Supplementary Evidence by the Complementary Healthcare Council for the Public Hearing of the Productivity Commission into Cost Recovery- 27 November 2000

CHC Statement:

1. **The CHC contends that 50% of the TGA activities, based on the TGA's own estimate, are not industry related but are 'public interest' activities which should be properly financed by the government. The CHC industry is prepared to fund the remaining 50% of TGA activities which deliver a service to the industry.**
2. **The CHC contends that the regulation of Complementary Healthcare Products under the Therapeutic Goods Act is inappropriate resulting in unacceptable levels of compliance costs estimated by industry to be equivalent to 15% of after tax profit.**

Background

The CHC is the peak industry body representing manufacturers. Suppliers, importers, exporters, retailers, practitioners and consumers of complementary healthcare products. (CHPs)

Total membership is 671 of which 105 members supply or manufacture CHPs. These members account for a conservative 85% of CHPs legally supplied in Australia

The CHC and was formed two years ago by the amalgamation of the Australian Council of Responsible Nutrition and the Nutritional Foods Association of Australia, which was established in 1976.

The CHC is addressing cost recovery as it applies to these products under the Therapeutic Goods Administration.

Complementary Healthcare Products

Complementary Healthcare Products include vitamin, mineral and nutritional supplements, herbal, aromatherapy and homoeopathic products. Surveys confirm that over 60% of the Australian public now use CHPs.

These products are extremely low risk, with three deaths over the last ten years being associated with CHPs. The cause of two of those deaths are now under dispute. According to government statistics there are 11000 deaths annually attributed to fully evaluated pharmaceutical products. 2.3 million food poisonings per year including deaths.

Mr Paul Coughlin, Director of the Office of Regulatory Review within the Productivity Commission has suggested that in fact CHPs lie at the very low end of the safety spectrum followed by foods, pharmaceutical OTCs and then prescription drugs at the high risk end.

International Regulation of CHPs
In most other countries, including UK, US, New Zealand, Canada and some European countries, CHPs are sold as food supplements without any need for evaluation or pre-market approval. In most countries these products can make health claims but not medicinal claims such as treatment and cure.

There is an international trend to establish a third regulatory category for CHPs situated between medicines and foods. Canada Health has recently established a Natural Health Products Directorate, the EU has announced a draft directive for supplements claiming that after examination of regulatory approaches to these products they clearly lie somewhere between foodstuffs and medicines, and Japan has also established a third category. New Zealand already has a third category of supplements under food law.

Australia is out of step with global moves in regulating these products.

The Therapeutic Goods Legislation
CHPs are regulated under the Therapeutic Goods Act 1989 and Regulations, which applies also to pharmaceutical OTCs and prescription drugs. Industry expectation was that this was to be a simple 'light touch' regulatory approach to these low risk products.

At that time TGA recovered 50% of its operating costs through fees and charges.

In August 1991, in answer to a Parliamentary Question, the Minister responsible at that time, the Hon. Peter Staples, acknowledged that some of the TGA's activities are public interest activities which were funded at that time by a Government appropriation. Mr Staples advised parliament that the are not undertaken at the request of industry but "*are performed in the interest of the public*" (attachment1)

For the year 1999/2000 the TGA estimated that TGAL costs were just on $2million out of a total $5.5million dollar estimated costs for the Complementary Healthcare sector.- attachment 1a.

In February 1993, the then National Manager of the TGA, Mr Geoffrey Vaughan, advised industry in writing that the level of fees and charges would be amended to recover 100% of the cost of specific industry related functions (amounting to 50% of the TGA activities as estimated by the TGA itself), and that government would finance the public interest activities. (attachment 2)

The basis for determining the 50% industry related component as prepared by the TGA at that time is presented at attachment 3, as well as the refined and accepted detailed breakdown of industry (50%) v. public interest (50%) activities at attachment 4.

