orig do team
copy do HO
JS
KS

1107

APMA Australian Pharmaceutical Manufacturers Association Inc. ARBN 023 580 663

Mr Alan H. Evans
Chief Executive Officer

13 November 2000

Mrs Helen Owens
Presiding Commissioner
Cost Recovery Inquiry
Productivity Commission
Locked Bag 2
Collins St East Post Office
MELBOURNE VIC 8003

Dear Mrs Owens,

I am providing this submission to the Productivity Commission Cost Recovery Inquiry on behalf of the Australian Pharmaceutical Manufacturers Association Inc (APMA). The APMA is the peak industry body representing prescription medicine manufacturers and suppliers in Australia.

Our 50 member companies are engaged in the research, development, manufacture, marketing and export of prescription pharmaceuticals, and the ongoing improvement of medical and scientific knowledge about their products. APMA member companies are responsible for the production of over 90% of the medicines available through the Pharmaceutical Benefits Scheme (PBS).

This submission will be directed to the cost recovery arrangements for the Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Aged Care.

The Principle of Cost Recovery

The *Therapeutic Goods Act 1989* commenced operation on the passing of the Therapeutic Goods Regulations in February 1991. The introduction of the legislation encompassed a Government requirement for the TGA to recover 50% of its operating costs through fees and charges. The Minister for Aged, Family and Health Services at the time, Mr Staples acknowledged in Parliament that some of the TGA's activities are performed in the interest of the public and were therefore funded by an appropriation from the consolidated revenue of the Government (Attachment 1).

In the first year of operation of the TGA (1991/92) cost recovery was lower than expected (Attachment 2). In February 1993 it was agreed that the basis for setting the level of fees and charges would be to recover 100% of the cost of all functions which are specifically industry-related. The Government would fund those functions that are related to "public interest" activities. It was agreed that 50% of the overall TGA budget related to "public interest" activities and 50% was industry related activities.

Level 7, 88 Walker Street, North Sydney, NSW 2060 Phone 02 9922 2699 Fax 02 9959 4860 www.apma.com.au

Attachment 3 provides details of the negotiations that took place between the industry Associations and the TGA during February – April 1993, including the final agreed classification of TGA functions into public interest activities and industry related activities. On this basis, fees and charges were gradually increased to achieve full cost-recovery for industry-related activities in 1996/97.

In the 1996 Federal Budget the Government announced that there would be an increase in the proportion of cost-recovery from industry to 75% of the TGA budget. The increase would occur over three years to 1998/99. At the time it was stated that the Government continued to recognise its role in meeting its public health obligations in the regulation of therapeutic goods (Attachment 4, TGA Budget measures 1996). However, there was no explanation provided to industry of how the balance of costs had altered such that the industry-related activity of the TGA therapeutics programme had increased to 75% and which areas required additional cost recovery measures.

The following year in the 1997 Federal Budget the Government announced that it had changed its policy on the source of funds for the TGA's therapeutics activities and that, from the 1998/99 financial year onwards, the therapeutic goods industry would pay for the full cost of these activities, including those not considered to be industry-related (Attachment 5).

This announcement represented a major shift in Australia's approach to cost-recovery for therapeutic goods regulation, but also reflected a very different attitude from other countries. In other countries, particular government- or public interest activities of the regulatory agencies are specifically funded from non-industry sources, or charges to industry have been specifically "ear-marked" for additional activities. Thus in the UK the Government funds standards development by the *British Pharmacopoeia*, which is managed by the Medicines Control Agency, and in the USA, user fees have been targeted to fund improvements in evaluation times. The European Medicines Evaluation Agency has simply stated that it will source 25% of its funding from non-industry sources to "guarantee its independence" (Attachment 6).

The Australian Government has taken a different direction, in deciding that industry is required to fund <u>all</u> TGA therapeutics activities (as distinct from its ag/vet, chemical or radiation-related tasks). These activities extend beyond establishing regulatory requirements, certifying the standards of manufacturing facilities, the evaluation of clinical trial proposals and marketing applications, and maintenance of the Australian Register of Therapeutic Goods. They include the assessment of information provided by healthcare professionals and the therapeutic goods industry about ongoing experience with the goods, participation in international scientific developments and the provision of information in response to requests from parliamentarians, consumers, health professionals, other government departments and other countries. For example, the TGA responded to 830 items of ministerial correspondence in 1999/2000, provided 40 Question Time Briefs, and provided 50 ministerial briefings (Attachment 7). It is not justifiable in our view that industry should pay for these services to Ministers and Parliament.

The industry has, to date, supported the existence of an Australian "sovereign" regulatory agency, making its own decisions in relation to the quality, safety and efficacy of therapeutic goods in this country. We have accepted the concept of cost-recovery for industry service activities, although we have sometimes expressed concern about the nature or extent of the "service" provided. However, the current policy of 100% cost recovery has greatly enlarged the range of TGA activities that industry will be paying for, beyond "industry service" activities.

The Government and TGA have been subject to public criticism of the possibility that the TGA will be unduly influenced by industry under the new proposal. We understand that when 100% cost recovery was introduced, members of the Australian Drug Evaluation Committee (ADEC) expressed concern that their activities would be funded by industry, and therefore their independence, may be perceived to be compromised. Industry has for its part considered that they would be required to pay the full costs of an agency that had no accountability to it for the actual cost, efficiency or productivity of the services it was undertaking. The Industry did not nor does it seek to influence the decisions of the TGA as they relate to its primary responsibilities. We do however have concerns that there is no independent mechanism to ascertain whether the industry is ***getting value for money***.

APMA considers that the therapeutic goods industry should not be required to fund 100% of TGA's therapeutics related activities. The Government should separately fund activities that are public service and public interest related.

The Productivity Commission would be aware of the proposed establishment of the Office of the Gene Technology Regulator under the *Gene Technology Bill 2000*. It has been proposed by Government that the activities of the Gene Technology Regulator will also be subject to 100% cost recovery. To date the interface between the OGTR and the current regulatory systems that cover gene technology products, such as the TGA, have not been fully described. Nor have the proposed OGTR activities that would attract a fee or the amount of any fees been revealed. APMA is concerned that there may be duplication of activities between the OGTR and TGA for which industry will be expected to pay for twice. This would certainly not be acceptable to APMA or other industry sectors similarly affected. APMA therefore supports the recommendation of the Senate Community Affairs References Committee that further discussion about, and proposals relating to, cost recovery and the operation of the OGTR should be deferred until the Productivity Commission has reported in relation to cost recovery and, in the interim, that Government should fully fund the operation of the OGTR.

Under a regime of cost recovery, there is an expectation that the organisations funding the activity should have substantial input into the efficiency and effectiveness of the agency. When fees and charges were introduced for therapeutic goods regulation in 1991 an Industry Government Consultative Committee was established which included representation from each of the four therapeutic goods industry sectors, TGA and the Department of Industry, Science and Technology (as it was then called) and the Department of

Finance. Over time this Committee has been reconstituted to form the current TGA Industry Consultative Committee (TICC). The Department of Industry, Science and Resources and the Department of Finance are no longer represented on the Committee and membership now includes a consumer representative. The Terms of Reference for the consultative forum have also been amended over time – the original Terms of Reference are provided in Attachment 8 and the current Terms of Reference in Attachment 9.

As is evident from the current Terms of Reference for the TICC, the industry members may "examine and comment" upon the TGA's performance and budget, but it has no directional powers, for example to require the TGA to achieve certain performance standards or to expend its revenue in ways that the industry members might consider most cost effective. In short, the industry pays for 100% of the TGA's therapeutics related activities, but the TGA is not directly accountable to the industry. The lack of any requirement for the TGA to be accountable is unsatisfactory to APMA. We recommend that the TICC should be reconstituted to require TGA to be accountable to both its industry clients and the Parliament.

Specific cost-recovery issues

Method of TGA cost recovery

The fees and charges described in Schedule 9 of the *Therapeutics Goods Regulations* and in the *Therapeutic Goods (Charges) Regulations* whilst attributed to particular activities, are only notionally related to the actual cost of an activity. To explain this it is necessary to consider the method for determining the amount of the fees and charges.

The TGA collects its revenue primarily through annual charges to maintain a product on the Australian Register of Therapeutic Goods, evaluation fees and licence fees.

