Community Affairs
Legislation Committee

Examination of Budget Estimates 2003-2004

Additional Information Received

VOLUME 3

Outcomes: whole of portfolio, Outcome 1

HEALTH AND AGEING PORTFOLIO

OCTOBER 2003

Note: Where published reports, etc. have been provided in response to questions, they have not been included in the Additional Information volume in order to conserve resources.

ADDITIONAL INFORMATION RELATING TO THE EXAMINATION OF BUDGET EXPENDITURE FOR 2003-2004

Included in this volume are answers to written and oral questions taken on notice relating to the budget estimates hearings on 2, 3 and 5 June 2003

HEALTH AND AGEING PORTFOLIO

Commonwealth Department of
Health and
Ageing

Business Group
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Telephone: (02) 6289 5801 Fax: (02) 6282 1832

Mr Elton Humphrey
Secretary
Senate Community Affairs Legislation Committee
Parliament House
Canberra ACT 2600

Dear Mr Humphrey

Budget Estimates Hearing of 5 June 2003: Whole of Portfolio

On 5 June 2003 I appeared before the Senate Community Affairs Legislation Committee and provided answers to questions from Senator McLucas in relation to Departmental staffing numbers.

Subsequent enquiry has identified that in those answers I provided some incorrect information.

Senator McLucas asked:
In question E03197 we asked what the department's staffing levels were. You provided us with an answer that goes from 1995-96 through to 2001-02. Are those numbers full-time equivalents?

In response, I said:
The figures provided in the answer to that question were ASL.

This is incorrect. The figures provided in answer to question E03197 are total headcount figures at the relevant financial-year end. In other words, these figures constitute the total number of staff employed by the Department on 30 June of the relevant year.

Alan Law
Chief Operating Officer
23 June 2003

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Mr Elton Humphrey
Secretary
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Parliament House
Canberra ACT 2600

Dear Mr Humphrey

Budget Estimates Hearing of 5 June 2003: Whole of Portfolio

My purpose in writing is to correct the answer provided by the Department to a question on notice from the February 2003 Additional Estimates hearing.

Following the recent Budget Estimates hearing, Senator McLucas placed a question on notice (E03-211) in follow-up to the answers provided to this previous question (E03-197). In researching the answers for the current question on notice, it has been discovered that an error was made in the answer provided in March 2003 to question E03-197.

This error in the answer provided to question E03-197 concerned the total Departmental staffing level for the 2000-2001 financial year. The figure provided for 2000-2001 should read 3580 not 3238.

Alan Law
Chief Operating Officer
25 June 2003

CORRIGENDUM
2003-04 PORTFOLIO BUDGET STATEMENTS
HEALTH AND AGEING PORTFOLIO

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The administered appropriations in Table C.1.: Resource Summary for Outcome 1 should read as follows:

	Estimated Actual 2002-03 ($'000)	Budget Estimate 2003-04 ($'000)
ADMINISTERED APPROPRIATIONS		
Administered Item 1: *Population Health*		
National Health Act 1953 – Essential Vaccines	192,656	143,193
Alcohol Education and Rehabilitation Account Act 2001	24,000	40,000
Total Special Appropriations	216,656	183,193
Appropriation Bill 1		
	111,775	169,814
to Services for Other Govts and Non-Depts Bodies (Special Account) *FMA Act 1997*, s20	453	720
to Australian Childhood Immunisation Register, *FMA Act 1997, s20*	6,742	6,737
~~to Alcohol Education & Rehabilitation Special Account, *FMA Act.1997*, s21 and the *Alcohol & Rehabilitation Account Act 2001*~~		
Total Bill 1	118,970	177,271
Appropriation Bill 2	197,383	159,681
Total Administered Expenses	**533,009**	**520,145**
from Special Accounts (estimated payments from Special Account balances)[1]		
Services for Other Governments and non-Depts Bodies Special Account, *FMA Act 1997*, s20	677	2,025
Strategic Intergovernmental Nutrition Alliance Special Account, *FMA Act 1997*, s20	46	36
Australian Childhood Immunisation Register, *FMA Act 1997*, s20	10,497	10,300
Human Pituitary Hormones Special Account, *FMA Act 1997*, s20	44	78
Alcohol Education and Rehabilitation Special Account, *FMA Act.1997*, s21 and the *Alcohol and Rehabilitation Account Act 2001*	24,000	40,000
	35,264	**52,439**
Total Special Account Outflows		

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Delete the words under Performance Assessment and Evaluations and Reviews:

'No major evaluation or reviews are planned for Outcome 7 for 2003-04'

and replace with:

'A Review of the Government's Aboriginal and Torres Strait Islander Health Program will be undertaken during 2003-04'.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-032

OUTCOME WHOLE OF PORTFOLIO

Topic: 10K A DAY PROGRAM

Written Question on Notice

Senator Denman asked:

(a) What is the cost of providing departmental staff with pedometers?
(b) From which output did these funds come?
(c) How were staff selected to be issued with pedometers?
(d) What mechanisms are in place to ensure the pedometers, once issued, are being used by staff?
(e) What benchmarks are being applied to measure whether this is a cost-effective initiative?
(f) On what basis was the decision made to issue pedometers to staff?
(g) Is the Department giving consideration to incentives for making pedometers more accessible to all Australians.

Answer:

(a) To date the Department has spent $84,000 on providing pedometers to staff.
(b) Departmental funds for Health and Life initiatives under the Certified Agreement, *People, Leadership and Performance Improvement*.
(c) All staff have been offered the opportunity to participate in the 10K A Day program, which includes being given a pedometer. The primary beneficiaries of the program will be staff who have not previously been regular exercisers. However in developing the program the Department decided not to target particular staff, noting:
    - that targeting may have stigmatised inactive people and therefore deterred involvement; and
    - that the involvement of active people in the program was likely to increase the participation of those less active.
(d) We have a range of activities at Departmental and Unit level to encourage the ongoing use of pedometers by our staff. We have also created an environment where staff are 'encouraged' to be wearing their pedometer, and are distributing pedometers from central administrative units.

(e) We are evaluating the initiative in a number of ways. In collaboration with the University of Queensland we are investigating whether the wearing of pedometers works to increase physical activity of staff, over a 7 month period. This research will compliment other research on the effectiveness of pedometers as a way of increasing activity, but for the first time examines effectiveness in a workplace, rather than community, setting. We will also be monitoring the Department's unscheduled absence rate and the injury rate over the next year, as part of our evaluation of the overall return on our investment in the program.

(f) The 10K A Day program is a key element of the Department's Health and Life Strategy which forms part of its Certified Agreement. The Department chose this approach to improving levels of physical activity given the highly successful outcomes of similar programs run in the community, including the 10,000 Steps Rockhampton program. The Department is very aware of the potential cost of illness and injury among its workforce. We believe we will demonstrate a positive and real benefit return from our investment in this program. We also believe the Department should manage its staff in a way that is consistent with its messages to the general Australian community.

(g) The Department is not considering incentives for making pedometers more accessible to all Australians. However the Department does provide funding for the Divisions of General Practice, and it was the Division of General Practice in Rockhampton that provided the initial impetus for this approach to increasing exercise in the Australian context.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June

Question: E03-255

OUTCOME: WHOLE OF PORTFOLIO

Topic: $800M INCREASE TO THE GENERAL ADMINISTRATION FUNCTION FOR THE HEALTH PORTFOLIO.

Senator McLucas asked:

Projected spending on general administration in the 4 years from 2002-03 to 2005-06 was estimated in 2001-2002 budget at $4.7billion (2002-2003 Budget Paper No 1 page 6-26 Box 6.1). In this year's Budget Papers, the total for the same 4 years is given as $5.5 billion – up by $800m or some 17% (2003-2004 Budget Paper No 1 Page 6-26 Box 6.1)

(a) What has caused the increase
(b) Please provide a detailed breakdown of where this additional $800m will be spent.

Answer:

The Department of Finance and Administration (Finance) advises that the sub-function code General Administration can contain expenses from a number of agencies and portfolios and should not be taken as a proxy for Health portfolio departmental expenses as a whole.

Finance advise that currently the greater part of departmental expenses for the Department of Health and Ageing and the Health Insurance Commission as well as some Health Administered expenses, are the main contributors to the sub-function.

The variance of $800m over four years can largely be explained as follows:

- The transfer of the Commonwealth Rehabilitation Service (previously classified to another function) from the Family and Community Services Portfolio to Department of Health and Ageing during 2002-03 resulted in an increase in the Health Portfolio's total Departmental expenditure of $685m over the four-year period.
- The *Health Insurance Commission Review* ($40m).
- An increase of approximately $69m in costs related to Health Administered programmes over the budget and forward years with increased funding for GP strategies, Rural medical training schools and HECS reimbursement for rural intern GP's being the main drivers.
- Policy decisions increasing Health Departmental expenses as shown on pages 29 to 38 of the 2003-04 Health and Ageing Portfolio Budget Statement.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 June 2003

Question: E03-211

OUTCOME WHOLE OF PORTFOLIO

Topic: STAFFING LEVELS

Hansard Page: CA 533

Senator McLucas asked:

With respect to the answer to Question E03-197 (Feb 2003):

(a) Are those FTE numbers? If not could you please advise FTE equivalents?

(b) What explains the large jump in staffing levels from 2000-2001 (3238 staff) to 2001-2002 (3771 staff)?

(c) Are staffing numbers available for 2002-2003?

(d) Could you please take on notice and provide an update to the answer to Question E03-197 for 2002-2003 when the financial year comes to an end?

(e) How many staff were employed in each Division and each Branch in 2000-2001, 2001-2002 and in 2002-2003?

(f) Have any projections been made for staffing levels in future years? If so, what are they?

Answer:

(a) The figures provided in response to Question E03-197 are headcount figures as at 30 June.

The following table provides both the headcount at 30 June and the Average Staffing Level (ASL) for the relevant years. The Average Staffing Level for a pay period is calculated by deducting the hours of unpaid leave from the hours worked by each employee during a pay period. This result is then calculated as a proportion of a standard full time employee. The ASL for the year is the average of the staffing level for each pay period.

Financial Year	**2001-02^**	**2000-01^**	**1999-2000^**	**1998-99^**	**1997-98#**	**1996-97***	**1995-96***
Headcount at 30 June	3,771	3,580	3,287	3,168	5,419	4,968	5,623
ASL	3,307	3,148	3,067	2,766	5,084	4,868	5,966

* includes core Department (including functions transferred to FACS in October 1998) , CRS, TGA and AGHS
# includes core Department (including functions transferred to FACS in October 1998), CRS, TGA
^ includes core Department and TGA

(b) From the above table, the difference in ASL between 2000-01 and 2001-02 is an increase of 159. The 2001-02 Portfolio Budget Statements indicate that an additional 156 ASL were estimated as being required for new policy initiatives in 2001-02.

(c) At 30 June 2003 the Departmental headcount was 5,980 with an ASL of 5,054. These figures include CRS who joined the Department on 1 July 2002. The headcount figure comprises 4,093 Departmental staff and 1,887 CRS staff. The ASL figure comprises 3,574 Departmental staff and 1,480 CRS staff.

Financial Year	**2002-03 ^^**	**2001-02 ^**	**2000-01 ^**	**1999-2000 ^**	**1998-99 ^**	**1997-98 #**	**1996-97 ***	**1995-96 ***
Headcount at 30 June	5,980	3,771	3,580	3,287	3,168	5,419	4,968	5,623
ASL	5,054	3,307	3,148	3,067	2,766	5,084	4,868	5,966

* includes core Department (including functions transferred to FACS in October 1998), CRS, TGA and AGHS
# includes core Department (including functions transferred to FACS in October 1998), CRS, TGA
^ includes core Department and TGA
^^ includes core Department, CRS, TGA

(d) The updated answer to Question E03-197 has been answered in (c) above.

(e) It is not possible to provide this information at Branch level without additional resources being allocated which are not available. Staff numbers by Division are available on the following pages in the relevant annual report:
2000-2001 annual report – page 474;
2001-2002 annual report – page 402;
2002-2003 will be available when annual report is published.

(f) No.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2,3 & 5 June 2003

Question: E03-216

OUTCOME WHOLE OF PORTFOLIO

Topic: PERFORMANCE MEASURES

Written Question on Notice

Senator McLucas asked:

Could you please take on notice and provide an update to the answer to Question E03-195 (Feb 2003) for January 03 to the most recent completed month?

Answer:

Attachment A provides an update of month-by-month breakdown of the number of responses to Ministerial correspondence, question time briefs, parliamentary questions on notice and ministerial briefings for the period of January 2003-June 2003.

January-03				
Outcome	**Responses to Ministerial Correspondence**	**Question Time Briefs**	**PQoNs***	**Briefings**
1. Population Health and Safety	70	0	4	8
2. Access to Medicare	197	0	4	4
3. Enhanced Quality of Life for Older Australians	63	0	0	9
4. Quality Health Care	19	0	0	12
5. Rural Health	1	0	0	2
6. Hearing Services	28	0	0	0
7. Aboriginal and Torres Strait Islander Health	2	0	2	0
8. Choice through Private Health	17	0	1	2
9. Health Investment	31	0	3	9
Whole of Portfolio	26	0	0	1
February-03				
Outcome	**Responses to Ministerial Correspondence**	**Question Time Briefs**	**PQoNs***	**Briefings**
1. Population Health and Safety	74	34	2	7
2. Access to Medicare	150	38	1	9
3. Enhanced Quality of Life for Older Australians	140	73	5	42
4. Quality Health Care	35	13	4	12
5. Rural Health	11	3	0	4
6. Hearing Services	3	0	0	2
7. Aboriginal and Torres Strait Islander Health	7	1	0	3
8. Choice through Private Health	39	9	0	0
9. Health Investment	44	17	0	16
Whole of Portfolio	20	2	0	1

March-03				
Outcome	**Responses to Ministerial Correspondence**	**Question Time Briefs**	**PQoNs***	**Briefings**
1. Population Health and Safety	89	45	2	9
2. Access to Medicare	282	52	0	12
3. Enhanced Quality of Life for Older Australians	122	71	1	32
4. Quality Health Care	27	16	0	11
5. Rural Health	4	2	0	6
6. Hearing Services	15	0	0	0
7. Aboriginal and Torres Strait Islander Health	3	1	0	2
8. Choice through Private Health	73	25	1	2
9. Health Investment	51	27	0	14
Whole of Portfolio	38	2	0	5
April-03				
Outcome	**Responses to Ministerial Correspondence**	**Question Time Briefs**	**PQoNs***	**Briefings**
1. Population Health and Safety	64	0	5	11
2. Access to Medicare	221	0	23	5
3. Enhanced Quality of Life for Older Australians	68	0	1	35
4. Quality Health Care	40	0	2	11
5. Rural Health	6	0	0	1
6. Hearing Services	4	0	0	0
7. Aboriginal and Torres Strait Islander Health	6	0	1	0
8. Choice through Private Health	124	0	0	4
9. Health Investment	66	0	0	4
Whole of Portfolio	36	0	1	2

May-03				
Outcome	**Responses to Ministerial Correspondence**	**Question Time Briefs**	**PQoNs***	**Briefings**
1. Population Health and Safety	130	62	3	9
2. Access to Medicare	529	62	5	14
3. Enhanced Quality of Life for Older Australians	122	86	1	24
4. Quality Health Care	24	23	1	10
5. Rural Health	10	1	0	4
6. Hearing Services	6	0	0	1
7. Aboriginal and Torres Strait Islander Health	6	3	0	3
8. Choice through Private Health	112	11	0	2
9. Health Investment	69	27	0	15
Whole of Portfolio	24	5	0	5

June-03				
Outcome	**Responses to Ministerial Correspondence**	**Question Time Briefs**	**PQoNs***	**Briefings**
1. Population Health and Safety	188	44	0	9
2. Access to Medicare	222	64	3	14
3. Enhanced Quality of Life for Older Australians	82	92	0	20
4. Quality Health Care	138	8	1	7
5. Rural Health	7	2	0	4
6. Hearing Services	11	0	0	1
7. Aboriginal and Torres Strait Islander Health	7	8	0	2
8. Choice through Private Health	73	8	0	0
9. Health Investment	75	14	0	13
Whole of Portfolio	38	0	1	4

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-217

OUTCOME WHOLE OF PORTFOLIO

Topic: VACANT OFFICE SPACE

Hansard Page : CA 762

Senator McLucas asked:

To provide an update to the answer to Question EO3-198, including with respect to any properties with vacant office space owned or leased by an agency?

(a) Does the Department or agency own or lease property with vacant space?
(b) If so, what is the location of the building?
(c) What is the vacant lettable space and the cost per square metre of that space and the contract term? Have there been any attempts to sub-let, make alternative arrangements or re-negotiate?

Answer:

(a) The Department leases one property with vacant space.

(b) The property is located at 2 Lonsdale Street, Melbourne Victoria.

(c) The vacant lettable space in 2 Lonsdale Street is approximately 370 square metres. The cost per square metre is $340 per annum and the contract term is 4 years. It is expected this space will be utilised, as part of a broader space consolidation strategy that is founded on an expiring lease on a significant tenancy in another building, by the 30 November 2003.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-218

OUTCOME WHOLE OF PORTFOLIO

Topic: GOODS AND SERVICES TAX

Written Question on Notice

Senator McLucas asked:

To provide an update to Question E03 – 191 (February 2003) taking into account any applications received since last estimate. Question E03 – 191 (February 2003) asked:

(a) How many applications have been received for a GST exemption for health goods under Clause 38–47 of the A New Tax System (Goods and Services Tax) Bill 1998? Can you provide a list of the applicants and the products for which exemption has been sought and which were granted?

(b) What difficulties have been experienced in applying the GST exemption to the items originally selected by the Government (sunscreen, folate, condoms and lubricants)? What work has been done to quantify the costs of these exemptions?

(c) What work has the Department done to assess the benefits of these exemptions and whether they should be extended to other products?

(d) Has the department examined the range of products which were previously free from wholesales sales tax because of their benefits to public health to see whether this exemption should be extended to them?

(e) What is the estimated loss of GST revenue from the exemption of goods specifically covered by this exemption?

Answer:

(a) A total of six applications for exempting 'other health goods' under Clause 38–47 of the A New Tax System (Goods and Services Tax) Act 1999 have been identified since 13 February 2003.

Having regard to privacy principles and rights under the Freedom of Information Act 1982, I am not able to release information identifying the applicants. However, applications were sought for:

- Hemo-home dialysis equipment (1);
- Boccia balls (1);
- Generators used to operate medical equipment (1);
- Prescription frames (1);
- Stinger suits (1); and
- Electricity consumed for health purposes (1).

None of these applications have been granted a GST-exemption.

Since the introduction of the A New Tax System (Goods and Services Tax) Bill 1998, there has only been one Ministerial determination issued under clause 38–47. This was the *GST-free Supply (Health Goods) Determination 2000*, which granted condoms, barrier dams, femidoms, personal and surgical lubricants, folate pills and SPF 15+ sunscreen GST-free status.

(b) There has been some difficulty applying the GST to sunscreen products. Under subsection 38–47(1) of the *A New Tax System (Goods and Services Tax) Act 1999*, the supply of a sunscreen preparation that is marketed principally for use as sunscreen, and has a SPF of 15 or more is GST-free. In some instances sunscreen has a dual use, as in the case of lip balm, and it is uncertain whether or not this item then meets the criteria for a GST-exemption under the Act. However, the Australian Taxation Office is working with industry to rectify this problem.

My department is not aware of any other problems with applying the GST to the items listed in the Determination.

My Department has not undertaken any work relating to the costs of these exemptions.

(c) None.

(d) No.

(e) This is a matter for Treasury.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-260

OUTCOME: WHOLE OF PORTFOLIO

Topic: FUNDING VARIATIONS

Hansard Page: CA 116

Senator Crossin asked:

In the publication 'Making Headway' the funding for the following programs has been reduced for 2003-04 from the 2002-03 estimated actual. Can you please explain the variations:

(a) National Indigenous Chronic Disease Self Management Service Delivery Project;
(b) National Child Nutrition Program – Indigenous Round (31); and
(c) Health Program Grants – General Practice Services Rural and Remote Areas of the Northern Territory (32)

Answer:

(a) This project received initial set-up funding for 2001-02 and 2002-03. Thereafter it is receiving only operational funding, hence the reduction.

(b) The National Child Nutrition Program is non-ongoing. This program funds community projects for up to 3 years duration through 2 separate rounds of funding which commenced in 2001 and 2002. Funding allocated during 2002-03 includes maintenance, completion of first round grants and the commencement of second round grants. Funding allocated during 2003-04 is mostly for maintenance and completion of second round grants only.

(c) This Health Program Grant ceased on 31 December 2002. Funding (and services) have been merged back into the Medicare Benefits Scheme from 1 January 2003.

Commonwealth Department of Health and Ageing
Population Health Division
GPO Box 9848
Canberra ACT 2601

Senator Knowles
Chair
Senate Community Affairs Legislation Committee
Parliament House
CANBERRA ACT 2600

Dear Senator Knowles

Budget Estimates Hearing of 2-3 June 2003

On 3 June 2003 I appeared before the Senate Community Affairs Legislation Committee to answer questions in relation to Outcome 1 communicable diseases.

I would like to amend a statement made by me at this time. When asked about the HIV/AIDS vaccine trail and whether the trial was for a preventative vaccine I stated:

It is therapeutic (see page CA 227 of the Proof Committee Hansard of 3 June 2003).

This was incorrect. The HIV/AIDS vaccine being trialed by the Australian Thai HIV Vaccine Consortium is actually classified as preventative.

Greg Sam
Assistant Secretary
Communicable Diseases Branch

11 June 2003

REVIEW OF

TGA

AUDIT AND LICENSING

OF

GOOD MANUFACTURING PRACTICE

[Please note: only the Executive Summary has been included in the electronic/printed volume]

Reviewer: Brian Corcoran
For: Therapeutics Goods Administration (TGA)

Canberra, March 2002

EXECUTIVE SUMMARY

INTRODUCTION

The Good Manufacturing Practice Audit and Licensing Section (GMPALS) of the Therapeutic Goods Administration (TGA) contributes to the overarching goal and legislative responsibility of the TGA to establish and maintain a national system of controls relating to the quality, safety, efficacy and timely availability of goods for Australian consumers and for export.

Regulations under the Therapeutic Goods Administration Act (the Act) establish the codes of Good Manufacturing Practice (GMP) for compliance by Australian Manufacturers, as well as the requirements for good manufacturing practice for overseas-sourced products. The regulations apply to all therapeutic goods registered or listed on the Australian Register of Therapeutic Goods (ARTG). Within the overall policy framework established by TGA, it is the specific role of GMPALS to assess the compliance of all Australian manufacturers against these codes of GMP, and to ensure that overseas supplies to the Australian market attain equivalent standards of GMP.

TGA Policy Framework

TGA's Corporate Plan outlines key policy goals of relevance to all functions of TGA including:

- A level of regulation appropriate to the assessed risk;
- Timely access of therapeutic goods to the market;
- Continued effort to ensure the quality, safety and efficacy of therapeutic goods coming on to the Australian market;
- Progress towards a more global environment for the regulation of goods; and
- Full costs recovery of activities.

Review Objectives

The objectives of the Review are to examine and report on:

- GMPALS role and objective to ensure consistency with contemporary practice;
- Its work practices, including scheduling and measures to provide for consistency of decision-making and compliance with procedures; and
- Appropriate performance indicators, professional and administrative support resource requirements and costs recovery arrangements.

Conduct of the Review

The Review is based on:

- Interviews with TGA executives;
- Interviews with industry associations;
- Discussions with overseas regulators;
- Interviews with staff of GMPALS; and
- Examination of internal procedural documents and of licensing and audit files.

SECTION TWO

REVIEW OF THE ROLE AND OBJECTIVES OF GMP LICENSING AND AUDIT TO ENSURE CONSISTENCY WITH CONTEMPORARY PRACTICE

OVERVIEW

Overall, the Review considers that most of the essential building blocks of a world-class GMP auditing and licensing functions are in place. These building blocks include a valuable and valued reputation of TGA overall, high quality GMP audit and licensing staff, strong connections with and alignments with global approaches to GMP, comprehensive and sound Standard Operating Procedures covering audit functions and quality, and a receptive and knowledgeable Australian industry. Thus, the following analysis and recommendations should be considered within this context.

However, these quality systems and performance require policies of continuous improvement. Further, the GMP audit and licensing function has a few significant systems weaknesses that detract from performance. These weaknesses include the quality and utility of management information systems, the imbalance in responsibilities between GMPALS and sponsors of products on the ARTG, aspects of the fee structure and audit scheduling and consistency. The following recommendations attempt to address these issues.

2.2.1 Industry Awareness and Information Strategies

As part of its mandate to ensure compliance with GMP, and in line with international practice, TGA should pursue an active strategy of industry-wide, or sectoral information and education, through:

1. The development of position papers on emerging or contentious issues; while the regulator must retain the right to its final position, industry acceptance and take-up will be enhanced if it is fully involved in the process of development of such policy papers;

2. The establishment of a web-based 'Question and Answer Series' on GMP policy and practice; and

3. The provision to industry of GMPALS Standard Operating Procedures that clarify its expectations of and processes of audit and licensing.

2.2.2 Focus of Audits

1. The conduct of and reporting on audits should seek to identify not only individual instances of non-compliance, but also where relevant focus manufacturers attention on possible weaknesses in higher-level quality systems that are the root cause of non-compliance.

2. Audit follow-up should require manufacturers to address the root cause of non-compliance and to describe actions taken to prevent reoccurrence.

3. The audit process should be scheduled to allow for effective two-way dialogue at exit on the audit findings and on associated risk ratings.

2.3 ISO 9000 Series Certification

Provided sufficient priority and staffing is given to achieving quality, the resources maintaining ISO 9000 Series Certification of the functions of GMPALS would be better utilised internally in GMPALS quality assurance.

SECTION THREE

SCHEDULING OF AUDITS

3.1 Overview

Noting that much of the improvement in management and monitoring of GMPALS performance will be dependent on more effective computer systems support, and as frontline activity of the TGA, the GMP audit function should be given high priority in the redevelopment of TGA's management information system.

3.2 Risk management

The four TGA regulators should have the opportunity, on at least an annual basis, to provide guidance on risk management issues that would guide GMPALS in shaping the licensing and audit program for the following year.

3.3 Scope for Improvement in Audit Scheduling

Scope for improvement in the scheduling of audits includes:

3.3.1 First Audits

First Audits should result in a standard report format that:

1. Includes a specific assessment of strengths and weaknesses of the manufacturer against the GMP code.

2. Audits, and preferably all audits of overseas manufacturers, should be for a longer duration than for audits in Australia, to compensate for the inherent communications barriers.

