Cost Recovery Inquiry
Productivity Commission
Locked Bag 2
Collins Street East Post Office
Melbourne VIC 8003

13th November 2000

Blackmores Submission into Cost Recovery arrangements

Dear Mrs Owens,

Thank you for the opportunity to provide additional comment to the Commission in relation to government cost recovery arrangements. The visit to Blackmores on 18th October by the Commission was a valuable exchange of ideas and issues. We are hopeful concerns raised by industry can be assessed and appropriate recommendations made.

Therapeutic Goods Administration (TGA)

Blackmores Ltd as a marketer of complementary healthcare products, is required to pay a variety of fees and charges imposed by the TGA, a branch of the Commonwealth Department of Health and Aged Care. The TGA is required by the Government to recover from industry the full cost of it operations. It is our understanding that few Commonwealth agencies are required to do this as many only charge fees for any direct services provided. The operational activities of the TGA are required to protect public health and safety. Some of their activities seem to lack accountability and performance standards. Internal policies are not made publicly known to industry. Parts of its monopoly services could be contested elsewhere at reduced cost.

1 Fees and Charges

- Enclosed at Appendix 1 is the current list of fees and charges from the TGA as at 1st July this year. There are a number of charges Blackmores contends are either grossly inappropriate for the service provided or do not equitably represent full cost recovery for certain sectors of industry.
- All therapeutic goods, where applicable, are required to maintain an entry on the Australian Register of Therapeutic Goods (ARTG) in order to supply to the Australian marketplace. The charges to maintain the database vary depending on the type of product but as a minimum it is $350 per product for a listed medicine, to a maximum of $950 for a prescription only medicine. Blackmores will spend in the financial year 2000/2001 approximately $160,000 to maintain the list of products we market on the ARTG. This charges is payable annually and over the last few years the cost per product has increased

as the TGA contend they need to meet cost recovery obligations. Blackmores questions why a cost of approximately $160,000 for 2000/2001 is justified to maintain a basic computer database of product information. These annual charges are a huge impost to industry. Changes to the ARTG are made on a fee per application service. It should be reasonable to expect these application fees should also cover the maintenance of the database as well. A computer database of this nature could be contracted out to the private sector at a greatly reduced cost. In addition to these annual charges many companies are not required to pay the full annual cost if their products are low value, low volume. If the annual charge represents 6% or more of the annual wholesale turnover of the goods the full fee is waived and a $70 charge per product applies. If it actually costs the TGA a minimum of $350 per product to maintain the entry on the ARTG the $70 low value, low volume charge must in fact be subsidised by other companies. This is not equitable across industry. Products for export only are also exempt from paying any charges to maintain the ARTG. These costs are presumed to be subsidised by other sectors of the medicines industry.

- Australian manufacturers of therapeutic goods are required to hold a licence issued by the TGA to certify compliance with Good Manufacturing Practices (GMP). The annual charge to maintain this licence varies depending on the type of products made. Audit fees charged by the TGA to certify GMP in Australia are reasonable but charges for overseas manufacturers audits seem excessive and industry has no avenue to scrutinise these costs. Overseas audits are charged out at $745 per hour, airfares and travel allowance payable separately. The $745 is the hourly rate for the auditor to perform the on-site audit. There seems little justification for such a high charge. The private sector could equally perform audits on a contract basis for the TGA at reduced cost.

2 Community Service Obligations

- Industry by and large funds many activities of the TGA it does not have any commercial interest in, they are primarily Community Service Obligations. For example the TGA's web site, briefings and policy advice to the Government, the provision of information to the public, laboratory analysis, operation of the TGA's legal unit, reciprocal arrangements with other countries and the TGA's surveillance and enforcement activities should not be paid for by industry. It is also important to note that while industry pays for these activities the TGA has no accountability to industry for the budget, expenditure or performance standards in relation to these activities. If industry is expected to pay for these activities there should be proper accountability for them. It is also recognised that consumers could be concerned that if industry pays for surveillance and enforcement programs it could exert influence over these activities and undermine the security of public health and safety. It would seem preferable that industry not pay for Community Service related activities.
- Industry also appears to pay for other pseudo-Community Service Obligation activities such as training, conferences, and networking. Attached at Appendix 2 is variety of articles published in the TGA News highlighting such activities. It is not clear where the resources and expenses to participate in these programs comes from.

3 Efficiency

- Many direct services industry pay for appear inefficient or are not performance based. For example, listing a product onto the ARTG involves the company (sponsor) completing an electronic application form, submitting payment to the TGA ($400) and waiting for the application to be processed. The processing time is not mandated and waiting times for approval have varied from several days to months depending on the product. Frequently the processing timeframes blow out dramatically due to staffing problems at the TGA, prescriptive analysis of the applications or inadequate expertise available resulting in applications being referred within the TGA to other departments. If industry is expected to pay for a service it is preferable there is agreed processing timeframes and a feedback service provided so sponsors are aware of the current timelines and the delays in processing. Fees to process applications by and large increase each year with no corresponding increases in levels of service or transparency of operations.

4 Export of Goods

- Blackmores has a growing export business in complementary healthcare products, primarily in New Zealand and South East Asia. In order to facilitate the export of a medicine to those countries the TGA requires that each export product maintain an entry on the ARTG. The cost to list a product for export only on the ARTG is $400. This cost presumably covers the processing of the application. Industry has long argued that the TGA are not responsible per se for the regulation of products for export markets other than a brief assessment of the product for inclusion onto the ARTG. It is the responsibility of the importing country to regulate the goods for import and make the decision that the product is suitable for marketing under their own regulatory framework. The TGA have advised industry it is a parliamentary directive to ensure that all medicinal goods for export are evaluated prior to being manufactured and shipped. The evaluation criteria has changed somewhat during recent times and industry has no input into the transparency of such policies but it is expected to pay the full cost to administer the service. The fees relating to the services the TGA provides for the export of medicines like many other charges increases most years.

Department of Foreign Affairs and Trade (DFAT)

1 Export of Goods

- Once a Certificate of Pharmaceutical Product is issued by the TGA ($70 per certificate) it requires certification by the DFAT, then some of the individual country embassies. It is a huge impost to industry that DFAT must certify an original government document the TGA has already produced. Companies spend inordinate amounts of time and courier costs waiting for documents to be shipped around the various state capital cities for certification, processing timeframes not mandated by these offices. Export opportunities can be lost due to the slow and prescriptive processing required for certificates for exported medicines by both the TGA and DFAT. In addition DFAT have increased their certification fees by 100% as at 1st July 2000. Previous to that a signature cost $20, it now costs $40 with no discernible increase in the levels of service or a decreased processing

time. Note that DFAT have advised that the 100% increase does not include any GST component.

Other Fees

- Blackmores pays approx. $80,000 per annum as membership fees to belong to the Complementary Healthcare Council (CHC), the peak industry association representing complementary healthcare manufacturers and retailers. A large percentage of the fees companies contribute to the CHC is allocated for resources to negotiate with the TGA on matters of regulatory reform. Issues such as appropriate regulation, cost recovery, new substance approvals, export facilitation and advertising being some of the major priorities for industry representation by the CHC. By being a member of the CHC the membership fees, by de-facto, become additional charges required to do business with the TGA for the regulation of medicines. As parts of the regulatory framework for medicines are self-regulatory or co-regulatory, costs such as membership fees form part of the funding from industry to regulate public health and safety in conjunction with the TGA.

In closing, it is hopeful the Commission is able to assess the monopoly services the TGA provides in addition to the costing structure for their services. Industry requires the TGA and DFAT to ensure that cost recovery activities are provided in the most cost-effective manner and would encourage ongoing strategies to improve their current service arrangements.