Essential elements of this agreement that are determined to be public interest include:

76% Executive costs
100% of evaluation committees

40% of general administration
20% of substance/product evaluation
20% of compliance costs
90% of TGAL
50% corporate overheads

In 1996 the government announced that the industry would be required to increase the level of cost recovery to 75% over the next three years to 1999 in "an effort to meet the savings required to public sector spending". There was continued recognition of the government's role in "meeting its public health obligations in the regulation of therapeutic goods" but no indication of how or why the industry related activities had increased to 75%. (attachment 5). The 1996 Review referred to as part of this announcement was oriented towards pharmaceutical products and did little to improve efficiencies for the Complementary Healthcare sector.

In 1997, the government announced that the 75% cost recovery from the regulation of the therapeutic goods industry would be moved forward by one year to 1998 and that full cost recovery would be achieved in 1999. Reference is made in the budget document to government initiatives arising from the Industry Commission inquiry into the pharmaceutical industry including a new Factor (f) scheme, extension of patent terms and new data exclusivity regime, which *"will contribute to industry viability and international competitiveness"*. (attachment 6)

These initiatives are not relevant to the Complementary Healthcare sector of industry and outcomes of the labelling review that is mentioned have not yet been implemented.

Further, this same document announced that the TGA *"will implement a range of reforms flowing form the Government's response to the recent independent review of the TGA"*, which are *"intended to free up business from complicated regulatory requirements, promote greater efficiencies ..... and to assist Australian industry in being more competitive in the international arena."*

Thus there was little benefit for this sector to compensate for increased fees and charges, and we would argue that in fact the regulatory burden has increased significantly.

Fees increased by 39% on 1 July this year, and the TGA has recently been advised that fees and charges are expected to increase next year by the previous March CPI increase.

The direct result of the increased fees and charges has been the cancellation of whole lines of products from the Register, and a decrease in new listing applications, with the potential that the budgeted revenue will not be met.

Cost recovery in other comparable countries
The CHC is a founding members of the International Alliance of Dietary Supplements Associations, which currently represents about 25 countries world wide. CHC heads up an IADSA Task Force on international regulation of supplements or CHPs. Recent

inquiries of IADSA members indicates that no other country has been identified to date, which imposes 100% cost recovery on the regulation of these products.

The US imposes fees on prescription drugs to expedite evaluation- no costs on supplements and not expected to be.

The UK Medicines Control Agency imposes cost recovery on the 'medicines' sector, not the borderline products or Complementary Healthcare Products sector.

Italy has recently introduced a fee for label notification of dietetic products going to market.

Canadian Government has allocated $10million towards establishing the new NHPD and expects that there will eventually be some form of cost recovery.

There is no cost recovery in New Zealand in relation to the regulation of dietary supplements, but it is expected that there will be some form of cost recovery in the future.

Inquiries are continuing.

(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

Attachment (a)

TGA THERAPEUTIC GOODS ADMINISTRATION
Office of Complementary Medicines
4/11/99

Health and Aged Care

1999/2000 COST ESTIMATES FOR THE COMPLEMENTARY MEDICINES SECTOR

This paper provides cost estimates for the 1999/2000 financial year. An analysis of actual costs for 1998/99 shows that a total of $5,580,481 was attributable to the sector across the TGA. Estimates of the activities to be undertaken in relation to the Complementary sector for the 1999/2000 financial year are detailed below. These estimates show a total of $5,485,022 would be attributable to the complementary medicines sector for the 1999/2000 financial year.

Table 1.1 - Summary of total estimated costs*

Work Category	Estimated Yearly Cost
Listing Activities	$1,187,293
Evaluation Activities	$1,608,925
Implementation Work	$700,544
TGAL	$1,988,261
Total	**$5,485,022**

Table 1.1.1 - Estimated (Annual) Costs for Listing Activities:

Activity	Estimated yearly cost	Detail of estimate
1. Eligibility Reviews	$686,771	Note 1
2. New section 30 processes	$343,386	Note 2
3. Guidelines, Specifications and Standards	$23,227	Note 3
4. Telephone & general enquiries	$133,908	Note 4
Total	**$1,187,293**	