In September 1997 TGA contracted an external consultant to conduct an activity based costing review of fees and charges to determine the cost and proportion of TGA's activities that were related to different types of therapeutic goods — prescription medicines, non-prescription medicines, complementary medicines or medical devices. This study was undertaken, in part, in response to industry concerns that there may be some cross-subsidy between the revenue paid by each industry sector. The Review found that there was some significant cross-subsidisation. The outcome of this Review was an allocation of a certain proportion of TGA's costs to different product groups and hence the need to obtain that proportion of revenue from the sponsors (companies who are responsible for) of those products. It is on this basis that the fees and charges relating to prescription medicines (and other product types) are determined. Based on the number of applications, licences and annual charges expected per annum, predicted from historical data, a mix of fees and charges is negotiated to provide the required revenue from each product group.

Thus, whilst there is a specific fee, for example, for the evaluation of between 20,000 and 40,000 pages of clinical data for a prescription medicine of $88,500, the fee is only notionally related to the actual cost of the activity. The fee includes the direct cost of the evaluation and many indirect costs related to the overall establishment and conduct of the TGA. The TGA's public interest activities are encompassed within the indirect costs, such as maintenance of the ADEC, post-marketing surveillance for adverse drug reactions, laboratory testing of products, analytical method development etc. APMA objects to the requirement for industry to pay for the Government's public health related activities.

Business Rules for calculating fees

Although the fees for evaluation of therapeutic goods are described in the *Therapeutic Goods Regulations*, the calculation of the fee for a particular application or notification often requires some interpretation. To promote consistency of individual TGA officers' interpretation of how the various fees are applied and to assist sponsors to calculate the correct fee, in association with implementation of the *Therapeutic Goods Act 1989* the TGA published Business Rules for calculating certain fees (Attachment 10). These Business Rules were subject to consultation with industry before they were published. However, the August 1996 Business Rules have apparently been replaced by an updated document which was not subject to discussion with industry nor has it been provided to industry (Attachment 11). APMA did request a copy of this document but was advised (verbally) that it is an internal document.

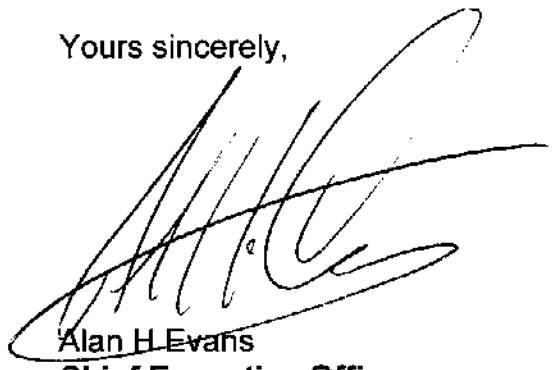
APMA does not agree with the policy contained in the updated, internal Business Rules document in relation to safety related changes and editorial changes to the Product Information. This new policy to charge multiple fees for processing an identical change to 2 PI documents has been subject to numerous complaints from APMA members. We have taken up this matter with the Drug Safety and Evaluation Branch of the TGA and requested they provide APMA with an updated, comprehensive Business Rules document for our consideration. This was first requested in February 2000 and again in early September 2000 when it was agreed that a document would be provided within three months.

The fact that certain fees are open to interpretation, and that fees are only notionally related to the actual cost of the activity, has led to concern within industry that TGA can generate more revenue by interpreting the fees in certain ways.

The principle should be that where there is cost recovery for industry-related activities, the applicable cost should be clearly described, without need for interpretation in particular cases, and should be subject to discussion and negotiation with the affected industry prior to implementation.

APMA appreciates this opportunity to inform the Productivity Commission Cost Recovery Inquiry of our concerns regarding cost recovery by the Therapeutic Goods Administration. APMA would be pleased to appear before the Commission at its Public Hearing on 27 November in Canberra.

Yours sincerely,



Alan H Evans
Chief Executive Officer

Attch.

(a) (i) the Australian Government and Australian woolgrowers would continue to support the industry through promotion and technical assistance; and

(ii) the AWC will, in consultation with the Wool Industry Policy Council, be reviewing the suitability of advances in this area in the new marketing environment, and if cost-effective methods can be established will be seeking to pursue these in consultation with the industry.

(b) Soviet customers for Australian wool have been encouraged by the AWC to make greater use of objective measurement in their use of Australian wool, and particular progress has been made recently in this regard in Soviet mills and testing procedures. There is no evidence that sale by description leads to a price discount.

Vicroads: Local Government Road Funds

(Question No. 844)

Mr Hawker asked the Minister for Land Transport, upon notice, on 28 May 1991:

(1) Has his attention been drawn to an instruction by the Victorian Government to the Victorian road authority, Vicroads, to withhold a portion of road funds for local government in 1990-91 until July 1991; if so, is he able to say (a) what proportion of the funds to be withheld is from the Australian Land Transport Program (ALTP) and (b) for what purposes that proportion of the funds is being used.

(2) What action will the Government take to ensure that any funds allocated from the ALTP for local government in 1990-91 is paid to local government in 1990-91.

Mr Robert Brown—The answer to the honourable member's question is as follows:

(1) (a) and (b) I am advised that the Victorian Government had given no instruction to Vic Roads to withhold Federal road funds for local government in 1990-91 until July 1991. State funding to local governments for roads and the procedure by which such State funds are paid is a matter between the Victorian Government and local governments.

(2) Vic Roads has advised that all Federal local road entitlements to councils under the Australian Land Transport Development (ALTD) Program were paid in 1990-91, and there was no carry-over of commitments into 1991-92.

Therapeutic Goods Administration Laboratories

(Question No. 848)

Mr Nehl asked the Minister for Aged, Family and Health Services, upon notice, on 29 May 1991:

(1) What is the total budget of the Therapeutic Goods Administration Laboratories (TGAL).

(2) What are the (a) breakdown of expenditure, (b) income and (c) sources of income of TGAL.

(3) Does TGAL provide (a) product testing or (b) quality control of pharmaceutical products; if so, what is the cost in each case.

(4) What proportions of (a) product testing and (b) quality control are performed (i) at the request of the pharmaceutical industry and (ii) in the interests of the public and what is the cost in each case.

(5) What percentages of the cost of (a) product testing and (b) quality control performed (i) at the request of the pharmaceutical industry and (ii) in the interests of the public are recovered from the pharmaceutical industry.

(6) Does TGAL serve any industries in addition to the pharmaceutical industry; if so, (a) what industries and (b) what percentages of the cost of (i) product testing and (ii) quality control is recovered from each industry.

Mr Staples—The answer to the honourable member's question is as follows:

(1) All figures relate to the 1990-91 financial year.

Total budget is $10,183,307.

(2) (a) Breakdown of expenditure:

Salaries & associated costs—$5,568,859
Administrative expenses—$1,816,684
Capital items—$423,264
Corporate overheads—$2,374,500

Total—$10,183,307

(b) and (c) Income and sources of income:

Appropriation—($10,091,060)
Other—($92,247):
Commercial testing—$25,883
Training courses—$43,252
Consultancies—$14,923
Sale of animals, cultures etc—$8,199

The appropriation comes from Therapeutic Goods Administration (TGA) Trust Account, which is in turn funded by an appropriation from consolidated revenue of the Government plus general fees and charges levied against industry, including the pharmaceutical industry. For 1990-91, industry fees and charges will make a very minor contribution to the TGA Trust Account.

(3) TGAL tests pharmaceutical products for compliance with acceptable standards of quality, safety and efficacy. TGAL does not perform quality control of pharmaceutical products.

(4) TGAL does not perform product testing at the request of the pharmaceutical industry. TGAL's compliance testing activities are performed in the interests of the public. The estimated cost of such testing in 1990-91 is $7,138,000.

(5) In 1990-91, none of the costs of product compliance testing performed in the interests of the public were recovered directly from the pharmaceutical industry. See reference to indirect funding in answer to question (2).

(6) (a) TGAL also tests therapeutic products produced by the medical devices, the natural medicines and the veterinary therapeutic products industries, but does not perform quality control.

(b) To date this testing has been performed solely in the interests of the public, although in future all testing of veterinary therapeutic products will be on a cost recovery basis.

The cost of product testing by TGAL in these industries in 1990-91 is estimated to be as follows:

Medical devices—$1,070,000
Natural medicines—$375,000
Veterinary products—$340,000

Honours and Awards

(Question No. 878)

Mr Barry Jones asked the Prime Minister, upon notice, on 4 June 1991:

(1) Which heads of state and government have visited Australia since the Order of Australia was established.