Yours sincerely,

Darin Walters
Chief Executive Officer
Blackmores Ltd

CC : Ms Jan Samuels, Mr Marcus Blackmore

TGA THERAPEUTIC GOODS ADMINISTRATION

APPENDIX 1

ABN: 40 939 406 804

NOTES ACCOMPANYING
SUMMARY OF FEES AND CHARGES AT 1 JULY 2000

GST STATUS

All of the fees and charges listed on the 'Summary of Fees and Charges' are exempt from GST under Division 81 of A New Tax System (Goods and Services Tax) Act 1999.

'No ABN Withholding' does not apply to TGA as our ABN is quoted on the fee schedule and various other documents. Also TGA is exempt from paying income tax.

ANNUAL CHARGES - All Therapeutic Goods

- Annual Charges have increased from 1 July 2000.

- The percentage of sales used for determining low volume / low value products for exemption from annual charges is 6%.

Low Volume and Low Value Products

Eligibility: Annual charges are not payable for 'low volume, low value' therapeutic goods. To be eligible for exemption from payment of annual charges in 2000/01, a sponsor must apply to the Secretary of the Department of Health and Aged Care for a declaration that the turnover of the therapeutic good is low volume and low value. Application forms are sent by TGA with Annual Charge invoices. To make this declaration, the Secretary must be satisfied that the charge for registration/listing is:

1. greater than 6% of the wholesale turnover of the good for the 1999/00 financial year or;
2. if there was no turnover in 1999/00, greater than 6% of the value of the estimated wholesale turnover in the 2001/02 financial year.

A non-refundable application fee of $70 per registration/listing is payable and must be forwarded with the application form. If the amount of application fees incurred by the sponsor in a year reaches $10,000 no further low volume/low value application fees are payable in that year.

PRESCRIPTION MEDICINES

Evaluation fees are calculated according to the number of pages of Part 2, Part 3 and Part 4 data included in the submission. Where there is Part 2, 3 or 4 data included in Part 1, the number of pages of this data is included in the page count.

- 75% of evaluation fees are payable on lodgement except Category 3 submissions, where 100% of the fee is payable on lodgement.

- Where the total fee payable is greater than $100,000, the submission may be lodged without payment, and an invoice for 75% of the fee will be sent after screening. If such a submission is not accepted or withdrawn before acceptance, a screening fee is payable immediately.

- If an application is not accepted for evaluation or withdrawn before acceptance for evaluation, part of the evaluation fee will be retained to cover the cost of screening the submission. This is

known as a screening fee.

- The screening fee is set at 10% of the evaluation fee to a maximum fee of $5000.

Variations

- When a variation requires evaluation, an evaluation fee, including both the screening and evaluation fee components is charged. This is calculated according to the number of pages of Part 2, Part 3 and Part 4 data included in the submission. Where there is Part 2, 3 or 4 data included in Part 1, the number of pages of this data is included in the page count.

- If an application for variation is not accepted for evaluation or withdrawn before acceptance for evaluation, a screening fee of 10% of the evaluation fee to a maximum fee of $5,000.

- Where no evaluation is required, either an administrative fee or a self assessable/notification fee is payable.

- An administrative fee is only payable for transfer of sponsorship. All other variations not requiring evaluation attract a self assessable / notification fee.

REGISTRATION OF NON-PRESCRIPTION MEDICINES (OTC AND COMPLEMENTARY MEDICINES)

- The additional/concurrent application fee only applies where a sponsor submits more than one application at the same time, each product has the same active ingredient(s) and the information is sufficiently common to enable a simultaneous evaluation to be made.

- Where clinical and/or toxicological data are included in a submission, the evaluation fee is calculated with reference to the combined number of pages of clinical and toxicological data. Expert reports and summaries need not be included in the page count.

LISTED MEDICINES

- Fees for listed medicines increased on 1 July 2000.

REGISTERED DEVICES

- Changes to Registered Device fees came into effect 22 June 2000.

- High Level Registrations requiring simultaneous evaluation:
  - an additional/concurrent application fee is payable for each additional application, up to a maximum amount payable of $7,000 (including the application fee for the principal device).

- High Level Registration of a new product or variation to an existing registration requiring confirmatory review of overseas evaluation report:
  - an evaluation fee is payable for the initial application.

- Low Level Registration of a new product or variation to an existing registration:
  - evaluation fees are now levied on a per category basis, and
  - a separate evaluation fee applies for disinfectants or diagnostics goods for in vitro use.

TGA THERAPEUTIC GOODS ADMINISTRATION

Summary of Fees and Charges at 1 July 2000

ABN: 40 939 406 804

PRESCRIPTION MEDICINES:

EVALUATION FEES - per submission

A submission may include any number of applications for registration which contain the same therapeutically active ingredient and for which the data submitted is sufficiently common to enable simultaneous evaluation of the goods to be made. It may be for a new registration or a variation to an existing registered medicine where evaluation is required.

Chemistry pharmaceutical & biological data - Part 2

Page counts	Fee $ - 100%	Fee $ - 75%
1 - 10	725	544
11 - 50	6,200	4,650
51 - 100	13,750	10,313
101 - 1000	18,500	13,875
1001 - 3000	29,000	21,750
3001 - 4000	38,500	28,875
> 4000	47,000	35,250

Pharmaco-toxicological data - Part 3

Page counts	Fee $ - 100%	Fee $ - 75%
1 - 25	3,125	2,344
26 - 200	10,650	7,988
201 - 2000	38,500	28,875
2001 - 7000	57,000	42,750
7001 - 20000	62,500	46,875
> 20000	67,500	50,625

Clinical data - Part 4

Page counts	Fee $ - 100%	Fee $ - 75%
1 - 25	5,400	4,050
26 - 300	16,500	12,375
301 - 2000	39,500	29,625
2001 - 7000	72,500	54,375
7001 - 20000	83,000	62,250
20001 - 40000	88,500	66,375
> 40000	93,500	70,125
Screening fee	10% of evaluation fee to maximum $5,000	

LISTED DEVICES

- Changes to Listed Device fees came into effect 22 June 2000.

- Labelling exemption applications:
  - an application fee is payable for processing an application for consent under S14 of the Act.

- Safety evaluation:
  - an evaluation fee is payable for assessing whether a listable or listed device is safe for the purposes for which it is to be used.

GOOD MANUFACTURING PRACTICE

Note: The term 'GMP certification fee' replaces 'Inspection fee'.

Licence application fee and Annual licence charge

- Licence application fees and annual licence charges have not changed.

Local GMP Certification Fees

- Local GMP certification fees are not payable in some circumstances. GMP certification fees are payable when a certification is undertaken before a licence is issued or if a manufacturer requires more than the average certification in terms of time, frequency or number of auditors. Average GMP certification times are:
  1. Manufacturers with low level licence charges - 1 auditor for 8 hours (1 day), with a certification frequency of 2 every 3 financial years.

  2. Manufacturers with high level licence charges - 2 auditors for 12 hours (1.5 days), with a GMP certification frequency of 2 every 3 financial years.
- GMP certification fees are charged at an hourly rate per auditor for on-site time and all types of certifications attract the same hourly rate per auditor.

Overseas GMP Certification Fees:

- GMP certification fees are charged at an hourly rate per auditor for on-site time and all types of certifications attract the same hourly rate.
- Travel allowance and air fare are payable separately.
- Overseas GMP certification fees are payable in advance.

