Australian Government Department of Health and Ageing submission to the Productivity Commission:

Public support for science and innovation

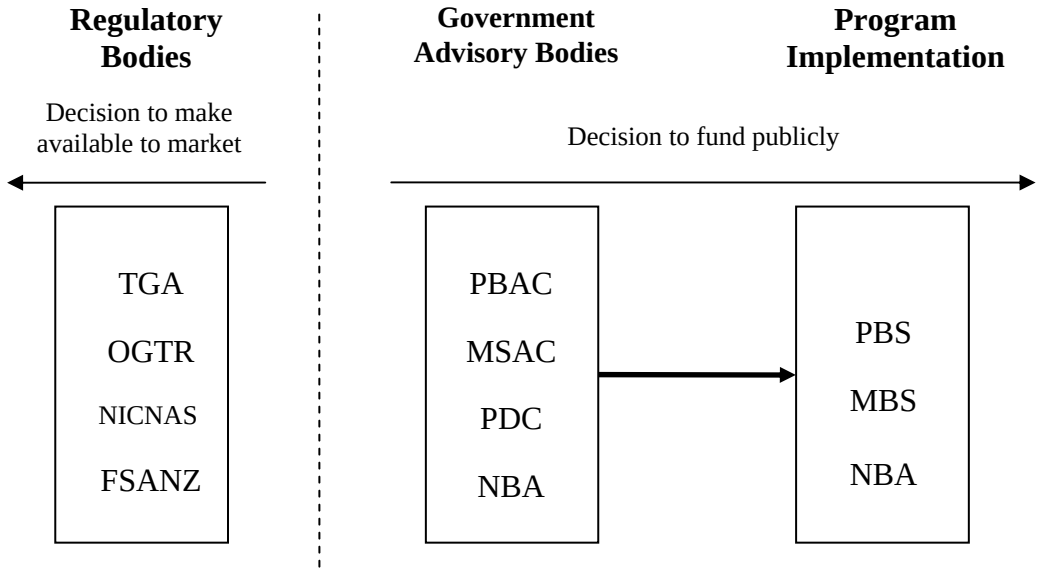
Introduction

The Australian Government funded National Health and Medical Research Council (NHMRC) holds primary carriage for health and medical research activities. The Department of Health and Ageing has a strong interest in health and medical research and has prime responsibility for research policy, including its regulation, accreditation and subsidisation. In terms of innovation in the health workforce, the Department has a key role in providing support for training and education. There are a range of portfolio bodies that regulate and provide advice and recommendations to the Australian Government relating to new medical procedures, technologies and services.

Health and medical innovation and public policy

The Health and Ageing portfolio includes a range of regulatory and advisory bodies whose purpose is to ensure that new health innovations are tested on efficacy, safety, and net-benefit grounds, and make recommendations for public funding where appropriate. These include the Therapeutic Goods Administration (TGA), the Gene Technology Regulator (GTR), National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Food Standards Australia New Zealand (FSANZ), National Blood Authority (NBA), Pharmaceutical Benefits Advisory Committee (PBAC), Medical Services Advisory Committee (MSAC) and the Prostheses and Devices Committee (PDC). Figure 1 provides a broad overview of these arrangements.

Figure 1 Overview of Australian Government regulatory and advisory processes relating to science and innovation in the health portfolio



Regulatory bodies

Bodies such as the TGA, OGTR, NICNAS and FSANZ decide whether new innovations are safe and efficacious, and hence appropriate for use by the Australian public.

TGA

The TGA is responsible for the regulation of therapeutic products (including medicines, medical devices, blood, tissues and cellular therapies) in Australia. Under the *Therapeutic Goods Act 1989* (the Act), the TGA's specific objective is to ensure the quality, safety, efficacy or performance and timely availability of therapeutic products imported into, supplied in and/or exported from Australia.

The TGA carries out regulatory activities consistent with the objectives of the Act and also provides advice to Ministers in relation to the operation of the current regulatory system for therapeutic products, as well as possible changes to the system to meet future needs of the Australian population.

The TGA regulates therapeutic products through:

- pre-market assessment;
- post-market monitoring and enforcement of compliance with standards; and

- licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

By and large, the TGA is not a driver of innovation and technology change. However, the TGA and the regulatory scheme it administers must be responsive to and able to meet the challenges of regulating innovative products and products incorporating technological changes. In order to fully discharge its public health responsibilities, the TGA responds to innovation and technological advances by reviewing and, where appropriate, amending its quality and safety standards.

