Machines and appliances for testing the hardness, strength, compressibility, elasticity or other mechanical properties of materials (for example, metals, wood, textiles, paper, plastics).
- 9025 Hydrometers and similar floating instruments, thermometers, pyrometers, barometers, hygrometers and psychrometers, recording or not, and any combination of these instruments.
- 9026 Instruments and apparatus for measuring or checking the flow, level, pressure or other variables of liquids or gases (for example, flow meters, level gauges, manometers, heat meters), excluding instruments and apparatus of 9014, 9015, 9028 or 9032.
- 9027 Instruments and apparatus for physical or chemical analysis (for example, polarimeters, refractometers, spectrometers, gas or smoke analysis apparatus); instruments and apparatus for measuring or checking viscosity, porosity, expansion, surface tension or the like; instruments and apparatus for measuring or checking quantities of heat, sound or light (including exposure meters); microtomes.
- 9028 Gas, liquid or electricity supply or production meters, including calibrating meters thereof.
- 9029 Revolution counters, production counters, taximeters, mileometers, pedometers and the like; speed indicators and tachometers, other than those of 9014 or 9015; stroboscopes.
- 9030 Oscilloscopes, spectrum analysers and other instruments and apparatus for measuring or checking electrical quantities, excluding meters of 9028; instruments and apparatus for measuring or detecting alpha, beta, gamma, X-ray cosmic or other ionising radiations.

- 9031 Measuring or checking instruments, appliances and machines, not specified or included elsewhere in this Chapter; profile projectors.
- 9032 Automatic regulation or controlling instruments and apparatus.
- 9033 Parts and accessories (not specified or included elsewhere in this Chapter) for machines, appliances, instruments or apparatus of Chapter 90.

### *Exceptions*

While the Commission has confined its discussion to subheadings 9011 to 9033, within these subheadings are tariff items covering instruments and components used in passenger motor vehicles. These items are listed below, and have been omitted from the discussion in this report as they will be considered in the Commission's inquiry into the passenger motor vehicle industry.

**Table I.1 Chapter 90 tariff items not under reference in this inquiry**

<i>Tariff item</i>	<i>Goods</i>
9026.10.10	Gauges for measuring or checking the flow or level of liquids of a kind used solely or principally in passenger motor vehicles. Other gauges for measuring or checking the flow or level of liquids of a kind used with internal combustion engines.
9026.20.10	Gauges for measuring or checking pressure of a kind used solely or principally in passenger motor vehicles. Other gauges for measuring or checking pressure (non electric).
9026.80.10	Other gauges of a kind used solely or principally in passenger motor vehicles.
9029.10.10	Revolution counters etc commonly used with motor vehicles.
9029.20.00	Speed indicators and tachometers.
9029.90.00	Parts and accessories of above.
9032.89.10	Automatic voltage regulators of kind commonly used with passenger motor vehicles.
9032.90.91	Programmable controllers of the kind used as replacement components in passenger motor vehicles.
<i>Source:</i>	Customs Tariff, Schedule 3



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## **J MAIN ANZSIC DIVISIONS FOR MEDICAL AND SCIENTIFIC EQUIPMENT INDUSTRY ACTIVITIES**

The activities covered by the main ANZSIC divisions relating to the medical and scientific equipment industries are listed below (from ABS & DSNZ 1993).

### **ANZSIC 2382 Medical and surgical equipment manufacturing**

This class consists of units mainly engaged in manufacturing (mfg) medical, surgical or dental equipment, including dentures.

#### *Primary activities*

Artificial eyes mfg	First aid equipment mfg
Artificial joints mfg	Hypodermic needles or syringes mfg
Artificial limbs mfg	Medical equipment mfg
Dental Amalgams mfg	Respirators mfg
Dental instrument or equipment mfg	Surgical equipment mfg
Denture fabrication	Thermometers, medical, mfg
Diagnostic apparatus mfg	Veterinary instruments mfg

### **ANZSIC 2389 Professional and scientific equipment manufacturing n.e.c.**

This class consists of units mainly engaged in manufacturing measuring, draughting, meteorological, surveying or other professional or scientific instruments or equipment n.e.c. (not elsewhere classified), or watches, clocks or other timing equipment.

#### *Primary activities*

Clocks mfg	Optical fibre cable, uninsulated, mfg
Control equipment, electrical mfg	Radar equipment mfg
Electricity meters mfg	Scientific instruments or equipment
Measuring instruments mfg	mfg n.e.c.
Meteorological instruments mfg n.e.c.	Surveying instruments mfg

Nautical instruments mfg

Watches mfg

Navigational equipment mfg

**ANZSIC 4612      Professional equipment wholesaling**

This class consists of units mainly engaged in wholesaling scientific, medical or other professional equipment.

*Primary activities*

Medical equipment wholesaling n.e.c.

Professional equipment wholesaling

Scientific equipment wholesaling



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## K SURVEY QUESTIONNAIRE

To augment official data on the Australian medical and scientific equipment industries, the Commission initiated a survey of the two industries. Major objectives of the survey were to get a better understanding of domestic factors affecting the viability of individual firms, factors affecting Australian companies' sales on export markets and the strengths and weaknesses of Australia as an investment location.

This appendix contains a copy of the survey questionnaire. Appendix L contains the survey results.

The questionnaire was initially prepared by the Commission and Susan Hocking, Research and Consulting. It was developed further by the Commission and Coopers & Lybrand Consultants. The Commission gratefully acknowledges the main industry associations who assisted with the preparation of the questionnaire and administration of the survey.





























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## **L SURVEY RESULTS**

As detailed in Appendix K, the Commission initiated a survey of the medical and scientific equipment industries. Appendix L contains Coopers & Lybrand Consultants' final report on the results of the survey. Appendix K contains a copy of the survey questionnaire.

The Commission wishes to thank the many individuals and companies who took time to complete the questionnaire.

The Commission also wishes to thank the Medical Industry Association of Australia, the Scientific Suppliers Association of Australia, and the Australian Medical and Services Exports Group. This survey benefited from previous surveys undertaken by these Associations and their extensive input and support for this survey.































































































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