Prescription Medicines (cont.)	Fee $
Annual charge	950
Administrative change/ Notification fee	500
Clinical Trials	**Fee $**
CTX 30 Days	1,100
CTX 50 Days	13,500
CTN	200
CTN-more than one trialing body	200

REGISTRATION OF NON-PRESCRIPTION MEDICINES (OTC & COMPLEMENTARY MEDICINES):	Fee $
Application fee	650
Additional /concurrent application fee	275
Processing fee (variation to an existing registration)	650
Annual charge	465
EVALUATION FEES per submission if the evaluation documentation does not contain Clinical or Toxicological data	**Fee $**
New product	4,300
Variation	1,550
New substance: CMEC, sunscreen excipients, all other	4,300
EVALUATION FEES - page counts	
New product – total page count of Clinical or Toxicological data per submission	**Fee $**
1-50 pgs	4,300
51-250 pgs	5,500
251-500 pgs	7,500
501-1000 pgs	10,000
1001-2000 pgs	15,000
2001-3000 pgs	20,000
>3000 pgs	30,000
Variations - total page count of Clinical or Toxicological data per submission	**Fee $**
1-50 pgs	1,550
51-250 pgs	5,500
251-500 pgs	7,500
501-1000 pgs	10,000
1001-2000 pgs	15,000
2001-3000 pgs	20,000
>3000 pgs	30,000

Registration of Non-prescription Medicines (cont.) Evaluation Fees – page counts (cont.)	
New Substance – total page count of Clinical or Toxicological data per submission	**Fee $**
1-50 pgs	4,300
51-250 pgs	5,500
251-500 pgs	7,500
501-1000 pgs	10,000
1001-2000 pgs	15,000
2001-3000 pgs	20,000
>3000 pgs	30,000
Multiple new excipients in listed or registered good for dermal use	**Fee $**
1-50 pgs	4,300
51-250 pgs	5,500
251-500 pgs	7,500
501-1000 pgs	10,000
1001-2000 pgs	15,000
2001-3000 pgs	20,000
>3000 pgs	30,000

LISTED MEDICINES:	Fee $
Application fee	400
Processing fee (variation to an existing listing)	200
Annual charge	350

REGISTERED DEVICES	Fee $
Application fee - high level registration	2,400
Additional/concurrent - high level registration	1,200
Application fee - low level registration	800
Additional/concurrent - low level registration	400
Processing fee - high level registration (variation to an existing registration)	800
Processing fee - low level registration (variation to an existing registration)	400
Annual charge	900
Device Clinical Trials	
CTN	200
Clinical Trial - other	1,500
Clinical Trial – Sched 3 Pt1 Item 3	10,000

EVALUATION FEES	Initial Application Fee $	Concurrent Application Fee $	Abridged Application Fee $
High Level Registration -type of data			
Design/materials/testing	17,600	3,000	6,000
Manufacture/quality control	12,000	3,000	5,000
Biocompatibility/pre-clinical	12,000	3,000	5,000
Human clinical	20,000	3,000	20,000
Software	12,000	3,000	5,000
Confirmatory review of clinical information	N/A	N/A	5,000
Confirmatory review of overseas evaluation report	12,000	3,000	5,000
Low Level Registration -type of data			
Design/materials/testing	3,000	N/A	N/A
Manufacture/quality control	3,000	N/A	N/A
Biocompatibility/pre-clinical	3,000	N/A	N/A
Human clinical	3,000	N/A	N/A
Software	3,000	N/A	N/A
Disinfectants and diagnostic goods for in vitro use	10,000	N/A	N/A

Registered Devices (cont.):

EVALUATION FEES (cont.)	Initial Application Fee $	Concurrent Application Fee $	Abridged Application Fee $
Variation – High Level Registration – type of data			
Design/materials/testing	6,000	1,000	N/A
Manufacture/quality control	5,000	1,000	N/A
Biocompatibility/pre-clinical	5,000	1,000	N/A
Human clinical	20,000	1,000	N/A
Software	5,000	1,000	N/A
Confirmatory review of clinical information	5,000	N/A	N/A
Confirmatory review of overseas evaluation report	5,000	1,000	N/A
Variation – Low Level Registration – type of data			
Design/materials/testing	800	N/A	N/A
Manufacture/quality control	800	N/A	N/A
Biocompatibility/pre-clinical	800	N/A	N/A
Human clinical	800	N/A	N/A
Software	800	N/A	N/A
Disinfectants and diagnostic goods for in vitro use	2,000	N/A	N/A

LISTED DEVICES:	Fee $
Application fee	240
Processing fee (variation to an existing listing)	240
Application for exemption under Section 14	240
Annual charge	450
Evaluation Fees	
Evaluation for assessing whether a listable or listed device is safe for the purposes for which it is to be used	4,000

GOOD MANUFACTURING PRACTICE	Fee $
Licence application fee	540
Examination of plant master file	5,625
Annual Licence Charge	
Single step/single medicine/type of device	3,500
In-vitro diagnostic products	3,500
Ingredients or components	3,500
Herbal/homoeopathic medicinal products	3,500
Other types of therapeutic goods manufacturer	6,800
Local Good Manufacturing Practice (GMP) Certification fee when payable - see note below table (previously Inspection Fee)	**Hourly rate per Auditor $**
Single step/single medicine/type of device	355
In-vitro diagnostic products	355
Ingredients or components	355
Herbal/homoeopathic medicinal products	355
Other types of therapeutic goods	355

GMP Certification fees are payable when a certification is undertaken before a licence is issued or if a manufacturer requires more than the average certification in terms of time, frequency or number of auditors.
Average GMP certification times are:
Manufacturers with low level licence charges - 1 auditor for 8 hours (1 day), with a certification frequency of 2 every 3 financial years.
Manufacturers with high level licence charges - 2 auditors for 12 hours (1.5 days), with a certification frequency of 2 every 3 financial years.

Overseas Good Manufacturing Practice (GMP) Certification Fee (previously Inspection Fee)	**Hourly rate per Auditor $**
Single step/single medicine/type of device	745
In-vitro diagnostic products	745
Ingredients or components	745
Herbal/homoeopathic medicinal products	745
Other types of therapeutic goods	745

MISCELLANEOUS	Fee $
Export Certificate & Certificate of GMP Compliance	70
ARTG reinstatement application fee - registered medicines or devices - per invoice	540
ARTG reinstatement application fee - listed medicines or devices - per invoice	270
Manufacturer's assessment fee	165
Application for Declaration that Turnover is Low Volume and Low Value – per product ($10,000 max.)	70
ARTG information - Freedom of Information (FOI) charges apply - contact ARTG for advice.	
The percentage of sales used in calculation of low volume and low value products for exemption from annual charges is 6%.	

APPENDIX 2

TGA news

The official newsletter of the Therapeutic Goods Administration

TGA TEAM EARNS US AWARD

Two scientists from the TGA in Canberra have been presented with US Vice-President Al Gore's Hammer Award for their work on exposing counterfeit medicines. Dr Larry Kelly and Mr Robert Prestridge accepted the award on behalf of the TGA at a ceremony in Washington D.C. on 29 June.

Hammer Awards are presented in recognition of innovative work performed in the public interest. The hammer symbolises the breaking down of barriers though teamwork, and a collaborative effort to achieve significant advances. Among scientists from several other national agencies who were also recognised for their work in this field, Dr Kelly and Mr Prestridge are founding members of an international group which first met in 1997 in response to increasing concerns over the spread of counterfeit medicines, especially the active raw materials used to formulate medicinal products. The group also includes members from the US, the UK, Germany, Canada and the Netherlands.

The Hammer Award recognises the TGA's contribution to the development of an analytical method to detect counterfeit and sub-standard ingredients in medicines. The method utilises the characteristic profile or 'fingerprint' of an impurity residue arising from the manufacturing process, which, when compared with data from other regulatory agencies, allows its source to be verified. The method can also be applied to herbal substances—herbal species can be characterised to enable the detection of substitution, adulteration and contamination in herbal medicinal products.

TGA Laboratories staff who assisted with development of the method include Jean Barrie, Bob Irvine, Vidya Jagadish, Adrian Krauss, Pam Larkin, Mali Maliyasenya, Tue-Hai Nguyen, Kirsten Sharp, Margaret Smith and Leonor Winter.