Note	Description of Estimate
Note 1	Estimate is based on the work undertaken by the listing unit for the month of July 1999, eligibility reviews amounted to 539 person hrs for the month of July. This figure was used to project the estimate of 6468 person hrs for a year. The listing unit has 6 full time staff and one part time staff member. The unit averages 850 reviews per quarter.
Note 2	Estimate is based on the work undertaken by the listing unit for the month of July 1999, assistance to sponsors under new section 30 processes amounted to 269 person hrs for the month of July. This figure was used to project the estimate of 3228 person hrs for a year. The unit is currently providing assistance to sponsors on average in over 50% of all applications received.
Note 3.	Estimate is based on work undertaken by two senior officers in the listing unit primarily involved in production and review of standards guidelines, specifications and user related materials (including listing news sheet, TGA News, roadmaps). On average over a year one officer spends 115 person hrs on these activities, with the other officer spending around 80 hrs of their time.
Note 4.	Estimate is based on each member of listing unit spending 45 minutes per day handling general enquiries, for July this amounted to 105 person hrs projected yearly this would amount to 1260 person hrs.

* **Note**: These estimates in this paper include all direct and indirect costs and overheads associated with the activity.

Table 1.1.2 - Estimated (Annual) Costs for Evaluation Activities

Activity		Estimated Yearly cost
1. Safety reviews	(estimate detail note 1)	$111,885
2. New Substances applications	(note 2)	$208,969
3. Registration evaluations	(note 3)	$208,969
4. Registration variations	(note 4)	$50,612
5. Assistance to sponsors in the registration and new substance application process (5)		$458,852
6. Servicing supporting and running CMEC	(note 6)	$258,915
7. Information service & 1800 line	(note 7)	$69,192
8. Herbal Task Force	(note 8)	$12,291
9. Foods/medicines interface	(note 9)	$28,089
10. Guidelines, Specifications and standards	(note 10)	$104,824
11. Complementary Healthcare Forum	(note 11)	$96,326
	Total	**$1,608,925**

Notes	Description of Estimates
Note 1	Estimate is based on information from OCM re safety reviews undertaken in 1998/99 financial year. Estimate is based on 8 safety reviews per annum ranging from a low range review of 50 person hrs to complex reviews requiring 300 person hours. The average for reviews undertaken is 120 person hrs per review. The annual total is 960 person hrs for 8 reviews.
Note 2	Estimate is based on information from OCM re new substance evaluations undertaken in 1998/99 financial year. Estimate is based on 12 evaluations per annum ranging from a low range evaluation requiring 40 person hrs to complex evaluations requiring over 300 person hours. The average for reviews undertaken is 150 person hrs per review. The annual total is 1800 person hrs for 12 reviews.
Note 3.	Estimate is based on information from OCM re new registration evaluations undertaken in 1998/99 financial year. Estimate is based on 12 evaluations per annum ranging from a low range evaluation requiring 50 person hrs to complex evaluations requiring over 350 person hours. The average for reviews undertaken is 150 person hrs per review. The annual total is 1800 person hrs for 12 reviews.
Note 4.	Estimate is based on information from OCM re registration variations undertaken in 1998/99 financial year. Estimate is based on evaluating 9 variations per annum with effort required ranging from a simpler variations requiring 10 person hrs to complex variations requiring up to 150 person hours. The average for variations processed is 50 person hrs per variation. The annual total is 450 person hrs for 9 variations.
Note 5.	Based on estimate provided by OCM evaluation unit for month of August 1999. 8 evaluators with time spent on providing assistance ranging from 3.5 hrs per day to 4 hrs per week. Total person hrs spent in providing assistance to sponsors/agents in month of August was 329 person hrs. Yearly this would amount to 3948 hrs.
Note 6	Estimate based on 8 meetings per year with the following cost components for each mtng: 1. Direct meeting costs:- includes sessional fees for members, fare & travelling allowance for members, Travel allowance and fares for TGA staff, venue and catering=$11,571. 2. Cost of secretarial support:- includes costs of support required for collating, dispatching papers, production of minutes, indexing, recording and disseminating decisions , organising meetings, venues etc, 17.5 person days= $12,513. 3. Cost of TGA staff attendance:- 6 staff in attendance = 6 person days = $4,680. 4. Cost of peer review of papers:- 30 person hours = $3,600.

