612 94118527

Sub no - 46
ID no - 1402 DSAA

Productivity Commission

Cost Recovery Inquiry

Dated:
Monday 27 November 2000

Submission by:
Direct Selling Association of Australia Inc
450 North Road
LANGWARRIN, VIC 3910

The Cosmetics, Toiletry and Fragrance
Association of Australia Inc.
Level 4, 140 Arthur Street
NORTH SYDNEY, NSW 2060

Introduction

This submission is made by the Direct Selling Association of Australia Inc (DSAA) which is the peak body for companies engaged in direct selling to the Australian public. The DSAA has seventy-two member companies who engage a sales force of the order of 650,000 independent sales agents. Our membership list is provided at Attachment 1. Our interest in the inquiry relates to cost recovery principles and processes as they relate to:

- The Therapeutic Goods Act
- The National Industrial Chemicals Notification and Assessment Scheme
- The Australian Customs Service
- The Australian Quarantine Inspection Service
- The Australian Bureau of Statistics

It would be apparent to the Commission that a great many of the people involved in direct selling operate small businesses. Whilst the direct interface with Government is at larger company level the fact is that the fees and charges imposed by Government flow directly to a very large number of selling enterprises that are becoming very aware of Government costs (through the GST) and the administrative costs created by regulatory compliance.

The Structure of Our Submission

Our intention in this submission is to signal and discuss, in principle, our major concerns in regard to Government cost recovery. We appreciate the need to factually support our contentions and hope that we will be able to do so in supplementary evidence prior to the Commission's completion of its draft report. Hopefully, we will be able to obtain some

benchmark data from overseas affiliates, which may assist the Commission to understand the relative cost recovery position taken by the Australian Government.

Our submission on the TGA is structured as follows:

- A discussion of the equity and fairness of the costs allocated and recovered.
- Consideration of the actual rationale for the quantum of those costs.
- A discussion of the transparency and extent of dialogue involved between the Government authority and the industry stakeholders.
- Aggregate regulatory compliance costs apart from Government fees and charges.
- Requests.

The Therapeutic Goods Administration

We have had the opportunity to examine the submissions made to date and generally agree with their overall stance. Our viewpoint follows:

Equity and fairness of costs

The purpose of the TGA is simple. It is intended to promote community health and safety through the regulation of the availability, marketing and consumption of therapeutic goods. To augment this purpose the cost recovery program would be intended, to use the Commission's theoretical reasons at page 6 of its Issues Paper:

- To provide resources for government activities additional to those available from government regulation
- To improve the equity of the distribution of the costs of government services.

If these reasons are true then the logical consequence is that the TGA provides services, which are additional to those available from government regulation, and improves the equity of the distribution of the cost of government service.

DSAA believes that public health and safety is, and always has been, a fundamental function of government. The regulation of that goal may be deficient but does not provide a reason to impose particular charges on the community (or a part of it) other than normal tax impositions.

DSAA accepts the equity argument. In circumstances, such as the present case, where a particular industry imposes a more than normal workload on government to preserve public health and safety then the industry should expect, in equity, to bear a cost that is additional to normal tax impositions.

This issue has been addressed since the inception of the TGA. The APMA submission provides correspondence from the National Manager of the TGA which clearly enunciates the need to split the costs of its administration between public interest and industry related activities (letter of 9/2/93 – reproduced as our Attachment 2). That letter envisages an increase in funding of the TGA function by industry from 33% in 1992/93 to 50% in 1996/97. There was no suggestion that the 50% ceiling would ultimately increase to 100% as this would have negated the concept of a public interest related cost element.

Fact Sheet 18 for the Budget of 1997-98 from the Department of Health and Family Services (see Attachment 3) states that Government initiatives on the Factor (f) scheme, extension of patents and data exclusivity will contribute to industry viability and international

competitiveness. The Fact Sheet goes on to say that "In this context" the government would proceed to full cost recovery from 1998-99.

DSAA considers that the move to full cost recovery was unfair in the context of the sensible original distinction of public interest benefits (for which the public should pay through the tax regime) and industry related activities. Furthermore the 1997-98 benefits are specifically related to the pharmaceutical industry rather than to complementary health care products. There is no particular benefit listed in the Fact Sheet as the outcome of the Pharmaceutical Industry Inquiry that justifies TGA cost increases for the DSAA.