In congratulating Dr Kelly, Mr Prestridge and TGA Laboratories staff, Parliamentary Secretary for Health and Aged Care Senator Grant Tambling said: 'Governments worldwide agree that international trade in pharmaceuticals and herbal products from unapproved sources is an area of great concern. If undetected, counterfeit preparations pose a serious threat to the supply of safe and effective legitimate medicinal products. The issue of counterfeit medicinal products was considered recently by the Parliament when changes were made to Australia's legislation to strengthen regulatory controls and increase penalties for the manufacture, supply or export of counterfeit therapeutic goods.'

The new method has been made available to industry and to other regulatory agencies, and was briefly outlined in previous issues of *TGA News*. Recent editions of the *TGA Laboratory Information Bulletin* contain more details of the methodology.

TGA staff who assisted with development of the method

The Hammer Award

ISO TECHNICAL COMMITTEE 194 BIOLOGICAL EVALUATION OF MEDICAL DEVICES, MAY 2000

ISO Technical Committee 194 is responsible for the standardisation of approach and test methods in the evaluation of medical devices and materials for biological safety; and administers the ISO 10993 Standard, which currently has 18 parts, of which 16 are published. In May 2000, 13 of the 15 working groups comprising the Committee (a total of 70 delegates from 13 countries) met in Japan to discuss technical and editorial issues. Doctors Shirley Bolis and Arthur Brandwood attended as TGA's delegates for Standards Australia.

In response to a questionnaire distributed prior to the Committee's meeting, several users of ISO 10993 had expressed concerns about inconsistencies of interpretation of the Standard by regulatory agencies. To address such concerns the meeting resolved that an 'informative annex' should be included in the Standard and that the Committee should investigate mechanisms through which it can play a greater role in the global harmonisation of regulatory requirements for the biological assessment of medical devices.

The need to improve the interpretation, consistency and relevance of the ISO 10993 series was a recurring theme throughout the meeting, and draft documents dealing with these issues will be circulated to member Standards Organisations for their approval within the next nine months.

APEC WORKSHOPS ON RISK ANALYSIS IN FOOD SAFETY REGULATION

In February and March 2000 Les Davies and Jack Dempsey from the TGA's Chemical Review and International Harmonisation Section made presentations at two APEC (Asia-Pacific Economic Cooperation) sponsored workshops on risk analysis in food safety regulation at the Chisholm Institute in Melbourne. They covered hazard and risk assessment for chemicals and food contaminants, risk analysis case studies on particular pesticides, and international sources of hazard and risk assessment information.

With responsibilities in areas such as food inspection, standards development and policy making, the 32 workshop participants hailed from a diverse range of Asia–Pacific nations including Thailand, the Philippines, Indonesia, Vietnam, the People's Republic of China, Hong Kong, Papua New Guinea, Singapore and Chinese Taipei.

Australia and New Zealand have contributed to APEC on food regulatory matters through the ANZFA (Australia New Zealand Food Authority) since 1995, and initiated a program of regional collaboration. The risk analysis workshops are an outcome of that collaboration. By facilitating information exchange, these workshops can help to align national and international standards, and promote the APEC goal of liberalising regional trade and investment.

TGA staff with ANZFA staff and some of the workshop participants at the first APEC workshop

Subject to the availability of funding, an evaluation of the effectiveness of the workshops will be undertaken later this year, and further workshops to train senior officials in the application of risk analysis in food regulation will be considered.

HOW TO REDUCE APPLICATION TIMES – IMPROVING THE QUALITY OF APPLICATIONS TO LIST MEDICINES SOLELY FOR EXPORT

It is estimated that information provided in around 50% of recently received applications for listing of solely-for-export medicines was either incomplete or incorrect. Sponsors are reminded that it is their responsibility to provide accurate information to the TGA—penalties may apply if they recklessly make false or misleading statements. Poor quality applications cause delays in processing and hamper the TGA's ability to meet target time frames. Sponsors can ensure the accuracy and completeness of their application by consulting the checklist on the TGA website.

Sponsors who wish to export medicines to Taiwan or South Korea are advised that the authorities in these countries have indicated that they will not accept solely-for-export medicines, and will not respond to Prior Informed Consent (PIC) letters. Where justified—for instance, if the product is supplied in Australia and an excipient has been changed to comply with the requirements of the destination country—the Export Unit is prepared to pursue matters with the Department of Foreign Affairs and Trade on a case-by-case basis.

REQUESTS FOR CERTIFICATES OF PHARMACEUTICAL PRODUCT (CPP) – HOW TO AVOID REJECTIONS

Applicants now have one opportunity to rectify errors in applications for a Certificate of Pharmaceutical Product (CPP) and resubmit the application or additional pages.

When an application for a CPP is lodged, the application and attached schedules are reviewed. If any errors are identified during the review process the sponsor is contacted by the TGA's Export Unit to make the necessary amendments and resubmit the application and/or attached schedules. Any discrepancies between Australian Register of Therapeutic Goods (ARTG) records and the sponsor's submissions are brought to the attention of the sponsor. The sponsor should liaise with ARTG staff to resolve any inconsistencies.

If the resubmitted information is still incomplete or incorrect, the application may be rejected; however, applications will not be rejected where errors are due to circumstances beyond the control of the sponsor; for example, if incorrect information has previously been entered into the ARTG. Refer to the TGA website for a list of the types of errors that constitute a basis for rejection.

Sponsors are also reminded that where an application has been made to vary a listing or registration, an application for a CPP should not be submitted until the variation has been approved. Further details on the information required in the application form, and the format of the schedules, will be published on the TGA website http://www.health.gov.au/tga.

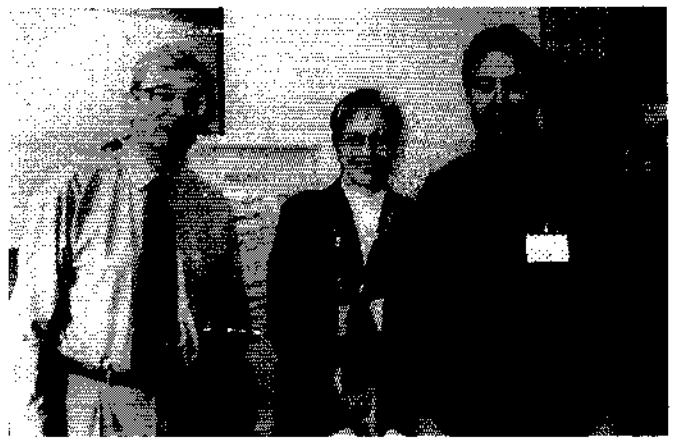
INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

The International Programme on Chemical Safety (IPCS) is a joint venture of the World Health Organisation (WHO), the United Nations Environment Programme (UNEP), and the International Labour Organisation (ILO). The IPCS Harmonisation of Risk Assessment Project is aimed at developing common risk assessment methodologies so that countries can reach transparent chemical management decisions using uniform processes and terminology.

One high priority area is the harmonisation of uncertainty and variability factors. At present, regulators use uncertainty factors (also known as safety factors) in the risk assessment of chemicals to allow for differences in toxicological effects between laboratory animals and humans (interspecies variability), and differences within the human population (human variability). The use of different uncertainty factors by different countries may lead to a variety of risk management outcomes for the same chemical, which can cause difficulties in trade and/or exchange of assessment information.

Drew Wagner, from the Chemical Review and International Harmonisation Section, is a member of the IPCS planning workgroup that met recently in the UK as part of the harmonisation project. At this meeting, case reports on several chemicals were presented in a common format developed by international experts in a workshop held in Berlin in May. The IPCS framework resulting from the Berlin meeting has been referred to a drafting group and will be circulated for comment by the end of the year. It will be an important tool for risk assessors and should result in more consistent risk assessment outcomes for chemicals.