Note 7.	Estimate is based on $500 per month Telstra fees for 1800 line. Line is manned by an officer from OCM who spends over 90% of their time on this activity. There are approx 100 calls per week , around 15 per day on average (12 to 20+ per day). Time taken per call ranges from 2 minutes to several hours depending on complexity and whether research is required to provide an answer .
Note 8	Estimate is based on 16.3 person days per year
Note 9	Estimate is based on 20.5 person hrs per month
Note 10	Estimate from OCM evaluation unit based on August 1999. Yearly estimate is based on 75.5 person hrs per month, a total of 906 hrs yearly.
Note 11	Estimate based on 2 meetings per year. Estimates are based on first meeting with the following cost components for each mtng: 1. Preparation of papers and distribution :- includes researching & production of papers, dispatching papers, organising venue and meeting, production of minutes etc. Time taken 52 person days = $39,276. 2. Cost of Holding meeting:- includes costs of venue, transcript service, catering and transport $2,543. 3. Cost of TGA staff attendance:- 8 staff in attendance = 8 person days = $6,344.

Table 1.1.3 - ImplementationWork attributable to the Complementary Sector

Project		Estimated cost for last 12 months
1. Advertising Review	(detailed in note 1)	$193,879
2. ELF Redevelopment	(note 2)	$486,380
3. Trans-Tasman Harmonisation	(note 3)	$20,285
	Total	**$700,544**

Note	Description of Estimate
Note 1	Estimate based on the following cost components: 1. Advertising Review meetings :- includes CMEC taskforce and industry consultation meetings, fares entitlements, venue costs, hospitality, equipment hire and mail out costs = $40,304. 2. TGA person time:- Estimate is based on 193 person days = $153,575.
Note 2	Estimate based on the following components: 1. ELF specifications development :- 175 person days = $132,291. 2. Cost of PAC meetings:- Based on 7 meetings per year, includes fares entitlements, venue and hospitality cost and costs of TGA officers attendance = $167,828 3. Smart ingredients processing:- Based on 213 person days = $147,311 4. project management:- Estimate is based on 3 person months @ 75% availability = $38,950.
Note 3.	Estimate is based on : 1. meetings :- includes fares & entitlements, for NZ meetings = $8,590. 2. TGA person time:- Estimate is based on 15 person days = $11,695.

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Attachment 2

COMMONWEALTH DEPARTMENT OF HEALTH, HOUSING AND COMMUNITY SERVICES

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

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Attachment 3

COMMONWEALTH DEPARTMENT OF HEALTH, HOUSING AND COMMUNITY SERVICES

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
TOAL	$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

Attachment 4

Draft 19.2.93 pm
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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.

		Government	Industry
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.

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c' **ADEC:**

Government	Industry
100%	0%

100% Government funded consistent with ADEC independence

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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.

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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

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k->r COMPLIANCE:

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

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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%		

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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.

Attachment 6

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**

Cost Recovery.

CORRS
CHAMBERS
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CONFIRMATION OF FACSIMILE

23 February 2000

Partner
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Our reference
TB/MEDI1080-3376101

Mr Brian Vale
Executive Officer
Medical Industry Association of Australia
126 Grenville Street
CHATSWOOD NSW 2067

Dear Sir

TGA CHARGES

You seek our advice in relation to charges imposed by the Commonwealth in relation to therapeutic goods regulation.

Put broadly, the charges concerned are for evaluation of drugs and devices (which are provided for in the Therapeutic Goods Regulations) and for maintaining an item on the Therapeutic Goods Register (which are provided for in the Therapeutic Goods (Charges) Regulations). We have sought the advice of Alan Robertson SC on the question and passed to you a copy of his advice.

The position can be summarised as follows:

1 Counsel concludes that therapeutic goods "charges appear clearly to be such as to constitute taxation rather than fees for services".

2 At least where it could be established that an evaluation fee (which is imposed under the Therapeutic Goods Act and Therapeutic Goods Regulations) "was not reasonably or rationally related to the service provided to" the particular applicant, that fee would not be properly imposed. That is because the Therapeutic Goods Act expressly does not authorise the imposition of taxation.

3 The Therapeutic Goods (Charges) Act is a law with respect to taxation and authorises the imposition of taxation on the industry.