3.3.2 Managing Pressures for overseas audits

Recommendations

In order to achieve the most effective and balanced program of auditing of overseas manufacturers, TGA should consider:

1. Extension of GMP currency of certain low risk products to four years;

2. Alignment with overseas regulators on any extension of GMP for active pharmaceutical ingredients;

3. Selectively, the TGA together with European Competent Authorities participate in either joint or observed audits of European and Australian medical device manufacture for export markets to establish and build confidence in the implementation of the Mutual recognition Agreement; and

4. Working closely with overseas regulators on harmonisation of requirements of audit frequency.

3.3.3 Duration of Audit

GMPALS should consider the duration and thoroughness of audit as more important than frequency.

3.4 Coordination of and Reporting on Audit Activity

Recommendations are:

1. A consolidated, quarterly audit schedule that covers all audits (ie domestic medicines, devices, blood and tissue bank and overseas) be produced for approval by the GMP Chief Auditor, with copies to the four TGA regulators;

    - the preparatory scheduling work should be done by an office manager rather than take up the valuable time of auditors;

2. That the overall capacity for audit, including by the Chief and Deputy Chief GMP Auditors where appropriate to their management functions, and TGA specialists be assessed at the beginning of each year, and an overall target of audits days be set;

3. That subject to efficient processes and support for the organisation of audits, auditors be scheduled to devote 180 days, a minimum of 72 in the field, on audits; with the balance on planning and close-out;

4. That blood and tissue auditors be trained to undertake other audits, and that other auditors also be trained to do blood and tissue audits, so that both groups can contribute to simpler audits outside their specialities;

5. The quarterly plan, plus approved amendments be used to track all audit activity, including reports, billing documents and close-out reports;

6. To reduce disruption to planned audits, TGA should require at least three months notification of requests for new Australian manufacturer licences.

7. Achievement against targets be monitored and reported on a quarterly basis.

SECTION FOUR

WORK PRACTICES INCLUDING MEASURES TO ACHIEVE CONSISTENCY AND COMPLIANCE WITH STANDARDS

4.2 Consistency in Auditing

Recommendations are:

1. As a priority, that the current position of Quality Systems Manager be expanded to also become responsible for the application of quality assurance.

2. That all change in audit process or practice that are warranted because of international practice or responses to risk, be subject to a change management protocol and clearly communicated to industry.

3. That the Standards Operating Procedure on the audit process and, especially on the complaints process be placed in the public domain.

4. That the Quality Systems Manager gives priority to actually undertake or to review at least 10% of 'close-outs', of audits, on a random or targeted basis as part of the consistency framework.

5. That the Quality Systems Manager also conduct shadow audits, including review of audit plans, exit reports as well as close-outs;

6. That the Standard Operation Procedure on the training of staff be followed to ensure that training is directed by the Manger, GMPALS and the training records are centrally held;

7. That data on individual audits, including the number of audits and findings and ratings of non-compliances per audit be monitored and taken into account in auditor training;

8. That the Standards Operating Procedures on Management Review be amended to cover quality outcomes on a quarterly basis, but other issues, eg, staff resources, objectives and strategies be addressed on an annual basis.

4.3 Clearance of overseas manufacturer's GMP status

The case for requiring greater sponsor responsibility in relation to clearance of overseas manufacturers' GMP status is strong. In this regard:

Unless pre-assessment of GMP clearance is required, all applications for listing/registration should be accompanied by sponsor application for clearance of GMP and the application fee should be introduced or increased to reflect the work involved for GMP clearance;

If sponsors require TGA to obtain evidence of acceptable GMP from overseas regulatory authorities, both a higher fee than at present should be paid, and up to eight weeks be set as the response time, reflecting the turn-around times included in MRAs (up to six weeks) plus two weeks internal TGA activity;

Consideration be given to the introduction of an annual sponsor fee to contribute to the upkeep of relevant databases;

GMPALS, in issuing GMP clearance, ensure that it is as broad as is allowed by the nature and the timing of overseas inspection reports, and consider the merits, based on risk, of some clearance of longer than three years duration from the date of last audit;

Sponsors should be given clear responsibility to maintain the currency of GMP clearance, including the requirement for contractual provisions with overseas suppliers that the latter advice the former immediately of any changes in relevant GMP status, so that sponsors can similarly inform TGA in a timely manner.

Rather than wait until certification is expired, TGA should notify sponsors, no later than four months prior to expiry, of their responsibility to update GMP certification; and to provide all relevant information to assist sponsors in that regard; this should be a first and final notification, with formal notification of cancellation being put in train if sponsors fail to respond;

- This renewal process should also be covered by a cost recovery fee, of similar size or marginally less than for initial clearance;

- And if GMP clearance is allowed to lapse, and additional TGA action is required to reinstate GMP currency, that action to reinstate should be accompanied by a fee that fully recovers TGA costs and provides signals for sponsors of the disadvantages and additional risks of allowing lapse of clearance of GMP;

TGA establish a small cell of dedicated administrative staff, suitably trained, to manage this work; three additional staff at appropriate non-auditor level should be sufficient to manage this program.

4.4 Overseas manufacturer GMP clearance: Suggestions from Industry

Other adjustments worthy of consideration in relation to overseas manufacturer GMP clearance are:

1. That the date of expiry be added to the GMP certification number, as a constant reminder to the sponsor;

2. That TGA should review its current policy that information on GMP clearance is "commercial-in-confidence" but should not assume responsibility for publication of a full register of foreign manufacturers with GMP clearance; and

3. That TGA should ensure that changes in company activities that do not materially affect GMP status should not require updates of GMP status

4.5 Entries on ARTG without GMP clearance

TGA should seek to clarify the GMP status of those items on the ARTG that currently appear to have no GMP clearance; this should be done in time for introduction of the new management information system.

4.6 Workflow

Recommendations are:

1. That a Standard Operating Procedure be developed to guide, register and monitor substantive communications to and from GMPALS;

2. On the assumption that an Internet based questions and answer system is introduced, that telephone enquiries from industry to auditors be restricted generally to the conduct of specific audits; and

3. That workflow be streamlined through:

    a. Consolidation of three payments for Australian licences (initial application, audit fees, and issue of licence) into one payment; and

    b. Direct entry by auditors of auditing data, and of licence details onto the relevant computing systems.

SECTION FIVE

PERFORMANCE INDICATORS FOR INTERNAL AND EXTERNAL ACCOUNTABILITY

The current mix of performance indicators do not provide clarity in relation to the performance goals required to effectively manage GMP auditing; nor do they provide effective accountability to external stakeholders. While full implementation of new performance indicators will depend on development of a new management information system, early action is desirable to introduce performance goals and monitor achievement. Recommended performance indicators follow.

5.2.1 Quality, Safety, Efficacy

The ultimate objective of Good Manufacturing Practice is to achieve quality, safety and efficacy of manufacture of products available to the Australian market. The mix of indicators of such performance could include:

- The number and percentage of critical and significant non-compliances identified per quarter;

  - These reports could identify performance for high-risk categories of manufacturers.

- The number of product recalls attributable to faulty manufacture (Reports 22 and 23 contain this information);

- Numbers of licences or certificates of compliance not issued, or cancelled because of unsatisfactory GMP.

5.2.2 Availability

TGA has a strong commitment to facilitate the timely introduction of new products to the market place to benefit Australian consumers. GMPALS contribution to this objective is to issue or vary Australian licences or overseas certificates in a timely and efficient manner.

Suggested indicators are:

- Percentage of new licences and variations issued within agreed timeframes of 90 days/30 days targets respectively; and

- Percentage of overseas supplies GMP clearances issues within agreed maximum timeframes

5.2.3 Value of Audits

The purpose of GMPALS audit should not be confined to identification of instances of

non-compliance, but to raise understanding of the need, and the practice of GMP at least in Australia.

The value of audit in achieving these development aims is not readily quantifiable. However, qualitative analyses can be undertaken, by structured feedback from manufacturers, on an annual basis. In addition, GMP development can be achieved through the issue of GMPALS policy or interpretation documents that address significant issues. As in Canada, a performance indicator could measure the quantum of GMPALS policy or interpretation documents, seminars and other modes of communications on significant GMP issues.

5.2.4 Audit Activity and Consistency

The Review suggests that GMPALS should give particular focus to planning and achieving its overall audit program on a risk-rated basis, and in improving consistency in its audits. Indicators must reflect these priorities. Proposed indicators are:

Audit activity

a) Number of audits and of total audit days per quarter, actual compared with planned:

   - Australian;
   - Overseas

b) Number of pre-clearance assessments and renewals, actual compared with planned numbers;

c) Mean time between audits, by risk category:

   a. Australian;
   b. Overseas.

   Audit Consistency

1. Number of shadow audits, reviews of auditors, reviews of audit plans, exit reports and ‘close-outs’ undertaken by proposed quality manager; and

2. Variations in the number of critical and significant non-compliances identified by each auditor, per quarter.

SECTION SIX:

PROFESSIONAL AND ADMINISTRATIVE SUPPORT RESOURCE REQUIREMENTS

Professional Resources

Recommendations are that GMPALS:

1. Develop a workforce plan covering attraction, skilling and retention issues;

2. That the Quality Systems Manager also be given responsibility for quality management practice and monitoring;

3. That scheduling be undertaken by an office manager rather than by auditors;

4. That auditors not be required to undertake GMP clearance for overseas manufacturers; and conversely

5. Auditors directly enter onto the system all audit information eg, F402g which logs the undertaking of the audit and upon 'close-out', the manufacturers compliance status, rather than require office staff to enter material prepared in handwriting or typed by the auditors.

Administrative support resources

Recommendations are that:

1. A dedicated cell of four staff, at least three additional, manage all assessments for GMP compliance in relation to overseas manufacturer including renewals of GMP compliance approaching expiry.

SECTION SEVEN:

APPROPRIATENESS OF STRUCTURE OF FEES AND CHARGES

GMPALS does not achieve full cost recovery in relation to its existing level of activities; and there are areas of activity in which there are highly inadequate levels of fees and resources to properly meet TGA responsibilities. These deficiencies should be rectified as a matter of priority.

The most urgent need is to begin to recover costs of initial and ongoing costs of GMP clearance of overseas manufacturers and to consider introduction of fees for tissue banks, as first steps to place GMPALS functions on a full cost recovery basis.

Recommendations are to:

1. Include in application fees for listing or registration a component of the order of $120 to cover GMP approval, in all circumstances where a TGA audit is not required; and a similar or marginally lesser amount to cover the costs of the processes of renewal of GMP clearance;

2. Introduce an annual fee of about $60 payable by sponsors to raise $120,000 to cover TGA management and upkeep of the GMPALS database, including for the monitoring and follow-up to provide for renewal of GMP certification (for efficiency sake, this fee should be added to the annual listing fee);

3. If GMP clearance is allowed to lapse, prior to renewal, a fee to cover the additional costs of such work on the part of TGA, of the order of $750, and to signal to sponsors the additional costs and risks of non-current GMP clearance, be charged;

4. Introduce full cost fees for tissue bank audits and licensing;

5. Give consideration to more equitable relativities between Australian major and minor license holders, with levels of $9,000 and $3,000 respectively being set;

6. To ensure that GMP activities are fully cost recovered, additional audit capacity coming on stream should be allocated to activities which raise revenues to cover their costs eg through overseas audits or the proposed new device-auditing program.

SECTION EIGHT: IMPROVING GMPALS INTERACTIONS WITHIN TGA

The Review recommends that:

1. One MOU be developed between GMPALS and all other functions of TGA to guide communication and decision participation needs of all parties.

Manufacturer Assessment Section

Implementation of Corcoran's recommendations

As at March 2003

Abbreviations: GMPALS = GMP Auditing & Licensing Section, ISO = International Organisation for Standardisation, MAS = Manufacturer Assessment Section, MOU = Memorandum of Understanding, MRA = Mutual Recognition Agreement, NATA = National Association of Testing Authorities, ODBT = Office of Devices, Blood and Tissues (formerly Conformity Assessment Branch), o's = overseas, P√ = partially accepted, PDS = Performance Development Scheme, Q&As = questions and answers, SOP = Standard Operating Procedure, TICC = TGA-Industry Consultative Committee, Yes (P) = partially accepted

Report ref.	Recommendation	Impl ref.	Recom. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
2	**CONTEMPORARY PRACTICE**							
2.2.1	**Industry Education and Information**							
1	The development of position papers on emerging or contentious issues; while the regulator must retain the right to its final position, industry acceptance and take-up will be enhanced if it is fully involved in the process of development of such policy papers	R1	√		H	Implemented		GMP webpages reviewed and reorganised. Many articles related to the new Code of GMP now appear in "what's new", eg Q&As, new classification of deficiencies, Aust Code of GMP – current status. This will be an on-going activity.
2	The establishment of a web-based 'Question and Answer Series' on GMP policy and practice.	R2	√		H	Implemented		See R1 above.
3	The provision to industry of GMPALS Standard Operating Procedures that clarify its processes of audit and licensing.	R3	P √		M	Progressing		*It is inappropriate to provide internal documents such as SOPs, which are also too detailed for such purpose. However, a summary of audit procedure can be put on the website.* Note: conformity assessment procedure (for manufacturers of medical devices) already on the website.
2.2.2	**Focus of Audits**							
1	The conduct of and reporting on audits should seek to identify not only individual instances of non-compliance, but also where relevant focus manufacturers attention on possible weaknesses in higher-level quality systems that are the root cause of non-compliance.	R4	√		H	Implemented		SOP 401 (GMP auditing of medical product manufacturers) and audit report formats changed to accommodate this recommendation and finalised (F401e and F401f).

Report ref.	Recommendation	Impl ref.	Recom. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
2	Audit follow-up should require manufacturers to address the root cause of noncompliance and to describe actions taken to prevent reoccurrence.	R5	√		H	Implemented		Addressed in R4 above.
3	The audit process should be scheduled to allow for effective two-way dialogue at exit on the audit findings and on associated risk ratings.	R6	√		H	Implemented		Incorporated into SOP 401, para 3.4 (Exit Meeting). Note however that 'risk' ratings are not assessed at audit. There are 'deficiency' ratings instead.
2.3	**ISO 9000 Series Certification**							
	Provided sufficient priority and staffing is given to achieving quality, the resources maintaining ISO 9000 Series Certification of the functions of GMPALS would be better utilised internally in GMPALS quality assurance.	R7	√		H	Implemented		• MAS no longer certified by NATA and the Certificate handed back to NATA. • Commitment has been made to maintain the MAS Quality System.
3	**SCHEDULING OF AUDITS**							
3.2	**Risk Management**							
	The four TGA regulators should have the opportunity, on at least an annual basis, to provide guidance on risk management issues that would guide GMPALS in shaping the licensing and audit program for the following year.	R8	√		M	Implemented	TGA Regulators	Chief GMP Auditor has provided list of manufacturers requiring audits in 2003 to other TGA Regulators and is waiting for response. This will be on-going.
3.3	**Scope for Improvements in Audit Scheduling**							
3.3.1	**First Audit** First Audits should result in a standard report format that: 1. Includes a specific assessment of strengths and weaknesses of the manufacturer against the GMP code.	R9	√		H	Implemented	All auditors	Incorporated into the final report format (F401f). Reports are to indicate positive and negative aspects of the quality system and not just the negatives.
	2. Audits, and preferably all audits of overseas manufacturers, should be for a longer duration than for audits in Australia, to compensate for the inherent communications barriers.	R10	√		H	Implemented		Office Manager has taken this into account when scheduling audits.
3.3.2	**Managing Pressures for overseas audits**							
1	Extension of GMP currency of certain low risk products to four years.	R11		X		NA		Although products such as sunscreens, skincare products, aromatherapy oils (used as examples in the Corcoran Report) are considered low risk products, they are not low

Report ref.	Recommendation	Impl ref.	Recom. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
								risk in manufacturing process. Also, there are very few preclearances for this type of products. Note that internal practice is audit frequency of 2 years resulting in GMP certificate's life of 3 years (allowing time for closeout, delays etc).
2	Alignment with overseas regulators on any extension of GMP for active pharmaceutical ingredients.	R12	√		L	Pending		**Chief GMP Auditor** to keep watch pending the outcome of an EC Directive on regulation of APIs due out in 2003. ---------- Note that currently TGA does not audit overseas manufacturers of APIs for non-prescription medicines, including complementary medicines. Also, TGA recently implemented ICH GMP Guide for APIs in agreement with Australian industry.
3	Selectively, the TGA together with European Competent Authorities participate in either joint or observed audits of European and Australian medical device manufacture for export markets to establish and build confidence in the implementation of the Mutual recognition Agreement.	R13	√		M	Progressing	EC	**ODBT Director** has commenced discussion with the European Community. Planning is underway to establish a process for working with designated European Conformity Assessment Bodies to enable TGA to confirm their competence.
4	Working closely with overseas regulators on harmonisation of requirements of audit frequency.	R14	√		M	Implemented		MAS audit frequency is 2 years. Chief GMP Auditor has confirmed that this practice is in line with that of overseas regulatory bodies including PIC/S members, Switzerland, Sweden, Denmark, UK, Belgium and Canada.
3.3.3	**Duration of Audit** GMPALS should consider the duration and thoroughness of audit as more important than frequency.	R15	√		H	Implemented		This has been covered in R10.
3.4	**Coordination of and Reporting on Audit Activity**							
1	A consolidated, quarterly audit schedule that covers all audits (ie domestic medicines, devices, blood and tissue bank and overseas) be produced for approval by the GMP Chief Auditor, with copies to the four TGA regulators;	R16	P √		M	Implemented		Overseas and local audits now in same schedule. However, blood/tissues audits are highly specialised and not suitable for integrating into the other audit schedule.

Report ref.	Recommendation	Impl ref.	Recomm. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
	- the preparatory scheduling work should be done by an office manager rather than take up the valuable time of auditors.					Implemented		Audit scheduling of local and overseas manufacturers for medicinal products now done by Office Manager.
2	That the overall capacity for audit, including by the Chief and Deputy Chief GMP Auditors where appropriate to their management functions, and TGA specialists be assessed at the beginning of each year, and an overall target of audits days be set.	R17	P √		M	Implemented		• In reality, it is not practical to set target audit capacity at the beginning of the year for the Chief and Deputy Chief Auditors due to unexpected demands on their time. • Annual target of 72 audit days now set for other auditors. • SOP for specialist qualifications amended to include annual review of the specialist list.
3	That, subject to efficient processes and support for the organisation of audits, auditors be scheduled to devote 180 days, a minimum of 72 in the field, on audits, with the balance on planning and close-out.	R18	√		M	Progressing		Implementation being phased in. The Jan-March 03 quarter was scheduled for 17 audit days, and Apr-June 03 quarter will be 18 days (72days/year).
4	That blood and tissue auditors be trained to undertake other audits, and that other auditors also be trained to do blood and tissue audits, so that both groups can contribute to simpler audits outside their specialities.	R19	√		L	Progressing		• Agreed with the following restrictions for blood audits at an initial phase: - main centres – specialist auditors only - secondary and mobile sites – 'other' auditors to audit collection only. • A Blood/tissues auditor now qualified to audit complementary medicines. • Training of other auditors to do blood/tissues audits is under discussion.
5	The quarterly plan, plus approved amendments be used to track all audit activity, including reports, billing documents and close-out reports;	R20	√		H	Implemented		Implemented manually at this stage. Need computerisation in new computer system.
6	To reduce disruption to planned audits, TGA should require at least three months notification of requests for new Australian manufacturer licences.	R21	√		M	Progressing		• **Quality Manager** to change the application form to indicate the requirement. • **Industry to be advised once finalised** (together with R3 if possible)**.**
7	Achievement against targets be monitored and reported on a quarterly basis.	R22	√		M	Implemented		**Office Manager** keeping manual records until the new IT system is available.
4	**WORK PRACTICES INCLUDING MEASURES TO ACHIEVE CONSISTENCY AND COMPLIANCE WITH STANDARDS**							

Report ref.	Recommendation	Impl ref.	Recom. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
4.2	**Consistency in Auditing**							
1	As a priority, that the current position of Quality Systems Manager be expanded to also become responsible also for the application of quality assurance.	R23	√		M	Implemented		Quality Manager appointed and responsible for quality assurance.
2	That all change in audit process or practice that are warranted because of international practice or responses to risk, be subject to a change management protocol and clearly communicated to industry.	R24	√		M	Progressing		• Already practised. • **Quality Manager** to prepare a SOP to ensure consistency of process. ---------- • Seminars already held to inform industry of changes to the Code of GMP. • Documents relating to the new Code now on the website.
3	That the Standards Operating Procedure on the audit process and, especially on the complaints process be placed in the public domain.	R25	√		M	Progressing		As per R3
4	That the Quality Manager gives priority to actually undertake or to review at least 10% of 'close-outs', of audits, on a random or targeted basis as part of the consistency framework.	R26	√		M	Implemented		This has been made a duty of Quality Manager.
5	That the Quality Manager also conduct shadow audits, including review of audit plans, exit reports as well as close-outs.	R27		X		NA		Audit quality addressed in R26. Regular shadow audits are not considered value-adding to the measure in R26 nor cost effective.
6	That the Standard Operation Procedure on the training of staff be followed to ensure that training is directed by the Manager, GMPALS and the training records are centrally held.	R28	√		M	Implemented		Training is discussed at PDS time. Training records from 2002 now held by Quality Manager.
7	That data on individual audits, including the number of audits and findings and ratings of non-compliances per audit be monitored and taken into account in auditor training.	R29	√		M	Progressing		**Office Manager** currently developing a proforma.
8	That the Standards Operating Procedures on Management Review be amended to cover quality outcomes on a quarterly basis, but other issues, eg, staff resources, objectives and strategies be addressed on an annual basis.	R30	p √		H	Implemented		Already being carried out. Management Review being conducted every 6 months (SOP 105.5). Quarterly review unnecessary.

Report ref.	Recommendation	Impl ref.	Recom. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
4.3	**Clearance of overseas manufacturer's GMP status**							
1	Unless pre-assessment of GMP clearance is required, all applications for listing/registration should be accompanied by sponsor application for clearance of GMP and the application fee should be introduced or increased to reflect the work involved for GMP clearance.	R31	√		M	Progressing	Industry	Fees agreed at February 03 TICC meeting and will be introduced from 1 July 2003. Other Branches being consulted regarding internal mechanism for the implementation of fees and new procedure.
2	If sponsors require TGA to obtain evidence of acceptable GMP from overseas regulatory authorities, both a higher fee than at present should be paid, and up to eight weeks be set as the response time, reflecting the turn-around times included in MRAs (up to six weeks) plus two weeks internal TGA activity.	R32	p √		M	Progressing	Industry	Agreed by TICC that a fee of $450, which is to include the assessment fee of $240, is to apply when TGA is requested to obtain GMP evidence from an overseas regulatory authority. 10-week response time should be the target as those authorities have between up to 60 days (8 weeks) to respond to TGA's requests under the MRA arrangements. This allows 2 weeks for internal process and assessment.
3	Consideration be given to the introduction of an annual sponsor fee to contribute to the upkeep of relevant databases.	R33		X		NA	Industry	No action required.
4	GMPALS, in issuing GMP clearance, ensure that it is as broad as is allowed by the nature and the timing of overseas inspection reports, and consider the merits, based on risk, of some clearance of longer than three years duration from the date of last audit.	R34	P √		M	Implemented	Industry	Clearance already includes as large a scope as possible with qualifying comments specifying the type (eg apiary, fish oils capsules) based on risks.
5	Sponsors should be given clear responsibility to maintain the currency of GMP clearance, including the requirement for contractual provisions with overseas suppliers that the latter advice the former immediately of any changes in relevant GMP status, so that sponsors can similarly inform TGA in a timely manner.	R35	√		M	Progressing	Industry	This is likely to be addressed by the re-instatement fee of $750. - - see R65.
6	Rather than wait until certification is expired, TGA should notify sponsors, no later than four months prior to expiry, of their responsibility to update GMP certification; and to provide all relevant information to assist sponsors in that regard, this should be a first and final notification, with formal notification of cancellation being put in train if sponsors fail to respond;	R36	√		M	Progressing	Industry	TGA will notify companies at least 3 months prior to expiry. Fee of $750 to apply (see also R65) if the approval is allowed to lapse and a new application for GMP clearance is made after expiry.

Report ref.	Recommendation	Impl ref.	Recom. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
	▪ This renewal process should also be covered by a cost recovery fee, of similar size or marginally less than for initial clearance; ▪ And if GMP clearance is allowed to lapse, action to reinstate should be accompanied by a fee that fully recovers TGA costs and provides signals for sponsors of the disadvantages and additional risks of allowing lapse of clearance of GMP.							
7	TGA establish a small cell of dedicated administrative staff, suitably trained, to manage this work; three additional staff at appropriate non-auditor level should be sufficient to manage this program.	R37	√		M	Progressing	Industry	To be funded by the set of fees agreed to by TICC. The establishment of this unit is being done in conjunction with the Branch reorganisation.
4.4	**Overseas manufacturer GMP clearance: Suggestions from Industry** Other adjustments worthy of consideration in relation to overseas manufacturer GMP clearance are:							
1	That the date of expiry be added to the GMP certification number, as a constant reminder to the sponsor.	R38		X		NA		Approval letter already has expiry date. No action required.
2	That TGA should review its current policy that information on GMP clearance is "commercial-in-confidence" but should not assume responsibility for publication of a full register of foreign manufacturers with GMP clearance.	R39	√			Under review	Industry	To be reviewed. The TG Act allows the publication of this information on licensed Australian manufacturers under s41A. However, the Act is silent on the release of details of overseas manufacturers (s61 of the Act and Regulation 46 on release of information not applicable). Legal advice was that in the absence of specific direction in the Act, common law would apply. Disclosure of overseas manufacturers details would be a policy change and we would need consultation with Industry.
3	That TGA should ensure that changes in company activities that do not materially affect GMP status should not require updates of GMP status.	R40		X		NA		This is applicable to only 2 categories: • Company's name change – still needs new information to maintain the integrity of the database.