For further information contact Drew Wagner on (02) 6270 4382



Professor Andrew Renwick OBE (University of Southampton), Ms Cynthia Sonich-Mullin (IPCS) and Mr Drew Wagner (TGA) at the IPCS planning workgroup meeting.

REVIEW OF DRUGS & POISONS

THE REVIEW OF DRUGS, POISONS AND CONTROLLED SUBSTANCES LEGISLATION

Ms Rhonda Galbally, Chair of the Review of Drugs, Poisons and Controlled Substances, recently released a Draft Report for comment by interested parties prior to finalisation of the Report. This Final Report will be passed initially to the Australian Health Ministers' Conference, and upon consideration of the report by AHMAC it will be forwarded to the Council of Australian Governments. The recommendations of the Draft Report moot changes to remove anti-competitiveness measures where the benefits of the regulation can be achieved in other ways. The draft recommendations also cover measures to improve the efficiency of both the Commonwealth and States and Territories legislation and related administrative changes. For further information and a copy of the Draft Report, visit the TGA web site: http://www.health.gov.au/tga or contact Ms Laurayne Bowler in the Review Secretariat: telephone 6270 4370.

LABELLING PROJECT

The new scheme for the regulation of the labelling of medicines is being developed in consultation with major stakeholders. The proposed scheme springs from the responses received from stakeholders to the discussion paper *Effective by design*, which set out several options for change. Further information can be found on the TGA web site: http://www.health.gov.au/tga or contact Ms Laurayne Bowler on 6270 4370.

WORLD HEALTH ORGANIZATION WORKSHOP ON INFORMATION EXCHANGE IN MANAGEMENT AND USE OF PHARMACEUTICALS, BIOLOGICALS AND HERBAL MEDICINES FOR PACIFIC ISLAND COUNTRIES: NADI, FIJI, 25-28 OCT 1999.

Workshop participants

A WHO-sponsored workshop was held in Fiji last October to assist Pacific Island nations in their management and use of medicines, including pharmaceutical medicines, biologicals and herbal medicines. The Workshop was attended by representatives of twenty Pacific Island nations, representatives of WHO and consultants from TGA and other organisations. Over four days the group reviewed procedures for procuring pharmaceutical drugs, biologicals and herbal medicines in each country, as well as procedures for assuring the quality of medicines and the sharing of information between the countries.

Dr Garry Hopkins from the TGA Laboratories presented the results of quality assurance testing undertaken by TGAL on samples of procured medicines submitted by the Pacific Island Countries. A separate presentation discussed the regulation of biologicals, focussing on considerations specific to biologicals and problems likely to be encountered with these products when used in the Pacific Region. Dr Hopkins also acted as a facilitator in discussion groups where country representatives developed recommendations and plans of action to improve the situation in their countries. After four days the WHO were presented with a number of clearly defined recommendations, each accompanied by a plan of action which identified specific actions to be undertaken and a detailed timetable for implementation.

HEPATITIS C VIRUS RNA TESTING OF PLASMA POOLS

The risk of Hepatitis C Virus (HCV) contamination of plasma-derived medicinal products has resulted in the introduction of new requirements for HCV testing of plasma pools by nucleic acid amplification techniques:

- European Pharmacopoeia Monograph on Human Plasma for Fractionation PA/PH Exp. 6B/T (97) 9 DEF.
- CPMP/BWP/390/97 The Introduction of Nucleic Acid Amplification Technology (NAT) for the Detection of HCV RNA in Plasma Pools.
- Council of Europe PA/PH/OMCL (98) 22, DEF Feb 1999 Validation of Nucleic Acid Amplification Technology for the Detection of HCV RNA in Plasma Pools.

In accordance with these requirements, the TGA Laboratories Branch has commenced validation assays for detection of HCV RNA in plasma pools. It is anticipated that the assay will be validated in the near future, enabling TGA to be in a position to test plasma pool samples if required.

OFFICIAL MEDICINES CONTROL LABORATORIES MEETING

Dr Clive Morris recently attended the 4th Annual Meeting of the European Network of Official Medicines Control Laboratories (OMCL) in Hillerød, Denmark. The OMCL Network was created to provide common resources, communications and quality assurance for all Official Medicines Control Laboratories. While the core group consists of member States of the European Union and the European Pharmacopoeia Commission, other countries have been invited to participate, including Australia and Canada.

In her opening address, Madame Agnes Artiges (Director, European Department for the Quality of Medicines) gave an outline of some of the achievements of the Network over the last year, including wider participation in the Mutual Joint Visit Program, development of common quality control procedures and discussions on coordination of OMCL activities. While oral and written annual reports from OMCLs were presented at the meeting, the agenda was arranged to include scientific discussion of specific issues, including the use of Capillary Electrophoresis and compliance with the European Phamacopoeia Sterility test.

Dr Morris presented three posters at the meeting, which generated considerable interest among the delegates. The posters were entitled *"Quality Testing of Pharmaceuticals from Pacific Island Nations"; "Identification of Scutellaria lateriflora (Skullcap) in herbal products"; and "Detection of Aristolochic Acids in Chinese Medicines".*

The second day of the meeting included a tour of the Danish OMCL facilities.

Outcomes from the meeting included:

- Formal adoption of principles defining the OMCL Network and its membership;
- Preparation of a template for preparation and submission of annual reports by all OMCL members;

will be initially for use within the TGA and will speed up the time taken in assessing applications. Later this year, the assessment engine will be available to clients as part of the new online Electronic Lodgement Facility for Listed Medicines. If you would like further information about the Listing Process or the Listed Medicine Assessment Engine, please contact Listed Medicines Team Leader, George Kokkinis on (02) 6232 8716.

We will continue to keep you updated in future issues of the TGA News on progress of the project and how you can be involved. For further information on the SIME Project or the Special Interest Groups please contact the TGA Project Manager –

Joanne Harper
Phone 02 6232 8794
Fax 02 6232 8423
Email joanne.harper@health.gov.au

ENFORCEMENT NEWS

Recent prosecutions

Recent prosecutions by the Surveillance Unit have resulted in the convictions of:

- A Sydney man and a Sydney company in relation to the importation of large quantities of a topical prescription medicine product; and
- The same Sydney man and company in relation to further importations of the same medicine.

Current prosecutions

Prosecutions currently before the courts include:

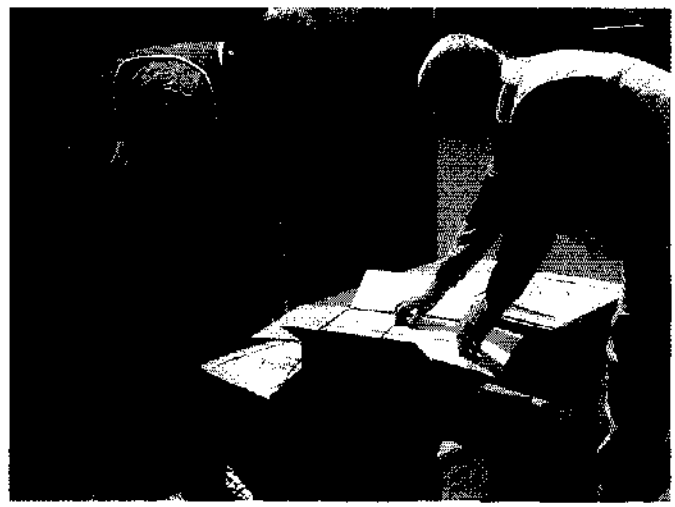
- A Cairns man and a Cairns company charged with multiple counts of importing and exporting both prescription and non prescription medicines;
- A Melbourne company charged with several counts of manufacturing and supplying non prescription medicines; and
- A Brisbane man and a Brisbane business charged with multiple counts of importing and supplying non-prescription medicines.