(2) Which of the persons referred to in part (1) have been honoured by an award in the Order.

(3) On what basis were some of those persons selected for an award and others not.

Mr Hawke—The answer to the honourable member's question is as follows:

(1) The Order of Australia was established under Letters Patent signed by Her Majesty The Queen on 14 February 1975. The following heads of state and government have made official visits to Australia since that date, listed in chronological order, by year:

1975

Rt Hon W E Rowling, Prime Minister of New Zealand

HE Hammer DeRoburt, President of the Republic of Nauru

Rt Hon Tun Haji Abdul Razak, Prime Minister of Malaysia

1976

TM King Hussein I and Queen Alia of Jordan

Hon Michael Somare, Prime Minister of Papua New Guinea

Hon James R M Mancham, Prime Minister of the Seychelles

HE Shaikh Khalifah Bin Sulman Alkalifah, Prime Minister of Bahrain

Mr Lee Kuan Yew, Prime Minister of Singapore

HE Hammer DeRoburt, President of the Republic of Nauru

1977

HRH Prince Fatafehi Tu'ipelehake, Prime Minister of Tonga

Hon Peter Kenilorea, Chief Minister of the Solomon Islands

Rt Hon R D Muldoon, Prime Minister of New Zealand

Hon Taisi Tupuola Tufuga Efi, Prime Minister of Western Samoa

1978

Shri Morarji Desai, Prime Minister of India*

Rt Hon R D Muldoon, Prime Minister of New Zealand*

Mr Lee Kuan Yew, Prime Minister of Singapore*

Rt Hon Michael Somare, Prime Minister of Papua New Guinea*

HRH Prince Fatafehi Tu'ipelehake, Prime Minister of Tonga*

HE Mr Bernard Dowiyogo, President of Nauru*

HE J R Jayawardene, President of Sri Lanka*

Hon Taisi Tupuola Tufuga Efi, Prime Minister of Western Samoa*

HE Ziaur Rahman, President of Bangladesh*

Hon Ratu Sir Kamisese Mara, Prime Minister of Fiji*

Datuk Hussein Bin Onn, Prime Minister of Malaysia*

* Commonwealth Heads of Government Regional Meeting

HE Sir Tore Lokoloko, Governor-General of Papua New Guinea

HH Malietoa Tanamafili II of Western Samoa

HE Mr Walter Scheel, President of the Federal Republic of Germany

TGA Therapeutic Goods Administration
PO Box 100, Woden, ACT 2606, Australia
☐ Woden Telephone: (06) 289 1555. Fax: (06) 289 8709
☐ Mawson Telephone: (06) 286 0222. Fax: (06) 286 1386

Attachment 2

COMMONWEALTH DEPARTMENT OF HEALTH, HOUSING AND COMMUNITY SERVICES

Mr K Bell
Chief Executive Officer
Australian Pharmaceutical
Manufacturers Association Inc
Level 2, 77 Berry Street
NORTH SYDNEY NSW 2060

FAX: 02-959-4860

FAX IN

Dear Mr Bell

AMENDED FEES and CHARGES

As you are aware, the introduction of the amended Therapeutic Goods Act in 1991 was accompanied by a Government requirement for the TGA to recover 50% of operating costs through fees and charges. This was accompanied by the opportunity for industry to provide input on TGA management issues through the IGCC.

In the first year of operation of the TGA (1991/92), cost recovery was lower than expected ie $9.4M (approximately 30% cost recovery) compared to the 16.8M required to meet the 50% cost recovery target after allowing for a $2.2M carry forward for 1990/91.

The shortfall was, in part, due to circumstances existing at the time of establishment of the TGA. There was a need to deal with grandfathered products and address a backlog of evaluation applications for which no fees were received. The number of applications also decreased following the introduction of fees and charges per se, affecting TGA income. In hindsight, there was also inadequate information to allow accurate workload forecasting, and poor estimates of actual TGA costs.

1992/93 is the first year of TGA operation when full 50% cost recovery is required. It has quickly became apparent that the actual level of cost recovery through fees and charges will continue to be much lower than necessary.

Management action was taken to minimise TGA expenditure consistent with maintenance of necessary services. This continues to be TGA management policy.

The only realistic option was a steep rise in fees and charges if the TGA was to recover 50% of costs. Following consultation during the second half of 1992 with all peak industry groups represented on the IGCC, a revised schedule of fees and annual charges was recommended to the Minister in late 1992.

The Minister, Mr Staples, has been fully briefed and has considered the comments of the peak organisations. He has now agreed to the proposed schedule of increased fees and charges (copy attached) with the following conditions -

1. That the increase in fees and charges be progressively phased in over the next five years in four increments ie

1992/93	32% cost recovery from industry (ie status quo)
1993/94	37% cost recovery from industry
1994/95	41% cost recovery from industry
1995/96	45% cost recovery from industry
1996/97	50% cost recovery from industry

2. That instead of requiring industry to meet 50% of the total operating costs of the TGA, the basis of setting the level of fees and charges be changed so as to recover 100% of the cost of all functions which are specifically industry related. Those functions which are of the nature of "public interest" activities would then become 100% Government financed.

3. That initially this "industry-related" component should be negotiated through the IGCC as 50% of the present TGA budget.

The TGA is presently drafting an initial classification of its functions as "industry-related" or "public interest" activities. A working paper will be posted to you early next week.

I must emphasise that the document will be a draft and is intended only as a starting point for further discussions with peak industry groups. Obviously, some functions will have elements which are both "industry-related" and "public interest" and there will need to be agreement of an appropriate apportionment in such cases.

The bottom-line split of the initial classification by the TGA will have to be close to the required present 50% cost recovery from industry; this is a requirement set by the Minister and is an essential element of the package.

The Minister's decision was taken after detailed discussions with the Departments of Prime Minister and Cabinet, Finance and Industry, Technology and Commerce. Government members of IGCC have already been briefed on the proposed new basis for setting future changes to fees and charges. They have indicated support for the proposal.

It is now proposed that industry and TGA members of the IGCC meet in Sydney at 9.00am, Tuesday 16 February, to discuss the proposed basis for determining future amendments to TGA fees and charges. Kerry Bell has kindly agreed to make available the APMA Conference Room, North Sydney.

Could you please advise of your availability for this meeting by contacting Roger Bateman on 06-289-8525.

Yours sincerely

(Dr) G N Vaughan
National Manager
4 February 1993

TGA Therapeutic Goods Administration

PO Box 100, Woden, ACT 2606, Australia
☒ Woden Telephone: (06) 289 1555. Fax: (06) 289 8709
☐ Mawson Telephone: (06) 286 0222. Fax: (06) 286 1386

Attachment 3

COMMONWEALTH DEPARTMENT OF HEALTH, HOUSING AND COMMUNITY SERVICES

Mr K Bell
Chief Executive Officer
Australian Pharmaceutical
Manufacturers Association Inc
Level 2, 77 Berry Street
NORTH SYDNEY NSW 2060

FAX: 02-959-4860

Dear Mr Bell

FEES AND CHARGES

Further to my letter of 4 February 1993, I wish to advise that the meeting of industry and TGA members of the IGCC to discuss the basis of setting future fees and charges will be held on Wednesday 17 February 1993 in the APMA Board Room, North Sydney commencing at 9.00am.

Unfortunately, I will be unable to attend due to other commitments, and I have asked Pat Griffin to chair the meeting with Roger Bateman as the secretary.

It would be helpful if the meeting were to consider two matters in particular; firstly the overall funding program under which the TGA will operate for the next five years, and secondly, the proposed division of TGA functions into public interest and industry-related activities as a basis for future amendments to fees and charges.

TGA funding:

The Minister has agreed to the future funding of the TGA as follows -

	$M 1992/93	1993/4	1994/95	1995/96	1996/97
Fees and Charges	11.79	13.22	14.65	16.46	18.28
TGA Budget	18.06	17.86	17.86	18.28	18.28
DHHCS subsidy	2.00	-	-	-	-
Dept Finance subsidy	4.26	4.64	3.22	1.83	0
Total	36.11	35.72	35.72	36.57	36.57
Industry contribution	33%	37%	41%	45%	50%

The TGA Budget allocations are based on forward estimates of the Dept of Finance as calculated on 28 September 1992. The estimates are all expressed in terms of 1992 dollars and will need to be amended in accordance with future updates from the Dept of Finance.