Report ref.	Recommendation	Impl ref.	Recomm. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
								• Site change – needs new audit or new evaluation.
4.5	**Entries on ARTG without GMP clearance**							
	TGA should seek to clarify the GMP status of those items on the ARTG that currently appear to have no GMP clearance; this should be done in time for introduction of the new management information system.	R41	√		L	Pending	Industry	• This is a large task - to be done when MAS new IT system is available, as part of data cleansing exercise - similar to the SIME Clients records. • Note this applies to medicines only; device database being updated progressively.
4.6	**Workflow**							
1	That a Standard Operating Procedure be developed to guide, register and monitor substantive communications to and from GMPALS.	R42	√		H	Pending		To be implemented as part of MAS workflow review and restructure of the Branch.
2	On the assumption that an Internet based questions and answer system is introduced, that telephone enquiries from industry to auditors be restricted generally to the conduct of specific audits.	R43	P √		H	Implemented	Industry	Q&As prepared. Currently sponsors are encouraged to communicate by email. Correspondence being collected to form further Q&As.
3	That workflow be streamlined through: a) Consolidation of three payments for Australian licences (initial application, audit fees, and issue of licence) into one payment; and	R44	√		M	Pending	Industry & TGA	To be implemented when the new IT system is ready.
3	b) Direct entry by auditors of auditing data, and of licence details onto the relevant computing systems.	R45	√		L	Pending		It is not worthwhile training auditors now as the current mainframe system is complicated and cumbersome to use. This recommendation will be implemented when the new IT system is in place.
5	**PERFORMANCE INDICATORS**							
5.2.1	**Quality, Safety, Efficacy**							
	The mix of indicators of such performance include: ▪ The number and percentage of critical and significant non-compliances identified per quarter; – These reports could identify performance for high-risk categories of manufacturers.	R46	√		M	Pending	TGA	To be incorporated into the new computer system with a requirement to produce periodic management reports.

Report ref.	Recommendation	Impl ref.	Recom. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
	▪ The number of product recalls attributable to faulty manufacture (Reports 22 and 23 contain this information).	R47	√		L	Progressing	Recalls	**Chief GMP Auditor** to produce a list of categories required for recording by the Recalls Section. (Recalls Section advised 4/10/02 that it is possible to record this cause as a category of 'problems' in their mainframe database but the database would need to be modify to suit.)
	▪ Numbers of licences or certificates of compliance not issued, or cancelled because of unsatisfactory GMP.	R48	√		M	Pending	TGA	To be incorporated into the new computer system with a requirement to produce periodic management reports.
5.2.2	**Availability**							
	Percentage of new licences and variations issued within agreed timefames of 90 days/30 days targets respectively.	R49	√		M	Pending	TGA	As above
	Percentage of overseas supplies GMP clearances issues within agreed maximum timeframes.	R50	√		M	Pending	TGA	As above
	Value of Audits							
	The purpose of GMPALS audit should not be confined to identification of instances of non-compliance, but to raise understanding of the need, and the practice of GMP at least in Australia. The value of audit in achieving these development aims is not readily quantifiable. However, qualitative analyses can be undertaken, by **structured feedback from manufacturers, on an annual basis**. In addition, GMP development can be achieved through the issue of GMPALS policy or interpretation documents that address significant issues. As in Canada, **a performance indicator could measure the quantum of GMPALS policy or interpretation documents, seminars and other modes of communications on significant GMP issues**.	R51	√		M	Progressing	TGA & industry	Already happening with **Chief GMP Auditor** regularly meeting with industry organisations. Bob will arrange for structural feedback to be included on the agenda of these meetings. These 'regular' meetings are to be arranged at least every 6 months. Feedback to industry will in future be enhanced by providing data on audit ratings of deficiencies as outlined in R29.
5.2.4	**Audit Activity and Consistency**							
	Audit Activity							
1	Number of audits and of total audit days per quarter, actual compared with planned: a) Australian; b) Overseas	R52	√		M	Pending	MAS	To be incorporated into the new computer system with a requirement to produce periodic management reports.

Report ref.	Recommendation	Impl ref.	Recomm. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
2	Number of pre-clearance assessments and renewals, actual compared with planned numbers.	R53	√		M	Pending	MAS	As above
3	Mean time between audits, by risk category: a) Australian; b) Overseas.	R54	√		M	Pending	MAS	As above
	Audit Consistency							
1	Number of shadow audits, reviews of auditors, reviews of audit plans, exit reports and 'close-outs' undertaken by proposed quality manager.	R55	√		M	Pending	MAS	As above
2	Variations in the number of critical and significant non-compliances identified by each auditor, per quarter.	R56	√		M	Pending	MAS	As above
6	**PROFESSIONAL AND ADMINISTRATIVE SUPPORT RESOURCE REQUIREMENTS**							
	Professional Resources							
1	Develop a workforce plan covering attraction, skilling and retention issues.	R57	√		L		MAS	**Chief GMP Auditor** to develop plan.
2	That the Quality Systems Manager also be given responsibility for quality management practice and monitoring.	R58	√		M	Implemented	MAS	Quality Manager appointed etc – see also R23, R26, and R27.
3	That scheduling be undertaken by a clerical officer rather than by auditors.	R59	√		M	Implemented	MAS	Office Manager now undertakes this task.
4	That auditors not be required to undertake GMP clearance for overseas manufacturers; and conversely	R60	√		M	Pending	Industry & TGA	To be implemented when a unit is fully established.
5	Auditors directly enter onto the system all audit information eg, F402g which logs the undertaking of the audit and upon 'close-out', the manufacturers compliance status, rather than require office staff to enter material prepared in handwriting or typed by the auditors.	R61	√		L	Pending	TGA	To be implemented when the new IT system is in place.
	Administration support resources							

Report ref.	Recommendation	Impl ref.	Recomm. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
1	A dedicated cell of four staff, at least three additional, manage all assessments for GMP compliance in relation to overseas manufacturer including renewals of GMP compliance approaching expiry.	R62	√		M	Progressing	Industry	Agreed by industry. The establishment of this unit is being carried out in conjunction with the reorganisation of the Branch.
7	**STRUCTURE OF FEES AND CHARGES**							
1	Include in application fees for listing or registration a component of the order of $120 to cover GMP approval, in all circumstances where a TGA audit is not required; and a similar or marginally lesser amount to cover the costs of the processes of renewal of GMP clearance.	R63	√		M	Progressing	Industry	Proposed fee of $240 agreed by TICC with no annual fee. Fees to be effective from 1 July 2003.
2	Introduce an annual fee of about $60 payable by sponsors to raise $120,000 to cover TGA management and upkeep of the GMPALS database, including for the monitoring and follow-up to provide for renewal of GMP certification (for efficiency sake, this fee should be added to the annual listing fee).	R64		X		NA	Industry	No action required.
3	If GMP clearance is allowed to lapse, prior to renewal, a fee to cover the additional costs of such work on the part of TGA, of the order of $750, and to signal to sponsors the additional costs and risks of non-current GMP clearance, be charged.	R65	√		M	Progressing	Industry	Re-instatement fee of $750 agreed by TICC – see also R36. Fees to be effective from 1 July 2003.
4	Introduce full cost fees for tissue bank audits and licensing.	R66	√		M		Industry	This needs consultation with industry and other stakeholders, as well as legislation amendments. Note that the current legislation exempts non-profit hospital supply units from licence and inspection fees – s59(3) of TG Act.
5	Give consideration to more equitable relativities between Australian major and minor license holders, with levels of $9,000 and $3,000 respectively being set.	R67		X		NA	Industry	The review appears to have no justification for this recommendation. Current annual charges of $7,250 and $3,730 cover 2 audits every 2 years. The charges are barely sufficient if audits are carried out as planned. Generally manufacturers have to pay additional amounts when these charges are exceeded. Therefore setting different charges would not achieve anything.
6	To ensure that GMP activities are fully cost recovered, additional	R68	√		M	Progressing	Industry	Related to and addressed in R60, R63-R66

Report ref.	Recommendation	Impl ref.	Recomm. accepted		Priority	Status of implementation	To liaise/ consult with	Comments / Action required or taken
			Yes	No				
	audit capacity coming on stream should be allocated to activities which raise revenues to cover their costs eg through overseas audits, or the proposed new device-auditing program.						& TGA	
8	**IMPROVING GMPALS INTERACTION WITHIN TGA**							
	One MOU be developed between GMPALS and all other functions of TGA to guide communication and decision participation needs of all parties.	R69		X		NA	TGA	An MOU would not add value to the process already in place, particularly in view of the regular consultation with the other TGA Regulators as recommended in R8.

RESOLUTION OF THE WORLD HEALTH ASSEMBLY
RÉSOLUTION DE L'ASSEMBLÉE MONDIALE DE LA SANTÉ
РЕЗОЛЮЦИЯ ВСЕМИРНОЙ АССАМБЛЕИ ЗДРАВООХРАНЕНИЯ
RESOLUCIÓN DE LA ASAMBLEA MUNDIAL DE LA SALUD

FIFTY-SIXTH WORLD HEALTH ASSEMBLY **WHA56.26**

Agenda item 14.17 **28 May 2003**

Elimination of avoidable blindness

The Fifty-sixth World Health Assembly,

Having considered the report on elimination of avoidable blindness;[1]

Recalling resolutions WHA22.29, WHA25.55 and WHA28.54 on prevention of blindness, WHA45.10 on disability prevention and rehabilitation, and WHA51.11 on the global elimination of blinding trachoma;

Recognizing that 45 million people in the world today are blind and that a further 135 million people are visually impaired;

Acknowledging that 90% of the world's blind and visually impaired people live in the poorest countries of the world;

Noting the significant economic impact of this situation on both communities and countries;

Aware that most of the causes of blindness are avoidable and that the treatments available are among the most successful and cost-effective of all health interventions;

Recalling that, in order to tackle avoidable blindness and avoid further increase in numbers of blind and visually impaired people, the Global Initiative for the Elimination of Avoidable Blindness, known as Vision 2020 – the Right to Sight, was launched in 1999 to eliminate avoidable blindness;

Appreciating the efforts made by Member States in recent years to prevent avoidable blindness, but mindful of the need for further action,

1. URGES Member States:

(1) to commit themselves to supporting the Global Initiative for the Elimination of Avoidable Blindness by setting up, not later than 2005, a national Vision 2020 plan, in partnership with WHO and in collaboration with nongovernmental organizations and the private sector;

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[1] Document A56/26.

(2) to establish a national coordinating committee for Vision 2020, or a national blindness prevention committee, which may include representative(s) from consumer or patient groups, to help develop and implement the plan;

(3) to commence implementation of such plans by 2007 at the latest;

(4) to include in such plans effective information systems with standardized indicators and periodic monitoring and evaluation, with the aim of showing a reduction in the magnitude of avoidable blindness by 2010;

(5) to support the mobilization of resources for eliminating avoidable blindness;

2. REQUESTS the Director-General:

(1) to maintain and strengthen WHO's collaboration with Member States and the partners of the Global Initiative for the Elimination of Avoidable Blindness;

(2) to ensure coordination of the implementation of the Global Initiative, in particular by setting up a monitoring committee grouping all those involved, including representatives of Member States;

(3) to provide support for strengthening national capability, especially through development of human resources, to coordinate, assess and prevent avoidable blindness;

(4) to document, from countries with successful blindness prevention programmes, good practices and blindness prevention systems or models that could be modified or applied in other developing countries;

(5) to report to the Fifty-ninth World Health Assembly on the progress of the Global Initiative.

Tenth plenary meeting, 28 May 2003
A56/VR/10

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Review of Health Warnings on Tobacco Products - Technical Advisory Group

Chair

Ms Jenny Hefford
Assistant Secretary
Drug Strategy Branch
Department of Health and Ageing

Members

Mr Klaus Klaucke
A/g Director
Tobacco, Drug Prevention & Youth Policy
Dept Health and Ageing

Ms Kerry Ashbolt
Safety Policy Unit
Consumer Affairs Division
Department of the Treasury

Ms Maree Rowe
Assistant Manager
Product Safety
Australian Competition and Consumer Competition

Dr David Hill
Chair
National Expert Advisory Committee on Tobacco

Dr Ron Borland
Director
VicHealth Centre for Tobacco Control

Research report: Evaluation of the health warnings and explanatory health messages on tobacco products

http://www.health.gov.au/pubhlth/strateg/drugs/tobacco/warnings.pdf

Executive summary:
http://www.health.gov.au/pubhlth/publicat/document/execsumm.pdf

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-033

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: NATIONAL ILLICIT DRUG STRATEGY

Written Question on Notice

Senator Denman asked:

The Portfolio Budget Statements for 2003-2004 contain a significant redirection of funding in the National Illicit Drugs Program. When the figures are compiled from the Initiatives which will gain money (Australian Drug Information Network, National Comorbidity Initiative, Psychostimulants Initiative, the Research Fund and the Rural and Regional Initiative –total of $14.4M) and the Initiatives that will lose money over the next four years (Cannabis Cessation Strategies, Community Partnerships Initiative, Retractable Needles and Syringes – total of $14.3M) this entire program actually only gains $0.1M in this Budget. This is despite the Government acknowledging in its Budget speech that "Illegal drug use is an enormous burden on our society in terms of waste and cost to human life".

Given the numbers of Australians currently addicted to illicit drugs and in need of treatment and assistance, why is the Government giving so little financial commitment to illicit drug initiatives in the health portfolio, at this time?

Answer:

The Commonwealth Government has committed more than $1 billion to the National Illicit Drug Strategy, including funding announced in the 2003-04 Budget. This is the biggest single initiative ever undertaken in Australia to address the harms associated with illicit drugs.

The National Illicit Drug Strategy (NIDS) is a partnership between the Health and Ageing, Justice and Customs, Education, Science and Training and Family and Community Services Portfolios.

As part of the 2003-04 Budget, an additional $14.2 million was allocated for a range of new demand reduction measures and a further $272.1 million for the continuation of lapsing programs and revision of existing initiatives under the NIDS. This comprises:

- $4.4 million for a National Comorbidity Initiative;
- $2.0 million for a National Psychostimulants Initiative;
- $4.0 million for a National Illicit Drug Strategy Rural and Regional Initiative;
- $2.8 million for a National Illicit Drug Strategy Research Fund;
- $1.0 million for the Australian Drug Information Network;

- $215.9 million for the continuation of the National Illicit Drug Diversion Initiative;
- $22.4 million for the continuation of the Increased Education, Counselling and Referral Services through Needle and Syringe Programs Initiative;
- $17.5 million for the revised Introduction of Retractable Needle and Syringe Technology into Australia Initiative; and
- $16.3 million for the continuation of the Diversification of Existing Needle and Syringe Programs Initiative.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-034

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: HEROIN

Written Question on Notice

Senator Denman asked:

(a) Do we have figures on the number of Australians currently dependent on heroin?

(b) Under the National Heroin Overdose Strategy, one of the aims is to 'increase the number of drug users entering and remaining in treatment'

i) Please provide these figures for the last five years.

ii) Do you have figures available on the shortfall of drug treatment places?

iii) Are figures available for the percentage of heroin addicts that remain drug free two years after drug treatment?

(c) In a written response to a question I asked last June, the Department advised me that information relating to the proportion of heroin dependent Australians estimated to be receiving some form of drug treatment each year since the commencement of 'Tough on Drugs' was not collected by the Department, why not?

(d) It has been commented, that the heroin drought has led to the popularity of other drugs.

i) What are these drugs?
ii) Do we have figures for the number of Australians currently dependent on each drug?

Answer:

(a) The most recent estimation of the number of dependent opioid users in Australia was undertaken by the National Drug and Alcohol Research Centre in 2000. This study estimated the total number of opioid users to be between 67,000 and 92,000.

(b)

i) The first report of the National Minimum Data Set for Alcohol and Other Drug Treatment Services, *'Alcohol and other drug treatment services in Australia 2000-01: First report on the National Minimum Data Set'*, released on 20 November 2002 by the Australian Institute of Health and Welfare found that 83,529 clients received treatment in 2000-01. Data for previous years are not available.

ii) There is no national mechanism that collects information on waiting lists for any particular service type.

iii)There are no figures currently available that identify the percentage of heroin addicts that remain drug free two years after drug treatment.

(c) Current data sources do not allow for a reliable estimation of this type.

(d) i) The term psychostimulants is used to refer to a variety of substances, which stimulate the central nervous system. Drugs commonly referred to as psychostimulants include amphetamine type stimulants (ATS), ecstasy and cocaine.

ii) There are no figures available for the number of Australians that are dependent on psychostimulants. The National Drug Strategy Household Survey reports on the use of illicit drugs within the general population. The 2001 Household Survey identifies that 3.4 percent of the population (534,200) had used amphetamines, 2.9 percent (456,400) had used ecstasy/designer drugs and 1.3 percent (206,600) had used cocaine within the last 12 months.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-035

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: PSYCHOSTIMULANTS INITIATIVE

Written Question on Notice

Senator Denman asked:

The Portfolio Budget Statements (p.66) allocate additional funding of $2M over two years for the Psychostimulants Initiative. It is indicated that this funding will provide for the evaluation of treatment options and the development of guidelines for frontline workers.

(a) Has a decision been made on which treatment options will be evaluated?

(b) If not, what will be the process of selecting treatment options involve?

(c) Who will develop the guidelines for frontline workers?

(d) Are figures available for the number of Australians currently dependent on Psychostimulants?

Answer:

(a-c) This information is not available at this time. A detailed implementation strategy for this initiative will be determined after a consultation process with a range of key stakeholders including the Australian National Council on Drugs, the Alcohol and Other Drugs Council of Australia and the National Expert Advisory Committee on Illicit Drugs.

(d) The National Drug Strategy Household Survey reports on the use of illicit drugs within the general population. The 2001 Household Survey identifies that 8.9 percent of the population (1,405,800) aged 14 years and over had used amphetamines, 6.1 percent (952,100) had used ecstasy/designer drugs and 4.4 (692,500) percent had used cocaine at least once in their lifetime. In relation to recent use of drugs, 3.4 percent of the population (534,200) had used amphetamines, 2.9 percent (456,400) had used ecstasy/designer drugs and 1.3 percent (206,600) had used cocaine within the last 12 months. These results remain stable from 1998.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-036

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: CANNABIS

Written Question on Notice

Senator Denman asked:

(a) In light of the announcement by the NSW Government of a four-year trial of cannabis for medicinal purposes, is the Commonwealth Government giving consideration to a trial of it's own?

(b) Is the Government giving consideration to a co-ordinated trial across all states and territories of cannabis for medicinal purposes?

(c) The Portfolio Budget Statements (p.64) state that $0.9M will be taken away from the Cannabis Cessation Strategies program as the resources that this money was intended to develop – have been developed and distributed. Why was this program overfunded?

Answer:

(a) No.

(b) No.

(c) In 1999-00, as a Supporting Measure under the COAG Illicit Drug Diversion Initiative, $1.179 million was allocated for the development of cannabis cessation strategies for adults and adolescents. A number of one-off projects have been funded, including brief treatment interventions for adults and adolescents. Funding was also used to conduct research in remote Aboriginal communities to assess the level of cannabis use and to develop and trial these interventions. These projects have been finalised and distributed. The funding for this initiative was to lapse in 2002/03.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03 - 037

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: NATIONAL COMORBIDITY INITIATIVE

Written Question on Notice

Senator Denman asked:

In the Portfolio Budget Statements (p.65) $4.4 M over two years will be allocated to improve service co-ordination and treatment outcomes for clients with both illicit drug addiction and mental illness. Could you please provide a further breakdown on how this money will be spent – who it will be distributed, and what initiatives will it fund?

Answer:

This information is not available at this time. A detailed implementation strategy for this initiative will be determined after a consultation process with a range of key stakeholders including the Australian National Council on Drugs, the Alcohol and Other Drugs Council of Australia and the National Comorbidity Taskforce.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-110

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: NATIONAL COMORBIDITY INITIATIVE

Hansard Page: CA 113

Senator Crossin asked:

Of the $4.4 m allocated in this Budget to look at the National Comorbidity Initiative, what percentage of that will actually be used for Indigenous communities of Indigenous issues ?

Answer:

This information is not available at this time. A detailed implementation strategy for this initiative will be determined after a consultation process with a range of key stakeholders including the Australian National Council on Drugs, the Alcohol and Other Drugs Council of Australia and the National Comorbidity Taskforce.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-038

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: RURAL AND REGIONAL INITIATIVE

Written Question on Notice

Senator Denman asked:

The Portfolio Statements (p.68) allocated $4M over the next four years, to improve access to treatment and referral for illicit drug users in rural and regional Australia.

(a) How will rural and regional areas be prioritised for this initiative?

(b) How will projects be selected under this Initiative?

(c) How many projects is this funding expected to provide?

(d) Has the Department taken any steps to identify the extent of the unmet need in rural and regional areas for the treatment and referral of illicit drug users?

Answer:

(a-c) This information is not available at this time. A detailed implementation strategy for this initiative will be determined after a consultation process with key stakeholders including the Australian National Council on Drugs and the Alcohol and other Drugs Council of Australia.

(d) Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-039

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: DRUG TREATMENT - ABSTINENCE PROGRAMS

Written Question on Notice

Senator Denman asked:

(a) How much of the Commonwealth funding for drug treatment has gone to abstinence programs?

(b) How many patients have abstinence based treatments provided for, over the last five years?

(c) Does the Department have any estimate of the cost of abstinence based programs per person, and the proportion of persons entering abstinence programs who are drug free 12 months later?

Answer:

(a) Under the National Illicit Drug Strategy the Commonwealth has allocated funding of $58.6 million (over four years) to 140 non-government organisations under the Non Government Organisation Treatment Grants Programme.

Treatment activities funded cover a range of strategies including brief interventions, self help programs, psychological therapies, outreach support, outpatient counselling, inpatient and outpatient detoxification, medium to long term rehabilitation counselling, social skills training and relapse prevention.

The Government is not able to identify how much of this funding has gone to abstinence programmes.

(b) The Government is not able to estimate how many patients have undertaken abstinence based treatments.

(c) The Government is not able to estimate the cost of abstinence programmes per person or the proportion of persons entering abstinence programmes who are drug free 12 months later.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-040

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: DRUG TREATMENT - PHARMACOLOGICAL TREATMENTS

Written Question on Notice

Senator Denman asked:

(a) How much of the Commonwealth funding for drug treatment has gone to programs using pharmaceutical drugs like methadone or buprenorphine?
(b) How many patients have pharmacological treatments such as methadone or buprenorphine provided for, over the last five years?
(c) What was the average length of stay for patients receiving pharmacological treatments such as methadone or buprenorphine?

Answer:

(a) The States and Territories are primarily responsible for the implementation of drug and alcohol treatment services in their jurisdiction, including registering prescribers for methadone and buprenorphine. None of the organisations funded under the National Illicit Drug Strategy Non Government Organisation Treatment Grants Programme provide pharmacotherapy treatment with methadone or buprenorphone. However, the Commonwealth subsidises the cost of methadone and buprenorphine through the Pharmaceutical Benefits Scheme.

(b) The Department collects annual statistics from each State and Territory, on the number of clients registered for treatment with methadone and buprenorphine as at 30 June each year. The number of clients registered over the last five years was as follows:

At 30 June	**No of Clients**
1998	24,657
1999	27,906
2000	30,237
2001	32,516*
2002	34,210*

*includes clients in both methadone and buprenorphine programs.

(c) The Government is unable to estimate the average length of stay for patients receiving pharmacological treatments in hospitals or treatment services.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-041

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: DRUG TREATMENT - SALVATION ARMY

Written Question on Notice

Senator Denman asked:

How much of the Commonwealth funding for drug treatment has gone specifically to the Salvation Army during the last five years?

Answer:

More than $11.5 million has been allocated to the Salvation Army under the National Illicit Drug Strategy for drug treatment and related activities.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-042

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: COMMUNITY PARTNERSHIPS INITIATIVE

Written Question on Notice

Senator Denman asked:

(a) Is the evaluation of the Community Partnerships Initiative complete? If so could a copy please be provided.

(b) The PBS (p.67) states that $4.4M over the next four years will be taken away from the Community Partnerships Initiative, why is there a significant change in the funding of this initiative?

(c) Under the Community Partnerships Initiative,

(i) How many organisations have put in tenders or expressions of interest?

(ii) How many organisations have not been successful in obtaining funding for their projects.

Answer:

(a) Yes. The final evaluation report is available from the Department's website: http://www.health.gov.au/pubhlth/strateg/drugs/illicit/evaluation.htm

(b) The Community Partnerships Initiative has been allocated funding in three instalments totalling $22.8 million. This includes $4 million which was allocated in 1999/2000. This funding was to lapse at the end of the 2002/03 financial year. As $14 million was announced in the 2002/03 budget for the continuation of the Community Partnerships Initiative, this lapsing funding was redirected to other illicit drug priority areas.

(c)

(i) A total of 764 applications have been received under the Community Partnerships Initiative.

(ii) A total of 629 applications have not been successful in obtaining funding under the Community Partnerships Initiative.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-043

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: ALCOHOL AND TOBACCO

Written Question on Notice

Senator Denman asked:

(a) Has a decision been made on the public release of the issues paper relating to the Review of the Tobacco Advertising Prohibition Act 1992? If so, could a copy please be provided.

(b) As the evidence that tobacco and alcohol are gateways drugs for later illicit drug use is far stronger than for cannabis, what does the government intend to do to delay or reduce alcohol and tobacco use by teenagers?

Answer:

(a) No decision has yet been made on the public release of the issues paper relating to the Review of the Tobacco Advertising Prohibition Act 1992.

(b) The Government will maintain its commitment to reducing tobacco use and risky drinking levels both in the community as a whole and in particular population groups. For example, in the form of a performing arts event for primary and secondary schools, the Rock and Croc Eisteddfods deliver drug and alcohol prevention messages to the target audience (teenagers 12-18 years). The recently launched Smoke Free Fashion initiative is an important example of how Government can work with communications industries to de-glamourise smoking and reduce exposure to pro-smoking images. The Government will continue to pursue similar opportunities.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-044

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: HEPATITIS

Written Question on Notice

Senator Denman asked:

(a) Has a decision been made on the public release of the Review of the National Hepatitis Strategy?
(b) If so, could a copy please be provided?

Answer:

(a) The report on the review of the National Hepatitis C Strategy will not be publicly released until a formal Commonwealth Government response to the recommendations is available.
(b) See above.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-052

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: FAMILY PLANNING ORGANISATIONS STATISTICAL DATA

Written Question on Notice

Senator Harradine asked:

In answer to Question E03-045 (Additional Estimates Feb 2003) the Department states that a first draft of a "nationally consistent narrative and statistical data reporting proforma" for the family planning organisations under the 2001-04 capital funding agreements is due at the end of April. Please provide a copy of this draft.

Answer:

This draft document is still being negotiated between the Commonwealth and the federation of Family Planning Organisations. It is expected that this document will be agreed and implemented by November 2003. Following agreement this information will be provided to you.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-053

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: FAMILY PLANNING ORGANISATIONS - COMMONWEALTH FUNDING

Senator Harradine asked:

(a) In Question E03-047 (Additional Estimates Feb 2003) I requested a table showing Commonwealth Government funding for family planning clinics each year over the past six years. The response stated that family planning organisations were not required to attribute costs to the type of services provided. However this was not what I was requesting. Please provide table as originally requested in part (a) of this question.

(b) In Question E03-047 (Additional Estimates Feb 2003) I requested an explanation of the formula for determining funding levels. You provided a one-sentence answer. Please provide me with a full explanation of the funding model and how it functions, including copies of the statistics that you use in the funding model to reach a dollar-funding amount for each State and Territory.

Answer:

(a) The information requested regarding Commonwealth Government funding for Family Planning Organisations each year over the past six years is provided at Attachment A.