The Quantum of costs

Other inquiry participants have provided specific data on particular costs for registration, Register maintenance and amendment and certification and audit charges involved with Good Manufacturing Practice assessment. It is important for us to participate in these pricing decisions. At the present time the industry provides the money for the operation of the TGA but has no say in how much is charged for particular activities and whether that amount is warranted. It would appear that some of the charges would be susceptible to cost efficiencies from technology and that an automatic periodic audit process, such as the TGA Good Manufacturing Practice audit, is not justified on normal risk assessment processes employed almost universally in both the private and public sector.

Transparency and dialogue

This is an area of considerable concern for the DSAA. The industry pays for the entirety of the operations of the TGA administration. Industry is aware of the budget but has absolutely no opportunity to participate in the development of that budget or to discuss the setting of

fees and charges. This situation would obviously be intolerable in any commercial environment.

The DSAA is directly involved in three committees with the TGA and understands that numerous other committees exist. We are also directly involved in the Minister's Complementary Health Care Forum. Given the close interaction between the TGA administration and the industry on marketing, operational and regulatory matters and industry funding it would be reasonable to allow the stakeholders to talk about and hopefully to rationally influence the nature and extent of expenditure.

The problem arises because the TGA does have public interest and industry benefit as its dual drivers. It is understandable that the administration should not want to be thought to be unduly influenced by the industry on matters of general public interest. The solution is simple. If the Government funds the public interest portion of TGA activities then the Industry will not want to debate the cost efficiency of that expenditure.

Aggregate Regulatory Compliance Costs

It is important to note that the industry's expense for therapeutic goods regulatory compliance is not restricted to the amount that it pays in fees and charges and the direct costs incurred in Committee meetings and associated activities.

DSAA considers that the actual level of cost to its members involved in the manufacturing and marketing of vitamins, food supplements and therapeutic devices is probably about three times its actual contribution to the TGA in fees and charges. Again, the level of cost arises because of an onerous regulatory process, which fundamentally caters for pharmaceuticals

with their much larger risk evaluation issues and processes. This is not a criticism but a statement of fact. In the context of public health and safety there is obviously a much larger question in respect of prescription drugs than there is in relation to our products or the products of the CHC and MIAA. A great deal of statistical data is available from the ABS to support this view.

Requests for Commission Recommendations

In the terms of reference for this Inquiry the Government has asked the Commission to make recommendations. DSAA requests that the Commission consider the following outcomes:

1. The Government separate pharmaceutical public health and safety regulation and compliance from the therapeutic goods administration required for food supplements, vitamins, devices and complementary health care in general.
   This has been partially achieved now through the creation of an Office of Complementary Health Care within the TGA. We believe that cost allocation equity and fairness will only be possible with tailored regulatory processes that would flow from a separate Agency with its own Act of Parliament.

2. That, alternatively, the Agency be separately funded from its own regulatory client base and operate independently of the TGA.

3. The industry should be involved in setting the price structure and determining the Budget except to the extent that the Government contributes an appropriation that takes account of its public interest responsibilities.

4. The Government should provide 50 per cent of the TGA funding.

5. An external review, chaired by a joint industry/TGA panel, should be undertaken to evaluate both the necessity for particular processes, their timing and their cost.

In summary, the TGA operates on a cost plus basis. That is not a process that is accepted by the private sector. The scope for inefficiencies, costly mistakes and strategic direction errors is immense in circumstances where there is no genuine ownership of the cost of a process or the general level of expenditure. If this process continues then, at the very least, the stakeholders and payers should be allowed to participate in setting the expenditure rules and monitoring the outflow of funds.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

The DSAA and the Cosmetics Toiletry & Fragrances Association of Australia Inc (CTFA) wish to make a joint comment on the charges associated with NICNAS registration and listing. A letter from the CTFA has been separately tendered to the Commission supporting our submission on both NICNAS and the costs and charges imposed by Customs, AQIS and the ABS. (This letter is also reproduced as our Attachment 4.)

NICNAS charges companies, on the basis of their turnover, for the inclusion of their product in the NICNAS inventory. The charges are:

- $1,200 per year - For companies with turnover of between $500,000 and $5 million.
- $7,000 per year - For companies with turnover in excess of $5 million.

The NICNAS evaluation of this programme also proposed discontinuing the netting out of packaging costs to arrive at the turnover amount and the creation of a three-tiered structure:

- $1,900 per year - Over $2 million
- $4,750 per year - Over $5 million
- $9,500 per year - Over $10 million

There is no cost based logic to this proposal. It would certainly increase the amount of registration revenue received by a significant amount. Additionally, the administration of the registration process involves such an onerous amount of substantiation of the turnover level that many companies simply opt to pay the higher amount at present. The proposal to increase the tier structure means that either the turnover evidence is supplied or an even larger differential is paid without good reason.