Trans Tasman training

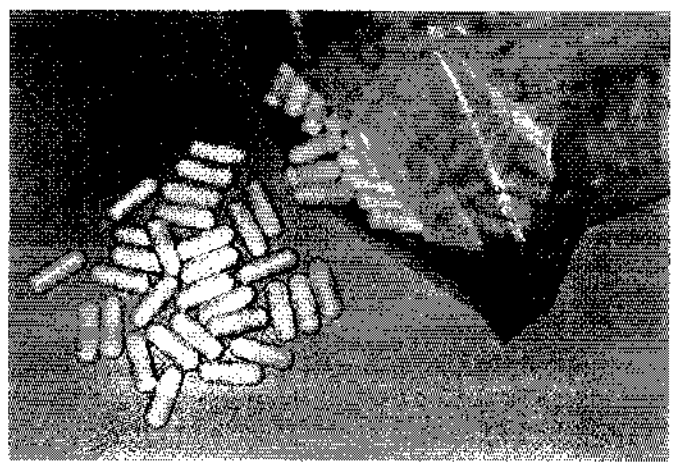
Surveillance Unit investigations, particularly in relation to counterfeit medicines, often have international links. A number of joint investigations have been conducted by the Unit with overseas agencies, including the New Zealand Ministry of Health. These investigations have resulted in criminal prosecutions in both Australia and New Zealand.

Investigators from both agencies recently completed specialist investigator training conducted by the TGA in Australia. The training focussed on law, evidence and techniques applicable to the investigation of crimes involving therapeutic goods.

An assortment of traditional Chinese medicine products unlawfully imported into Sydney. These products include prescription medicines, complementary medicines and medical devices. Some of these medicines contained "prohibited imports" under Customs legislation and "protected species" under international conventions.



Surveillance Unit investigators examining a container load of unapproved complementary medicines at the Melbourne waterfront. These goods had been unlawfully imported and falsely described as "foods and condiments".



Part of a shipment of steroids, in oral dosage form, smuggled into Brisbane. This importer was bottling these capsules and labelling them as "dietary supplements" to supply in Australia to the health and fitness industry.

TGA INTERNATIONAL ACTIVITIES

Consultancy on drug regulation for Singapore and Hong Kong

The TGA is currently assisting the Centre for Drug Evaluation (CDE) of Singapore to build its capability for drug evaluation on a consultancy basis. In September 1999, Dr Susan Alder, Principal Medical Adviser of TGA, visited CDE to discuss and review Singapore's current evaluation system. A report has been provided to the CDE. As part of the consultancy, a CDE regulatory scientist was attached to DSEB for 4 weeks late last year.

The TGA was also requested by the Hong Kong Department of Health to conduct a consultancy study on their registration system of pharmaceutical products. Dr Suzanne Hill of the University of Newcastle was contracted by TGA to conduct this review in December and later joined by Dr Leonie Hunt of DSEB. The report of the review was finalised in February this year.

DIA-TGA Fellowship Program

This Program is financially sponsored by the Drug Information Association (DIA). The 1999 Fellowships have been awarded to Singapore, Thailand and Malaysia.

Mrs Marie Tham of the National Pharmaceutical Administration of Singapore took up her Fellowship at TGA from 22 November to 17 December 1999. The key areas of her Fellowship were on complementary medicines and health supplements.

Ms Worasuda Yoongthong and Mr Pinpong Intarapanich of the Thai Food and Drug Administration were in Australia from 28 February to 7 April 2000.

The last Fellow of the 1999 Program is Mr Che Mohd Zin B Che Awang, Deputy Director of the Drug Evaluation and Safety Division, National Pharmaceutical Control Bureau of Malaysia.

Mrs Marie Tham with her Fellowship Certificate and members of the Fellowship Management/Mentor Group (L to R) Drs Cheng Bui, Gordon Burch, Udomsri Low, Clive Morris and John Hall)

Technical assistance program for Vietnam

In 1999, TGA was granted funding from AusAID under the APEC Support Program to provide technical assistance to the Drug Administration of Vietnam (DAV).

In November 1999, three DAV legal officers visited TGA for a week to discuss Vietnam's draft drug law with TGA senior legal officers.

In March 2000, two DAV pharmacists were attached to the TGA Adverse Drug Reactions Unit for two weeks. This attachment enabled them to learn about adverse drug reactions monitoring in Australia.

GMP training programs for Asia-Pacific countries

In September 1999, a GMP auditor of the National Pharmaceutical Administration of Singapore underwent training in Australia. In February 2000, two pharmacists of the Pharmaceutical Service Headquarters of Hong Kong undertook a GMP training program at TGA. Both training programs were funded by their respective governments.

Under the APEC Support Program and the Government Sector Linkages Program (GSLP) funded by AusAID, four Indonesian GMP auditors from the Indonesian Directorate of Indonesian Drug Control, were trained in Australia for a period of 2 weeks in October 1999.

Also under the APEC Support Program, Mr David Buckley, a senior TGA GMP auditor, conducted two GMP training workshops in Vietnam for the DAV in November 1999. Following that, three DAV officers underwent a 3-week GMP training program in February 2000 in Australia. A second group of DAV GMP trainees will be in Australia late this year.

From 16 to 22 November 1999, Mr David Buckley was invited by WHO to be a trainer for a Workshop in China. This workshop was organised by the State Drug Administration of China in Beijing on behalf of WHO.

Contact officer: Dr Udomsri Low, International Operations Section, (02) 6232 8090

A HEALTHY ATTITUDE TO GENE TECHNOLOGY REGULATION

The *Draft Gene Technology Bill 2000* – which will provide a comprehensive framework to protect the health and safety of Australians and our environment from any risks associated with Genetically Modified Organisms (GMOs) – will be introduced into Parliament this year.

The Bill will complement existing regulatory Acts, including the Australia *New Zealand Food Authority Act 1991* and the *Therapeutic Goods Act 1989*.

In last year's Federal Budget, the Commonwealth Health portfolio was given responsibility for overseeing the development of the new regulatory system. Following this transfer of responsibilities from the Industry, Science and Resources portfolio, the Interim Office of the Gene Technology Regulator (IOGTR) was formed in TGA.

- establishment of an Export Desk to advise and refer sponsors with export problems and concerns.

Contact details

Margaret Burdeu, acting Manager, International Cooperation, Tel 03 9665 8982, Fax 03 9665 8979.

Time is of the essence...

Top tips to avoid delays in obtaining a Certificate of Pharmaceutical Product (CPP).

- Please read the *Guide to Application for Certification of a Pharmaceutical Product* before completing the application form. Make sure the form has been completed correctly, appropriate boxes have been ticked and all questions are answered.
- Check all information, including formulation, to ensure it matches with information on the Australian Register of Therapeutic Goods (ARTG). If not, please contact the ARTG and/or relevant areas to have the discrepancies rectified *before* applying for a CPP. Changes to the CPP application after it has been submitted result in delays in CPP issue.
- Australian Approved Names (AANs) must be used for all ingredients other than proprietary ingredients
- Herbal extracts should use Approved Herbal Names, plant parts, type of extract (soft, dry, liquid etc), ratios, solvents and percentages used as well as dry/fresh herb equivalents as appropriate.
- Metric units must be used to express quantities.
- If more than one manufacturer is to be included in the Certificate, please provide details in a Schedule, as the Certificate accommodates details of only one manufacturer.
- Schedules must be numbered consecutively. Formulation details as Schedule 1 is mandatory but subsequent schedule numbers are not linked to specific information. (The *Guide's* example on Schedule numbering is provided only for guidance.)
- Each Schedule should contain a signed and dated declaration that the information provided is current and correct.
- Remember to tick the relevant box next to the declaration on page 4 of the application form to indicate which declaration applies to the product.