The $2.0M subsidy provided by the Departmental of Health, Housing and Community Services in 1992/93 is a one-off subsidy to offset the shortfall in TGA revenue resulting from the timing of the Ministerial decision.

As mentioned in my previous correspondence, the increase in fees and charges is to be phased in over five years. During that time the size of the Dept of Finance subsidies will become progressively smaller.

Basis of future fee/charges increases:

A proposed division of TGA functions into "public interest" and "industry-related" categories is attached for your consideration.

The allocations of the TGA Budget to Branch activities is similar to the distribution previously considered by the IGCC.

The division of each Branch budget allocation into costs associated with "public interest"or "industry-related" activities (or a division of costs between both categories), has been calculated by each Branch in accordance with the nature of the resources needed to carry out those activities by the Branch.

It is proposed that this distribution of budgetary costs should form the basis of any future increases (or decreases) in fees and charges. The proposal envisages that industry would fully fund those activities which the IGCC agrees to be primarily industry-related. Similarly, government would fully fund those activities which were undertaken primarily in the public interest. Those activities with a perceived benefit to both industry and the public would be jointly funded in the agreed proportions by both industry and the government.

The cost of the three main corporate overheads (property operating expenses, Information Services Division charges, and Corporate Services Division charges) have been divided between industry and government in the same overall ratio as the other costs.

The final division would appear to be close to the 50%:50% split of present TGA budget costs between government and industry funding as required by the Minister as a condition to phasing in the new fees and charges.

Yours sincerely,

(Dr) G N Vaughan
National Manager
9 February 1993

ATTACHMENT

	PUBLIC INTEREST (Govt funded) $M		INDUSTRY RELATED (Industry funded) $M		TOTAL $M
EXECUTIVE	$1.165M	(100%)	$0.0M	(0%)	$1.165M
ADEC	$0.473M	(100%)	$0.0M	(0%)	$0.473M
GENERAL ADMIN	$0.865M	(40%)	$1.298M	(60%)	$2.164M
DRUG EVALUATION	$1.018M	(15%)	$5.706M	(85%)	$6.724M
COMPLIANCE	$0.460M	(13%)	$2.962M	(87%)	$3.422M
TGAL	$6.517M	(90%)	$0.724M	(10%)	$7.241M
DEVICES	$1.348M	(53%)	$1.186M	(47%)	$2.534M
SUB-TOTAL	$11.847M	(50%)	$11.876M	(50%)	$23.723M
CORPORATE OVERHEADS					
POE	$2.854M	(50%)	$2.854M	(50%)	$5.708M
ISD	$1.044M	(50%)	$1.044M	(50%)	$2.087M
CSD	$2.298M	(50%)	$2.298M	(50%)	$4.595M
SUB-TOTAL	$6.195M	(50%)	$6.195M	(50%)	$12.390M
TOTAL	$18.042M	(50%)	$18.071M	(50%)	$36.113M

Draft 19.2.93 pm
5333

RECORD OF MEETING of TGA AND INDUSTRY MEMBERS OF IGCC
Wednesday 17 February 1993
APMA Board Room, North Sydney

The purpose of the meeting was to consider the basis of industry contribution to TGA costs in accordance with the Minister Staples's agreement to phase in increased fees and charges.

The meeting agreed that formal minutes would not be taken but that a brief summary of main points raised at the meeting should be prepared and circulated following the meeting.

Present:

Mr Pat Griffin	TGA (Chair in absence of Dr Vaughan)
Mr Kerry Bell	APMA
Dr Janice Hirshorn	APMA (advisor)
Mr Terry Murphy	NFA
Mr Derek Tye	PMAA
Mr Sheriff Vallance	MIAA
Dr Roger Bateman	IGCC Secretary

Points of clarification:

The Government decision of 50% recovery of TGA costs from industry phased in over the next 4 financial years as outlined in Dr Vaughan's letter of 9 February 1993, was accepted.

Mr Bell explained that the Government decision of 50% cost recovery from industry followed industry concern that it was not in a position to influence the cost of services provided by TGA. Government had agreed that if industry-related activities could be identified and partitioned from other TGA public interest activities, then industry would be obliged to pay for only industry-related activities (and any extension of those TGA activities sought by industry) in the future.

However, an over-riding condition to the phasing in of new fees and charges aimed at eventually raising 50% of the present TGA budget, was that the base overall costs from which future fees and charges adjustments were to be calculated, should initially be shared equally by industry and Government.

The present meeting was to agree on the relative industry or government contribution to cost elements that made up that total TGA base cost.

The base TGA costs, as considered at the meeting, would continue to be shared 50:50 in future years. Additional TGA activities would be funded by either industry or government depending on the agreement on whose responsibility it was to fund activity of that nature. The overall relative contributions of industry and government to funding of the TGA could therefore move away from 50:50 sharing in future years.

- Fees and charges for all individual categories will progressively increase from their present level (33% industry contribution) to the proposed fees and charges (which will result in a 50% industry contribution) by 1996/97. For example, a current $60 fee to be increased to $200 could be expected to rise in equal steps to $95 (1993/94), $130 (1994/95), $165 (1995/96), and $200 (1996/97).

  These increases will occur annually and will require new Regulations to be tabled each time.

- In answer to a query from Mr Bell, the $11.79M actual fees and charges expected in 1992/93 (see Table in Dr Vaughan's letter of 9.2.93) had been calculated to include the whole of the 1992/93 financial year.

  Mr Tye queried what would happen in the event of a revenue shortfall from anticipated fees and charges. Mr Griffin saw a need either for the TGA to quickly act to reduce expenditure in those areas affected in this way, or an approach to be made to the Dept Finance for a loan/supplement to balance the TGA budget for that year.

- In answer to a query from Mr Bell, additional revenue arising from successful prosecution of surveillance activities will be retained as TGA revenue. (Mr Griffin to confirm)

Industry/Government Cost Distribution:

A proposed distribution of costs between industry and government prepared by the TGA (reference documents 5299 & 5276) was considered.

The following points were seen as requiring further consideration:

Executive

- A proportion of the "Executive" costs could be ascribed to industry if necessary to achieve a final 50% government:50% industry split.

ADEC

- ADEC costs are entirely Govt funded to retain committee independence. Agreed.

Drug Evaluation Branch

- SAS costs were not specifically identified. However TGA had identified them as 100% Government funded and equivalent to 4 man years (80%) of the government funded proportion of Coordination Unit costs. Dr Hirshorn queried this cost of approximately $150,000 as SAS cost estimates previously quoted to the APMA were closer to $500,000. To be checked.

- 50% industry contribution to ADRAC costs was queried. The APMA suggested that there needs to be a degree of consistency with the Device Problem Reporting split (90% govt:10% industry). To be

reconsidered.

- 70% industry contribution to DEB ISDS costs was queried. A proportion was ascribed to cost of sponsor access to the tracking system. APMA understood sponsor access was intended to be revenue neutral with fees to be set to cover TGA costs. To be reconsidered.

- APMA queried whether the Australian Prescriber was to be removed from the functions of the TGA and if so, what happened to the TGA budget allocation. Mr Griffin's understanding was that the Prescriber was to be relocated in another Division of the Department. Funds allocated to that function would be transferred from the TGA allocation.

- APMA pointed out cost implications of moving Poisons Scheduling to the TGA. This had not been included in the present list and negotiations with industry on its funding might be needed.

Compliance

- 100% industry contribution to GMP costs was not accepted. GMPALS activities includes a contribution to ADEC, hospital pharmacy advice and input to TGC. 90% industry contribution would be acceptable to APMA. PMAA and NFA argued for 70% industry contribution. To be reconsidered.

- All industry representatives agreed that Surveillance should not be 100% industry funded. APMA argued that it should be 100% government funded. PMAA and NFA disagreed and suggested perhaps 40% industry funding based on the benefit to industry of discouraging poor quality manufacturing/marketing. To be reconsidered.

TGAL

- The proportion of TGAL costs ascribed to Methodology Development was noted. This function would be fully government funded and industry contribution was not an issue. Nevertheless, the APMA suggested that it was a matter that needed to raised for further discussion at the next full IGCC meeting.

Therapeutic Devices Branch

- The basis for 10% industry funding of Device Problem Reporting was queried by MIAA. The level of industry contribution needs to be reconsidered.

- Device Information costs were proposed as 90% industry funded. MIAA pointed out that much of the information generated by TDB went to customers other than industry eg only 10% of the Devices Bulletin circulation was distributed to industry. The rationale or basis needed to be clarified.