(b) In the 2001-02 financial year, the Department commenced implementing a funding redistribution model for the Family Planning Program. This model was developed to better reflect the identified sexual and reproductive health service needs in each State and Territory and to address historical funding inequities between the Family Planning Organisations.

The funding redistribution model identified significant changes needed to the funding structure. The developed model identified these funding inequities by applying a range of population-related adjustments similar to that used to determine State and Territory allocations under the Population Health Outcome Funding Agreements (PHOFAs). These population-related adjustments, including their relative weightings, are described below.

The redistribution model determined the potential female service population for each of the Family Planning Organisations (the 15-54 age cohort). This service population was then adjusted for the social and economic population status in each State and Territory (30% weighting); a population-level summary health outcome measure (5% weighting); the percentage of Aboriginal and Torres Strait Islander people (5% weighting); and Commonwealth Grants Commission relativities (public health and community health categories; 60% weighting). This resulted in a picture of the relative funding needs for Family Planning Organisations in each State and Territory.

To minimise organisational disruptions when applying the model, the Department and the Family Planning Organisations agreed to maintain their individual base funding amounts at the 2000-01 level, so that no State and Territory experienced a drop in nominal funding levels. However, new growth funds arising from indexation are being distributed towards those States and Territories with identified historical inequity in funding levels, over a period of 3 years, while other States and Territories receive no growth. This process will be completed by July 2005, at which time a relative needs-based funding will have been achieved.

The idexation was withheld from each of six Family Planning Organisations (i.e., FPA Health (NSW), Family Planning Queensland, Family Planning Western Australia, Family Planning Welfare Northern Territory, Family Planning Victoria, and Family Planning Tasmania) for the 2002-04 financial years. This indexation funding is being redistributed to Family Planning Victoria and Family Planning Welfare Northern Territory over the 2002-04 financial period.

This model was implemented with agreement from the Family Planning Organisations.

Organisation	1997-98	1998-99	1999-00	2000-01	2001-02	2002-03
FPA Health (NSW)	4,750,910	4,780,078	4,630,651	4,741,214	4,845,521	4,983,204
Family Planning Victoria	1,617,510	1,659,410	1,701,100	1,741,716	1,947,765	2,281,754
Family Planning Queensland	2,534,100	2,598,641	2,663,925	2,727,530	2,787,536	2,866,743
Family Planning Western Australia	1,446,860	1,483,808	1,521,094	1,557,412	1,591,675	1,636,902
Family Planning Tasmania	473,090	485,426	497,625	509,506	520,715	535,511
Family Planning Welfare Northern Territory	335,560	344,133	352,781	361,204	411,204	432,065
Sexual Health and Family Planning Australia	83,190	85,012	87,143	89,224	(1) 81,789	(2) 105,391
Working Women's Health	94,640	96,632	99,065	101,430	103,661	109,125
Australian Episcopal Conference of the Roman Catholic Church	763,180	779,787	799,377	818,463	836,469	880,558
Australian Federation of Pregnancy Support Services (Not funded until 2000)	0	0	0	(3) 208,274	230,060	(4) 252,186
Total	**12,099,040**	**12,312,927**	**12,352,761**	**12,855,973**	**13,356,395**	**14,083,439**

Includes in the total:
1. withheld June 2002 payment of $9,398;
2. June 2002 payment of $9,398 added to 2002-03 payments;
3. underpayment of $16,834 in 2000-01 ; and
4. underpayment of $16,834 from 2000-01 made in 2002-03.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 June 2003

Question: E03-054

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: ADRAC - IMPLANON

Written Question on Notice

Senator Harradine asked:

In answer to Question E03-053 (Additional Estimates Feb 2003) the department advised that the Adverse Drug Reactions Advisory Committee (ADRAC) had received reports of women becoming pregnant despite being fitted with the implant Implanon. An analysis of these reports showed that in 20 cases there was "insufficient information to make an assessment".

(a) Does ADRAC provide to health professionals standard forms and/or other information to ensure all necessary information for assessment is collected?

(b) What were the reasons for insufficient information in the 20 cases ie. was it the medical practitioner or patient or the sponsor company who supplied insufficient information?

(c) Where it was the lack of information provided by the sponsor company (Organon Australia) in how many of the 20 cases was this so?

(d) Does ADRAC have any way of trying to gain information in these 20 cases in order to derive a complete picture of the reasons for pregnancy in these 20 cases?

(e) In the 57 cases where the implant was not inserted correctly, how many practitioners were involved in these insertions and what is the department doing to ensure this does not happen again?

Answer:

(a) ADRAC provides ‘blue card’ adverse drug reaction reporting forms to health professionals. These are distributed in the Schedule of Pharmaceutical Benefits book and with the ADRAC Bulletins in Australian Prescriber. Information on how to report an adverse drug reaction is included in each ADRAC Bulletin and on the TGA website.

(b) & (c) All 20 cases where ADRAC received insufficient information were reports from the sponsor company. These were reported to the sponsor company by medical practitioners (18), a nurse (1) and a patient (1). Despite contacting these reporters, the sponsor company says it did not receive sufficient information to further categorise these cases.

(d) ADRAC has a number of options for obtaining further information about reports. If ADRAC receives a report with insufficient information directly from a health professional, then that health professional may be contacted for further details. If ADRAC receives a report with insufficient information from a sponsor company, then that company may be asked to obtain and provide further details. In both circumstances, if the reporting health professional was not responsible for the insertion or is not involved in the long term management of the patient, there are limitations to the information that can be obtained from enquiring of the health professional.

(e) In the 57 cases where it appears that the implant was not inserted correctly, 37 involved medical practitioners and 20 involved 'health professionals' whose qualifications were not specified.

The prescribing information for Implanon gives detailed instructions for inserting Implanon correctly. The Consumer Medicine Information instructs patients to make sure their doctor shows them how to feel for the implant after insertion, and that they should tell their doctor if they cannot feel the implant and use another contraceptive method until the presence of the rod can be confirmed. The CMI also states that patients should avoid manipulating the rod after insertion to prevent it from moving from its original position.

Physicians who have little experience with subdermal insertion are advised to acquire the correct technique under surveillance of a more experienced colleague. The Australian sponsor of Implanon also conducts courses to train physicians on how to correctly insert and remove Implanon. The course materials include booklets and a video tape which doctors keep. At the course a 'practice dummy' is used.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-055

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: IMPLANON

Written Question on Notice

Senator Harradine asked:

The Department also provided information that in 43 cases, either the woman was already pregnant at the time of Implanon insertion, or "the timing of Implanon insertion was too late (more than 5 days after the start of the menstrual cycle)".

(a) Could the Department enquire of the drug company as to whether it advises pregnancy tests prior to the insertion of Implanon? If not, does the Department consider it appropriate that it advise that a pregnancy test should be standard prior to insertion?

(b) Does the Department know what the impact of Implanon is on the developing foetus in cases where the pregnancy was continued in the 43 cases? Are cases of ongoing pregnancy being monitored to determine possible adverse outcomes to the child?

(c) Could the Department please explain what is meant by "the timing of Implanon insertion was too late"?

Answer:

(a) The TGA referred the Senator's question to the sponsor of Implanon. Organon (Australia) Pty Ltd have provided the following response:

"The Product Information for Implanon states that known or suspected pregnancy is contraindicated. This means that the doctor should rule out pregnancy before insertion of the implant. Additionally the Product Information states that the implant is to be inserted on days 1-5 of the menstrual cycle. This precludes the possibility that the user is pregnant at the time of insertion. Organon does not specifically advise the use of pregnancy tests".

The TGA agrees that these precautions should be adequate.

(b) To clarify the earlier response of the Department, the TGA response was based on Organon's first analysis of 129 reports and said that, "in 43 cases, either the woman was already pregnant at the time of Implanon insertion, or the timing of Implanon insertion was too late (more than 5 days after the start of the menstrual cycle)". Subsequently the Adverse Drug Reactions Unit (ADRU) has completed its full analysis and has assessed that there are 41 cases where either the woman was already pregnant at the time of Implanon insertion, or the timing of Implanon insertion was too late (more than 5 days after the start of the menstrual cycle).

Of these 41 pregnancies for which full information was available, 4 pregnancies continued to the delivery of healthy children, 14 pregnancies continued but no further report of the pregnancy outcome has been provided, 14 pregnancies did not continue, and in 9 cases insufficient information was provided about the pregnancy outcome.

Of the 4 pregnancies that continued to the delivery of healthy children, the Implanon implant was documented to have been removed in 2 cases, and information was not provided for the other 2 cases. Of the 14 pregnancies continued but with no further report of the pregnancy outcome provided, the Implanon implant was documented to have been removed in 7 cases, and information was not provided for the other 7 cases. No other information has been received on the impact of Implanon on the developing foetus in these cases.

The sponsor company, Organon, has been requested by the TGA to provide information on the outcome in children following unintended exposure to Implanon. Adverse Drug Reactions Advisory Committee (ADRAC) is maintaining a watching brief in regard to possible adverse outcomes following unintended exposure to Implanon.

Organon has assured the TGA that it is monitoring ongoing pregnancies and will advise the TGA of any adverse outcomes in infants.

(c) The statement "the timing of Implanon insertion was too late" refers to cases where the implant was inserted more than 5 days after the start of the menstrual cycle. In such cases, as clearly outlined in the approved PI, additional contraceptive measures should be used.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-056

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: IMPLANON – TGA INVESTIGATION REPORT

Written Question on Notice

Senator Harradine asked:

The Department advised that the sponsor company had indicated that it is further investigating a number of these reports, and will provide the results of this investigation to the TGA. Could the TGA please provide a copy of the results of this investigation when available?

Answer:

Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-057

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: INTERNET AVAILABILITY OF PRESCRIPTIONS AND PRESCRIBED MEDICINES

Written Question on Notice

Senator Harradine asked:

I refer to a website described as "the net's first true drug store- easy and private" (http://rxstore4.da.ru/) which states "our doctors will write you a prescription for free, buy your prescription meds online" and "our US licensed doctors will prescribe your medication for free and have the medication shipped overnight to your door."

(a) What is the Department's view of this and similar websites?

(b) Does the Department have any concerns about the possible impact on health and safety of Australians who may access such sites and receive medications without any physical examinations or consultations regarding medical history etc?

(c) Does the Department issue any warnings about such sites? If so, what are they and how are they circulated?

(d) Does the Department have control over drugs from such companies entering the country?

Answer:

(a) & (b)

Clearly, a situation in which a patient is dispensed a prescription drug without proper medical assessment and examination is undesirable. The Therapeutic Goods Administration (TGA) encourages people to use medicines that are registered in Australia if they are available.

It is of some concern that the website described by Senator Harradine advertises that "US licensed doctors" will prescribe medication for online patients. This practice is contrary to the 'personal import' requirements specified by Australia's *Therapeutic Goods Act 1989* ("the Act"). The TGA has therefore raised this matter directly with the US Food and Drug Administration (FDA). The site is offshore and beyond Australian jurisdictional reach.

For further details regarding the personal import requirements in Australia, please refer to the controls outlined in (d).

(c) The TGA is concerned about the use of the Internet as a mechanism to unlawfully promote and supply medicinal products. The TGA approach to 'Internet advertising' is that such promotions fall within the definition of "advertisement" in the Act and are therefore regulated in the same manner as other "advertisements".

However, as these legislative controls are confined to Australian corporations and/or individuals who import, export, manufacture or supply therapeutic goods from, or between the States and Territories of Australia, the TGA does not have jurisdiction over complaints about a company and/or its Internet site which is based in, or on a server in another country.

Under these circumstances, the Australian Competition and Consumer Commission (ACCC), as president of the International Marketing and Supervision Network (IMSN) is able to investigate and action complaints about overseas Internet sites. In recent times, the TGA has forwarded several such sites to the ACCC for their consideration.

The IMSN is an international organisation that consists of a network of 31 member countries. Their role includes dealing with consumer problems that arise with international transactions in goods and services such as E-commerce fraud and international postal scams. It shares a database on fair trading laws in member jurisdictions and targets Internet fraud with Internet Sweep Days.

The 2002 Sweep Day focused on Internet sites promoting misleading claims about health products. As part of the close working relationship between the ACCC and TGA on such issues, officers from the TGA took part in the 2002 Sweep Day at the ACCC's Canberra office.

Consumers who believe they have been the victim of a health scam on an overseas based Internet site can report the matter to IMSN members at http://www.econsumer.gov or the ACCC Infocentre on 1300 302 502. Further information about IMSN and their activities may be found at the following websites: www.imsnricc.org and www.econsumer.gov

In relation to the actual supply of medicines via the Internet, the TGA website warns readers that medicines should not be ordered in this manner, unless both the contents of the preparations, and the legal requirements for importation and use in Australia, are known.

(d) Any medicines shipped to an Australian resident are subject to import controls imposed through the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations 1990, as well as the Customs (Prohibited Imports) Regulations 1956.

As far as the Therapeutic Goods legislation is concerned, persons importing, **by mail**, goods classified as prescription medicines in Australia, may only do so for the treatment of themselves or a member of their immediate family, where:

- The goods are not a prohibited import as listed in the Schedules to the Customs (Prohibited Imports) Regulations 1956;
- The goods are not injectables of human or animal origin (except insulins);
- The quantity imported in each importation does not exceed 3 months supply of the goods at the manufacturer's maximum recommended dose, and no more than 15 months' supply is imported in any 12 month period; and

- If entered in Schedule 4 or 8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) [ie. encompassing prescription medicines in Australia], the goods must be the subject of a written authority issued by a medical practitioner registered in an **Australian State or Territory.**

Therefore, it is unlawful to personally import prescription medicines of any sort from another nation into Australia unaccompanied unless a written authority has been issued by a medical practitioner registered in an Australian State or Territory.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03 - 058

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: HIV/AIDS - STATISTICS BY STATE AND TERRITORY

Written Question on Notice

Senator Harradine asked:

(a) I refer to new figures which show HIV/AIDS infections in Australia rose 20% in some states last year. Please provide a copy of these statistics including details for all states and territories.
(b) Please provide a statistical analysis which shows statistical breakdown by state and territory, by age group, gender, ethnicity and any other appropriate categories and specific causes for each infection.
(c) Can the Department provide reasons for the 20% increase in infections?

Answer:

(a) States and Territories report notifications of new HIV infections. These data are aggregated and analysed by the National Centre in HIV Epidemiology and Clinical Research. The most recent data are:

New diagnoses of HIV infection by State/Territory for the two previous yearly intervals.

State/Territory	**2001**		**2002**		**Cumulative to 31 December 02**		
	male	female	male	female	Male	female	Total
ACT	6	1	5	0	238	28	266
NSW	311	31	353	29	11941	689	12890
NT	4	0	4	4	116	14	130
QLD	87	17	117	13	2257	193	2457
SA	34	9	21	5	750	77	827
TAS	5	0	3	2	85	7	92
VIC	183	21	193	23	4399	272	4713
WA	38	11	30	13	1020	147	1173
						Total:	**22548**

1. Cumulative totals include diagnoses for people whose sex was not reported. The NSW total contains 235 such people, and the Victorian total contains 24.

2. Estimated cumulative number of new diagnoses of HIV, adjusted for multiple reporting, was 19,680 (range 19,220 to 20,140) ref: Law MG, McDonald AM and Kaldor JM, Estimation of cumulative HIV incidence in Australia, based on national case reporting. *Aust NZ J Public Health* 1996; 20: 215-217.

(b)

Number of new diagnoses of HIV infection for which exposure category was reported, by sex and exposure category, for two previous yearly intervals

Exposure category	**2001 - male**	**2001 – female**	**2002 - male**	**2002 – female**
Male homosexual/ bisexual contact	466	0	523	0
Male homosexual/ bisexual with injecting drug use	36	0	26	0
Injecting drug use	32	8	14	1
Heterosexual contact	78	77	85	82
Haemophilia or other coagulation disorder	1	0	0	0
Receipt of blood tissue	0	0	0	0
Health care setting	0	0	0	1
Mother with/at-risk of HIV, in children under 13 years	0	3	1	1

1. In addition to these diagnoses, there were 81 diagnoses for which no exposure category and/or no sex was reported and/or were reported as transgender.

Number of new diagnoses of HIV infection by sex and age group for two previous yearly intervals.

Age group	**2001 - Male**	**2001 – Female**	**2002 - Male**	**2002 – Female**
0-2	0	2	0	0
3-12	0	1	1	1
13-19	13	4	1	5
20-29	157	39	173	26
30-39	273	29	313	39
40-49	142	12	150	10
50-59	59	3	61	4
60+	16	1	25	4
Not reported	8	1	2	0

[Source: *Australian HIV Surveillance Report*, Vol 19, No 2, April 2003. National Centre in HIV Epidemiology and Clinical Research, University of New South Wales.]

(c) The Department funds the National Centre in HIV Social Research, University of New South Wales to monitor and investigate practices which may impact on the risk of transmission of HIV, and practices related to the social and behavioural aspects of the treatment and care of people living with HIV/AIDS. This research informs the development of preventive strategies.

According to the Centre's *2002 Annual Report of Behaviour: HIV/AIDS, Hepatitis C & Related Diseases in Australia* –

- Much of the unprotected anal intercourse within *regular relationships* is safe with regard to HIV transmission as it occurs within seroconcordant relationships. Levels of unprotected anal intercourse between *casual* partners have increased in some cities.

- HIV positive men are *almost universally more likely* to take part in unprotected anal intercourse than HIV negative men (although some of this unprotected anal intercourse is safe with respect to HIV transmission as it occurs between HIV-positive partners).
- In general, the majority of homosexually active men have sustained a 'safe sex culture' even though sustaining safe sex since the advent of the HIV epidemic is difficult. New therapies have lessened the burden on most people living with HIV and AIDS: there are fewer deaths and, despite often serious side effects, less debilitating illness among many people living with HIV/AIDS.
- For some homosexually active men, there is a significant association between 'HIV optimism' (with regard to the efficacy of new combination therapies slowing progression to AIDS and reducing the burden of illness) and unprotected anal intercourse, notably with casual partners.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-059

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: HIV/AIDS - DEPARTMENT POLICY

Written Question on Notice

Senator Harradine asked:

(a)
- (i) Does the Department consider that this sharp rise in the number of new cases is indicative of a failure of Government policy in this area?
- (ii) Will the Department be undertaking an investigation into these new figures and the reasons for them? Please provide a copy.

(b) What has been the Department's main policy emphasis in dealing with HIV/AIDS since the advent of the disease?

(c) Will the Department be changing its approach in light of these figures?

Answer:

(a)
- (i) No. Transmission of HIV peaked in Australia in 1984, with about 2,500 new infections per year. Subsequently, under the series of National HIV/AIDS Strategies, new HIV infections declined.
- (ii) Yes. The Department expects to receive the 2003 Annual Surveillance and Behaviour Reports on HIV/AIDS in August 2003. The Department will analyse the data in cooperation with the National Centre in HIV Epidemiology and Clinical Research and the National Centre in HIV Social Research.

(b) Since 1989, Australia's HIV/AIDS policy has been expressed in a series of National HIV/AIDS Strategies. The national strategies have maintained a strong emphasis on HIV/AIDS related prevention, education and health promotion targeting population groups that are most vulnerable to HIV transmission.

(c) Independent reviews of the current National HIV/AIDS and Hepatitis C Strategies and the strategic HIV/AIDS and hepatitis C research program were completed in October 2002. They were conducted well in advance of the end date for the current Strategies (June 2004) to enable a considered and informed response. This will allow time for the development of the next national strategies which will take into account emerging epidemiological trends and set the priorities for the continued response to HIV/AIDS.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 June 2003

Question: E03-060

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: SEXUALLY TRANSMITTED DISEASES

Written Question on Notice

Senator Harradine asked:

(a) (i) Does the Department see a role for specific abstinence education in preventing the increase in sexually transmitted diseases?
(ii) Is the Department funding any such programs at the present time?

(b) (i) Please provide a table detailing the incidence of sexually transmitted diseases by name over the past five calendar years in each state or territory.
(ii) What are the policy approaches taken by the Department to address each of these diseases?

Answer:

(a) (i) The Department supports the development and implementation of public health measures which are designed to reduce the harm that may be associated with sexual behaviour.
(ii) No.

(b) (i) Incidence of Sexually Transmitted Infections, 1999-2003 by State/Territory

Chlamydia

Year	ACT	NSW	NT	QLD	SA	TAS	Vic	WA	Total
1999	178	2418	855	4482	973	257	2949	1910	14022
2000	243	3456	990	4962	964	335	3256	2564	16770
2001	298	4476	1245	5566	1461	375	4027	2774	20222
2002	474	5555	1421	6482	1795	473	4846	3088	24134
2003*	175	2552	624	2936	747	418	2460	1456	11368

Gonococcal infection

Year	ACT	NSW	NT	QLD	SA	TAS	Vic	WA	Total
1999	19	1317	1158	1184	215	18	785	999	5695
2000	15	1063	1166	1151	243	18	742	1310	5708
2001	20	1335	1436	1128	235	21	692	1365	6232
2002	15	1433	1492	945	202	14	802	1405	6308
2003*	9	499	596	427	123	26	478	578	2736

Donovanosis

Year	ACT	NSW	NT	QLD	SA	TAS	Vic	WA	Total
1999	0	0	6	4	0	0	0	8	18
2000	0	0	6	6	0	0	0	1	13
2001	0	0	15	10	0	0	0	13	38
2002	0	0	9	52	0	0	0	2	63
2003*	0	0	4	7	0	0	0	1	12

Note: The increase seen in 2002 occurred as a result of the Commonwealth's donovanosis eradication initiative. Of the 63 cases, 19 were new infections and 44 were old infections detected as a result of case-note reviews undertaken by Project Officers during this period.

Syphilis

Year	ACT	NSW	NT	QLD	SA	TAS	Vic	WA	Total
1999	12	590	342	831	12	8	5	112	1912
2000	15	532	194	910	8	10	8	103	1780
2001	12	693	400	228	25	15	16	218	1407
2002	13	792	389	385	32	15	382	197	2202
2003*	4	326	105	58	6	14	134	79	726

* Calendar year to date.

[Source: Communicable Diseases Network Australia, National Notifiable Diseases Surveillance System, 12 June 2003]

(ii) To address chlamydia, gonococcal infection, syphilis, HIV/AIDS and other sexually transmissible infections, the Department has funded development of a range of prevention and education activities and resources, including 'safe sex' oriented materials, under the aegis of the National HIV/AIDS Strategy. Under the Family Planning Program, family planning organisations are funded to provide targeted sexual and reproductive health initiatives to special need and high-risk population groups such as regional and rural Australians, youth, migrants, the homeless and people with a disability.

The Department is also developing a National Sexually Transmissible Infections Surveillance Plan, which is due for completion by end 2003. In addition, the Department is working with States and Territories through the National Public Health Partnership Group to assess the feasibility of developing a national approach to sexually transmissible infection control.

State and Territory Health Departments have also developed disease control and health promotion strategies to address specific sexually transmissible infections.

Donovanosis almost exclusively affects Indigenous Australian populations in remote areas of Western Australia, Northern Territory and Queensland. Under the auspices of the National Indigenous Australians' Sexual Health Strategy, the Department continues to collaborate with Queensland, Northern Territory and Western Australian State Health Departments to eradicate donovanosis from Australia.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-061

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: HUMAN EMBRYOS – CONSUMER INFORMATION

Written Question on Notice

Senator Harradine asked:

I refer to the commitment of the Minister for Health on 15 May to refer the matter of consumer information about drugs manufactured or tested using human embryos to the TGA for examination as to feasibility and options for the best way of achieving a consumer's right to know.

(a) Please give details of the contractors and the brief provided to the contractors appointed by the TGA to undertake tasks required.

(b) Please provide the actual terms of the request made of the States and Territories to ascertain their views on this project. What exactly was the response from each of the States and Territories? To what level was the request directed?

(c) Was the NHMRC consulted? If so, what was their view?

(d) What companies, institutions and individuals have been or are expected to be consulted by the contractors?

(e) Have the contractors been engaged previously by pharmaceutical or related companies? If so, please provide details?

Answer:

(a) The contractors engaged for this project are Matthews Pegg Consulting (Ms Andrea Matthews, Principal) and Oceania Health Consulting (Mr Brian Wall, Principal). The contractors were provided with:
- Senator Harradine's proposed amendments;
- a copy of the letter from the Minister for Health and Ageing, Senator Patterson, to Senator Harradine regarding the need to examine the impact on the pharmaceutical industry and to consult with them about the feasibility and practicability of the requirements in the proposed legislative amendment; and

- a copy of the Hansard outlining the Minister's commitment to refer the proposed amendment to the Therapeutic Goods Administration (TGA) for urgent consideration and advice, and to include an analysis of the regulatory options available to meet Senator Harradine's proposal.

(b) The request to the States and Territories was made through the National Coordinating Committee on Therapeutic Goods (NCCTG). The NCCTG's role is to take action necessary to bring about coordination of legislative and administrative controls on therapeutic goods and poisons and to make recommendations to the Australian Health Ministers' Advisory Council as necessary on matters relating to therapeutic goods.

Members of the NCCTG were asked to provide jurisdictional comments on a proposal by Senator Harradine in relation to the labelling and advertising of products derived from human embryos or human embryonic stem cells. Members were also asked to comment on the draft report prepared by the consultants.

The States and Territories noted Senator Harradine's proposal and agreed with the recommendations in the consultants' draft report.

(c) The NHMRC was consulted. The NHMRC advised that:

"The NHMRC considers that in some circumstances there may be sound reasons for requiring information relating to the safety of products to be included in the advertising or labelling of therapeutic and other consumer goods. The NHMRC believes that mandatory labelling should be limited to issues of content and safety where the health benefit outweighs the cost. The NHMRC is not aware, in the time available, of any evidence in general which indicates that the use of human embryos or embryonic stem cells in the manufacture, creation or testing of therapeutic goods constitutes an issue of safety that requires mandatory labelling. We believe that product specific issues of safety are already adequately covered by TGA's regulatory processes."

(d) The following organisations were consulted:
the Australian Self-Medication Industry;
Medicines Australia;
Medical Industry Association of Australia;
the Complementary Healthcare Council;
Bresagen;
the National Stem Cell Centre;
Stem Cell Sciences;
Johnson and Johnson Research;
the National Health and Medical Research Council;
the Department of Industry, Tourism and Resources.

(e) No.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-083

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: EXPERT REVIEW COMMITTEE ON COMPLEMENTARY MEDICINE

Written Question on Notice

Senator Nettle asked:

The Parliamentary Secretary announced the members of the expert review committee on 15 May. An additional member, Mr Phil Daffy, was appointed subsequently. Why was Mr Daffy appointed after the original appointments?