Contact: Agnieszka Prygiel, Export Unit, Tel 02 6270 4333, Fax 02 6270 4336

ACCEPTABLE DAILY INTAKES (ADI) LIST ON THE NET

The ADI List for agricultural and veterinary chemicals is now available through the TGA web site. The List is a compilation of Acceptable Daily Intakes for agricultural and veterinary chemicals used on food producing crops or animals.

An ADI is defined as the daily intake of a chemical which during an entire lifetime appears to be without appreciable risk to the health of the consumer on the basis of the known facts at the time. More detail on the process of establishment of ADIs has been published previously in TGA News (Issue 27, August 1998) and is also contained in the web document.

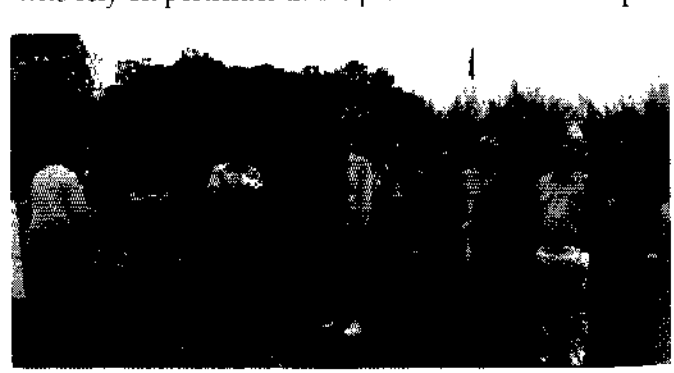
The ADI List can be accessed, as an Adobe Acrobat pdf file, through the TGA web site at www.health.gov.au/tga. Links to the document are provided on both the chemicals page (www.health.gov.au/tga/chem/chem.htm) and the TGA publications page (www.health.gov.au/tga/pubs/pubs.htm).

PESTICIDE REGULATORS TAKE PART IN A FIELD TRIP TO SOUTH-EAST QUEENSLAND

Monday 30th August – Friday 3rd September, 1999

A tour of south-east Queensland was organised by the Queensland Fruit and Vegetable Growers (QFVG) Association and the Queensland Department of Primary Industries (QDPI), to provide federal pesticide regulators with a better understanding of pesticide use in various agricultural crops in the region. A number of pesticide regulators took part in this field trip including one from the TGA.

The trip was useful, both as a means of improving liaison between the National Registration Scheme agencies and as a means of increasing communication with stakeholders, in this case, fruit and vegetable growers who rely on pesticides in the production of their crops.



Field trip participants (photo courtesy of the Queensland Department of Primary Industry)

TGA SATELLITE SEMINAR AT THE AUSTRALASIAN SOCIETY FOR BLOOD TRANSFUSION (ASBT) CONFERENCE

A successful seminar on the theme *"Blood Safety and Supply – Scientific and Regulatory Perspectives"* was attended by 100 participants during the October 1999 conference of the ASBT in Melbourne. Opening the Seminar, Terry Slater, National Manager of the TGA, spoke about the TGA's commitment in maintaining best practice in the blood products area. These have included TGA's establishment of a Blood Products Group, TGA's international initiative towards establishing a global blood safety initiative through WHO and TGA's support of the Commonwealth Review of the Australian blood system. The participants heard talks from eminent Australian and overseas experts on a wide range of issues including the delivery of blood services, the regulatory mechanisms involved in fresh blood regulation, current problems such as new variant CJD and the introduction of NAT testing. The Commonwealth Review process was also described by Penny Rogers. Feedback on the Seminar was very positive and it is anticipated that similar events will be held next year.

Liana Harvath of the FDA, Albert Farrugia of TGA's Blood Products Group and Penny Rogers of the Commonwealth Blood Review Secretariat at the TGA Seminar.

HEAD OF BLOOD PRODUCTS GROUP AWARDED PROFESSIONAL DEVELOPMENT AWARD

Albert Farrugia, TGA's Senior Advisor on Blood Products and Head of the Blood Products Group, has been awarded a Professional Development Award for studying blood delivery and regulatory systems in a number of overseas countries. The award will see Dr Farrugia spending three months in the Canadian Blood Safety Council, Health Canada's Blood and Tissues Division, the FDA's Office of Blood, the Paul Ehrlich Institute's Division of Transfusion Medicine and other agencies. Dr Farrugia is expected to take up the award from February to April 2000. This significant resource allocation demonstrates the Department's and TGA's commitment to improving regulatory practice in the blood products sector.

5TH SOUTH EAST ASIA REGIONAL OFFICE OF THE WORLD HEALTH ORGANISATION (SEARO) NATIONAL CONTROL LABORATORY NETWORK "ASSAY VALIDATION AND STATISTICAL ANALYSIS" WORKSHOP, YANGON, MYANMAR, 20–24 OF SEPTEMBER, 1999.

As part of the curriculum development for the TGA Global Training Network course in Vaccine Regulation, Chris Rolls, Immunobiology Section, TGA Laboratories, with funding from AusAID, assisted the WHO and National Institute for Biological Standards and Control (NIBSC) team presenting the 4th SEARO National Control Laboratory Network "Laboratory Quality Systems" Workshop in Barog, India. In recognition of TGA's contribution, Chris Rolls was invited to the follow-up 5th SEARO National Control Laboratory Network "Assay Validation and Statistical Analysis" Workshop, in Yangon, Myanmar from 20–24 of September, 1999.

Chris, together with two scientists from NIBSC in the UK, presented three days of interactive lectures and discussion on the theoretical and practical aspects of vaccine QC assay validation, analysis, and monitoring. The Hepatitis B, Diphtheria, and Tetanus vaccine assays, and the problems associated with assaying combination vaccines, were featured and the Biostatistician from NIBSC provided the statistical detail. The 14 participants, from Thailand, Sri Lanka, Myanmar, India, Indonesia, and Bangladesh, all shared their experiences and work in this field.

The final day involved the co-ordinator of the Global Training Network, WHO, Geneva, and a representative from the Vaccine Supply and Quality unit of SEARO, Delhi, facilitating ongoing action plans for the implementation and follow-up training which the workshop

REVERSE OSMOSIS AS A BASIS FOR PRODUCTION OF WATER FOR INJECTION

In March 1999, TGA's Shelley Tang attended a Scientific Workshop in Strasbourg, organised by the European Department for the Quality of Medicines, to consider whether the European Pharmacopoeia should include Reverse Osmosis (RO) as an allowable method for the production of Water for Injection. The Workshop provided an excellent opportunity for debate with background papers presented by speakers from the European Pharmacopoeia, the Joint CPMP/CVMP* Quality Working Party, United States Pharmacopoeia and FDA, and the views presented from producers and users of RO water, as well as those of regulators and inspectors.

The Workshop recommended that **RO water not be included as an acceptable method for production of Water for Injection at the present time, pending collection of more data.** The Workshop's Chairman, Professor D Calam, expressed disappointment at the lack of data from producers and users of RO systems. The same lack of data led the workshop to conclude that there was insufficient evidence to demonstrate that RO systems could consistently produce water of a quality at least equal to that of distilled water.

However, the European Pharmacopoeia (EP) will keep the matter open, and encourages the submission of data on the quality of RO water as compared to that of distilled water. Data published in a refereed scientific journal is preferred; information on test results should include the details of the methods used for testing.

Anyone wishing to submit data or requiring further information should contact Shelley Tang on (02) 6232 8793.