- The justification for 10% industry funding of Device Laboratory Activity was unclear. Explanation was sought.

Overheads

. The meeting agreed that, consistent with normal accounting practices, the overheads be split 50% industry:50% government funded.

Other matters:

1. Mr Vallance proposed that the overall industry contribution also needed to be considered in terms of the different industry sectors involved. Mr Vallance pointed out that overall contribution to costs by the different industry sector contribution needed to be linked to the setting of the levels of fees and charges.

2. Mr Tye and Mr Murphy suggested the need for TGA to maintain separate records on the costs of activities involving non-prescription proprietary medicines (PMAA) and products made by members of the NFA eg herbal preparations.

3. Mr Bell suggested that the full IGCC meeting on 26 March 1993 would need to agree on the finalised basis of funding the TGA. There was general discussion on the need to ensure the necessary Fees and Charges to apply in 1993/94 were adopted in Regulations as soon as possible.

4. Dr Hirshorn would write to TGA shortly seeking clarification of some of the terminology used in the Fees and Charges Schedule.

SUMMARY OF FUTURE FUNDING OF TGA

	1992/93	1993/4	$M 1994/95	1995/96	1996/97
Fees and Charges	11.79	13.53	14.93	16.71	18.96
TGA Budget	18.06	18.29	18.21	18.57	18.96
DHHCS subsidy	2.00	-	-	-	-
Dept Finance subsidy	4.26	4.76	3.28	1.86	0
Total	36.11	36.58	36.42	37.13	37.92
Industry contribution	33%	37%	41%	45%	50%

DIVISION OF TGA COSTS BETWEEN GOVERNMENT AND INDUSTRY

Ref	PUBLIC INTEREST ACTIVITY (Govt funded) $M		INDUSTRY RELATED ACTIVITY (Industry funded) $M		TOTAL $M
EXECUTIVE					
a'	Executive	$0.595			
b'	Discretional	$0.285	Discretional	$0.285	
	$0.880M	(76%)	$0.285M	(14%)	$1.165M
c' **ADEC**	$0.473M	(100%)	$0.0M	(0%)	$0.473M
GENERAL ADMIN					
a			ARTG	$0.776	
b	BMU	$0.098	BMU	$0.389	
c	Gen Admin	$0.767	Gen Admin	$0.133	
	$0.865M	(40%)	$1.298M	(60%)	$2.164M
DRUG EVALUATION					
d			Clinical	$2.727	
e			PCE	$0.880	
f			Toxicology	$0.795	
g	Drug Eductn	$0.447			
h	Coordination	$0.186	Coord	$0.744	
i	ADRAC	$0.510			
j	ISDS	$0.174	ISDS	$0.261	
	$1.317M	(20%)	$5.407M	(80%)	$6.724M
COMPLIANCE					
k			NDP Reg)	$1.660	
l			Listing)		
m	GMP	$0.112	GMP	$1.008	
n	Surveillance	$0.109	Surveillance	$0.072	
o	Management)				
p	Recalls)	$0.460			
q	Advertising)				
r	TGC)				
	$0.681M	(20%)	$2.741M	(80%)	$3.422M
TGAL					
s			Evaluation	$0.724	
t	Testing	$5.337			
u	Method devel	$1.174			
v	Internatl	$0.006			
	$6.517M	(90%)	$0.724M	(10%)	$7.241M
DEVICES					
w			Reg & List	$0.500	
x	Prob Report	$0.454	Prob Report	$0.053	
y	Information	$0.040	Information	$0.380	
z	Lab activity	$0.500	Lab activity	$0.053	
z'	TDEC/policy	$0.354			
	$1.348M	(53%)	$1.186M	(47%)	$2.534M
SUB-TOTAL	$12.082M	(50.9%)	$11.641M	(49.1%)	$23.723M
CORPORATE OVERHEADS					
POE	$2.854M	(50%)	$2.854M	(50%)	$5.708M
ISD	$1.044M	(50%)	$1.044M	(50%)	$2.087M
CSD	$2.298M	(50%)	$2.298M	(50%)	$4.595M
SUB-TOTAL	$6.195M	(50%)	$6.195M	(50%)	$12.390M
TOTAL	$18.277M	(50.6%)	$17.836M	(49.4%)	$36.113M

RATIONALE OF DIVISION OF TGA COSTS BETWEEN INDUSTRY AND GOVERNMENT

Ref

EXECUTIVE:

	Government	Industry
a' Executive	100%	0%

100% Government funding is consistent with independence of TGA Executive.

b'	Discretional funds	50%	50%

The total costs ascribed to "Executive" include funds allocated over the financial year to operational areas at the discretion of the National Manager. Since the bottom-line split of total TGA costs is to be 50:50 between industry and government, these discretional funds are split likewise.

---

c' **ADEC:**

Government	Industry
100%	0%

100% Government funded consistent with ADEC independence

---

abc **GENERAL ADMINISTRATION:**

Total Salaries (to pay 16)

ARTG	$407,000	(23%)
BMU	$255,000	(36%)
Gen Admin	$467,000	(41%)

		Government	Industry
a	BMU	20%	80%

Business Management Unit activity is concerned primarily with activities linked to drug/device evaluation & registration. The evaluation and ARTG functions are 100% funded by industry. Therefore BMU is also 100% industry funded minus 20% funding by Government to cover activity related to Government payments.

b	ARTG	0%	100%
c	Gen Admin	85%	15%

A small proportion of costs relate to BMU support.

---

d->j **DEB:**

	Allocation less overheads	Staff numbers	
Clinical	$2,727,478	24/96	(25% + clinical loading)
PCE	$ 880,042	14	(15%)
Toxicology	$ 795,489	12	(12%)
Drug educ	$ 447,313	3	(3% + clinical loading)
Coord	$ 929,091	26	(27%)
ADRAC	$ 510,508	10	(11% + clinical loading)
" ISDS	$ 434,243	8	(8%)
	$6,724,164	96	

cont ...

		Government	:	Industry
d->f	Evaluation	0%	:	100%

Sole client is industry which pays for the assessment service as a precondition of marketing the goods

g Drug Education

100% government funding of Australian Prescriber ensures independence.

h Coord Unit

20% : 80%

(5 staff)	(21 staff)
DEB budgeting 0.5	Applic Entry Cell checking 6
Staffing 0.5	ASC indust & extl eval liaison 8
Accommodation 0.5	Data entry & file distribution 7
SAS support 4	

i ADRAC 100% : 0%

ADRAC post marketing surveillance functions are primarily of a public interest nature and therefore are funded 100% by Government.
(cf the 90% government:10% industry split for the Device Problem Reporting costs since the device function includes a considerable amount of problem reporting and testing time that originates from requests from industry).
Adverse Drug Reaction Bulletin & Committee - 100% Government funding ensures independence.

j ISD Section

40% : 60%

(3.5 staff)	(4.5 staff)
MIS - TGA management 3	
IRS - Management 0.5	IRS - Evaluation 1.5
	CTN/CTX 1
	Patents 1
	International harmonisation 1

Ongoing costs of sponsor access to the DEB tracking system are minimal and have been deleted from industry contribution to Information, Service & Development Section (ISDS) costs.
Ferntree contract to run sponsor access involves no cost to TGA. Non-Ferntree requests are minimal.
Any upgrades of sponsor access are only at industry request - 100% industry funded

---

k->r **COMPLIANCE:**

	Salaries	Admin	Total	
Management Recalls Advertising TGC secretariat				8 staff
	$380,000	$80,000	$460,000	
NPD Registration) NPD Listing) GMP audit Surveillance	$637,000 $880,000 $146,000	$1,023,000 $240,000 $35,000	1.660M 1.120M 0.181M	35 staff
	$1,664,000	$1,298,000	2.962M	

		Government	:	Industry	
k	NPD Registration	0%		100%)	($1,660,000)
l	NPD Listing	0%		100%)	
m	GMP audit	10% ($112,000)		90%	($1,008,000)

Recovery of GMPALS costs from industry reduced to 90% on the basis of GMP auditors are also involved to a small degree in public interest activities ie 10% Government funding covers GMPALS involvement in hospital pharmacy advising & TGC input.

n	Surveillance	60% ($108,600)	40%	($72,400)

TGA surveillance have been ascribed 40% industry:60% government cost shared on the basis that a substantial benefit mainly to OTC drug/herbal industry sectors is afforded by this function discouraging poor manufacturing standards and marketing practices ("level playing field" benefit to industry).