Answer:

On 12 May 2003 the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth MP, announced that the Government would establish an expert committee to examine the role of complementary medicines in the health system. On 15 May 2003, Ms Worth announced the terms of reference of the committee and a list of members. As indicated in the announcement, the names of members were not finalised.

In finalising membership of the committee, consideration was given to ensuring that the committee had the necessary breadth and depth of expertise to address all aspects of the terms of reference. Final membership, which includes four members that were not named in the previous incomplete list, was announced on 27 May 2003. These four members are Professor Terry Campbell, Mr Philip Daffy, Dr Paul Dugdale and Associate Professor Anne Tonkin.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-124

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: EXPERT COMMITTEE ON COMPLEMENTARY MEDICINES IN THE HEALTH SYSTEM

Hansard Page: CA183

Senator Nettle asked:

Do we have an idea how much the review is expected to cost?

Answer:

Yes. The review is estimated to cost $207,000.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-125

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: COMPLEMENTARY CONSULTATIVE HEALTHCARE FORUM

Hansard Page: CA191

Senator Forshaw asked:

Can you provide the Committee with the minutes of the five meetings held by the Complementary Consultative Healthcare Forum?

Answer:

Attached are the five Outcome Notes from the meetings of the Complementary Healthcare Consultative Forum.

Outcomes of the Complementary Healthcare Consultative Forum

10AM – 4PM THURSDAY 1 JULY 1999

Parliament House, Canberra

Item 1

Welcome and Introduction by the Parliamentary Secretary, Senator the Hon Grant Tambling

- Senator Tambling (Chair) welcomes the members to the inaugural meeting of the CHCF, with a special welcome to the New Zealand observers.
- Forum members introduce themselves and give background on their expertise.

ITEM 2

Operation of the Complementary Healthcare Consultative Forum

- The Chair informs the Forum that there have been two changes made to the CHCF Charter, but there are just slight word changes, and it is not vastly different from the Charter the Working Party into Complementary Medicines agreed upon.

ITEM 3.1 & 3.2

Presentation by the Office of Complementary Medicines on the Regulation of Complementary Medicines

Briefing on the Therapeutic Goods Administration and the Regulation of Complementary Medicines.

International Trends in Complementary Medicines

- A brief overview on reforms in Australia in the regulation of complementary medicines and the regulation of complementary medicines in the United States of America, Canada, Germany and New Zealand was given.
- The Forum was informed that the EU was far from harmonised.
- USA model has not solved problems it was meant to solve and has caused more.
- Forum discussed labelling requirements of complementary medicines in the USA and in Australia. It was stated by the TGA that all complementary medicines sold in Australia must have a full description of contents, but that practitioner made products for a patient after a consultation does not require this.

Item 4.1

Research and Development in Complementary Medicines

Recent government initiatives in health research

Identified needs for research and development in complementary healthcare

- Discussed options of funding (GST not a direct source of funds).
- Discussed the different types of research that were open to complementary medicines (clinical v's blind placebo trials)
- There is a lack of evidence to support claims that are being made.

- It was stated that the complementary medicines sector needs to be organised in the way it lobbies for funding and not to ignore the NHMRC when it comes to looking at sources of funding.
- The issue of incentives for research was raised (ie-exclusive use of research findings for a set period of time or tax concessions). It was discussed that there are no incentives for industry to research at this point in time.
- Need to convince the NHMRC that complementary medicines are a priority area.
- It was suggested to invite a NHMRC representative to the next Forum to discuss funding and complementary medicines.
- Discussion about patents and how even though you cannot patent a particular herb, you can patent the way it is manufactured or produced.
- The possibility of making complementary medicines a priority area for the government was raised.
- Need to get complementary medicine experts onto research panels.
- The need for population exposure data with complementary medicines was raised to help when looking at the need of research.
- The need for a central research database to coordinate research and findings.
- It was suggested the industry discuss with the TGA about setting up a research trust funded from a levy on fees and charges, to have as a resource for research.
- It was suggested that there needs to be stronger links between complementary healthcare research and education.

Item 4.2

Post-Market Vigilance

Post Market Vigilance in Relation to Complementary Medicines
Reporting and Assessment of Adverse Reactions to Complementary Medicines as Part of a Post Market Vigilance System

- Australian Funds Advisory Council currently looking at how consumers can be involved in the adverse drug reporting system (Professor Samson invited representation from this Forum to be on that committee).
- It was discussed that the current reporting system is biased against complementary medicines, and the need for a complementary medicine expert(s) to be involved in the system that covers complementary medicines.
- ADRAC needs to be in touch with complementary medicine products and practitioners in setting up the new system.
- The suggestion of a stand-alone system for complementary medicines was raised and the pros and cons were discussed.
- It was suggested that it would be beneficial to strengthen links between ADRAC and CMEC.

Item 4.3

Review of the Therapeutic Goods Advertising Code

- Industry is pleased with the efforts in this area so far, but will wait for final judgement when the findings are released. It was suggested that this is the most important issue facing the complementary medicines industry at the moment.
- The current system is a reactive one, not a pro-active code. It deals with issues when they arise, not prescribing what is and isn't allowed.
- Need to take into account consumer's safety with the findings that are released (industry's right to advertise v's the public interest and also the issues of choice v's safety).
- The issue of 'rogue' parts of the industry that do not comply with regulations regarding advertising. TGA informed that the code would be co-regulatory, but that there will be 'black letter law' to work alongside it.
- Consumers are happy with the review as they have been involved and it is a more transparent process.
- The issue of the editorial/ advertorial/ advertising interface was discussed and the need of better definition of the boundaries.

ITEM 4.4

Practitioner Issues – Training and Accreditation

- Chair invites comments to pass onto Government discussions with the Democrats.
- Forum discussed the necessity to have minimum requirements for practitioners (benchmark entry-level competency statements).
- Forum discussed that there are numerous organisations that accredit courses, but there are many courses that have no accreditation.
- The Forum was informed that there are General Practitioners taking very short courses in complementary therapies and consumers are assuming that there are qualified since there are a qualified GP and getting Medicare rebates for the services provided.
- It was noted that there are organisations that are trying to for standards. It was also noted that there is no cap on graduates so there is a potential glut of complementary healthcare graduates.
- It was noted that there are some complementary healthcare organisations that are making efforts to standardise curriculum for training courses.
- There are competency statements on the National Training Register, but there is no way to enforce these at the moment.
- The apparent lack of accountability of practitioners at the moment is a concern for consumers.
- The issue of Medicare rebates for complementary healthcare practitioners was discussed.
- Two models of regulation were discussed; government regulation and self-regulation.

- Traditional Aboriginal Healers were discussed and the Chair was informed of the progress is this area, including three forums to take place later this year to discuss this issue.
- The Chair informed the Forum that there is a unique window off opportunity to get all the states to agree to registration of complementary healthcare practitioners.

ITEM 4.5

Industry Issues

- Export
  - Commercial potential is great as our system is seen to be legitimate and credible.
  - Opportunity for export of products and growth and supply of herbs.
  - No Australian Bureau of Statics data available regarding complementary healthcare products and services.
- Gene Technology
  - Numerous international pharmaceutical companies conducting research in this area.
  - Consumers afraid of the new advances in this area as the risks are unknown.
  - The Chair invited the groups and organisations represented at the table to get involved in the debate as the time for new legislation is approaching.
  - The Forum was informed that a new area in the TGA would be set up to regulate gene technology.

Item 4.6

Quality Use of Medicines

- The policy started in 91,92 to ensure that consumers are provided with safe and efficacious products.
- APAC stance is that complementary medicines need to be included into the National Medicines Policy (NMP), if complementary medicines are to be recognised as part of the Australian health industry sector.
- There was concerned raised that the NMP ignored complementary medicine practitioners.
- Industry stated that they were happy to be involved in initiatives that improve quality, safety and efficacy and improve health outcomes.
- Practitioners support any move to improve access to quality medicines.
- Chair invited members to make specific responses to APAC via APAC Secretariat, David Pearsons, regarding the review of NMP. Forum was reminded that the NMP was developed by consumers, for consumers.
- It was suggested that a few members from APAC and the Forum form a working party to discuss this issue. The Chair invited people to self nominate to Dr Cummings, Office of Complementary Medicines.
- The Chair emphasised that it was important not to make this issue political, as it had unilateral parliamentary support, and would therefore outlast any change of government.

ITEM 5

Other Issues to be Raised by Forum Members

- This item was combined with item 6.

ITEM 6

Identifying Areas for Future Consideration

- Potential areas for discussion for next Forum
  - Aboriginal Bush Tucker, Traditional Medicine and Healing.
  - Cost implications of the health sector for consumers.
  - Scheduling of herbs and therefore loss of access to them.
  - Medicare funding for complementary healthcare practitioner and therapies.
  - Further discussion of an Adverse Reaction Reporting System.
  - Research models and funding sources.
  - Reporting of COAG Committee looking into pharmacy ownership.
  - Cooperation between complementary medicines industry and Health Insurance Commission and the new initiatives that they are making.
  - Comparing 'traditional ' medical care with 'complementary healthcare' to see if it is more cost effective in some areas of the healthcare sector.

Closing

The next meeting is envisaged to be in October/ November 1999. Please ensure that papers of potential topics to discuss at the next Forum are delivered to the Office of Complementary Medicines by the end of July.

Outcomes Note for the Second Meeting of the Complementary Healthcare Consultative Forum

9:30AM – 1:30PM FRIDAY 26 NOVEMBER 1999

Parliament House, Canberra

Item 1 Welcome by Senator, the Hon Grant Tambling

Senator Tambling welcomed Members to the second meeting of the Complementary Healthcare Consultative Forum (CHCF), welcoming invited guests Commissioner Sitesh Bhojani from the Australian Competition and Consumer Commission and Mr Bob Wells from the Office of the National Health and Medical Research Council. Senator Tambling also noted several alternate members and apologies which are provided along with a list of attendees at Attachment 1.

Senator Tambling thanked members for contributions to the agenda forwarded through the Office of Complementary Medicines (OCM) and for ongoing interactions with the OCM on matters related to the Forum. He foreshadowed that the agenda would raise important issues and encouraged members to engage freely in the discussion these would provoke. He commented that the complementary medicines reforms, including the outcomes of the first meeting of the Forum, had placed complementary healthcare matters firmly on the public agenda and that this area would continue to gain prominence as the interested parties worked through the emerging challenges together.

The Senator reflected briefly on his recent experiences in the Asia-Pacific region where he lead a delegation of government, professional and industry nominees in discussions with senior government officials involved with medicines and food regulation in China, Vietnam and Thailand. He noted the fact that these countries were following closely the development of the Australian framework for regulating complementary medicines, particularly at the food/medicine interface, and that opportunities for co-operative approaches were already resulting from these discussions. The Senator indicated the visits were very successful and that a solid basis for further collaboration had been established. He said that, arising from the visit, a new agreement was being formulated with the State Drug Administration in China, opportunities for joint research programs had presented themselves and joint ventures with Australian industry were likely to be initiated in the near future.

Item 2: Outcomes Note from the previous meeting

Forum members adopted, without amendment, the Outcomes Note from the first meeting of the Forum with Senator Tambling commenting that it had been made available through the TGA website.

Outcome Summary
Members adopted the Outcomes Note from the first meeting of the Forum.

Item 3 Matters Arising

Member's attention was drawn to the list of matters arising from the previous meeting. Senator Tambling noted that these would be adequately covered under the specific agenda items and there was no need for separate discussion at this point.

Item 4 Advertising review

Senator Tambling invited Commissioner Sitesh Bhojani of the Australian Competition and Consumer Commission (ACCC) to overview consumer protection issues which arise in the promotion of complementary healthcare products and the role of the *Trade Practices Act (TPA)* in relation to those issues.

During his presentation, Commissioner Bhojani

- commented that the *TPA* applies notwithstanding any code such as the Therapeutic Goods Advertising Code;
- pointed out that Commonwealth legislative power only applies to corporations and that State and Territory legislation covers the remaining, unincorporated businesses (noting however, that since 1995, State and Territory arrangements, including legislation, ensure that the *TPA* applies to all in business, whether incorporated or not);
- outlined the areas of the *TPA* which apply to consumer protection and which deal with unconscionable conduct in the form of misleading, deceptive or false representations and illustrated such behaviour with a number of examples from the complementary healthcare sector; and
- commented on the "information asymmetry" which exists in areas like complementary healthcare where members of the community may be vulnerable because they do not have as detailed an understanding of the goods and services which are being provided to them as they may do in other areas.

A senior TGA officer then gave a summary of the process of the review of the Therapeutic Goods Advertising Code highlighting

1. the extensive involvement of industry, consumer and government officials in drafting the new Code;

2. the formal consultations held at State level and the important contribution from the Complementary Medicines Evaluation Committee (CMEC), the Medicines Evaluation Committee (MEC) and the Australian Drug Evaluation Committee (ADEC);

3. the role of the Therapeutic Goods Advertising Code Council (TGACC) in overseeing the entire process;

4. the particular efforts of CMEC which developed the "levels of evidence" measures underpinning the new Code;

5. the emphasis and reliance on an evidence-based approach to permitted claims;

6. the proposed transitional arrangements for phasing in the new Code including an education campaign to explain its implications for consumers, industry and regulators; and

7. the sanctions, including existing co-regulatory measures like the complaint resolution panels, to be put in place for ensuring compliance with the Code.

Another senior TGA officer provided members with a brief overview of the guidelines for levels and kinds of evidence to support claims for therapeutic goods which CMEC had developed in conjunction with the review of the TGAC. This work had arrived at the evidence-based approach to assessing claims where that evidence was based on scientific information or was based on traditional use, recognising that for many products there exists a combination of both types of evidence. The approach relies upon stratifying the claims according to the "degree of promise" they hold. For those products claiming to treat, manage, cure or prevent disease a higher level of evidence would be needed than for those products claiming to promote general well-being or to maintain health.

Members were invited to comment on the proposed approach. There was general support for the review process and for the outcomes it had achieved. There was strong support for the need for a level playing field across the board for therapeutic claims.

Senator Tambling reminded the meeting that the recommendations of the Therapeutic Goods Advertising Code Council would be considered by government in the near future.

Outcome Summary
Members of the Forum were generally supportive of the review process and the outcomes it had achieved, particularly for the level playing field it had created. Some caution was expressed by members from the Complementary Healthcare Council about the possibility of some existing product claims being caught in a more restrictive environment.

ITEM 5 PRACTITIONER REGULATION

Senator Tambling made members aware of the continuing work within the Department of Health and Aged Care on a strategy for the disbursement of funds ($500,000) included in the GST package to complementary practitioner groups representing herbalists, naturopaths and acupuncturists to assist them to move toward regulation in order to retain GST-free status beyond an initial three year period. He emphasised that the regulation of health professionals is a State and Territory responsibility and that it may not be possible to develop a cohesive approach to the regulation of these practitioner groups through State and Territory registration within the timeframe available.

Forum members affiliated with various practitioner groups provided an overview of initiatives being taken within their own organisations to prepare for future regulation.

Subsequent discussion by Forum members highlighted major issues still needing to be addressed before a suitable regulatory framework for the complementary healthcare professions could be arrived at. These included

- the absence of a cohesive approach by major practitioner associations in dealings with Government;
- the lack of agreed competency standards within the complementary healthcare modalities and disciplines;
- the need for agreement on the most appropriate model for regulation – either a government registration model, a co-regulatory model or a self-regulatory model;
- the wide disparity in the standard and variety of courses being offered by educational institutions in complementary healthcare modalities;
- the desire by complementary practitioners to be afforded 'parity of esteem' with conventional medical practitioners in State and Territory government approaches to the regulation;
- the challenge of developing an appropriate regulatory model for a practitioner group which is commensurate with the potential for that practitioner group or modality to adversely affect public health and safety (rather than developing regulation for its own sake);
- the need to ensure that in any regulatory model, the needs of those longstanding practitioners who may not hold the minimum qualifications deemed necessary for regulation or registration but who have a history of good practice are addressed; and
- concern by some complementary healthcare providers that medical practitioners can undertake various courses in complementary healthcare, incorporate complementary healthcare modalities into their own practice, and be able to provide services which attract Medicare benefits (which are not available to all patients who consult complementary healthcare practitioners).

A member of one major practitioner group indicated that the group was conducting a survey of its members to gain views on what type of regulation they prefer and offered to bring the results to a future meeting of the Forum. A member of another major practitioner group put the view that a co-regulatory model was the best way of achieving the outcomes which have been requested from the Federal Government.

The Forum was informed that those States which had previously taken the running on complementary practitioner regulation, Victoria and New South Wales, were meeting the following week to advance the matter and that the newly elected government in Victoria had a stated policy of consumer protection through registration of complementary and alternative medicine practitioners.

While one member expressed disappointment that the criteria for GST exemption for complementary practitioners were not ready for this meeting, a representative of the Department of Health and Aged Care who was invited to observe the meeting for this item, outlined the complexities associated with developing those criteria. Included among these were the fragmentation of the complementary healthcare industry, the diversity both within and between the various modalities, the wide discrepancy in levels of training required to 'practice' and the difficulty of balancing the potential benefits to practitioners against the potential benefits to consumers.

Reference was made to the fact that most of the allied health professions which had gained GST-free status were identified in the taxation legislation as requiring an undergraduate degree or higher qualifications and that this criterion provided a starting point for further consideration. A discussion paper is due from the Department early in the new year following a initial consultation period.

Another member made the observation that the professional associations still had much work to do in terms of developing an agreed set of competencies and accreditation standards, preferably national standards, and that these were essential before effective regulation could be achieved. Mr Bob Wells, who was present for this item, put the view from his role on the Australian Medical Council (the body responsible for assessing the competency of overseas-trained medical practitioners) that issues of quality of practice and ongoing accreditation, not simply regulation or registration alone, are becoming increasingly important.

Members were informed that some encouraging developments had been made by Australian National Training Authority which is moving to standardise natural medicine education in Australia.

Senator Tambling suggested that this matter be included as high priority agenda item for the next meeting of the Forum and that a representative from the Department of Education, Training and Youth Affairs be invited to address the next meeting of the Forum on the subject of methods of assessing the level of appropriate professional training necessary to achieve recognition of particular professions for purposes of uniform regulation and for special taxation arrangements.

Outcome Summary
Members noted the progress being made on number of fronts towards the regulation of complementary healthcare practitioners and the responsibilities of the States and Territories, the Department of Health and Aged Care and practitioner groups in this process. The Forum identified a number of major issues still needing to be addressed before a suitable regulatory framework for the complementary healthcare professions could be achieved.

Action Item
A representative from the Department of Education, Training and Youth Affairs be invited to address the next meeting of the Forum on the subject of methods of assessing the level of appropriate professional training necessary to achieve recognition of particular professions for purposes of uniform regulation and for special taxation arrangements.

Item 6 Research

Senator Tambling introduced this item by announcing the 'in principle' agreement by government to a government-industry initiative, to develop a research fund for complementary healthcare research in Australia. Discussions to date have focussed on the possibility of a $2 million fund to be administered over 3 years, where the government will match industry contributions to the fund on a dollar-for-dollar basis. He referred to the challenges of making Australia a centre of excellence in such research and of putting in place mechanisms to disburse and administer these funds including identifying and

prioritising the most appropriate areas in which to conduct research. These matters had been the subject of papers submitted for this and the previous meeting.

The agenda paper included a preliminary report of discussions between the TGA, the Complementary Healthcare Council of Australia and the Department of Health and Aged Care on a jointly funded complementary healthcare research program within the National Health and Medical Research Council (NHMRC) program. Mr Bob Wells of the Office of the NHMRC provided the meeting with an overview of how the NHMRC goes about its work of making grants for research explaining that:

- the bulk of the funding under the NHMRC program is distributed on the basis of open peer-reviewed competition and that while this was open to researchers working in the complementary healthcare area, this area had not had a strong representation in the past;
- arising from the Wills review, the NHMRC is striving to direct funding into areas where the health system needs are greatest and has established the Strategic Research and Development Committee for this purpose; and
- the NHMRC was enthusiastic about participating in a joint Government and industry funding exercise for complementary healthcare research and is willing to assist with developing joint processes for setting research priorities and assessing applications against those priorities.

Members were supportive of the moves towards developing a program for recognising and funding complementary healthcare research and during subsequent discussion made the following points:

- the importance of having the right people on expert panels assessing the type of research likely to be brought forward in the complementary healthcare area;
- consumer interests in, and expectations from, complementary healthcare research are not the same as researcher interests and mechanisms should be developed to take account of these interests;
- agreement over the need for clear separation between those making the funding decisions and those benefiting from them;
- suggestions for possible research endeavours might include
  - an examination of the nature and extent of complementary healthcare service and product usage, possibly by linking with existing population health survey infrastructures;
  - a “mapping” of complementary healthcare research work already being undertaken in Australia;

- a wide range of research projects to provide a broad evidence base;
- the possible establishment of a 'co-operative research centre' approach to this area; and

- the importance of finding ways to link practitioners and industry members with established research institutes and with researchers who are familiar with the NHMRC program.

Outcome Summary
Members were supportive of moves towards developing a program for recognising and funding complementary healthcare research and made a series of constructive suggestions as to how to progress research in this area.

Item 7 National Medicines Policy

Senator Tambling invited Professor Lloyd Sansom, Chair of the Australian Pharmaceutical Advisory Council (APAC), to give Forum members a brief overview of the National Medicines Policy (NMP) which was now in final draft form.

Professor Sansom summarised the history of the NMP highlighting the fact that over two years ago APAC commenced dialogue with the complementary healthcare industry about the policy out of recognition that it was an important component of healthcare delivery in Australia. He emphasised that the NMP is a framework document which proposes a "partnership" approach for better health outcomes for Australians and, although originally framed without any direct consultation with the complementary healthcare industry, the document now identifies clearly the role of the industry and its products.

Members broadly endorsed the document which is to be launched on 10 December 1999.

Outcome Summary
Members noted that the final draft National Medicines Policy now identifies clearly the role of the complementary healthcare industry and its products and broadly endorsed the document.

Item 8 Other business

The papers under this item had been considered elsewhere in the agenda.

Item 9 Issues for future consideration

The following issues were listed for consideration at the next Forum meeting:

- as part of the ongoing consideration of practitioner regulation and GST matters, consider the methods of assessing the level of appropriate professional training necessary to achieve recognition of particular professions for purposes of uniform regulation and for special taxation arrangements (DETYA representative to be asked to attend next meeting);
- funding and recognition of complementary healthcare modalities within the continuum of healthcare and as an integral part of broader government health policies;
- better links between the complementary medicines industry and the APAC, the Australian Health Ministers Advisory Council and the allied health professions;
- follow-up on progress with the implementation of the revised Therapeutic Goods Advertising Code; and
- safeguards for consumers against poor complementary healthcare practice – sanctions, fines and censures.

Item 10 Next meeting

Senator Tambling suggested the next meeting of the Forum be held on 14 April 2000. This is to be confirmed at a later time.

CLOSURE

Senator Tambling thanked members for their participation and encouraged them to maintain contact with the Office of Complementary Medicines and to forward suggestions and agenda papers for the next meeting to the Office.

ATTACHMENT 1

Forum Members and Guests in Attendance – Second Meeting

Senator, the Hon Grant Tambling Chair

Mr Sitesh Bhojani	Australian Competition and Consumer Commission
Mr Marcus Blackmore	Complementary Healthcare Council of Australia
Mr Kevin Darke	Proprietary Medicines Association of Australia
Mr David Fitts	Practitioner
Ms Janne Graham	Consumer representative
Ms Assunta Hunter	Practitioner
Mr David Johnston*	Complementary Healthcare Council of Australia
Dr Vivien Lin	State/ Territory representative
Mr Justin Lovelock	Practitioner
Mr David McLeod	Practitioner
Ms Lila Notley	Consumer representative
Mr Craig Pennifold	Department of Industry, Science and Resources
Ms Claire Pontin	Australia New Zealand Food Authority
Prof David Roberts	Chair, Complementary Medicines Evaluation Committee
Prof Lloyd Sansom	Chair, Australian Pharmaceutical Advisory Council
Mr Robert Scott	Practitioner
Ms Juliet Seifert	Proprietary Medicines Association of Australia
Mr Terry Slater	Therapeutic Goods Administration
Dr Iggy Soosay	Practitioner
Dr Furio Varant **	Australian Medical Association
Mr Bob Wells	Office of National Health & Medical Research Council

* Alternate for Mr Euan Murdoch for this meeting.

** Alternate for Dr Stephen Phillips for this meeting.

Apologies

Mr Les Dell	Marketing and advertising
Dr Avni Sali	Research
Dr Susan Martindale	MedSafe, New Zealand
Mr Warren Sanderson	New Zealand industry

Department of Health and Aged Care. Participants: Mr Graham Peachey and Dr Fiona Cumming, TGA; Ms Christine Harrington, Portfolio Strategies Division. Observers: Dr John Hall, TGA; Mr David Pearson, Health Access and Financing Division.

Draft Outcome Note for the third Meeting of the Complementary Healthcare Consultative Forum

FRIDAY 14 APRIL 2000

Parliament House, Canberra

Item 1 Welcome by Senator, the Hon Grant Tambling

Senator Tambling opened the third meeting of the Complementary Healthcare Consultative Forum (CHCF), welcoming Members, alternates for Members and invited guests and observers. A complete list of those in attendance, including apologies, is at Attachment 1.

Senator Tambling noted the contribution to the work of the Forum of Dr Vivian Lin, for whom this was the last meeting following her appointment to an academic post.

Senator Tambling gave a summary of the achievements in the regulation of complementary medicines over the twelve months since the introduction of the package of reforms. He referred to the implementation of important legislative and administrative reforms including the completion of the review of advertising arrangements for therapeutic goods, the establishment of the Office of Complementary Medicines and the work of the Complementary Medicines Evaluation Committee.

In noting important events since the previous meeting of the Forum, Senator Tambling referred to the launch, in December 1999, of the National Medicines Policy, to Juliet Seifert's appointment as Chair of the Therapeutic Goods Advertising Code Council, to the first Annual General Meeting, in March 2000, of the Complementary Healthcare Council and to the first anniversary, this month, of the Office of Complementary Medicines.

Item 2: Outcomes Note from the previous meeting

Members were asked to comment on and endorse the Outcome Note from the previous meeting of the Forum held in November 1999.

One industry member requested that a change be made to the summary of discussion under Item 4 at that meeting on the progress of the review of the advertising arrangements. He suggested, and Members agreed, that the outcome summary for that item be amended by changing the word "caution" to "concern" such that it reads as follows:

> "Members of the Forum were generally supportive of the review process and the outcomes it had achieved, particularly for the level playing field it had created. Some **concern** was expressed by representatives from the Complementary Healthcare Council about the possibility of some existing product claims being caught in a more restrictive environment."

There being no other changes, the Outcome Note of the second meeting was endorsed with the above amendment.

Outcome Summary
Members adopted the Outcome Note of the second meeting of the Forum with one minor amendment.