GTR

The GTR was established to administer the *Gene Technology Act 2000* (the GT Act). The Office of the Gene Technology Regulator (OGTR) assists the GTR. The object of the GT Act is to protect the health and safety of people and the environment by regulating dealings with genetically modified organisms (GMOs). Gene technology is a constantly changing area of science. The recent independent statutory review of the GT Act found that it effectively deals with changing circumstances and emerging trends. The focus of the gene technology regulatory scheme is the protection of human health and safety and the environment. States retain the responsibility for economic issues, such as trade, under the gene technology regulatory scheme. There are also mechanisms to address social and ethical issues.

NICNAS

NICNAS is a statutory regulatory scheme in relation to the notification and assessment of industrial chemicals. The object of the Scheme is to aid in the protection of the Australian people and the environment by finding out the risks to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals. NICNAS also provides advice to the Australian Government, state and territory bodies and the community on the safety of industrial chemicals (including cosmetics) and gives effect to Australia's obligations under international agreements relating to the regulations of chemicals.

FSANZ

FSANZ is an independent statutory agency which works within an integrated food regulatory system, involving the governments of Australia and the New Zealand Government. FSANZ develops, varies and reviews food regulatory measures. States and territories implement these standards.

FSANZ's key statutory objectives are: (i) the protection of public health and safety; (ii) the provision of adequate information relating to food to enable consumers to make informed choices; and (iii) the prevention of misleading or deceptive conduct.

In meeting these objectives, FSANZ has regard to a number of additional factors, including the need for standards to be based on risk analysis using the best available scientific evidence. In order to enhance the evidence base, FSANZ commissions scientific studies and coordinates some of the scientific research undertaken by jurisdictions. The successful application of science, is critical to the effectiveness and appropriateness of most food regulatory measures, and underpins the risk management decision making process.

Over recent years, the FSANZ Board has agreed various types of food regulatory reform which are being implemented to facilitate innovation in the food industry, while continuing to protect public health and safety. These food regulatory reforms are usually evidence based and utilise scientific risk assessment methodology. Current examples are: Health Claims and the Fortification of food with iodine and folic acid.

NBA

While not a regulatory body by definition (the TGA is responsible for regulating the blood sector), the NBA aims to improve the management of the Australian blood banking and plasma product sector at a national level, through the National Blood Agreement 2003 and the *National Blood Authority Act 2003*. The NBA manages supply contracts on behalf of the Australian, State and Territory Governments and promotes adherence to national safety and quality standards.

The National Blood Agreement requires that decisions about changes to products and services funded under the national arrangements be supported by evidence-based evaluation, information and advice, as determined by the Jurisdictional Blood Committee (JBC). In

accordance with this requirement, the NBA will soon be conducting a tender process to procure services for the development of a blood-sector specific cost-effectiveness evaluation framework. This will assist the JBC to make recommendations to Health Ministers, who are responsible for deciding whether blood products and services are subsidised by governments, by including them in the National Blood Products and Services List.

Advisory bodies

Bodies such as PBAC and MSAC advise the Australian Government on the appropriateness and cost-effectiveness of listing pharmaceuticals and procedures, on either the Pharmaceutical Benefits Schedule (PBS) or the Medical Benefits Schedule (MBS).

The PDC makes recommendations to the Minister for Health and Ageing on the listing of new prostheses, and the setting of benefit levels of new and existing prostheses and devices that health insurance funds will need to cover for their Members with private health insurance.

PBAC

The PBAC evaluates applications from pharmaceutical companies for pharmaceuticals to be subsidised under the PBS, and makes recommendations to the Minister for Health and Ageing. The appraisal process is evidence-based and in line with international best practice.

The Pharmaceutical Benefits Pricing Authority (PBPA) is an independent non-statutory authority established in 1988, which determines, or recommends to the Minister for Health and Ageing, the prices of items listed as pharmaceutical benefits or recommended by PBAC for listing on the PBS. In considering the price of drugs, PBPA takes into account PBAC's advice on the clinical and cost-effectiveness basis of its recommendation, as well as a number of other factors including the prices of alternative brands, comparative prices of drugs in the therapeutic class, cost information from manufacturers, prescription volumes and overseas prices.

MSAC

The principal role of the Medical Services Advisory Committee (MSAC) is to advise the Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures. This advice informs Australian

Government decisions about whether new technologies and procedures are considered for reimbursement under the MBS.

The Committee's terms of reference are to:

- advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost effectiveness and under what circumstances public funding should be supported;
- advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost effectiveness;
- advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures; and
- undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC), and report its findings to AHMAC.