20%	:	80% ($2,741,000)

---

s->v **TGAL:**

	Staff	<- TGAL Budget allocation -> Salaries	Admin	Total
TGAL evaluation	13.3	$0.682	0.042	$0.724M(10%)
Lab testing	85.0)			
Method development	18.6)	proportional split of		$6.517M
International	0.1)			
	117			$7.241M

	Government	: Industry
TGAL evaluation	0%	100%
Lab testing	100%	
Method development	100%	
International	100%	

---

w->z' **DEVICES:**

		Government	: Industry
w	Registration/Listing	0%	100%
x	Problem report investig.	90%	10%

10% industry funded because a considerable amount of problem reporting and testing time originates from requests from industry. Industry seeks help and assistance from TGA in matters of design, quality and product correction. Is in industry's interests to minimise risk and often approaches TGA to help solve problems.

y	Information	10%	90%

90% industry funded since enquirers are almost entirely persons or companies who wish to supply therapeutic devices in Australia (1.5 staff allocated full time).
Although the Device Bulletin is widely circulated to other than industry, the costs of the Bulletin are a very small part in the overall information costs and are included in the 10% government funded costs.

z	Lab activities	90%	10%

10% industry funded since TGA receives many requests from industry for advice or assistance with testing. Device laboratory testing is separate from other TGAL testing and it is intended that it should remain so.

z'	TDEC/policy	100%	0%

100% Government funding is consistent with independence of policy development.

[Therapeutic Goods Administration] Therapeutic Goods Administration
Budget Measures 1996

This year's Budget announces an increase in the proportion of cost recovery for the regulation of therapeutic goods. In an effort to meet the savings required to public sector spending, the industry will be required to increase the proportion of its support.

The government has recognised its role in meeting its public health obligations in the regulation of therapeutic goods. Consequently it has kept the target for cost recovery from industry to only 75%. This represents an increase of 25% above the current 50% cost recovery which was introduced over five years. The increase will also be introduced gradually, over the next three years to 1999. The reform will provide approximate savings of $3 million in 1996-97, $6 million in 1997-98, $9 million in 1998-99 and $9 million in 1999-00.

Year	1996-97	1997-98	1998-99
Cost recovery target	58.33%	66.67%	75%
Savings $m	-3.041	-6.143	-9.312

The therapeutics goods industry has been performing strongly in Australia and the community has confidence in the regulatory measures undertaken by the Therapeutic Goods Administration to provide safe and efficacious products. For example, pharmaceutical sales in Australia have grown from around $1.9b in 1991 to over $3.8b in 1995, including exports. Therefore, according to the user-pays principle, the industry is being asked to contribute an additional $17.932m of user charges over three years.

Since cost recovery commenced, the TGA has worked in partnership with industry and the service to industry has improved, with tangible benefits. For example, reduction in the turn around times for applications for registration has facilitated earlier marketing of products. Further improvements in the performance of the TGA will be sought through a review of its operations, as announced by the Government in May 1996. The review is scheduled for completion by the end of this calendar year.

Many of the benefits to industry will be realised through this review of Australia's current approach to the regulation of medicinal products as administered by TGA. The review will produce recommendations on the means of improving the speed, effectiveness and cost-efficiency of the current approach. The 1996 Budget measures have been introduced at a time when TGA is passing on improved productivity and efficiency gains including: reduction in evaluation times; adoption of he European Classification System of low risk medicinal devices which will reduce approval times; pursuit of an MRA with the European Union to provide Australian suppliers with automatic approval in selected overseas countries; and substantial reductions in approval times through the electronic lodgement facility.

The implementation of the additional user fees and charges will be the subject of detailed discussion with the pharmaceutical industry.

Contact officer:

Mr Terry Slater
National Manager
Therapeutic Goods Administration
Ph +61 6 289 7450

[TGA home page] | [Health and Family Services home page]

FACT SHEET 18

Budget 97-98

THERAPEUTIC GOODS ADMINISTRATION

Recent government initiatives arising from the Industry Commission inquiry into the pharmaceutical industry include a new program to follow the existing Factor (f) scheme, extension of standard (20 year) patent terms and the new data exclusivity regime. These initiatives, plus a review of labelling requirements recommended by the Small Business Deregulation Task Force, will contribute to industry viability and international competitiveness.

In this context, the Government will increase the operational cost recovery from industry for the regulation of therapeutic products, moving to 75 per cent in 1997-98 (rather than by 1998-99 as outlined in last year's Budget) and to full cost recovery from 1998-99.

This measure will result in an increase in revenue of some $32 million over the next four years. The Therapeutic Goods Administration (TGA) has been progressively increasing the level of cost recovery from industry since 1992-93, and the cost recovery target for 1996-97 was 58 per cent. With industry turnover now estimated to be more than $4 billion, the proposed increased industry contribution represents a very small percentage of this amount.

The effect of the measure on revenue over the next four years will be an increase as follows:

1997-98 $m	1998-99 $m	1999-2000 $m	2000-2001 $m
3.1	9.9	9.7	9.8

At the same time, the TGA will implement a range of reforms flowing from the Government's response to the recent independent review of the TGA. These measures are intended to free up business from complicated regulatory requirements, promote greater efficiencies, boost the already high standard of medicinal products produced in Australia and to assist Australian industry in being more competitive in the international arena.

The changes will include:

- increased use of medicinal evaluation reports and decisions from comparable overseas regulatory bodies;
- examination of export arrangements to remove unnecessary regulatory obstacles for Australian manufacturers and exporters; and
- maximising opportunities for mutual recognition or harmonisation of Australia's regulatory requirements with those of countries with comparable standards.

Consumers are also expected to benefit by having more timely access to new products and to the information necessary to ensure appropriate use.

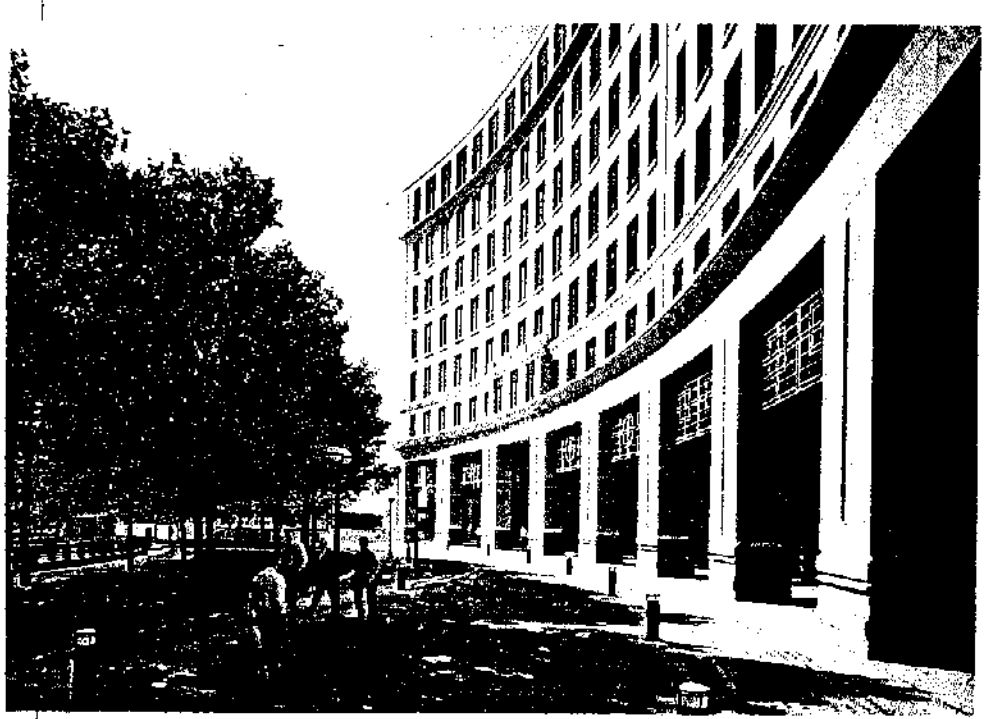
The regulation of therapeutic products by the TGA provides considerable benefits to industry by allowing Australian companies to import, manufacture, supply and export quality medicines and medical devices. The high standing of the Australian regulatory system also ensures consumer confidence in the domestic market and ready acceptance of Australian export of therapeutic goods by importing countries.