Action Item
The Outcome Note be amended in accordance with the comments noted above.

Item 3 Matters Arising

Members' attention was drawn to the list of matters arising from the previous meeting. Dr Tony Holland, from the University of Technology, Sydney, had been invited to the present meeting to address the Forum on methods for assessing professional training for purposes of uniformity in professional regulation.

Another paper on the role and recognition of complementary healthcare modalities within the continuum of healthcare had also been prepared following a recommendation of the previous meeting and was the subject of the paper at Item 8 of this meeting.

Euan Murdoch, of Herron Pharmaceuticals Pty Ltd was invited to provide the Forum with a brief overview of his company's recent experience in relation to the deliberate contamination of paracetamol product. Mr Murdoch described details of the events leading up to the incident, the strategies put in place to deal with it and the lessons learnt from it. Senator Tambling thanked Mr Murdoch and expressed the concern and support of Forum members over what had been a difficult time for the company.

Item 4 Advertising review

Senator Tambling informed Members that he had launched the new Therapeutic Goods Advertising Code the previous week in Sydney. Juliet Siefert, as incoming Chair of the Advertising Code Council, summarised the process and outcomes of the review of advertising arrangements for therapeutic goods and concluded by encouraging the industry and other interested groups to trial the new arrangements during the implementation period. Ms Seifert subsequently tabled the new Code for dispatch to Members.

Professor David Roberts, on behalf of the Complementary Medicines Evaluation Committee (CMEC) gave a brief outline of the development and application of the 'Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods' document which had been developed by CMEC to underpin the review of the advertising arrangements and ensure an evidence base for the greater flexibility able to be exercised in the labelling and promotion of medicines. Feedback on the way in which the Guidelines are facilitating the aims of the advertising review, and assisting manufacturers to make responsible claims to the public about medicines, will assist in the evolution of the document during the six month trial period and beyond.

Commissioner Sitesh Bhojani of the Australian Competition and Consumer Commission (ACCC) congratulated the Forum and others involved on both the review and the guideline initiatives. He indicated the ACCC's support of the general thrust of these measures aimed at better informing consumers about available medicines and health services. He indicated that the ACCC would continue to have an interest in monitoring the outcomes of the new arrangements and would be prepared to act in any cases where significant consumer detriment could be shown to have occurred.

An industry representative on the Forum indicated that, while the industry was generally supportive of the new Code and the evidence-based approach to permitting claims on complementary medicines, the trial period would be monitored to ensure that this did not reduce public access by consumers to complementary medicines. The Member also communicated that the approach to generic information was a serious concern to the industry and sought clarification of the proposed approach. The Member shared his view that the complementary medicines sector was being subjected to a "pharmaceutical" model of regulation inappropriate to the complementary sector and tabled a statement to this effect as well a legal document which put the Complementary Healthcare Council's opinion on the matter.

Another industry representative put the view that the new Code was simply about truth in advertising and about providing balanced information that can be relied upon and which is neither misleading nor deceptive in any way. This Member also commented that the position of generic advertising had become clearer under the new arrangements and that it, like other advertising information, would need to comply with the provisions of the new Code. This Member indicated that the need for prior approval of generic advertising had been specifically excluded from the new arrangements and that such advertising would simply need to include a reference to the approved indications.

A consumer representative on the Forum sought an early resolution to the definition of "advertisement" and Senator Tambling was able to confirm that the amended regulations which would help to clarify the definition had recently gone to Executive Council and would shortly be available to the public. The same Member welcomed the incorporation of complementary medicines into the National Medicines Policy given the expanding use of these products and their integration into the range of treatment and therapies available to Australian consumers.

Dr Martindale foreshadowed new Healthcare and Therapeutic Products legislation in New Zealand which would regulate vitamin, mineral and herbal preparations (currently regulated as foods in NZ). She congratulated those involved in the advertising review and the launch of the new arrangements and indicated that NZ would be observing the experiences of the trial period with interest in order to be better placed to introduce appropriate measures in NZ. Dr Martindale overviewed the results of a NZ advertising compliance survey indicating a significantly higher compliance for prescription medicines compared to over-the-counter medicines. Senator Tambling asked Dr Martindale to convey to the Ministry of Health an invitation for observer status at future meetings of the Therapeutic Goods Advertising Code Council.

An industry representative commended the TGA for its recent decision to conduct meetings of the Chairs of the various expert committees in that it would assist uniform application of the Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods across the various product categories.

The representative from the Australian New Zealand Food Authority (ANZFA) expressed the Authority's keen interest in the regulation of therapeutic claims given the close proximity in regulatory status of certain foods and therapeutic goods and the importance of maintaining consistency in the manner in which ANZFA is developing a framework to authorising health claims on foods, should they be permitted in the future.

Outcome Summary
Members noted the details of the development and implementation of the new advertising arrangements for therapeutic goods and the evidence-based approach on which claims for therapeutic goods are based and shared a range of comments and concerns surrounding the implementation phase.

Action Item
The new Code to be provided to all Members.

ITEM 5 PRACTITIONER REGULATION

Senator Tambling invited Dr Tony Holland to present an overview of the way in which professional competencies are developed and used for health professions.

Dr Holland distinguished the two current usages in Australia of the term 'competency', namely the 'ANTA' and the 'Attribute' definitions as follows:

1) 'Competency' as used by the Australian National Training Authority (ANTA) which declares that someone is 'competent' if they have certain skills and knowledge and can apply those skills and knowledge in the workplace. These competencies tend to be highly prescriptive and are developed to a format prescribed by ANTA. They are associated with training packages and qualifications, ranging from certificates to advanced diploma issued by the vocational educational sector ie TAFE or TAFE-like institutions. These sorts of competencies are universally recognised by all members of a particular occupation. At this stage, about 80% of jobs or occupations in the Australian workforce are covered by these competencies; and

2) The so-called 'attribute' definition of 'competency' is widely used by many professions, including health professions. Attribute competencies, often called 'professional competencies', describe the attributes possessed by the competent workplace performer and include knowledge, skills and attitudes. Unlike the ANTA competencies, attribute competencies are not directly linked to qualifications or registration but are used more broadly to inform the curriculum of a degree or graduate diploma or other qualification. They are also used for licensing or membership of a professional group or association, in continuing professional education, for helping to demarcate between technicians and professionals within a discipline, and, in Australia, for assessment of overseas qualified professionals.

Senator Tambling then invited Ms Natasha Cole from the Department of Health and Aged Care (the Department) to advise the Forum of progress with the policy arrangements for extending, beyond an initial three year period, the exemption from GST for services provided by key complementary healthcare professional groups (acupuncturists, herbalists and naturopaths), contingent upon these groups achieving regulation within that time.

Ms Cole explained that the precise wording of the GST legislation was still under consideration by the Australian Taxation Office as well as finalisation of the definition of 'entry level criteria' needed for practitioners to be eligible for the exemption.

Ms Cole also updated the Forum on progress of a discussion paper being prepared by the Department for consultation with complementary healthcare practitioners and other interested parties including State and Territory governments and the general public. The paper will discuss options to facilitate the regulation of acupuncture, herbalism and naturopathy services in the context of the GST legislation, sets out what the Commonwealth considers to be the minimum desired level of professionalism for these professions, and explores means of bringing these professions up to that level. Ms Cole advised that the paper was currently with the Minister for Health and Aged Care, that she expected it to be available within two or three weeks and that she anticipated that the period for public comment on the paper would operate until 30 September 2000.

The suggestion was made by Ms Cole that, should the various professions be unable to agree on mechanisms to achieve regulation which was uniform across their modality, the financial incentive provided by the Government for this purpose might better be utilised by one or other of the States which had successfully put regulation measures for healthcare practitioners in place.

Dr Lin informed the meeting that the Victorian *Chinese Medicine Registration Bill* was likely to be debated soon after Easter.

One practitioner Member enquired whether homoeopathic and massage therapy services were to be included among the GST exempt professions. Ms Cole indicated her understanding that these would be included where these therapies were provided by a naturopath.

Mr McLeod had included two papers with the agenda, one concerned with an interpretation of wording of the GST Bill and the other commenting on the Review of Drugs, Poisons and Controlled Substance Legislation Options Paper. Senator Tambling agreed to forward the issues raised in these papers to the relevant parties.

Outcome Summary
Members noted the manner in which professional competencies were developed for the health professions and discussed these and other issues associated with achieving uniform national regulation of complementary healthcare practitioners. Members learned of progress of a discussion paper being prepared by the Department to raise with stakeholders issues relating to the regulation of acupuncture, herbalism and naturopathy.

Action Item
The Department's discussion paper to be sent to Members once it becomes available.

Item 6 Research

Members were reminded by the Chair that the Government had agreed in principle to the allocation of $1 million toward research into complementary medicine on a dollar-for –dollar basis with industry and was now looking for a commitment from the industry to such a fund subject to other details being worked out. Senator Tambling also reminded Members that the concept of, and support for, a research fund had emerged mainly from the efforts of the Forum and encouraged industry representatives to foster the idea among their members.

Industry Members welcomed the Government's offer of research funding but indicated that the industry's ability to commit to the fund was governed by a number of factors including:

- concern over the possible need to introduce a 'research' levy on products/manufacturers in addition to existing compliance costs and the GST;
- the continuation of the low volume/low value subsidy currently applied to industry members;

- the relatively modest amount of money being offered by Government for research compared to, for example, the United States where Government - funded randomised controlled clinical trials were now being conducted on key complementary medicines;
- a view that governments have a general responsibility to fund research into complementary medicine because of its potential to promote health and thereby reduce healthcare expenditure; and
- the need to clarify a role for industry input into research funding decisions but at the same time minimise the potential for conflict of interest in those decisions.

One Member reminded the meeting that, while the discussion on research funding appeared to be focussed around complementary medicines research, there were other areas of complementary medicine which might also be considered appropriate for funding.

In response to these comments, Mr Robert Wells of the Office of the National Health and Medical Research Council (ONHMRC), explained, by way of example that, in broad terms, the NHMRC operated a research funding system based on open competition where the research techniques and the track record of the researchers was of prime importance in funding decisions rather than the subject of the research being the deciding factor.

At this point Mr Craig Pennifold of the Department of Industry, Science and Resources reminded Members of the range of other sources of research funding support including the Co-operative Research Centre grants, applications for which close in July. He indicated that some of these resources could assist industry members not only in research and development activities but also in assisting the progress of products through to the market place.

Another Member experienced with the NHMRC system commented that the initial funding being offered would be enough to fund four or five significant research projects per year. He suggested that the development of research priorities by a 'research management committee' would serve as a beginning which would in turn provide an incentive for industry to maintain support of the concept.

One practitioner Member suggested that part of the research endeavours be directed at trainee-ships for graduating complementary practitioners to undertake research into how complementary medicines are used. Another practitioner Member expressed the need to ensure that research proposals in particular disciplines of complementary medicine be assessed by people with expertise in those disciplines. Mr Wells explained that within the NHMRC system the researcher is invited to nominate particular assessors familiar with the discipline in question.

One consumer Member suggested that the setting of research priorities could benefit from the views of consumers, many of whom had considerable experience in understanding areas of community need and issues of community concern. This Member also suggested, in response to the industry view that any contribution it made to a joint research fund would be on top of existing costs associated with regulation, that the issue of what a viable industry really means in Australia be examined, and how this fits with the National Medicines Policy. Senator Tambling agreed that the Australian Pharmacy Advisory Committee could be invited to take the matter up.

Outcome Summary
Members discussed a range of issues and concerns to be considered prior to the establishment of a research fund for complementary medicines.

Item 7 Complementary Medicines and Healthcare

Senator Tambling introduced this item by highlighting the growing concern by Government and others over the availability of medicines on the Internet. He explained his reason for including this item on the agenda was to explore the impact that Internet promotion and sale of medicines, particularly complementary and other OTC medicines, is having and to seek the Forum's views on the matter.

The Senator provided the meeting with a brief overview of current approaches for dealing with Internet medicines in several other countries and Dr Cumming, from the Office of Complementary Medicines (OCM), provided the meeting with some examples of promotion and advertising of both complementary and prescription medicines taken directly from the Internet.

Senator Tambling then invited Members to discuss possible options for dealing with the emerging challenges of Internet medicines in Australia. In the discussion which followed, the following issues and views emerged:

- that there is an international trend within the industry toward voluntary approval processes for Internet advertising;
- that some interest was expressed in developing an industry standard or code of conduct for Australian manufacturers specifically related to advertising on the Internet, recognising that such advertising is already subject to the Advertising Code;
- that Australian-based interests with sites which link to overseas sites be held accountable for the information contained in the those overseas sites;
- that the use of branding or a logo on a web-site, indicating it had been endorsed in some way, was considered an attractive option with Members noting that mandatory certification of pharmacy sites and the issuing of a 'seal of approval' was being seriously considered in USA;
- that there was a general reluctance for attempting to impose a prescriptive regulatory approach in this area, given the size of the problem and the offshore location of many of the advertisers;
- that consumer education was seen by some Members as a key element in balancing the wide range and quality of information on medicinal products found on the Internet; and
- that there exists the potential for international co-operation, perhaps through reciprocal arrangements, in addressing identified problems with the way particular medicines are promoted on the Internet.

Ms Seifert offered to seek the views of the Australian Pharmacy Advisory Council (APAC) on this issue as part of her report to APAC in association with her report on the outcomes of the revised advertising arrangements for therapeutic goods.

Members agreed that that there was no easy or obvious solution to the challenge posed by Internet medicines and that it will be important to stay abreast of international and technological developments in order to identify options for monitoring and addressing the problem.

Outcome Summary
Members discussed a range of issues associated with the promotion and sale of medicines via the Internet and agreed that that there was no easy or obvious solution to the challenges this posed and that it will be important to stay abreast of international and technological developments in this field.

Item 8 Issues for future consideration

The following issues were listed for consideration at the next Forum meeting:

- Report on the trial of the new advertising arrangements for therapeutic goods;
- Further developments with the levels of evidence framework;
- Further discussion as to what a viable medicines industry in Australia means in the context of the National Medicines Policy and the views of the Australian Pharmacy Advisory Committee on this matter.
- Practitioner regulation issues and 'transition' to uniform systems of regulation;
- Assessment of the regulatory model in TGA and the autonomy of CMEC in being able to make decisions on issues which may impact on other expert committees;
- Overall contribution of Government to complementary medicines and complementary therapies and the possibility in the future of coverage within Medicare and the PBS respectively; and
- Development of regulatory frameworks for food/therapeutics – regulatory roles and functions – the future

Item 9 Next meeting

Senator Tambling suggested the date for the next meeting of the Forum be tentatively set at 17 November 2000. He also mentioned the World Self Medication Industry conference in Sydney from 21st to 24th November and encouraged interest from Forum members.

ATTACHMENT 1

Forum Members and Guests in Attendance – Third Meeting
Senator, the Hon Grant Tambling Chair

Mr Marcus Blackmore	Complementary Healthcare Council of Australia
Mr Kevin Darke	Proprietary Medicines Association of Australia
Mr Les Dell	Marketing and advertising
Mr David Fitts	Practitioner
Ms Janne Graham	Consumer representative
Ms Assunta Hunter	Practitioner
Ms Janine Lewis*	Australia New Zealand Food Authority (ANZFA)
Dr Vivian Lin	State/ Territory representative
Mr Justin Lovelock	Practitioner
Dr Carmel Martin**	Australian Medical Association (AMA)
Mr David McLeod	Practitioner
Mr Euan Murdoch	Complementary Healthcare Council of Australia
Ms Lila Notley	Consumer representative
Mr Craig Pennifold	Department of Industry, Science and Resources
Prof David Roberts	Chair, Complementary Medicines Evaluation Committee
Prof Avni Sali	Research
Mr Robert Scott	Practitioner
Ms Juliet Seifert	Proprietary Medicines Association of Australia
Mr Terry Slater	Therapeutic Goods Administration
Dr Iggy Soosay	Practitioner

Invited Speakers and Observers

Commissioner Sitesh Bhojani	Australian Competition & Consumer Commission
Dr Susan Martindale	MedSafe, New Zealand
Dr Tony Holland	University of Technology, Sydney
Mr Robert Wells	Office of National Health & Medical Research Council

Apologies

Mr Warren Sanderson	New Zealand industry (Observer)
Prof Lloyd Sansom	Chair, Australian Pharmaceutical Advisory Council
Dr Stephen Phillips**	AMA (Dr Martin as alternate)
Ms Claire Pontin*	ANZFA (Ms Lewis as alternate)

Other Observers

Ms Penny Lovibond	National Office of Overseas Skills Recognition (NOOSR)

Department of Health and Aged Care:
Participants: Dr Fiona Cumming and Mr Graham Peachey, TGA; Ms Natasha Cole, Portfolio Strategies Division.
Observers: Dr John Hall, TGA; Mr David Pearson, Health Access and Financing Division

Draft Outcome Note for the fourth Meeting of the Complementary Healthcare Consultative Forum

FRIDAY 17 NOVEMBER 2000

Parliament House, Canberra

Item 1 Welcome by Senator, the Hon Grant Tambling

Senator Tambling opened the fourth meeting of the Complementary Healthcare Consultative Forum (CHCF), welcoming Members, alternates for Members and invited guests and observers. A complete list of those in attendance, including apologies, is at Attachment 1.

One industry representative expressed disappointment that a request that a member of the Complementary Healthcare Council (CHC) Secretariat act as an alternate for one of the standing Members representing the CHC was refused.

Senator Tambling gave a brief overview for members of the contents of the agenda and highlighted some of the issues from previous meetings of the Forum and which were ongoing issues for the consideration of Forum Members.

The Senator briefly described some of the achievements in the regulation of complementary medicines in Australia as part of his reforms including recognition of the work carried out by the Complementary Medicines Evaluation Committee (CMEC). Members noted that fifty-four new Listable substances had been approved for use in complementary medicine products in less than three years.

Item 2 Outcome Note from the previous meeting

Members were asked to comment on and endorse the Outcome Notes from the third meeting of the Forum held in April 2000.

One member requested that a change be made to the summary of discussion on page 4 of the Outcome Note from the third meeting in relation to comments on the regulation of Healthcare and Therapeutic products legislation in New Zealand (see Attachment 2).

One Member queried the lack of detail of the Outcome Note in recording Forum discussions. The Senator explained that the role of the Forum was as an advisory body rather than a decision making body and that the role of the Outcome Note is to serve as an indicative record of the main issues discussed for future information and to serve as a point of reference.

There being no other changes, the Outcome Note of the third meeting was endorsed with the above amendment.

Outcome Summary
Members adopted the Outcome Note of the third meeting of the Forum with one minor amendment.

Action Item
The Outcome Note of the third meeting of the Forum be amended in accordance with the comments noted above.

Item 3 Matters Arising

Members' attention was drawn to the list of matters arising from the previous meeting. It was noted that the TGA had followed up on a number of topics that Members were keen to have considered by the Forum.

Item 4.1 Trial of the *Guidelines on Levels and Kinds of Evidence to Support Claims for Therapeutic Goods*

Senator Tambling invited Dr Fiona Cumming and Mr Pio Cesarin of the TGA to provide an overview of the work carried out by the Advisory Group established to provide guidance to product sponsors in relation to claims for therapeutic goods following the introduction of revised advertising arrangements.

Dr Cumming tabled an advanced draft of the document *Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods* (the Guidelines) which she explained was the result of broad stakeholder input, including from the Medicines Evaluation Committee and CMEC. She indicated that following a final round of stakeholder comment, the document should be in a form which would stand for some time before requiring further review.

Mr Cesarin summarised the outcomes of the Advisory Group's work indicating that 454 claims from industry members were examined. Members noted that under the new advertising arrangements a significantly greater range of claims are able to be made, providing sponsors hold appropriate evidence. Members also heard that, at the request of the industry, the operation of the Advisory Group had been extended by six months until the end of the year.

Professor Roberts (representing CMEC on the Advisory Group) and Ms Juliet Seifert (as Chair of the Therapeutic Goods Advertising Code Council (TGACC)) both responded by stating they were very satisfied with the outcomes resulting from the work of the Advisory Group and the implementation of the Guidelines. The Chair of the TGACC commented that the process had provided industry with the opportunity to see how the new Therapeutic Goods Advertising Code and the Guidelines work together and expressed her desire that the Guidelines be regarded as a standard for the preparation of advertising material.

An industry representative expressed mixed views on the appropriateness of the Guidelines and claimed a lack of industry consultation and representation in setting up the Advisory Group. He indicated that the cost, prescriptiveness and complexity of the new system continued to be real issues for industry, but indicated that the Complementary Healthcare Council (CHC) would do its best to work with the Guidelines.

The Australian Medical Association (AMA) fully supported the revised framework for advertising and evidentiary requirements for claims and commended the TGA in taking leadership in developing the Guidelines.

A consumer representative on the Forum indicated broad-level support for the levels of evidence framework and also that establishing evidence-based requirements for claims was welcomed by consumers. The Member expressed concern over the short time frame allowed for comment on the Guidelines but recognised that it was a living document and, as such, would be subject to future review as required.

Another Member urged that the Forum not lose sight of the fact that the beneficiary of these changes should always be the consumer.

Outcome Summary
There was general support for the new advertising arrangements and the supporting levels of evidence Guidelines, although some parts of industry expressed some reservations with the new system.

Item 4.2 Internet Advertising

Senator Tambling invited Mr Cesarin to speak to the paper included in the agenda in which specific criteria were suggested against which to measure the appropriate level of regulatory intervention over the use of Internet for the advertising and sale of complementary medicines.

Mr Cesarin outlined challenges as well as opportunities presented by the merging or 'convergence' of different types of media. He alluded to the dramatic increase in Internet usage and the measures introduced in several overseas countries in an attempt to regulate against inappropriate usage. This information, he suggested, was strongly supportive of the 'mainstream' nature of the internet medium and he invited Members to consider, in the light of this, whether or not the current mechanisms for handling of complaints were sufficient.

Senator Tambling then invited Forum Members to respond to these issues.

Mr Ziv Gavrilovich spoke on behalf of the Australian Competition and Consumer Commission (ACCC). He stressed that the need for a regulatory solution to the issues posed by the Internet should be clearly demonstrated and that the objective of that regulation be clearly identified before any measures are introduced. He emphasised that the degree of any regulatory intervention should be the minimum necessary to meet that objective and be weighted in the interest of the consumer. On the issue of the Internet as a form of media, Mr Gavrilovich expressed the view that the ACCC would not have any problem with Internet being classified as 'mainstream' and recognised that this would put the complaint handling responsibilities within the jurisdiction of the Complaint Resolution Panel (CRP).

One consumer representative put the view that consumers desire consistency in the standards which apply across the range of different media types. He suggested that a seamless approach for dealing with advertising complains would best serve the needs of consumers and that, in his view, a co-regulatory approach would be the most appropriate method for achieving this.

The Chair of CMEC felt that there was little doubt that Internet advertising was mainstream and that in terms of consistency, the existing co-regulatory model was the preferred way to progress the issue.

The alternate for one of the Members representing industry commented that, from a company perspective, the Internet was viewed as a form of mainstream advertising. He also indicated that, while a self-regulatory approach is preferred, there would be a preparedness to accept a co-regulatory environment.

Another Member, also representing industry, suggested that the issue was not whether Internet advertising was mainstream or not, but whether the current existing self regulation model was working. In his view the present system was working and he questioned the need the change it.

This view was supported by the Member representing marketing and advertising, remarking that his industry could not support any change to the current self-regulation model.

There was an exchange of views as to how well both the clearance of advertisements and the handling of advertising complaints were working under the existing self-regulatory arrangements. As with the previous Forum meeting, there were concerns voiced over the limited ability to control Internet advertising when it came from an offshore source.

The Chair of the Australian Pharmaceutical Advisory Committee (APAC) indicated that it was the unanimous view of APAC that Internet advertising was mainstream. He outlined what APAC had done in dealing with Internet promotions and consumer medicines information. He urged Members to consider, in the interest of the consumer, a single mechanism for handling complaints over the advertising of all therapeutic goods.

The Australian Medical Association (AMA) representative commented that for people not in the industry, lodging a complaint was a complex issue and that the AMA had sent people directly to the TGA for assistance.

Senator Tambling summed up the discussion on this topic by reiterating that any approaches to the regulation of Internet advertising of therapeutic goods would have to be consistent with the Government's broader strategies for control of Internet advertising across the range of consumer goods and services and across the range of relevant Government portfolios.

Outcome Summary
Members exchanged views on the mainstream nature of Internet advertising in relation to therapeutic goods and on the most appropriate methods of controlling internet advertising. While there appeared to be a majority view that the internet was a form of mainstream media, there were diverging views as to whether the existing self-regulatory arrangements by which complaints about internet advertising are handled or the co-regulatory mechanism by which other complaints about mainstream advertising of therapeutic goods are handled, might offer the best method for handling consumer complaints about advertising of therapeutic goods. Members heard that future regulation of Internet advertising in regard to therapeutic goods would need to be consistent with the Government's broader approach to the regulation of this medium.

ITEM 5 GST Initiative for Providers of Acupuncture, Herbalism and Naturopathy

Senator Tambling invited Mr Stanford Harrison from the Department of Health and Aged Care (Workforce Regulation Section) to advise the Forum of progress with the GST initiative for providers of acupuncture, herbalism and naturopathy.

Mr Harrison informed Forum Members that there had been a delay in the promised consultation paper being prepared by the Department seeking comment on options to facilitate the regulation of acupuncture, herbalism and naturopathy services in the context of the GST legislation. Mr Harrison explained that finalisation of the paper had been awaiting the meeting last month (October) of the Australian Health Minister's Advisory Council (AHMAC) which was to consider proposals for developing of a national framework to determine minimum standards for the conduct and safety of complementary medicine. The AHMAC proposed that a working party be established for such a purpose and that that it be headed by New South Wales Department of Health. In the light of this development, Mr Harrison explained that the long-awaited Commonwealth consultation paper would now be revised, although he was unable to provide a precise time for its release.

A practitioner Member expressed concern over the lack of consultation in developing the existing draft of the consultation paper. He outlined the anxiety of the affected professional groups in regard to who might be included in the definition of a 'recognised professional' in order to be included in the GST-free arrangements for provision of practitioner services. There was particular concern that there be appropriate 'grandfathering' arrangements in place to recognise practitioners of long-standing and experience who might not necessarily possess the required 'paper' qualifications. Members learned that an industry reference group had been formed to commence work on uniform competency standards in naturopathy and that there had been a good level of co-operation between several complementary professional groups.

This same Member spoke briefly to three papers which he had submitted to the agenda (itemised under 8.4) and covering the issues of professional recognition of the Western herbalist profession, discrimination against herbalists in the GST laws and competition between orthodox and complementary healthcare professions. Members agreed that these issues followed on from the previous discussion and Senator Tambling agreed to forward the issues raised in these papers to the relevant parties and to do what he could to facilitate the consultation process in time for next year's budgetary considerations.