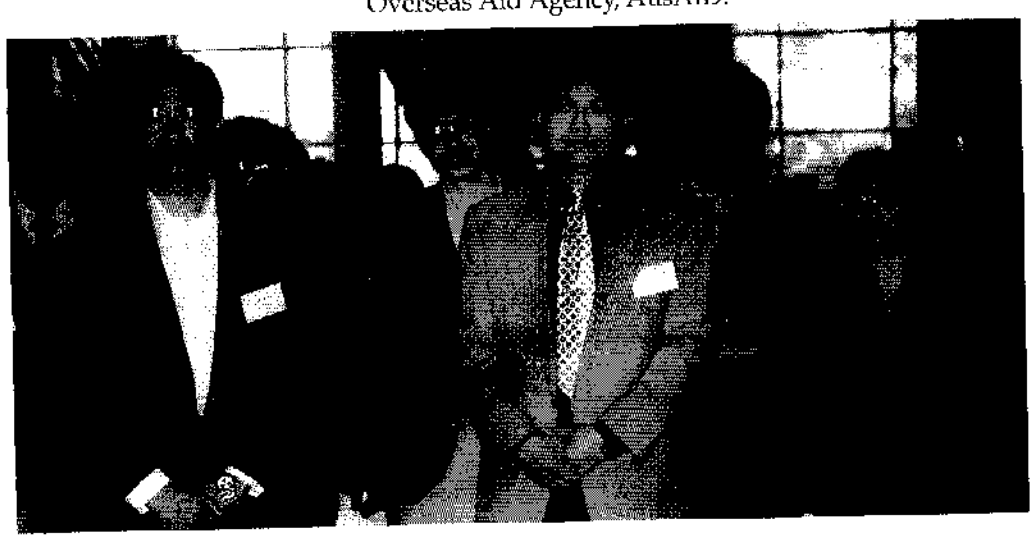
During the Workshop it also became evident that there was general confusion on the use of water in accordance with the two monographs in the EP. This confusion needs to be addressed, and a third monograph was proposed for grades of water not already covered in the EP. There was also general agreement that the microbiological test method for water in the EP needs revision, and this recommendation was passed to the Group of Experts responsible for microbiological matters.

*CPMP is the Committee for Proprietary Medicinal Products. CVMP is the Committee for Veterinary Medicinal Products.

WHO VACCINE REGULATORS' COURSE

The TGA Laboratories and the International Services Branch recently organised a training course on vaccine regulation for staff from other National Control Authorities (NCAs). The trainees were selected by the World Health Organization (WHO) as representatives of NCAs that require assistance in strengthening the regulation of vaccines. The curriculum was developed by staff from the TGA Laboratories, the Drug Safety and Evaluation Branch and the GMP Audit and Licensing Section of the Conformity Assessment Branch and has been accredited by the WHO Global Training Network (GTN). The GTN coordinates training that is designed to achieve worldwide vaccine quality and supply and is comprised of representatives of the six WHO regional offices, twelve training institutes and two regulatory authorities, including the TGA.

The training course was held from May 5-12, 1999 at the TGA. WHO-sponsored Fellows from NCAs in China, Thailand, Philippines, Singapore and Brazil attended six days of lectures and interactive workshops. The course was structured around the six critical control functions identified by the WHO as being essential for any NCA engaged in regulation to ensure the safety, quality and efficacy of vaccines produced in, or procured for use in, the country of responsibility. Training modules were presented on Essential Functions of a Vaccine NCA, Licencing of Vaccines, Laboratory Facilities for Final Product Testing, Batch Release of Vaccines, Compliance with Good Manufacturing Practice and Post-marketing Surveillance of Vaccines. The course concluded with an Implementation Workshop in which trainees discussed the organisation and functions of the NCAs in their home countries and formulated plans to implement changes when they returned home. These changes were identified during the course, on a country-by-country basis, as having the potential to strengthen the capacity of their NCAs to ensure vaccine quality. The development of the curriculum and presentation of the course was made possible by funding from the WHO and Australia's Overseas Aid Agency, AusAID.



Course Participants

Note: TGA is providing this information as a reference only. Manufacturers should not rely on the TGA or the Commonwealth in relation to the existence, content or effect of:

- *The EC directives;*
- *Other laws/directives or guidelines of the European Community or other organisations; or*
- *National laws of member states of the European Community.*

DEPARTMENT OF INDUSTRY SCIENCE AND RESOUCES EC-MRA SEMINARS 8 AND 10 JUNE 1999-A SAGA OF CE MARKING

The Department of Industry, Science and Resources recently held seminars on *Trading with Europe*, to explore the Mutual Recognition Agreement with Europe in relation to conformity assessment and what it means for Australian exporters. The seminars were held in association with the Delegation of the European Commission to Australia and New Zealand, and were conducted in Sydney and Melbourne. Several TGA staff attended; Robert Tribe conducted a Workshop on Pharmaceutical GMP, and Keith Smith, Michael Flood and Anthony Gould conducted the Workshop on medical devices.

Keith Degenhardt, of Ellex Laser Systems, in Adelaide, presented a case study of his company's path to CE marking for their solid-state ophthalmic surgical YAG laser device. The product has been well established in Europe for some years, but had trouble breaking into the German and French market in particular because of the complexity of regulatory requirements. In late 1995, the company launched an operation to get the product CE marked and contracted a European Notified Body. However, the Australian office of the Notified Body had no experience or understanding of the Medical Devices Directive. Overseas experts were assigned, but assessment visits were postponed several times.

Ellex then went to another Notified Body (NB) represented by an Australian office. This office seemed at first to know what they were doing, but relations gradually deteriorated. Ellex was issued with an ISO 9002 certificate, but the overseas NB determined that the local office auditors were not qualified or certified to audit to EN 46000. The company underwent three audits conducted by the local office, all of which were acceptable, but EN 46000 certificates were not issued until an overseas auditor was brought in. Type testing was still required in order to complete the process. The company worked with a local testing facility, but the NB decided that the product had to be tested in their laboratories in the USA. The NATA certificates obtained for the product in Australia were rejected. Ellex was now locked out of Europe.

It was at about this time that the MRA came into force. Ellex contacted TGA, and for the first time found people who understood the requirements of the European system, and who shared the company's objectives of getting the product CE-marked. TGA had highly skilled technical people, including an expert in medical lasers. The company established a cooperative working relationship with the TGA, and the assessment process went smoothly. The only hitch was a brief delay in Europe of the publication of TGA as a recognised Conformity Assessment Body; until this was done, TGA could not issue certificates of conformity.

Mr Degenhardt concluded with the comments that the interpretation of MDD requirements by consultants is variable, and the company's initial experiences led them to believe that the objective was to keep them out of the European market. The European Notified Bodies appeared to promote their own chosen paths, rather than allow the company to control the process. He stated that the TGA's knowledge is greater than that of any of the Notified Bodies with which his company has come into contact.

GMP TRAINING FOR VIETNAMESE DELEGATES

Three Vietnamese pharmacists visited Australia for three weeks during May for Good Manufacturing Practice (GMP) training organised by the Good Manufacturing Practice Audit and Licensing Section (GMPALS) and the International Services Branch (ISB) of the Therapeutic Goods Administration.

They were Pharmacist Ta Thi Phuc Chan, Head of Drug Quality Management Division, Drug Administration of Vietnam, Pharmacist Tran Duc Chinh, GMP Auditor and Head of the Drug Information Division Drug Administration of Vietnam, and Doctor Trinh Van Lau the Deputy Director of the Vietnamese National Institute of Drug Quality Control (NIDQC).

The NIDQC is TGA Laboratories' equivalent but as well as the Hanoi central laboratory it has 61 regional laboratories to look after with a total of over 700 staff.

The visitors' training schedule saw them spend a week in Canberra with courses arranged by the TGA Laboratories and GMPALS and two weeks in Sydney observing GMP audits and attending a filter theory and validation course.

The delegates were very impressed with Australia and TGA, especially the TGA building and the organisation and construction of the TGA Laboratories. They indicated they would like to return and send other staff members over for further training.