Over the next few years, the TGA will continue to develop a world class regulatory system for therapeutic products which also takes account of the Australian community's attitudes and expectations in relation to self-medication and the role of preventive and complementary medicines.

The TGA will also pursue a regulatory partnership with New Zealand, including harmonised and joint standards for therapeutic products, and will look at setting up a single joint regulatory agency. Further efficiency gains will be made by adopting the European Union classification system for self-regulation of low-risk medical devices and by implementing the Mutual Recognition Agreement with the European Union.

Contact: **Terry Slater, First Assistant Secretary, Therapeutic Goods Administration, (06) 232 8200**

Industry opposes proposed EMEA fees



Proposal would introduce annual fees to keep licences and fees for advice

Proposed increases to the fees payable to the European Medicines Evaluation Agency (EMEA) are meeting resistance from both the British Government and the European pharmaceutical industry.

The proposal is for the full evaluation fee to rise from a sliding scale of ECU140,000 to ECU200,000 to a flat rate of ECU200,000 (£128,400). Companies using EMEA marketing authorisations would also have to pay new annual fees for each product of ECU60,000. Another proposed new fee would be a ECU60,000 charge for advice on the design of research programmes.

The Government's view, made clear in a memorandum to the House of Commons Select Committee on European Legislation, is that the European Commission has not justified the scale of the increase.

A spokeswoman for the European Federation of Pharmaceutical Industries and Associations (Ms Emer Cooke) said of the proposed increase: "We don't see any real justification for it. We do not think it is clear what work it will cover that is not already covered by existing fees."

A Commission report says that the annual fee would cover the funding of post-authorisation maintenance activities. As for the general rise in fees, the report says that EMEA's work was expected to grow by 80 per cent from 1998 to the year 2002, and that this should be funded by fees, rather than EC grant.

"The current fee level does not cover the real costs incurred by either the national component authorities or the agency and would therefore have to be increased," the report says.

When the EMEA was set up, the Council of Ministers decided to set fees lower than those recommended by the Commission and to subsidise the agency from the EC general budget. New fees were to apply from January, 1998.

Even at the proposed levels, the new fees would not cover the full costs of the EMEA and a 25 per cent subsidy would be needed. This, the Commission says, would guarantee the agency's independence.

New professor at Nottingham pharmacy school

Dr Saul Tendler has been awarded a personal chair in biophysical chemistry by the University of Nottingham. Professor Tendler is co-director of the Nottingham school of pharmacy's laboratory of biophysics and surface analysis. Over the past 10 years, Professor Tendler has undertaken research at the university on biomolecular structure and recognition using novel methods of biophysical characterisation.

Professor Tendler is the third member of the school's staff to be awarded a personal chair in recent years, with Professor Paul Williams receiving a chair in molecular microbiology and Professor Martyn Davies, the other co-director of the laboratory of biophysics and surface analysis, receiving a chair in biomedical surface chemistry.

The school of pharmacy has also promoted Dr Clive Washington and Dr David Barrett to the post of senior lecturer.

Use pharmacists, says BMA

The British Medical Association is once again using its Doctor-Patient Partnership campaign to urge people to make better use of pharmacists so as to lighten the load on general medical practitioners during national holidays.

Urging people not to call out a doctor unless it is really necessary, Dr Simon Fradd (chairman, DPP) said on March 24: "Patients can help themselves by ensuring that their prescriptions are up to date and by asking their pharmacists for advice for the treatment of minor conditions."

NPA and SPF election results

Both the National Pharmaceutical Association and the Scottish Pharmaceutical Federation have elected new management boards.

The NPA management board for 1998-2001 is: area 1, Umesh Patel; area 2, Ian Conquest; area 3, John Hind; area 4, Hemant Patel; area 5, Gerald Alexander; area 6, Ashok Soni; area 7, Kirit Patel; area 8, Ben Zadland; area 9, Graham Phillips; area 10, Wally Dove; area 11, Michael Smith; area 12, Gaz Clapinski; area 13, Andrew Murdoch; area 14, David Sukert; area 15, Jeremy Clitherow; area 16, Rajesh Patel; area 17 Peter Jenkins and Richard Evans; and area 19, Terence Hannawin.

The membership of the Scottish Pharmaceutical Federation's executive council is: Argyll and Clyde, Andrew Taylor; Ayrshire and Arran/Dumfries and Galloway, Gilmour Milligan; Fife, John Hughes; Forth Valley, no representative; Greater Glasgow, Elizabeth McConechy, Elizabeth Roddick and Iain Smyth; Highland/Western Isles, Ronald Shiels; Lanarkshire, Ian Johnstone; Lothian/Borders, George Allan, Thomas Beattie and Kenneth Black; Tayside, Ewen Jenkin.

The election of representatives for the Grampian/Orkney/Shetland region is to be rerun due to an error in determining the electorate. Maps for the region provided by the health board omitted two counties, resulting in 20 per cent of the electorate being wrongly placed in the Highland region. The candidates for the region, which was to have one representative, were Alan Cruickshank and David Forbes. The additional electorate means that the region will probably be entitled to two representatives.

Performance measure	Result
Agreed timeframes met for responses to ministerial correspondence, Question Time Briefs, Parliamentary Questions on Notice and ministerial requests for briefings.	Agreed timeframes were met for 81 per cent of the ministerial correspondence and 88 per cent of the ministerial requests for briefings. All Question Time Briefs were provided to the Minister's Office before Question Time. Due to the development and implementation of a new electronic tracking system during the year data is not available for the timeliness of Parliamentary Questions on Notice.
Quantity: Number of responses to ministerial correspondence, Question Time Briefs, Parliamentary Questions on Notice and ministerial requests for briefing will be recorded during 1999–2000 as a benchmark.	Responses were prepared for approximately[27]: • 830 items of ministerial correspondence; • 40 QTBs (as well as 10 updates of existing briefs); • 5 PQoNs[28]; and • 50 Ministerial requests for briefing.

3. National Leadership; including:

- **input to setting of international standards for therapeutic goods; and**
- **appropriate national policies and controls for medicines, medical devices and chemicals.**

Performance measure	Result
Quality: Departmental input is taken into account in the setting of national and international standards for therapeutic goods and chemicals, and the adoption of such standards where appropriate.	The TGA has had significant involvement during the past year in the setting of national and international standards for therapeutic goods and chemicals, particularly in the areas of gene technology, medical devices and blood. Examples of the level of TGA involvement in setting international standards include Australia being selected to chair the Global Harmonisation Task Force for medical devices, Mr Robert Tribe was elected Chairman of the Pharmaceutical Inspection Cooperation Scheme for a period of two years. Dr Larry Kelly and Mr Robert Prestridge were also presented with US Vice-President Al Gore's Hammer Award for their work on exposing counterfeit medicines.

[27] All figures are approximate as Departmental systems only allow for reporting on structural lines and not by outcome.

[28] This figure includes only the questions from the Senate and the House of Representatives, and not questions from the Senate Community Affairs Legislation Committee during Senate Estimates Hearings.

Attachment 8

THERAPEUTIC GOODS ADMINISTRATION

INDUSTRY-GOVERNMENT CONSULTATIVE COMMITTEE (IGCC)

1. General

From 1 July 1990, Industry is to contribute directly to the costs of operating the Therapeutic Goods Administration (TGA). So that Industry may contribute to the TGA's budgetary process, an Industry/Government Committee of Review is to be established to meet at least once a year to review both the past application of resources and future budgetary proposals.

2. Terms of Reference

The terms of reference of the Industry-Government Consultative Committee shall be as follows:

(i) To review and report to the Minister on the utilisation of resources in pursuit of the Administration's objectives. This review process to cover both:
- Financial outlays; and
- Performance indicators.

(ii) To review and comment on the Administration's budgets, including:
- The size of the budget; and
- The pattern of fees and charges in support thereof.

(iii) To recommend strategies for improving the efficiency of the Administration's operations, within the context of its established goals and objectives.

3. Membership

(i) One industry representative from:

- Australian Pharmaceutical Manufacturers Association
- Proprietary Medicines Association of Australia
- Medical Industry Association of Australia
- Nutritional Foods Association of Australia.

(ii) Four Government representatives:

- National Manager, TGA
- Director, Business and Services Branch, TGA
- Representative of Department of Finance
- Representative of Department of Industry, Science and Technology.