4 Counsel notes that at the time the Therapeutic Goods (Charges) Act 1989 was introduced to and considered by the Parliament there was a substantial re-arrangement of Commonwealth legislation imposing

charges in light of the decision of the High Court in *Air Caledonie International*. It was usual practice at that time for the Government in its second reading speeches or explanatory memoranda to refer to that decision or to otherwise indicate its intention to have the Parliament authorise the imposition of taxation.

5 We have perused the explanatory memoranda and Parliamentary debates in relation to the Therapeutic Goods (Charges) Act. At no point did the Government of the day disclose to the Parliament that the Therapeutic Goods (Charges) Act would authorise the imposition of taxation on the industry. The Act itself avoids use of the term "taxation" and rather refers to "the charges".

6 We understand that regulations under the Therapeutic Goods (Charges) Act are made on the recommendation of the Department of Health without consultation with the Treasury. We note that under the Administrative Arrangements Orders the Treasury is responsible for taxation. We do not know whether it is in accordance with good administrative practice for line Departments to settle the details of taxation without consultation with the Treasury.

7 We understand that the evaluation charges made under the Therapeutic Goods Act are to be increased shortly by up to 300 percent in order to enable the Government to achieve its stated policy of 100 percent recovery of the costs of administering the TGA. In our view, such an increase would render those charges taxation (see paragraph 2 above). The Regulations under which they are principally imposed would be invalid (see paragraph 2 above).

8 It would be in accordance with good Parliamentary practice for the Parliament in considering amendments made to the regulations under the Therapeutic Goods Act and Therapeutic Goods (Charges) Act to consider them as a package imposing taxation on the industry.

Yours faithfully
CORRS CHAMBERS WESTGARTH

Tom Brennan
Partner

MEDICAL INDUSTRY ASSOCIATION OF AUSTRALIA

MEMORANDUM OF ADVICE

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Lawyers
DX 5746 CANBERRA

Ref: TJB:RN
Attention: Rhondda Nicholas

A Robertson S.C.
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MEDICAL INDUSTRY ASSOCIATION OF AUSTRALIA

MEMORANDUM OF ADVICE

1. In this matter my instructing solicitors act for the Medical Industry Association of Australia.

2. The Medical Industry Association is concerned about the Commonwealth Government's declared policy of recovering 100% of the costs of the Therapeutic Goods Administration in charges levied on the industry.

3. The issue upon which my advice is sought is whether the charges levied on the industry by the Government are charges for services or taxation.

4. In my view the short answer is that, on the limited facts available, the charges appear clearly to be such as to constitute taxation rather than fees for services.

5. The starting point is that the nature of the legislation is regulatory. In contrast to the position of Airservices Australia in *Airservices Australia v. Canadian Airlines International Limited* (1999) 167 ALR 392 no services in the sense in which that word is understood in this area of the law are provided. The position is closer to that of the Department of Immigration in *Air Caledonie International v. Commonwealth of Australia* (1988) 165 CLR 462.

6. The next point is that the charges appear to be directed substantially to defraying the expenses of the Commonwealth Government incurred in the administration of the regulatory regime established by the **Therapeutic Goods Act**. I refer here to the judgment of Dixon CJ in *Swift Australian Co (Pty) Limited v. Boyd Parkinson* (1962) 108 CLR 189 at 200-201 where the following appears:

> "But when the regulation is examined it appears that the fees are not payable in respect of any particular service but generally for the purpose of defraying expenses. Further, and this perhaps is fatal to the argument, the expenses are not merely those of inspecting meat but those of carrying the Act considered as a whole into effect, that is to say, for administration expenses generally. The fees collected are payable into Consolidated Revenue and there they are of course subject to appropriation by Parliament. They are not directed by law into any particular fund the expenditure of which is limited even to the administration of the Act. ... the fees seem to me clearly to be imposed as a tax ...".