Outcome Summary
Members noted the reasons for delay in the awaited Commonwealth consultation paper on options to facilitate the regulation of acupuncture, herbalism and naturopathy services in the context of the GST legislation. Concerns were expressed by practitioner groups over the level of consultation to date and of the need to carefully define 'recognised professional' for GST purposes. Members also noted encouraging moves at the AHMAC level to establish a national framework to determine minimum standards for the conduct and safety of complementary medicine practice.

Action Item
The Commonwealth discussion paper to be sent to all Members as soon as it becomes available.

Item 6 Post-market Strategy for Complementary Medicines

Senator Tambling invited Dr Cumming of the TGA to outline the objectives of the post-market strategy being developed by the Office of Complementary Medicines. These included:

- ensuring on-going safety of complementary medicines;
- providing a high level of consumer confidence in the safety, quality, and efficacy of complementary medicines; and
- ensuring a high level of industry compliance with regulatory standards and guidelines for complementary medicines.

Dr Cumming described the emerging importance of post marketing measures once the rapid pre-market entry arrangements offered by the new Electronic Lodgement Facility (ELF) came on line some time in 2001. These measures included the enhanced monitoring of adverse reactions to complementary medicines, laboratory testing, surveillance in the market place, recall procedures, auditing of good manufacturing procedures and the co-regulatory approach to controlling advertising and complaints.

The Chair of APAC described plans being made by the APAC for a system for consumers to report adverse drug reactions and offered to investigate the possibility of having a complementary medicines representative included in the group which is putting the system together. The development of such a system was welcomed by a consumer representative on the Forum.

An industry representative expressed concerns over the level of complexity, the costs and the delay in implementation of the new ELF.

Outcome Summary
Members noted the objectives and key elements of the post market strategy for complementary medicines being developed by the TGA in anticipation of the new Electronic Lodgement Facility. The importance of a system for consumer reporting of adverse reactions to complementary medicines and industry concerns over the new ELF were also noted.

Item 7 Export Reforms

Senator Tambling invited Ms Margaret Burdeu of the TGA to provide an overview of recent recommendations arising from a review of regulatory procedures associated with the exportation of medicines (including complementary medicines). Ms Burdeu told the Forum that these recommendations, which were in the process of being implemented, were aimed at removing unnecessary regulatory obstacles, enhancing transparency and improving administrative efficiency.

An industry representative commented that the measures arising from the review reflected a major improvement in the export arrangements although he identified the differing regulatory requirements in different countries as an ongoing concern.

Outcome Summary
Forum Members noted the recommendations being implemented to improve the export environment for Australian exporters of therapeutic goods, including complementary medicines.

ITEM 8 MEMBERS' REQUESTS AND INPUTS

8.1 Regulatory Frameworks For Foods And Complementary Medicines In Australia

Dr Cumming was invited by the Chair to provide a description of the regulatory challenges which arise at the food/medicines interface as the opportunities to make a greater range of claims on foods and medicines are increasing. Dr Cumming reinforced the importance of the TGA and ANZFA working closely together to ensure consistency in both policy objectives and operational decisions in relation to products which lie close to the food/medicine interface.

Mr Peter Liehne, as the ANZFA representative on the Forum contributed further information from the ANZFA perspective including the issues which arise in harmonising food standards as a result of the existence in New Zealand of dietary supplement products. He also alluded to the difficulties in enforcement of food legislation in this area, this being exclusively a State and Territory role. Mr Liehne outlined the current ANZFA health claims proposal which was seeking to put in place a framework for recognising and regulating various nutritional and health related claims and he invited comments on the proposal from interested Forum Members.

The subsequent exchange of views by Members as to the relative risks posed by foods and by medicines was a recognition of the regulatory challenges posed by products increasingly testing the interface.

Outcome Summary
Members noted the regulatory challenges emerging at the foods/medicines interface that require careful co-operative approaches for their resolution.

8.2 Maintaining a Viable and Responsible Medicines Industry

Senator Tambling invited Mr David Pearson from Health Access and Financing Division of the Department of Health and Aged Care to speak to the agenda paper on this topic. Mr Pearson outlined the issues surrounding the integration of the various National Medicines Policy objectives in maintaining a responsible and viable medicines industry.

The Chair then invited members to consider the potential implications for the complementary medicines sector.

Ms Anne Holmes from the Department of Industry, Science and Resources provided an overview of the current Government incentives aimed at stimulating activities which will have a positive economic impact in the medicines arena. This includes the Pharmaceutical Industry Investment Program (PIIP) which is aimed at identifying and encouraging innovative research and development activity.

The AMA representative and an industry representative questioned the emphasis in these incentive programs of maintaining the pharmaceutical industry compared with directing resources to other parts of the health system or the other parts of the medicines industry, particularly the complementary part, respectively. The APAC Chair suggested that the apparent barriers to access by the complementary medicines industry to such incentives were not insurmountable and encouraged the industry to assemble its case for recognition as a viable player in a considered and logical manner. The lack of patent protection was seen by some Members as another issue relevant to this debate.

Outcome Summary
Members noted the issues surrounding the integration of the various National Medicines Policy objectives in maintaining a responsible and viable medicines industry and considered a number of potential implications for the complementary medicines sector.

8.3 A View on One Alternative Treatment

Ms Lila Notley was invited by the Chair to make a presentation on her personal experience of electrochemical therapy for treatment of tumours. Ms Notley explained that this form of treatment is used in China and that it was gaining increased recognition for its benefits in reducing the mass of certain types of tumours.

Ms Notley explained that such examples demonstrate the value of alternate therapies and highlighted the need for orthodox and alternative medicine to work together to find ways of integrating their approaches in the best interests of the patient. She also urged Members to consider ways of making complementary medicines affordable and within the reach of lower income earners.

Members responded to the presentation by discussing ways in which there could be a greater level of debate and of better ways of gathering evidence to assist in the rational risk-benefit assessment of emerging therapies.

The AMA representative informed Members of the recent establishment of the AMA Advisory Committee on Complementary Medicines. She indicated that this was recognition of the preparedness by mainstream medicine to explore the value of complementary approaches with a view to integrating them into the range of treatment options offered to the healthcare consumer.

Outcome Summary
Forum Members noted the positive personal experience by one Member with an alternate therapy and discussed ways in which there might be a greater level of debate and better ways of gathering evidence to assist in the rational risk-benefit assessment of complementary therapies with a view to further integrating them with orthodox medical practice.

8.4 Practitioner Issues

These issues, raised by a Member, were addressed under Item 5.

8.5 World Self Medication Industry Conference

Ms Juliet Seifert provided a brief overview of the World Self medication Industry Conference to be held the following week (from 21st- 24th November 2000) in Sydney.

Item 9 Issues for Future Consideration

The following issues were listed for consideration at a future Forum meeting:

- Further consideration of the issue of Internet advertising;
- Further examination of the regulatory framework around the food/medicines interface;
- An analysis of the potential health economic impacts of the complementary medicine industry in Australia.
- Consideration of a 'summit' in order to provide opportunity for debate on issues related to the integration of orthodox and complementary medicines and related consumer issues.

Item 10 Next meeting

Senator Tambling suggested the date for the next meeting of the Forum be tentatively set at 22 June 2001.

ATTACHMENT 1

Forum Members and Guests in Attendance – Fourth Meeting

Senator, the Hon Grant Tambling Chair

Mr Marcus Blackmore	Complementary Healthcare Council of Australia
Dr Mark Bowden*	Australian Self Medication Industry
Mr Les Dell	Marketing and advertising
Ms Anne Holmes**	Department of Industry, Science and Resources
Ms Assunta Hunter	Practitioner
Mr Peter Liehne	Australia New Zealand Food Authority
Mr Justin Lovelock	Practitioner
Dr Carmel Martin***	Australian Medical Association
Mr David McLeod	Practitioner
Dr Cathy Mead	State/ Territory representative
Ms Lila Notley	Consumer representative
Prof David Roberts	Chair, Complementary Medicines Evaluation Committee
Prof Avni Sali	Research
Prof Lloyd Sansom	Chair, Australian Pharmaceutical Advisory Council
Ms Juliet Seifert	Australian Self Medication Industry
Mr Terry Slater	Therapeutic Goods Administration
Dr Iggy Soosay	Practitioner
Dr Derek Weir ****	Consumer representative

Invited Observers

Mr Ziv Gavrilovich	Australian Competition and Consumer Commission

Apologies

Dr Rosanna Capolingua-Host***	AMA (Dr C Martin as alternate)
Mr Kevin Darke*	ASMI (Dr M Bowden as alternate)
Mr David Fitts	Practitioner
Ms Janne Graham****	Consumer representative (Dr D Weir as alternate)
Dr Susan Martindale	MedSafe, New Zealand
Mr Euan Murdoch	Complementary Healthcare Council of Australia
Mr Craig Pennifold**	Dept Industry, Science & Resources (Ms A Holmes as alternate)

Other Absences

Mr Robert Scott	Practitioner, did not attend the meeting

Other Observers

Ms Penny Lovibond	National Office of Overseas Skills Recognition

Department of Health and Aged Care.

Participants: Mr Graham Peachey, Dr Fiona Cumming, Mr Pio Cesarin, Ms Margaret Burdeu, Therapeutic Goods Administration (TGA);
Mr David Pearson, Health Access and Financing Division.
Mr Stanford Harrison, Workforce Regulation Section.

Observers: Dr John Hall, Dr Susan Alder, Ms Sharyn McGregor, TGA.

Draft Meeting Summary for the Fifth Meeting of the Complementary Healthcare Consultative Forum

FRIDAY 29 JUNE 2001

Parliament House, Canberra

Item 1 Welcome by Senator, the Hon Grant Tambling

Senator Tambling opened the fifth meeting of the Complementary Healthcare Consultative Forum (CHCF), welcoming Members (including Professor Chiang Lin for the first time), alternates for Members and invited guests and observers. A complete list of those in attendance, including apologies, is at **Attachment 1**.

It was noted with regret that five Members were prevented from attending the meeting due to heavy fog conditions in Canberra, which prevented their planes from landing. An attempt was made during the meeting to include some of these Members by teleconference but this was not possible in the time available and given the complexity of the sound system in the meeting room. Absent Members were given the opportunity to comment on this summary. Their comments are included at the end of the relevant agenda items in this meeting summary.

Senator Tambling reflected on a number of the issues which had been considered by the Forum over its four previous meetings.

Mr Peachey of the Therapeutic Goods Administration (TGA) chaired the meeting for Item 4 while Senator Tambling was absent for a Parliamentary commitment.

Item 2 Outcome Note From The Previous Meeting

Members were asked to comment on and endorse the Outcome Note from the fourth meeting of the Forum held in November 2000.

One Member representing the Complementary Healthcare Council (CHC) criticised the Outcome Note as not being adequate as a formal record of the

fourth meeting and, with the agreement of the Chair, tabled his own printed version of the meeting.
Subsequent discussion amongst Members about the reporting requirements most appropriate to the operation of the Forum included the following points:

- Senator Tambling indicated his desire to have a record of Forum meetings which could be included on the web-site to serve as a guide to the Forum's discussions for interested observers;
- Other Members were concerned that the general style of the current Outcome Note did not reflect the full nature and extent of discussion and debate which occurs at meetings;
- There was a view by some that the term 'outcome note' implied agreement and that this was not always the case with Forum discussions;
- That a more detailed 'minute' style of report would assist in demonstrating accountability of Member's to their constituency but that this was not always practical or suitable; and
- Some Members considered that a more detailed record of discussions would enhance the opportunity for the work of the Forum to serve as advice to Government.

Finally it was accepted that the discussions of the Forum be presented as a "Meeting Summary" which, while not being full minutes, should reflect as clearly as possible the nature and extent of matters discussed. As a way of providing "take home messages" for Government for its further consideration, it was thought that the Meeting Summary should, where appropriate, include a 'Chairs Note'. This practice has been adopted in the compilation of this document.

With the above reservations, the draft Outcome Note of the fourth meeting was adopted.

Comments from absent Members about the draft Outcome Note of the fourth meeting were as follows:
A Member representing the Australian Self Medication Industry (ASMI) raised the following issues:

- Regarding Item 4.1: The next crucial step is to develop the Australian Guidelines for the Registration of Complementary Medicines and to ensure consistency of principles and approaches with the Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods and the Australian Guidelines for the Registration of Medicines.
- Regarding Item 7: Major changes of practice are being proposed, all related to interpretation of the legislation. Current interpretation is different to practice over the past ten years and has the potential to be an enormous

administrative and financial burden to industry and a strain on TGA resources.

- Regarding Item 8.1: It needs to be recognized that there is a food standard being considered for food type dietary supplements to accommodate such products coming in from New Zealand. The scope is by no means clear at this stage.
- Regarding Item 8.2: Industry is looking to TGA for opportunities for exclusivity arrangements via protection of proprietary data (i.e. avoiding the 'piggy back' effect of generics for a five year period) and also an exclusivity period for an applicant following re-scheduling.

Chair's Note
Members adopted the Outcome Note of the fourth meeting of the Forum. Future reports of Forum meetings are to take the form of a Meeting Summary which will reflect as clearly as possible the nature and extent of matters discussed and capture important outcomes for the attention of Government as a 'Chairs Note'.

Item 3 Matters Arising

Members' attention was drawn to the list of matters arising from the previous meeting. Senator Tambling invited Members to make further comments on the matter of Internet advertising which had been discussed at the previous meeting. He invited Mr Cesarin of the TGA to outline TGA's current position. Mr Cesarin briefly commented that while the Internet was an emerging media, the TGA believes that it is a mainstream mechanism of information dissemination which in a regulatory sense should be addressed in a similar manner to other forms of mainstream media. He underlined the importance of achieving consistency in approach across all sectors and accessibility to a single and transparent complaints resolution mechanism.

Senator Tambling then invited Mr Gavrilovich of the Australian Competition and Consumer Commission (ACCC) to outline for Members the strategies being implemented by the ACCC with regard to Internet advertising. Mr Gavrilovich indicated that the ACCC also sees the mainstream status of Internet advertising as being a particularly important issue and informed Members that the ACCC had recently stepped up its capacity to deal with Internet issues. He alluded to the growth in Internet use by traders where the number of new

domain names registered last year grew by 211% and the number of global users of the Internet increased by 67% over the same period.

Among the activities being undertaken by the ACCC, Mr Gavrilovich mentioned:

- an on-line complaint logging system called *Slam a Cyber Scam* for receiving complaints about Internet traders and which had already received 70 complaints since its launch in April 2001;
- International Internet Sweep Days run in conjunction with other agencies and other countries where over 3,300 sites were swept by 48 agencies in 19 countries;
- the ACCC's involvement in the International Marketing Supervisory Network (IMSN) which is a network of law enforcement agencies in 30 countries working together to protect consumers by getting involved with cross-border enforcement, alternative dispute resolution, codes of conduct, and the like;
- a new ACCC publication called *Fair.com* to educate Internet service providers and businesses about fair dealing with regard to websites and domain name registration; and
- a number of recent cases in which the ACCC had taken action with regard to certain health services or products.

In subsequent discussion on the topic of Internet advertising, Members expressed the following views or made the following comments:

- Members representing the CHC and the Direct Sellers Association of Australia spoke in favour of the current self-regulatory system dealing with complaints in regard to Internet advertising saying that, in their view, it was working well and that complaints were being handled in a quick and effective way with sanctions being applied to both members and non members of the industry bodies; and
- A consumer Member commented that the existence of one complaint handling mechanism for Internet and another for other mainstream media highlighted the weakness of having a complaints driven process. He put the view that there was real value in the kind of approach that the ACCC was taking with a proactive sweep of internet sites to identify problems.

As a final matter arising from the previous meeting Professor Sansom, the former chair of the Australian Pharmaceutical Advisory Committee (APAC), reported that the APAC recently held a consumer focus group as part of looking at the feasibility of an adverse drug reaction reporting system for consumers and that there had been a submission sent to the Australian Council on Quality and Safety for funding for a pilot project. Later in the meeting Professor Sansom urged that the complementary healthcare sector become involved in

Quality Use of Medicines initiatives through APAC rather than develop approaches of its own.

Professor Sansom also reported that a set of best practice model statements concerning the integrated use of complementary medicines by residents in residential care facilities had been developed. He reflected that this was evidence of the growing recognition that complementary medicines are part of the totality of the management of people in those institutions.

Comments from absent Members about internet advertising:
The Chair of the Complementary Medicines Evaluation Committee (CMEC) made the following comments:

- In noting the discussion on Quality Use of Medicines, a common reporting system for adverse events to medicines, whatever their origin, was urged.
- In noting the discussion on internet advertising, reiterated the view that it was mainstream and should be regulated as such.

Chair's Note:
While Internet advertising of therapeutic goods is considered a form of 'mainstream' advertising there remain divided views as to the best form of regulating it and dealing with complaints. The ACCC has made strident moves in line with increasing use of the Internet by both consumers and traders, to ensure that the use of the Internet for advertising purposes adheres to the principles of fair-trading.

Item 4 Practitioner Regulation

Senator Tambling invited Mr Stanford Harrison from the Department of Health and Aged Care (Workforce Regulation Section) to advise the Forum of progress with the implementation of a funding program for the establishment of uniform national registration systems for suitably qualified practitioners in acupuncture, herbal medicine and naturopathy.

Mr Harrison referred to his paper (item 4.1), which outlined the process for consultation with professional associations and included proposals for how the Government's incentive funding might be disbursed. Mr Harrison explained that the strategy being followed by the Department was to target the assistance of the professional associations and thereby encourage

collaboration amongst practitioner groups. He indicated that final decisions as to the disbursement of the funding had not yet been reached and that further information was being sought from some of those who had made submissions. He further indicated that until decisions had been made on disbursement of the funding, he was not in a position to speak about details of the work in progress.

Mr Peachey of the TGA, acting as Chair of the Forum, invited Ms Hunter to speak to her paper on complementary therapies education and regulation (item 4.2). The following points were raised:

- That having focussed attention in the past on how complementary medicines were regulated, there was now a pressing need to direct attention to the question of how complementary healthcare practitioners are regulated;
- That, while the present issue is centred around GST matters, the emergence and increasing acceptance of complementary medicine raises a much wider variety of issues related to the changing nature of safety and risk management in relation to complementary medicine;
- That there is a need to make certain medicines accessible to practitioners in a more rational manner but that finding a better way of regulating practitioners needed to be addressed first;
- That there was a need for national systems for accreditation of training and continuing education courses and for establishing core curricula and that this would, in turn, make it possible for the public to identify appropriately trained practitioners;
- That caution needs to be exercised when developing a regulatory model based only on a narrow self-regulatory framework; and
- That some further research needs to be done to identify the full range of regulatory options.

Members responded to these papers including making the following points:

- A number of the practitioner Members expressed disappointment over the lack of consultation with practitioner associations in the development of the funding disbursement process and the uncertainty experienced in understanding the process;
- Members representing Medsafe and APAC provided examples of moves to provide increased access to medicines by certain healthcare practitioners both in Australia and New Zealand;
- Practitioner Members alluded to the need for greater cohesion between and within the various complementary healthcare disciplines and requested that there be greater involvement of Government in the process;

- One practitioner Member expressed concern that the homoeopathy speciality had not been included among the complementary healthcare services eligible for GST exemption;
- The ACCC representative reminded Members of the need to take into account competition principles when professional registration arrangements are being contemplated by professional associations. He underlined the importance of having such arrangements authorised to ensure they were consistent with such principles and that they are in the public interest. He also encouraged Members to read the article in the February edition of the *ACCC Journal* prepared by the ACCC which addressed these and related issues within the context of the health sector. The Chair agreed that the article be forwarded to Members with the Meeting Summary (see Attachment 2). The Member representing the Australian Medical Association (AMA) expressed concern over the ACCC's approach to the health care sector and that its concept of the public interest did not necessarily reflect an adequate appreciation of public health principles;
- The competency of orthodox medicine practitioners versus complementary medicine practitioners to deliver appropriate medical care and to use complementary medicines was queried, given the differences in length and types of formal training;
- The importance of focussing on uniform healthcare outcomes rather than just on uniform training per se was raised;
- That there were lessons from the journey to professional regulation taken by other professional groups (chiropractors, Traditional Chinese Medicine) and that this process takes considerable time (a brief overview of the development of the registration scheme in Victoria for practitioners of Traditional Chinese Medicine was given by a practitioner Member);
- That with the Government having recognised the importance of the complementary medicines sector and worked on the more obvious issues of regulation and advertising, the effort now needs to be put into the more challenging issue of practitioner regulation (and then of access by practitioners to medicines). The point was made that the practitioner groups must not expect governments to carry the responsibility for this and that they must continue to exert pressure to ensure satisfactory outcomes, including efforts directed at legislative change; and
- That moves to respond to the Government's incentive for uniform practitioner regulation have been complicated by the fact that it was being addressed concomitantly with the GST issue.

Comments from absent Members about practitioner regulation:
From the Chair of CMEC:

- The quality of the paper by Ms Hunter was noted and the need for action in appropriate practitioner regulation was endorsed now that regulation of complementary medicines was essentially settled.

From a practitioner Member:

- Frustration over the lack of consultation was expressed, especially given that the strategy to be followed by the Department was to target the assistance of professional associations and thereby encourage collaboration amongst practitioner groups. A similar level of frustration amongst practitioners in general on this issue was noted.
- The ability and expertise of the complementary healthcare sector to expedite the process of the establishment of a national uniform registration system was noted and greater communication with the Department was required.

Chair's Note:
The uniform practitioner regulation issue is complex and may require a long term strategy to implement which may not be possible in the timeframe associated with the Government's GST incentive initiative. While the Government has recognised complementary medicines by reviewing the regulatory aspects, responsibility for practitioner regulation resides primarily with the States and Territories and the professional associations. There is some disquiet over the Commonwealth's consultation process with practitioners on this matter.

Item 5 International Approaches to the Regulation of Complementary Medicines

Senator Tambling invited Dr Cumming of the TGA to speak to the TGA's paper which provided Members with an overview of the variety of approaches taken by countries around the world to the regulation of complementary medicines. Dr Cumming compared and contrasted the attributes of the Australian system of regulation to other countries by reference to the following aspects of the Australian system:

- Quality – with GMP required on all therapeutic goods – this confers an advantage both domestically and in the export market;
- Safety – with pre-market substance evaluation and then pre-market product assessment based on approved substances or pre-market product evaluation, which deliver the safety assurances consumers want; and
- Efficacy - where sponsors holding evidence can go to market and have the right to make supportable medicinal claims, as opposed to other countries where 'dietary supplements' are regulated as foods and cannot carry medical claims.

Subsequent discussion on this paper by Members included the following issues:

- The level of regulation versus the cost of the regulatory system in Australia. On this point, several Members representing industry pointed to aspects of the Canadian, USA and New Zealand systems which they felt warranted closer examination.
- A consumer Member referred to the fact that, because promotion of complementary medicines was largely on the basis of their therapeutic value, it was reasonably appropriate to provide some assurance to consumers that certain standards are being met;
- A CHC Member commented that despite the level of regulation in Australia, the cost of complementary medicines in Australia was lower than in some other countries where standards were lower;
- One practitioner Member relayed that Australian practitioners, to a large degree, prescribe with confidence knowing that there is GMP behind the process of manufacture of the goods. He further noted the variable quality of complementary medicines in the United States and the high cost of extemporaneously compounded complementary medicines in the United States;

- The Member representing the Department of Industry, Science and Resources (DISR) raised the issue of whether the level of regulation and the standards that produced did, or did not, confer a level of credibility to Australian made complementary medicine products;
- A practitioner Member noted that because of the Australian reputation for quality, Australian manufacturers are now starting to sell product into the United States among other countries;
- A CHC Member commented that with the current regulatory structure, Australian manufacturers have not been as successful as other countries in exporting product;
- A consumer Member commented that low income earners in Australia cannot afford complementary medicine because it is not subsidised like orthodox medicine; and
- It was noted that the AMA recently featured a session on Complementary Medicines at its National conference and was supportive of the current regulatory direction.

Before concluding this item, the Chair invited the Member representing ANZFA to briefly summarise ANZFA's work in regard to 'dietary supplements'. The ANZFA representative explained that products known as dietary supplements in New Zealand are being looked at to determine which ones will remain in a harmonised trans-Tasman food standards code to ensure that there is a harmonized boundary between foods and medicines.

The ANZFA Member also briefly overviewed the ANZFA initiative in regard to health claims where a proposal to allow individually assessed enhanced function claims and reduced risk claims as foods was well advanced.

Comments from absent Members on international approaches to complementary medicines:
The Chair of the CMEC:

- Drew attention to the recent AMA conference, which included a session on complementary medicines, and the establishment of a working party to investigate the evidence base behind complementary medicines.

Chair's Note

The Australian regulatory system sets a high standard for complementary medicines and provides a model similar to those being explored by some other countries. There is concern by some sectors of the industry that the level of regulation in Australia is costly and that the export opportunities which high standards should confer on Australian products have not been fully realised.

Item 6 Progress on Trans-Tasman Regulatory Reform

The Chair invited Mr Peachey of the TGA to provide members with a summary of the process to harmonise the regulatory regimes that apply to the supply of therapeutic goods in Australia and New Zealand.

Mr Peachey indicated that both the Australian and New Zealand Health Ministers have agreed to explore further the prospect of joint trans-Tasman regulatory scheme operated by a single agency. He reported that heads of government had supported a recommendation that further work be done and the New Zealand government has recently agreed 'in principle' to the proposal subject to clarification of some issues.

A number of aspects of the proposal were explained, including:

- that its scope covers all of the functions currently performed by the TGA and Medsafe (NZ);
- that the final agency will have a legal identity in both countries;
- that the agency will be directly accountable to Ministers;
- that the regulatory arrangements will feature a common regulatory review and appeal mechanism;
- that efforts are being made to ensure the separation of broad public health policy from regulatory policy;
- that effort will be put into ensuring that there is shared decision making;
- that the TGA and MedSafe will no longer exist as they are at present and that a new agency with new legislation will take their place;
- new rules of engagement between the jurisdictions will be developed and will include 'opt out' arrangements;
- effort will be made to delegate decision making where possible;
- that if negotiations proceed smoothly, the new agency might be functional within two or three years;
- the agency would operate under the guidance of a Board; and

- there will be separate enabling legislation to establish it and there will be a Treaty covering over the entire set of arrangements.

Mr Peachey summarised by saying that a cost benefit analysis of the proposal which has been done was favourable. He pointed to the advantages in creating a scheme which developed common regulatory outcomes for both countries in terms of freeing up market impediments, lowering compliance costs for industry and effectively creating a single market. Mr Peachey indicated that the process so far included extensive consultations on the proposed arrangements and that they appeared to have been met with general support.