Because the vast majority of cosmetics are imported in a "ready for sale" condition the Customs value includes a substantial value for packaging and the non-chemical items included in the product formulations, for example, water.

Under the present arrangements a discount factor of 80% is used to account for the added value of packaging in imported cosmetics and it is proposed by NICNAS that the use of this discount is to be discontinued in the proposed new funding arrangements.

We believe that such a proposal will be a departure from the NICNAS charter and raises serious questions of fairness and equity. The actual cost of ingredients in the average cosmetic product is approximately 10% of the Customs value and this is the cost that should be used by NICNAS to determine the value of chemicals introduced.

In essence our view on NICNAS relative to our submission criteria is that:

- There is no equity or fairness in either the present or the proposed tier structure because it does not relate to work required by NICNAS or benefit to a particular company.
- The rationale for costs may be said to be based more on capacity to pay rather than the actual costs of the listing on a company basis.
- The CTFA and the DSAA has not agreed to the amended packaging proposal and the three-tiered structure.

Requests for Commission Recommendations

1. That the Government should not introduce the recommendations made by NICNAS as a consequence of the review by The Allen Consulting Group.
2. That NICNAS costs be reflected in its charges to ensure that companies, to the extent possible, are not disadvantaged by the registration cost structure.
3. That different charging bases be established for the major industry segments e.g.
   - Chemicals
   - Cosmetics, toiletries and fragrances.

Australian Customs Service, Australian Quarantine Inspection Service and Australian Bureau of Statistics

DSAA and CTFA support the submission made by Electronic International Trade Services Pty Ltd. Our members would import probably in the vicinity of two thirds of their total product range by value. We collectively would be responsible for about 6,000 customs

entries per annum and pay the associated electronic user fees and AQIS charges. Our members also avail themselves of ABS services.

Many of our members are small businesses and the actual import value of an individual shipment would not be high. Accordingly, the plethora of charges and the associated Customs broker fees in meeting those regulatory requirements may add a considerable amount to the actual cost of importing. It would be common for such charges and costs to actually exceed the duty paid on small shipments even if freight (which is usually the largest charge) was ignored.

Conclusion

DSAA and CFTA accept that where the Government provides specific services to industry such as NICNAS, Edifice (ACS), Statistical Consultancy (ABS) and Good Manufacturing Practice Corporation (TGA) there are grounds to ensure that particular benefits accruing to an industry or work done for an industry are not undertaken at the expense of the community as a whole. Conversely, legitimate matters of concern such as public health and safety should be funded through conventional tax impositions.

Additionally, even if such charges are appropriate it then becomes very important to ensure that they are imposed equitably and with due concern to ensure that the money collected is efficiently spent. As noted previously, many of our members and many more of the people in our sales force operate small businesses. Compliance with Government regulations covers both compliance costs and direct disbursements for fees and charges. This inquiry is very important for us and we thank the Commission for the opportunity to participate in the process.

DIRECT SELLING ASSOCIATION OF AUSTRALIA INC ESTABLISHED 1967

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Membership List November 2000