TGA-INDUSTRY CONSULTATIVE COMMITTEE [TICC]
TERMS OF REFERENCE

PREAMBLE

The Therapeutic Goods Administration (TGA) has as its principle objective, the administration of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in or exported from Australia. The Government has endorsed this objective and other TGA activities which are consistent with its policies. Although industry does not determine these policies, from 1 July 1998 industry will pay the full costs of TGA's activities which result from the implementation of the *Therapeutic Goods Act 1989.*

PURPOSE

A TGA- Industry Consultative Committee (TICC) will be established to facilitate consultation between TGA and the industry in two broad areas:

- Input to forthcoming budgets;
- Open and transparent input to and accounting against the TGA Corporate Plan

The TICC is a consultative forum, not a management or advisory committee. The TICC is the highest level forum for industry to provide direct feedback to TGA on broad policy, resource allocation and program performance issues.

MEMBERSHIP

The TGA-Industry Consultative Committee (TICC) was established in late 1997 and comprises representatives from TGA and peak therapeutic goods industry groups as follows:

- Australian Pharmaceutical Manufacturers Association (APMA)
- Proprietary Medicines Association of Australia (PMAA)
- Complementary Healthcare Council of Australia (CHC)
- Medical Industry Association of Australia (MIAA)
- The National Manager, TGA (Chairman)
- The Director, Business and Services Branch, TGA
- A nominee of the Chairman to act as Secretary

In addition, a representative of the Consumers' Health Forum will be invited to attend TICC meetings.

The Chairman, TICC, may also co-opt TGA managers, public health experts and other industry representatives as required.

Industry membership of the TICC shall ensure that there is a national, authoritative representation of each of the four principal sectors of the therapeutic goods industry namely: prescription medicines; non-prescription medicines; complementary medicines; and medical devices.

OPERATION OF THE COMMITTEE

The Committee is chaired by the National Manager of the Therapeutic Goods Administration.

The TICC shall meet formally a minimum twice per year in May and November. Meetings with industry will also be conducted in March of each year to discuss fees and charges as necessary for the following financial year. Other meetings with industry sector groups are conducted throughout the year as the need arises.

Industry representatives will be provided with information by TGA which enables members to make informed comment on TGA policy, resource allocation and program performance.

TERMS OF REFERENCE

The terms of reference of the TICC shall be as follows:

(i) To examine and comment on the TGA corporate strategic plan developed within the context of Government policies;

(ii) To examine and comment on TGA performance against the key performance indicators set out in the Corporate Plan and Budget Statements; and

(iii) To examine and comment on the TGA budget, including new initiatives and other budget measures, and on the proposed industry fees and charges.

The Terms of Reference will be reviewed periodically.

TGA Therapeutic Goods Administration
Conformity Assessment Branch

COMMONWEALTH DEPARTMENT OF HEALTH AND FAMILY SERVICES

BUSINESS RULES FOR PROCESSING/VARIATION FEES

Fees for processing data in relation to a variation of an entry in the Australian Register of Therapeutic Goods (ARTG) are provided for in the Therapeutic Goods Regulations, Schedule 9, Item 2A. From 1 July 1993, processing fees are payable for variations which must be notified to, or approval sought from, TGA under Section 32 of Therapeutic Goods Act.

The following business rules have been adopted by TGA in relation to calculation of processing fees.

- Fees apply to changes to information relating to a therapeutic good rather than to information about the company, except when the change involves a transfer of sponsorship or a new sponsor name.
- The fee payable for processing a variation is not to be more than the application fee for a new product of that type. This does not exclude an evaluation fee being payable as well.
- Only one fee is payable for simultaneous applications for variation effecting an identical change, as this is seen as one 'event.'

To be considered an 'event' applications must arrive together, i.e. if some are received one day and others the next, they are considered 2 events even if effecting an identical change.

To be considered an 'event', applications must effect the same change even if they are received simultaneously, e.g. if applications to vary warning messages are received on the same day, but the new warning messages are different, they are considered 2 events.

- Where there are simultaneous applications for variation effecting an identical change for different categories of therapeutic goods, (i.e. drugs registered through Drug Evaluation Branch, drugs registered through Compliance Branch, listed drugs, registered devices and listed devices) a separate fee is payable for each type of application, and the applications must be submitted on the appropriate forms.

- If a change is forced on a sponsor by another agency, TGA may charge a processing fee and will examine each case on its merits. If a sponsor considers a change falls into this category, he/she should submit the necessary applications with an explanation and a request that no fee be payable. The situation will then be assessed.

- Changes to manufacturing licences including change of company name, change of nominated person or change of conditions do not attract a processing fee because of the higher level of annual charges applying to manufacturing licences.

Specific Instances

The following specific instances have been identified as having a fee payable or not as a guide. The list is not exhaustive and any variations not covered should be referred to the Business Manager for determination in consultation with the processing area. In each case the actual fee payable depends on whether the variation applies to a registered or a listed product.

• Cancellation of good from ARTG	No fee
• Change of sponsor's address	No fee
• Change of sponsor's phone number	No fee
• Change of Authorised agent	No fee
• Change in label colour, size or print style	No fee
• Correction of grandfather or other data - if error is caused by TGA	No fee
• Correction of grandfather data - if error is caused by company	Fee per event
• Change of name of sponsor (same sponsor)	Fee per event
• Change of name of manufacturer	Fee per event
• Change of site of manufacture	Fee per event
• Correction of data on ARTG	Fee per event
• Add/change warning statement	Fee per event
• Change of Poison Schedule	Fee per event

Conformity Assessment Branch
2 August 1996

FEES FOR NOTIFICATIONS INCLUDING SELF–ASSESSABLE, SAFETY RELATED NOTIFICATIONS AND EDITORIAL CHANGES AND CHANGES UNDER 32(3) OF THE TGA ACT.

Sponsors can submit notifications to vary the conditions of registration in accordance with Appendix 7 & 8 of the Australian Guidelines for the Registration of Drugs (AGRD). Notifiable changes can only be made to products that are already on the Australian Register of Therapeutic Goods (ARTG).

These notifications can be in the form of minor Part 2 changes to products already registered on the ARTG or safety related changes or editorial changes to approved Product Information documents and changes under 32 (3) of the Therapeutic Goods Act (correction of an error on the ARTG).

SELF-ASSESSABLE NOTIFICATIONS

Self–Assessable notifications attract a processing fee. The processing fee is calculated according to the number of changes and the number of products being affected.

For Example : 1 identical change to 1 product = 1 processing fee
2 identical changes to 2 products = 2 processing fees
1 identical change to 3 products = 1 processing fee
3 identical changes to 1 product = 1 processing fee

If there are separate changes to different strengths or different products on the one notification then the processing fee charged is per change/per product.

SAFETY RELATED CHANGES (8N)

These notifications attract a single processing fee per product information (PI) document regardless of whether the changes are identical or different to each document.

For example: If the Sponsor submits a notification for a safety related change for their product but have 2 PI documents – one each for different strength/dose form or one PI for their marketed products and one for their registered products – then each PI document would attract a processing fee.

If data accompanies a safety related notification or data is requested during the review of that PI document, that data is not charged for. Policy document from Dr Susan Alder –DSEB Branch Head - issued on the 14 November 1996 refers.

EDITORIAL CHANGES (8G)

These notifications attract a single processing fee per product information (PI) document regardless of whether the changes are identical or different to each document.

For example: If the Sponsor submits a notification for minor editorial changes for their products but have 2 PI documents – one each for different strength/dose form or one PI for their marketed products and one for their registered products – then each PI document would attract a processing fee.

32 (3) CORRECTION OF ERROR ON THE ARTG

32(3) notifications attract a processing fee. The processing fee is calculated according to the number of changes and the number of products being affected.

For Example : 1 identical change to 1 product = 1 processing fee
2 identical changes to 2 products = 2 processing fees
1 identical change to 3 products = 1 processing fee
3 identical changes to 1 product = 1 processing fee

If there are separate changes to different strengths or different products on the one notification then the processing fee charged is per change/per product.

It should be noted that if a notification is received and has data attached, evaluation fees plus the processing fee may be payable.

For example a 32(3) notification with data can be charged a processing fee as per item 2A of Schedule 9 of the Therapeutic Goods Regulations 1990 plus an evaluation fee as per item 12 of Schedule 9. The evaluation fee is charged for at the current fee scale rate and is dependent upon the data type.

EVALUATION FEES ARE NOT TO BE CHARGED FOR DATA ACCOMPANYING A SAFETY RELATED NOTIFICATION.