7. The third matter which I should mention is that the **Therapeutic Goods (Charges) Act 1989** appears to have been introduced because of the decision of the High Court in *Air Caledonie International* to which I have referred above. That case was decided in 1988 and the **Therapeutic Goods (Charges) Act** was introduced in 1989. There was at that time a substantial rearrangement of Commonwealth legislation imposing fees in light of the *Air Caledonie* decision. I am not briefed with the explanatory memorandum to the **Therapeutic Goods Bill 1989** but I would expect *Air Caledonie* to be referred to in that explanatory memorandum.

8. Next I would observe that the fact that the legislation is called the **Therapeutic Goods (Charges) Act** does not have the consequence that it may not be a law imposing taxation. So much may be seen from the decision in *Northern Suburbs General Cemetery Reserve Trust v. Commonwealth of Australia* (1993) 176 CLR

555 where the **Training Guarantee Act 1990**, which imposed on an employer a training guarantee charge, was held to be a law with respect to taxation.

9. It follows that, although it appears from the judgments in *Airservices Australia v. Canadian Airlines International Limited* (above) that there is no absolute dichotomy between a tax on the one hand and a fee for service on the other, it is reasonably clear that the **Therapeutic Goods (Charges) Act** does not impose fees for service and does impose a tax. The charges are compulsory exactions for public purposes enforceable by law. The fees are not closely related to the value of the benefit which the payer derives, although this is a matter for further instructions on that question of fact.

10. However I should make it clear that the fact that the legislation does or may impose a tax would appear to have been within the contemplation of the Government when in 1989 the separate **Therapeutic Goods (Charges) Act** was introduced. As a matter of constitutional law the Commonwealth Parliament may, of course, make laws with respect to taxation. The point in *Air Caledonie* (above) was in substance a question which arose under section 55 of the Constitution which provides relevantly as follows:

> "55 Laws imposing taxation shall deal only with the imposition of taxation, and any provision therein dealing with any other matter shall be of no effect".

11. Logically it is possible that the **Therapeutic Goods (Charges) Act** could impose charges that were either all taxes or which were all fees for service or which were a mixture of each. In the latter case it may be possible to argue that section 55 would operate on the fees for service such that those fees would be of no effect. I have no factual material to support that approach.

12. I would therefore conclude that the fees imposed under the **Therapeutic Goods (Charges) Act 1989** are taxes but, for the reasons which I have explained, that would not make those charges invalid as a matter of constitutional law. Neither would I see the level of charges as rendering the regulations *ultra vires* the legislation since the Act clearly contemplates that an annual charge of any amount may be prescribed.

13. For completeness I should add that I have not considered any charges that may be imposed by the **Therapeutic Goods Act 1989** itself. I note that in section 6C of that Act there is a reference to fees payable to the Commonwealth under State laws but that provision is not of any present relevance. I also note that a fee is payable by an applicant for the registration of therapeutic goods, such fee being imposed under section 24 of the **Therapeutic Goods Act** in an amount specified or determined in accordance with the regulations. I have not examined separately the validity of that fee although I note that section 59 provides as follows:

> "59(2) Fees prescribed under this Act must not be such as to amount to taxation".

14. It follows that if, as a matter of fact, it could be established that a fee imposed by or under the **Therapeutic Goods Act** itself was not reasonably or rationally related to the service provided to that person the consequence would be that the fee, at least to the extent of the excess, would be *ultra vires* the **Therapeutic Goods Act**. In short, the effect of section 59(2) would be, at most, to render a particular fee invalid in whole or in part. No doubt the presence of such a provision in the **Therapeutic Goods Act 1989** also tends to show that the **Therapeutic Goods (Charges) Act** is a law with respect to taxation.

15. I advise accordingly.

9 February 2000

A ROBERTSON S.C.

RE THERAPEUTIC GOODS ACT AND

THERAPEUTIC GOODS (CHARGES) ACT 1989

SECOND MEMORANDUM OF ADVICE

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Lawyers
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Ref: RN/MED11080-3376101
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RE THERAPEUTIC GOODS ACT 1989 AND
THERAPEUTIC GOODS (CHARGES) ACT 1989

SECOND MEMORANDUM OF ADVICE

1. I refer to the brief in this matter, to my memorandum of advice dated 9 February 2000 and the facsimile letters to me, both dated 15 February 2000, from my instructing solicitors.