A Better Chance Pty Ltd
AFS Pty Ltd
A Touch of Tahiti
Amway of Australia
AussiDynamics Pty Ltd
Avon Products Pty Ltd
Bears in the Woods
Bessemer Sales
Crafty Kids Pty Ltd
Creative Memories Australia Pty Ltd
Cutco (Australia) Pty Ltd
Dine Rite Pty Ltd
Dominant (Australia) Pty Ltd
eClub Limited
Emma Page Pty Ltd
Enjo Pty Ltd
Enrich International – Australia
Essential Additions
Equilibrium Corporation Pty Ltd
Furlong Wine Tastings
Giftware Plus
GNLD International Pty Ltd
Happy Homewares
Harvest Grove
Herbalife Australasia Pty Ltd
Homecare Direct Shopping - EBEL
Hsin Ten Enterprise (Aust) Pty Ltd
Hyla Australia Pty Ltd
Intimo Lingerie Pty Ltd
Jeunique International (Aust). Pty. Ltd
Jigsaw Toy Factory Pty Ltd
Lorraine Lea Linen Pty Ltd
Lux Direct Pty Ltd
Mannatech Australia Pty Ltd
Mary Kay Cosmetics Pty Ltd
Master O.P.M.
MIA Maralyn's Intimate Apparel
Morinda International (Aust) Pty Ltd
Nature's Sunshine Products of Australia Pty Ltd
New Image International Australia Pty Ltd
Niagara Therapy Manufacturing (Aust) Pty Ltd
NSA (Australia) Pty Ltd
Nu-Skin Australia. Inc.
NutriMetics Int. (Australia) Pty Ltd
Omegatrend Australia Pty Ltd
Pola Cosmetics (Aust) Pty Ltd
Postie Fashions
Pro-Ma Systems (Aust) Pty Ltd
Pro-Sales Direct Pty Ltd
Rawleigh Pty Ltd
Reliv Australia Pty Ltd
SADI Pty Ltd
Shoe Girls
Sunrider International Australia
Sympatico Bodyworks Pty Ltd
Tall Poppy Creations Pty Ltd
The Body Shop at Home
The Commonwealth Key & Property Register
Time Life International
Tupperware Australasia
Vintage Wines Direct Pty Ltd
Watch 24 Pty Ltd
Weekenders Australia Pty Ltd
Woodwork Junction Country Homewares
USANA Australia Pty Ltd

Participating Companies
November 2000

Country Clutter

Le Rêve

Rendez-Vous Collection

Smile Direct

The Little Black Dress Company

Supplier List
November 2000

Brand Promotions Pty Ltd

C & R Printing Company

Chocolate Graphics Pty Ltd

Frost Promotions

In Home Marketing Pty Ltd

John Watt Consulting Pty Ltd

Robert Forbes & Associates Pty Ltd

Spectrum Marketing Services

Transport & Distribution Consultants Pty Ltd

Voice-Tel Pty Ltd

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TGA Therapeutic Goods Administration

Attachment 2

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☐ Mawson Telephone: (06) 286 0222. Fax: (06) 286 1386

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 increaments 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

Attachment 3

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**

Attachment 4

C T F A

THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION OF AUSTRALIA INC.
ABN 90 187 366 173

23 November 2000

Mrs Helen Owens
Presiding Commissioner
Cost Recovery Enquiry
Productivity Commission
Locked Bag 2
Collins Street East
MELBOURNE VIC 8003

Dear Mrs Owens

The Cosmetic Toiletry and Fragrance Association of Australia (CTFAA) is the relevant peak body for the cosmetics industry in Australia and a copy of our Annual Report for 1999-2000 is enclosed.

We would like to participate in your Enquiry and in particular we wish to register our total support for the comments made by the Direct Selling Association of Australia (DSAA) in regard to the National Industrial Chemical Notification and Assessment Scheme (NICNAS).

We also register our total support for the submissions made by Electronic International Trade Services (EITS) in relation to the fees charged by Australian Customs Service (ACS), Australian Quarantine Inspection Service (AQIS) and Australian Bureau of Statistics (ABS).

We will welcome the opportunity to make further submissions to you on any issues of concern which may arise during the conduct of the Enquiry.

Yours faithfully

John Woods
Executive Director

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Attachment 5

DSAA and CFTA Comments on future Guidelines

Developing Guidelines for the Future (Page 7)

DSAA and CFTA would like to make some general suggestions for Cost and Charge guidelines. They are:

1. Costs and charges should never be a substitute for tax increases or new taxes. They should only be imposed when the Government activity creates a clear and specific industry benefit.

2. To the extent possible care should be taken to avoid bundling industries with some overlap into one cost and charges centre where one industry segment is made to bear costs that should be borne by another segment. This is occurring to our member's disadvantage in both the TGA and NICNAS.

3. The people who pay the costs and charges should have some say in the development of budgets and pricing structures. Public policy interests are in the interest of the industries too and there is a great opportunity for partnership in this common area when the industry and Government regulators work closely together for operational regulation.

4. All of the taxation principles of equity, transparency, fairness and avoidance of regression are appropriate to Government fees and charges.

5. Fees and Charges reviews should be chaired by representatives from industry and government. Industry should be given a role in the determination of new fees and charges or increases.

6. A standard code of conduct for cost recovery programmes should be developed. It is cost inefficient and anomalous to allow each portfolio to set its own standards.

7. In establishing audit programmes involving significant expertise regard should be had to usual risk assessment processes. It is not appropriate to conduct regular overseas investigations when there is no evidence of significant regulatory breaches or risk.