PDC

The PDC makes recommendations to the Minister for Health and Ageing on the listing of new prostheses, and the setting of benefit levels of new and existing prostheses and devices that health insurance funds will need to cover for their Members with private health insurance. These recommendations will be based on advice from the Clinical Advisory Groups (CAGs) and the Panel of Clinical Experts, primarily in relation to the clinical effectiveness and relative clinical effectives of prostheses and devices, and advice from benefit negotiators about appropriate prices for the different effectiveness categories of items.

The CAGs and the Panel of Clinical Experts are comprised mainly of specialist clinicians. They are required to address clinical effectiveness and relative clinical effectiveness in doing this will review data relating to:

- absolute clinical effectiveness of individual or groups of prostheses and devices;
- relative differences in clinical effectiveness between prostheses and devices which are used for the same or similar purposes; and
- impact on patient outcomes of the prostheses or devices.

Once an item is included on the Prostheses List, health insurers must fund either the full cost of the prosthesis in the case of a no gap prosthesis, and up to the minimum benefit amount that is set for a gap permitted prosthesis. They may fund the difference between the minimum benefit and the maximum benefit amount determined.

Funding decisions

Following recommendations from these bodies the Government will decide whether to fund new pharmaceuticals or medical procedures, or include new devices on the Prostheses List. The MBS and the PBS directly support patient access to affordable health care by subsidising patients for the costs of services and therapies delivered predominantly by private medical practitioners and suppliers. In 2005-06, the Australian Government provided an estimated $16.9 billion to subsidise access by individual Australians to medical and pharmaceutical services.

A recent example is Herceptin, which will be listed on the PBS from 1 October 2006 for the treatment of patients with HER2 positive early stage breast cancer following surgery. It is estimated that 2,000 people will commence Herceptin in the first full financial year of listing. Herceptin will cost approximately $470 million between 2006-07 and 2009-10.

In terms of new medical procedures, following the Minister's endorsement in November 2005 of an MSAC recommendation, the Australian Government listed Selective Internal Radiation Therapy (SIRT) using SIR-Spheres for the treatment of colorectal cancer on 1 May 2006. Medicare funding for these items is available for four years until May 2010, before which time MSAC will review the results of trials conducted in the intervening period.

Innovation in the health workforce

Technological innovation

From 2006-07 to 2008-09 the Australian Government will contribute $65 million to the COAG initiative to develop a national electronic health records system. This will build the capacity for health providers, with their patient's consent, to communicate quickly and securely with other health providers across the hospital, community and primary medical

settings. This funding is in addition to the $9 million already committed by the Government for progressing e-health initiatives.

The Australian Government supports investment in information technology to assist health workers to carry out their work more efficiently and effectively. Examples include the Broadband for Health measure and the Information Management/Information Technology component of the Practice Incentives Program, which provides incentives to general practitioners to send and receive clinical information electronically, including radiology and pathology reports.

As part of the 2004-05 Budget measure, Investing in Australia's Aged Care – Streamlining administration for better care, eBusiness is being introduced to the aged care sector. This measure assists aged care providers to take advantage of new technology and improve their business practices.

Education and Training

General Practice Education and Training Ltd (GPET) was established in 2001 by the Australian Government to develop, oversee and fund general practice training for postgraduate medical practitioners. GPET is responsible for the national management of the Australian General Practice Training Program, which provides high quality general practice education and vocational training for registrars wishing to pursue a career in general practice.

Training is delivered through 22 regional training providers. Different methods of training delivery and support are being implemented to cater for individual differences among registrars and the varying demands of urban and rural environments. These include the implementation of an "e-portal" for online access to medical education resources.

The Australian Government funds a range of initiatives to assist the health workforce maintain and update their skills and knowledge (including new innovations in health care) to enable them to provide high quality services.

The Government is supporting innovation and quality improvement in primary care through the Australian Primary Care Collaboratives Program. The program assists general

practitioners improve their clinical and business systems, which leads to improved clinical outcomes for patients with chronic and complex conditions.

The Divisions of General Practice, funded by the Australian Government, continue to provide education and training to general practitioners in a range of clinical and non-clinical areas to assist them with responding to new innovations in medicine. This includes, chronic disease management, information management/technology and working with nurses and allied health workers.