2. My further advice is sought on the issues raised in the earlier of those two facsimiles. The first issue is whether it is possible to argue that the charges are in fact fees for service and not taxes. In this regard the second letter says that if the charges imposed under the Therapeutic Goods (Charges) Act are not taxes but fees for service then the industry would bring the matter before the appropriate Senate Committee or may bring proceedings to challenge the validity of the charges. The industry is confident, I am instructed, that a significant amount of the proposed charges is excessive and not authorised if the charges are fees for service. I am instructed that if it could be argued that the charges are fees for service the industry has material to put before the Senate Committee but if the charges are a tax there is no such material to put before the Committee.

3. In my view this question tends to confuse what is or may be politically permissible or impermissible on the one hand with what is lawful or not on the other. The explanation is as follows: since the charges are imposed by a separate Act then

there is no problem with section 55 of the Constitution. It will be recalled that in the *General Practitioners' Case* (1980) 145 CLR 532 the relevant argument was a section 55 argument. If the fees in that case were not fees for service then they would have been taxes with the consequence that part of the legislation would have dealt with other than the imposition of taxation and would have been of no effect.

4. Similarly, in the *Air Caledonie Case* (1988) 165 CLR 462, if the charges had been imposed by separate legislation then there would have been no section 55 question.

5. I therefore cannot understand why, in the present case, it makes any difference from a legal perspective whether the cases are taxes or fees. Accordingly I cannot see on what basis the industry would bring proceedings to challenge the validity of the charges.

6. It seems to me that if the proposed charges are excessive then that is a political problem in the sense, I understand, that it would be asserted that the proposed charges grossly exceed the cost of providing the services or perhaps the value of the services to the industry. But the very fact that the charges were said to be excessive would strongly suggest that the charges are taxes and not fees for service: thus the conclusion in my memorandum of advice dated 9 February 2000.

7. The second issue raised by the first facsimile letter dated 15 February 2000 is the point that section 3 of the Therapeutic Goods (Charges) Act purports to incorporate the Therapeutic Goods Act. But, as Dawson J said in the *Northern Suburbs General Cemetery Reserve Trust Case* (1993) 176 CLR 555 at 595-596, although the precise effect of incorporating an assessment Act with a taxing Act appears not to have been the subject of actual decision, it has generally been

accepted that the result is that, if the incorporation means that the taxing Act deals with matters other than the imposition of taxation, then the incorporation is ineffectual by reason of section 55 of the Constitution (save to the extent that the assessment Act deals with the imposition of taxation), leaving the assessment Act otherwise to remain in existence and to operate separately: see *Federal Commissioner of Taxation v Munro* (1926) 38 CLR at 185; *Cadbury-Fry-Pascall Pty Limited v Federal Commissioner of Taxation* (1944) 70 CLR 362; *Moore v The Commonwealth* (1951) 82 CLR 547 at 565 and *State Chamber of Commerce and Industry v the Commonwealth* (1987) 163 CLR 329 at 341. This mechanism is a convenient means of avoiding the difficulty which might otherwise arise should the legislature misconceive where the line is to be drawn between a law dealing with the imposition of taxation and a law simply dealing with taxation. Dawson J saw no reason to doubt that the accepted view was the correct one. As suggested by the age of the decisions of the High Court I have referred to above the practice has been established for some 75 years.

8. I see no significance in the fact that the extrinsic materials for the 1989 legislation do not refer to the *Air Caledonie* decision. Nor do I see it as being significant that it refers generally to fees and charges since, as I have indicated, the distinction has no legal consequence where the charges are imposed by a separate Act.

9. As I have indicated above I fear that the present questions may arise from a conflation of political matters with legal issues. Since the question of validity is only a section 55 question then because the Therapeutic Goods (Charges) Act is a separate Act no question of consequential invalidity arises. Whether at the political level it could be shown that a particular charge bore no relation to the service to which it was intended to be referable is another question altogether, and, I would have thought, a matter that may well be of interest to the Senate Committee. But that conclusion does not, in my view, turn on the distinction

between whether the charges are a fee for service or a tax.

10. I advise accordingly.

Chambers
16 February 2000

A ROBERTSON S.C.

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.