Supporting research infrastructure and the science community

NHMRC

From 1 July 2006 the NHMRC became an independent agency which now reports directly to the Minister of Health and Ageing. The majority of health innovation research funding is allocated by the NHMRC on a basis that combines peer review and research directed into priority areas. An example of directed research funding of $7.5 million announced in the latter half of 2005 for suitable research proposals that targeted better ways to tackle the emergence of a pandemic influenza outbreak in this country[1].

The 2004 Grant Review notes the positive return on Australia's health and medical research investment to the treatment, health and wellbeing of Australians since 1960. This includes gains in our lifespan of eight years and markedly improved quality of life and avoided costs of illness.

The 2006-07 Budget finalised the Government's response to the Grant Review, which assessed implementation of the Wills six-year funding expansion program from 2000-01. Since the beginning of that program, Government funding for medical research grants and fellowships has quadrupled. In the 2006-07 Budget the Australian Government announced the allocation of an additional $905 million of new funding in support of Australian health and medical research. This includes $500 million over four years to increase funding for health and medical research grants provided through the NHMRC.

[1] http://www.health.gov.au/internet/ministers/publishing.nsf/content/health-mediarel-yr2005-ta-abb117.htm accessed 01/08/06

National Adult Stem Cell Research Centre

Research involving adult stem cells has great potential to provide benefits in an increasing number of fields in health and medicine. The Government will provide $20 million over four years towards establishing a National Adult Stem Cell Research Centre at Griffith University, and an additional $2 million towards the fit out costs of the centre. The extra funding will enhance its capacity to undertake cutting-edge research.

Office of Hearing Services

The Australian Government, through the Office of Hearing Services, provides Australian Hearing with funding of $3 million each year for scientific research and innovation in hearing rehabilitation protocols and hearing device development conducted in its research division, the National Acoustic Laboratories.

Medical research facilities

In order for Australia to maintain its international reputation for important medical research and advancement, our medical research facilities must be of a standard capable of carrying out complex research activities to attract world class researchers and maximise returns on investment. Building Australia's physical capacity to undertake medical research is vital to these objectives.

The Australian Government provides funding for research facilities to expand and improve their capacity and their reputations for quality research into the causes, diagnosis and treatment of disease. The 2004-05 Budget included $200 million over seven years to fund infrastructure for independent medical research facilities in receipt of NHMRC research grant funding. The 2006-07 Budget allocated a further $221 million in grants to medical research facilities, which builds on the Government's strong record of support for medical research, including infrastructure.

The funding comprises:

- $50 million for the Walter and Eliza Hall Institute of Medical Research
- $10 million for the Macfarlane Burnet Institute for Medical Research and Public Health
- $10 million for the Murdoch Children's Research Institute Australia
- $10 million for the Children's Cancer Institute Australia

- $10 million for the Centenary Institute
- $5 million for the Woolcock Institute of Medical Research
- $10 million for Heart Research Institute
- $15 million for the Westmead Millennium Institute
- $14 million for the Garvan Institute and Victor Chang Cardiac Research Institute
- $10 million for the Olivia Newton-John Cancer Centre
- $5 million for the Gallipoli Research Foundation
- $6 million for the Sydney Melanoma Unit
- $2 million for the Brain and Mind Research Institute
- $10 million for the Queensland Brain Institute
- $37 million for the Howard Florey Institute
- $4 million for the Marshall Centre for Infectious Diseases
- $5 million for the Hunter Medical Research Institute
- $8 million for the following national research centres in HIV/AIDS, hepatitis C and sexually transmissible infections:
    - The Australian Centre in HIV and Hepatitis Virology Research
    - The National Centre in HIV Epidemiology and Clinical Research
    - The National Centre in HIV Social Research
    - The Australian Centres in Sex, Health and Society

New research fellowships

The highly competitive environment for health and medical research in Australia has meant that deserving research projects have missed out on the limited resources available. In turn, this has deterred some of Australia's most outstanding and talented researchers from pursuing careers in health and medical research in Australia.

In the 2006-07 Budget the Australian Government allocated $170 million over nine years to establish a new Australian Health and Medical Research Fellowship (Australian Fellowship) Scheme. The Australian Fellowship will be the pre-eminent award of its type in Australia and aims to attract and retain leading health and medical researchers.

It is intended that this scheme will support outstanding senior health and medical researchers across all disciplines both nationally and internationally and will facilitate the establishment of research teams in Australia. Australian Fellowship will support between 50 and 65 senior

research positions. These fellowships, which are in addition to the existing 70 to 80 new NHMRC fellowships every year, will be awarded to Australian researchers who would otherwise not obtain research funding. The scheme will see approximately 10 to 13 new fellows commence a five year-long research program each year.

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