Plans were mentioned to establish a regulators' forum where all the regulators, like the gene technology regulator, the food regulator, the therapeutic goods regulator, would meet from time to time to address issues related to the trans-Tasman arrangements. He also indicated that the small team doing most of the work he had described was funded separately from TGA.

Members' comments on the presentation included:

- concern was expressed by the APAC and AMA Members that every effort be made to ensure a suitable separation of public health policy and regulatory policy and to ensure appropriate stakeholder input into how public health policy is actually proposed to be changed
- a comment from the MedSafe attendee that MedSafe was not attracted to retaining the status quo for dietary supplements in terms of the way they are regulated; and
- concern by a CHC Member over the cost effectiveness of establishing a single joint agency and also over additional compliance costs for the New Zealand industry which at the moment is not part of a cost recovery arrangement. The MedSafe attendee confirmed that full cost recovery is already proposed for New Zealand independently of any joint agency arrangements.

Comments from absent Members about a joint agency:
A Member representing ASMI made the following comments:

- The need for industry representation on the board of the joint agency was strongly expressed.
- The impact of harmonisation on scheduling was noted. If scheduling is not harmonized nationally and trans-Tasman then this means different labels and patient information depending on the level of professional intervention.

- The absence of advertising of medicines in trans-Tasman harmonization was queried. It was felt that advertising regulations should be harmonized, at least for non-prescription medicines.

The Chair of CMEC noted the progress being made in the area of trans-Tasman harmonisation and endorsed the proposal of joint regulation as a cost-effective solution.

Chair's Note
Members noted details of the proposal to establish a joint trans-Tasman regulatory arrangement for therapeutic goods. Members foreshadowed potential issues related to the separation of public health policy from regulatory policy and to the costs of establishing and operating such a single joint agency and the accompanying legislative and administrative arrangements.

Item 7 Demonstration of the New Electronic Lodgement Facility

There was insufficient time for this item so Senator Tambling offered Members the opportunity to preview the new electronic lodgement facility at the conclusion of the meeting.

Item 8 Members' Requests and Inputs

The Complementary Medicines Industry In Australia

Dr Cumming of the TGA was invited by the Chair to provide a brief overview of the TGA's paper which examined the current state of play of the complementary medicines industry in Australia from a market performance point of view. The paper also provided some limited comparison with the complementary medicine market in Canada and USA.

Dr Cumming alluded to the difficulty in obtaining detailed market data on complementary medicines in Australia and the fact that no comprehensive and reliable analysis had been attempted since 1993. She overviewed current sales trends by both product and by outlet and also the emerging trends in the market indicative of consumer demand for particular products. The available data indicated a downturn in sales over the past year of around 12 – 27%, but Dr Cumming noted that this had not been reflected in applications to the TGA for new Listable products which had remained reasonably constant. She mentioned

a decline in sales of dietary supplements in the USA which commentators had attributed to a lack of 'blockbuster' products and to a downturn in consumer confidence in the quality of some products.

Members' comments confirmed the estimate of the extent of the downturn referred to by Dr Cumming and implicated the GST as a significant contributing factor. Mr Cesarin commented that the GST had not had as big an impact on the OTC sector as it has on the complimentary medicine sector and the New Zealand industry observer indicated this trend had not been seen at all in New Zealand.

The former chair of APAC commented that the difficulty in obtaining reliable and current data illustrates the real dilemma with not having a comprehensive drug utilisation data base. He put the view that this was impeding policy development and evaluation. A CHC Member responded that data was available but that there was a fee involved in obtaining it. However, more data than was available for this paper was held by the industry and could be made available in the future.

Comments from absent Members about Complementary Medicines Industry in Australia:
Regarding page 10 of the paper, an ASMI Member questioned how the import/export portion of the market would adapt to the new regulatory arrangements and noted that US sourced product was unlikely to comply with Canadian requirements.

Chair's Note
It has been reported that there has been a downturn in the sales of complementary medicines in Australia. Several reasons were advanced, including the suggestion that the downturn is, in part, attributable to the GST.

Report on the Complementary Healthcare Summit

Senator Tambling invited Mr Blackmore of the CHC to report on the Complementary Healthcare Summit hosted by the CHC in February/March 2001.

A number of highlights of the Summit were raised, including the presentation from Dr Kerryn Phelps of the AMA and the fact that the Summit had

contributed to 'bridge building' between orthodox and complementary medicine. He also alluded to the Parliamentary representatives who contributed and thanked Senator Tambling for his attendance and interest in the proceedings of the Summit. He mentioned the attendance by a number of key overseas industry and regulatory representatives and that, given the success of the event, the Summit was likely to be repeated next year.

Chair's Note
Organisers of the Complementary Healthcare Summit were appreciative of the Parliamentary attendance and interest in the event, particularly that of Senator Tambling.

Papers Submitted by Mr Blackmore of the CHC

Four short papers were submitted for the agenda on the following:
1. The viability of the complementary medicines industry;
2. International competitiveness;
3. Internet advertising; and
4. The regulatory model for complementary medicines.

The small business concerns of the complementary medicines industry were raised, including the cost of compliance and the proposed increase in TGA fees. He alluded to the draft report of the Productivity Commission which he said supported the industry's assertion that it should not be paying 100% cost recovery although he expressed concern over the proposal to resolve this over a five year period.

Mr Blackmore explained that his paper dealing with international competitiveness related mainly to issues to do with export. Senator Tambling noted a comment in Mr Blackmore's paper that 'there is a great export potential for Australian complementary healthcare products due to the international recognition of the high quality standards and credibility of the Australian therapeutic goods and to Australia's clean and green image'.

Mr Blackmore conceded that there had been some significant gains in the new export arrangements, but there was still a concern in the industry that there remained unnecessary regulatory obstacles to the export of complementary medicine products. He indicated his concern at the need to place Australian warning statements on these products. In response Mr Cesarin commented that

the approach taken to retaining warning statements on products for export was based on the view that such statements were necessary for the safe and appropriate use of a product. He indicated however that the TGA had acknowledged the need to review this practice in view of both the recent exports review (reported to the previous meeting of the Forum) and in view of the fact that the issue of 'prior informed consent' may also represent a barrier to facilitating exports. Senator Tambling referred to his very recent visit to a major supplier of both pharmaceutical products and complementary medicines indicating that this company also considered the issue of exports was one in which they had a significant interest.

Nothing further was added to the Forum's earlier discussions on Internet advertising other than to allude to the CHC's Internet Guideline for Complementary Healthcare Products (included in the agenda papers) and that this document had the support of the TGA.

In addressing his paper on a Regulatory Model for Complementary Healthcare Products, Mr Blackmore reiterated a preference for a separate, third category for complementary medicines and that he wished Members to note that position. In response, the former Chair of APAC commented that some of the content and examples used were, in his view, not conducive to co-operative relationships necessary for the successful operation of the co-regulatory approach espoused for the sector in its working with Government.

Chair's Note
That there are ongoing concerns by the Complementary Healthcare Council over Costs of compliance and increasing fees;
Export arrangements for complementary medicines; and
The current regulatory model for complementary medicines.

8.4 Invited input from Professor Lin

Senator Tambling invited Professor Lin to make a concluding comment given that he had, earlier in the meeting, provided Members with an overview of the registration scheme for practitioners of Traditional Chinese Medicine in Victoria.

It was noted that, at the international level, there had been rapid growth in the market for Traditional Chinese Medicine products. His view was that Australia was well positioned to take advantage of this trend by growing and processing quality Chinese herbs for export. It was further commented that the positive reputation enjoyed by Australian therapeutic goods by virtue of Australia's high regulatory standards and reliance on GMP meant that there were real opportunities for industry in this area. He intimated that the Government agencies in China were open to explore this area with interested members of the Australian industry and Senator Tambling invited Members to contact the Department of Industry Science and Resources should there be interest among all groups represented at the Forum in exploring this opportunity.

Item 9 Other Business

Mr McLeod, a practitioner Member, referred to some legislation currently before the South Australian Parliament to enable complaints to be made about alternative health practitioners, along with other practitioners. He indicated his concern that there was no provision to have a complementary therapist on the complaints Panel.

Mr McLeod also advised of a recent mail out to all natural therapists concerning a scheme offering to 'accredit' their practices for a fee. He indicated that the various state governments and the ACCC had been written to in regard to this scheme and he advised Forum Members to both make their constituencies aware of it and also to let their members know that they do not need to pay this money to be accredited.

In closing the meeting, Senator Tambling expressed his appreciation of Members' contributions to the work of the Forum over the two years it had been meeting. With the likelihood of Federal elections in the second half of the year, Senator Tambling encouraged Members to take issues of concern separately to the various political parties as considered necessary.

Senator Tambling indicated that it was unlikely that there would be a further meeting of the Forum before the election and left open the possibility of a meeting early next year.

ATTACHMENT 1

Forum Members and Guests in Attendance – Fifth Meeting

Senator, the Hon Grant Tambling (Chair)

Mr Marcus Blackmore	Complementary Healthcare Council of Australia
Mr Les Dell	Marketing and advertising
Ms Janne Graham	Australian Pharmaceutical Advisory Council
Ms Anne Holmes	Department of Industry, Science and Resources
Ms Assunta Hunter	Practitioner
Mr Janine Lewis	Australia New Zealand Food Authority
Prof Chiang Lin	Practitioner
Mr Justin Lovelock	Practitioner
Dr Carmel Martin	Australian Medical Association
Mr David McLeod	Practitioner
Mr Euan Murdoch	Complementary Healthcare Council of Australia
Ms Lila Notley	Consumer representative
Mr Graham Peachey	Therapeutic Goods Administration
Prof Avni Sali	Research
Mr Robert Scott	Practitioner
Dr Iggy Soosay	Practitioner
Dr Derek Weir	Consumer representative

Invited Observers

Mr Bill Bracks	Industry, New Zealand
Mr Ziv Gavrilovich	Australian Competition and Consumer Commission
Ms Penny Lovibond	National Office of Overseas Skills Recognition
Dr Susan Martindale	MedSafe, New Zealand
Prof Lloyd Sansom	Pharmacy

Unable to attend (due to fog conditions in Canberra)

Dr Mark Bowden	Australian Self Medication Industry
Mr David Fitts	Practitioner
Dr Cathy Mead	State/ Territory representative
Prof David Roberts	Chair, Complementary Medicines Evaluation Committee
Ms Juliet Seifert	Australian Self Medication Industry

Apologies

Dr Rosanna Capolingua-Host	AMA (Dr Martin as alternate)
Mr Kevin Darke	ASMI (Dr Bowden as alternate)
Mr Peter Liehne	Australia New Zealand Food Authority (Ms Lewis as alternate)

Mr Craig Pennifold	Dept Industry, Science & Resources (Ms Holmes as alternate)
Mr Terry Slater	Therapeutic Goods Administration (Mr Peachey as alternate)

Department of Health and Aged Care.

Participants: Dr Fiona Cumming, Mr Pio Cesarin, TGA
Mr Stanford Harrison, Workforce Regulation Section.

Observers: Dr John Hall, TGA.
Ms Nola Witchard, Health Access and Financing Division.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2,3 & 5 June 2003

Question: E03-219

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: PREVENTIVE HEALTH AND TOBACCO COSTS

Senator McLucas asked:

Has any allocation yet been made for the National Tobacco Campaign in 2003-04 or in subsequent years? How much has been allocated?

Answer:

A decision is yet to be made about the funding allocation for the National Tobacco Campaign in 2003-04 or in subsequent years.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-220

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: EYE HEALTH

Written Question on Notice.

Senator McLucas asked:

With respect to the answer to Question E03-147 (Feb 2003):

Has the Government yet responded to the National Eye Health Strategy?

Answer:

Yes

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-221

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: IMMUNISATION

Written Question on Notice

Senator McLucas asked:

With respect to the ATAGI recommended changes to the Australian Standard Vaccination Schedule:

(a) If these changes are to be funded, and how and when will the decision to fund these new vaccines and vaccine combinations be made?

(b) If these changes are recommended but not funded, what will be the estimated cost to a family to vaccinate a child according to the new recommendations?

(c) Will information be made available to heath care professionals and the public to address confusion and public confidence in the immunisation program that may arise if the funded program is different to that recommended by ATAGI and endorsed by the NH&MRC?

Answer:

(a) The Australian Technical Advisory Group on Immunisation (ATAGI) recommendations are with Government for consideration of future funding. The timeframe for this has not yet been established.

(b) The estimated cost to a family to vaccinate one child according to the recommended Australian Technical Advisory Group on Immunisation (ATAGI) schedule is difficult to calculate as vaccine prices vary depending on the wholesale price and the price that individual pharmacies charge.

(c) The Department will produce a comprehensive package of information and education materials in consultation with the National Immunisation Committee (NIC). This material will be provided and distributed to immunisation providers at the time when the National Health and Medical Research Council endorses changes to the Australian Standard Vaccination Schedule, and when changes are made to the National Immunisation Program (NIP).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-109

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: IMMUNISATION

Hansard Page: CA 111-2

Senator Crossin asked:

Are you able to provide, State by State, immunisation rates for Indigenous children?

Answer:

The following table contains immunisation coverage data for children aged 12 months to less than 15 months (age calculated at 31 December 2002) that are fully immunised for Diphtheria, Tetanus, Pertussis, Polio, Haemophilus influenzae type b and Hepatitis B and who are identified as Aboriginal or Torres Strait Islander on the Australian Childhood Immunisation Register (Aboriginal and Torres Strait Islander indicator is reported by encounter or Medicare update).

State	% Fully Immunised
ACT*	n/a
NSW	86.43
VIC	83.74
QLD	85.71
SA	82.86
WA	84.74
TAS	86.21
NT	90.87
AUS	**86.37**

*To ensure that individuals are not able to be identified, this data is not available for public release as the absolute numbers of Indigenous children registered on the ACIR in the ACT small.

Data Source: Australian Childhood Immunisation Register

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-111

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: IMMUNISATION

Hansard Page: CA 215

Senator Allison asked:

(a) Is there a list of submissions to the eighth draft available? And are those submissions available?
(b) Are they on the web site?

Answer:

(a) The Department has compiled a list of submissions received during the public consultation period (October to November 2002) for the draft 8th Edition of the Australian Immunisation Handbook.

The list of submissions is available, however the submissions are not available. Submissions were made in confidence for the purposes of reviewing the draft 8th Edition of the Australian Immunisation Handbook.

(b) No.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-113

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: IMMUNISATION

Hansard Page: CA 225

Senator McLucas asked:

Can I ask on notice that you provide me with a time line that shows when each of these vaccinations was, shall we say, processed through the system, including varicella, diphtheria, tetanus and pertussis for adolescents, childhood pneumococcal conjugate vaccination and meningococcal C?

Answer:

The time line is as follows:

ATAGI Activity	**Varicella**	**Adolescent dTpa**	**Childhood pneumococcal**	**Meningococcal C**
Included in work program	April 2000	April 2000	April 2000	April 2000
Working party established	June 2000	July 2001	June 2000	August 2001
Working Party report complete	January 2002	June 2002	June 2002	June 2002
ASVS recs finalised	Nov 2001: 10 to13yr July 2002: 18mo	July 2002	July 2002	July 2002
Public consult on ASVS recs	Sep-Oct 2001 Oct-Nov 2002 (with ASVS)	Oct-Nov 2002 (with ASVS)	Oct-Nov 2002 (with ASVS)	Oct-Nov 2002 (separate and with ASVS)
ASVS recs endorsed by HAC	May 2003	May 2003	May 2003	December 2002
ASVS recs endorsed by Council	Not yet finalised	Not yet finalised	Not yet finalised	January 2003

ATAGI Activity	Varicella	Adolescent dTpa	Childhood pneumococcal	Meningococcal C
NIP funding recs developed	July 2002	July 2002	July 2002	July 2002
NIP funding recs to Govt	November 2002	November 2002	November 2002	August 2002

Key to table

ATAGI – Australian Technical Advisory Group on Immunisation
ASVS – Australian Standard Vaccination Schedule
HAC – Health Advisory Committee of Council
Council – National Health and Medical Research Council
Govt – Federal Government
recs – recommendations
consult – consultation

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-116

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: MELBOURNE GRAND PRIX - HANDOUT OF FREE CIGARETTES

Written Question on Notice

Senator Allison asked:
Was there a cigarette tent or marquee at the Melbourne Grand Prix handing out free cigarettes?

Answer:
There is no evidence to suggest that free cigarettes were being handed out at the Melbourne Grand Prix.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-222

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: GRAND PRIX ADVERTISING

Written Question on Notice

Senator McLucas asked:

The Minister for Health and Ageing was reported as confirming that she wrote to her European counterparts ahead of a December 2002 meeting, asking them to reject their plans to bring forward the ban on Formula One tobacco advertising to 2005.

(a) Did the Minister receive a request to write such a letter? If so, who made the request/s and when, and the rationale for the request/s.

(b) Did other members of the Cabinet also write letters to lobby the EC on this issue.

Answer:

(a) Yes. The request was made by the Federation Internationale d'Automobile (FIA) in late November 2002. The rationale for the request was to ensure a consistent date for the world-wide phase out of tobacco sponsorship by 1 October 2006.

(b) I am not aware of other members of the Cabinet writing letters to the EC on this issue.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-112

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: MENINGOCOCCAL C AND PNEUMOCOCCAL INFECTION

Hansard Page: CA 222

Senator Allison asked:

(a) Is it correct that Western Australia has at present time no cases of Meningococcal C Infection?

(b) What is the rate of pneumococcal infection in Western Australia?

Answer:

(a) No. There were 4 cases of meningococcal C disease reported in Western Australia in 2002 and 3 cases of meningococcal C disease reported so far in 2003 (as at 18 June 2003).

(b) The notification rate for invasive pneumococcal disease in Western Australia in 2001 was 10.8 per 100,000 for all ages (Roche P, Krause V. *Invasive pneumococcal disease in Australia, 2001*. Communicable Diseases Intelligence 2002;26.). Data for 2002 is not yet available.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-115

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: HEALTH WARNINGS ADVISORY GROUP

Hansard Page: CA 232

Senator Allison asked:

When was the date of the first meeting of that advisory group?

Answer:

The first meeting of the advisory group was a teleconference held on 3 November 2000.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-117

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: REVIEW DETAILS

Hansard Page: CA 245

Senator Moore asked:

(a) I am particularly interested in the evaluation of the National Q Fever Management Program and how it is going. In the budget paper it says. 'Whilst the program is going for another year or so, it is now being evaluated midstream, and I would like to get information on that as it goes through.

(b) The National injury prevention plan – I would like some information on this.

Answer:

(a) As stated on page 93 of the Health and Ageing Portfolio Budget Statements 2003-04, it is anticipated that the evaluation of the National Q Fever Management Program will commence towards the end of 2003.

(b) The *National Injury Prevention Plan: Priorities for 2001-2003* (the Plan*)* was endorsed by Australian Health Ministers in August 2001. The Plan represents a broad strategic framework for national activity in the areas of high priority in injury prevention for health portfolios. The four priority areas for action are falls in older people, falls in children, drowning and poisoning in children. These were chosen on the basis of the following criteria: evidence of injury burden and potential gains, effectiveness, cost benefit and acceptability of a range of interventions, and a clear and actionable role for the health sector.

The Plan is being implemented by the Strategic Injury Prevention Partnership (SIPP), a sub-committee of the National Public Health Partnership. SIPP is an inter-jurisdictional committee made up of the Injury Program Managers from the Commonwealth and States and Territories, a representative of the Consumer Affairs Division of the Commonwealth Department of Treasury, the Australian Institute of Health and Welfare, and the Australian Injury Prevention Network.

An Evaluation of the Plan is planned for 2003 – 04. This review will address the extent to which the aims of the Plan have been achieved. These aims are to:

1. Focus national efforts on four key injury prevention priority areas.
2. Strengthen national infrastructure.
3. Promote evidence-based, sustainable interventions.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-118

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: BOWEL CANCER SCREENING PILOT

Written Question on Notice

Senator Moore asked:

The evaluation of the Bowel Screening Pilot – How is this going and what are the updates on it?

Answer:

All three Bowel Cancer Screening Pilot sites (Mackay, Melbourne and Adelaide) are now operational. The Pilot commenced with the launch of Mackay in November 2002 and will be completed mid 2004. A monitoring and evaluation plan for the Pilot has been developed under the auspices of the Monitoring and Evaluation Task Group (one of the expert advisory groups guiding the Pilot).

A Knowledge, Attitudes and Practices Survey has been undertaken to establish a baseline for subsequent evaluation of the extent to which the Pilot has impacted on participants and the general population. Another survey will be conducted at the end of the Pilot.

The major evaluation of the Pilot will be undertaken at the end of the project when the full range of data is available. The evaluation will include studies by the Australian Institute of Health and Welfare on all quantitative aspects of the Pilot and a cost effectiveness study by the Medical Technology Advisory Group as well as qualitative studies.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-215

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: NATIONAL FALLS PREVENTION FOR OLDER PEOPLE INITIATIVE

Hansard Page: CA 245

Senator Moore asked:

National Falls Prevention for Older People Initiative (Portfolio Budget Statements 2003 – 2004, Page 93). What is the status of the initiative and the proposed review?

Answer:

$6.6 million was allocated in the 1999/2000 Federal Budget to the National Falls Prevention for Older People Initiative. To date the Initiative has funded five Demonstration Projects, a range of Community Development and Research Projects and a number of publications.

To progress the Review, a request for tender is currently being developed and should be finalised by the end of July 2003. The actual review process will be undertaken over 10 weeks and the report will be due at the end of October 2003.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-214

OUTCOME 1: POPULATION HEALTH & SAFETY

Topic: POPULATION ESTIMATES

Senator McLucas asked:

What ABS series is used when using population estimates and how is it broken down into SLAs and RRMAs?

Answer:

The ABS series used for population estimates is the Estimated Resident Population (ERP) series. These population estimates have been adopted as the official population series. The estimates are updated quarterly at the State level and annually at the Statistical Local Area (SLA) and Local Government Area (LGA) levels and released under ABS catalogue number 3101.0 "Australian Demographic Statistics".

RRMA uses populations and SLA boundaries from the 1991 Census to categorise SLAs according to their remoteness.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-268

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: RECOMMENDED VACCINE PROGRAMS

Hansard Page: CA 220-2

Senator Allison asked:

What best-case scenario vaccines are currently not on the list.

Answer:

This question was answered at the Senate Community Affairs Legislation Committee meeting on 3 June 2003 (refer to pages CA 220-221 of the Proof Committee Hansard of 3 June 2003). Further clarification is provided below.

The Australian Technical Advisory Group on Immunisation (ATAGI) has recommended several changes to the Australian Standard Vaccination Schedule, which are scheduled for presentation to the National Health and Medical Research Council in September for approval.

They are:

- Pneumococcal polysaccharide vaccination for people 65 years and older
- Removal of the 18 month DTPa booster dose in the childhood schedule and the substitution of ADT with adult formulated dTpa at 15-17 years.
- Introduction of varicella vaccination at 18 months for all and at 10-13 years for children with no varicella (chickenpox) history.
- Expansion of the existing high risk program for childhood pneumococcal disease to include vaccination for all infants at 2, 4 and 6 months of age.
- Replacement of OPV with IPV-containing combination vaccines at 2, 4, 6 months and 4 years of age.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-121

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: REVIEW OF TGA AUDIT AND LICENSING OF GOOD MANUFACTURING PRACTICE

Hansard Page: CA164, CA165, CA207

Senator Forshaw asked:

(a) Is Diagnosis Pty Ltd Mr Corcoran's own consultancy company or does he work for this company? What is his relationship with Diagnosis Pty Ltd?

(b) Did the contract with Mr Corcoran for $20,000 include a provision whereby Mr Corcoran or his company could obtain a greater amount by agreement? Can you provide the Committee with a copy of the contract?

(c) When was the tender called?

(d) How long was Mr Corcoran previously employed by the Department of Health and Ageing, and when did he leave the Department?

Answer:

(a) Diagnosis Pty Ltd is not Mr Corcoran's own consulting company. He was an associate consultant of the company at the time he undertook the review of the TGA Audit and Licencing of Good Manufacturing Pracice.

(b) The contract with Mr Corcoran was for $29,700. The $20,000 cited in the Department of Health and Ageing Annual Report 2001-02 was the amount paid in that financial year. He was paid the remaining $9,700 in 2002-03. There was no provision that he could be paid more by agreement. A copy of the contract is attached.

(c) The tender was called in late August 2001.

(d) Mr Corcoran was employed by the Department of Health and Community Services in July 1989 and he resigned from the Department of Health and Ageing on 15 August 2001.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-122
Revised

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: UNSCHEDULED AUDITS OF MANUFACTURERS

Hansard Page: CA165

Senator Forshaw asked:

Are you able to provide the Committee with a list of those manufacturers that have been audited through unscheduled audits in 2001-02 and 2002-03?

Answer:

<u>2001-2002</u>	
Soul Pattinson Manufacturing, NSW	11/12/01
Afford Packaging, Mayfield, NSW	6/6/02
<u>2002-2003</u>	
CSL Bioplasma, Broadmeadows, VIC	1-3/7/02
CSL Bioplasma, Broadmeadows, VIC	21-22/1/03
Pan Pharmaceuticals, Moorebank, NSW	30-31/1/03
Pan Pharmaceuticals, Moorebank, NSW	24-25/2/03
Gosford Blood Bank, NSW	17/3/03
Southbank Blood Bank, VIC	19/3/03
Pan Pharmaceuticals, Moorebank, NSW	7-14/4/03
CSL Bioplasma, Broadmeadows, VIC	5-7/5/03
Sigma, Clayton, VIC	8-9/5/03
Alphapharm, Carole Park, QLD	16/5/03
Lipa, Minto, NSW	11-13/6/03

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 June 2003

Question: E03-123

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: TGA LABORATORIES STAFF – TESTING PROGRAM

Hansard Page: CA172, CA174

Senator Forshaw asked:

(a) On the TGA's web site there is a statement which says:

"*TGAL has 125 staff consisting of scientists, engineers, technicians and support staff. Approximately one-half of the staff are graduates in science, with over one-third of these holding doctorates*"

Can you give us a break-up of the functions of the staff in terms of numbers out of that 125, for instance, how many are involved in actual testing?

(b) What is the budget for product testing? Could you provide the Committee with a break-up of the budget, which shows such things as employee wages, costs, equipment depreciation, etc.?

(c) On average how many products would an individual member of the staff test in a year?

Answer:

(a) The website entry to which the Senator referred is not entirely correct and it has been since updated. The TGA Laboratories Branch has a staff complement of around 100, of whom around 14 are virtually fully engaged in pre market evaluation and 10 in management and administration. The remaining staff (76) work in both the pre and post market areas. Their activities can include provision of specialist advice to the pre market evaluation areas and to the GMP inspection service, as well as undertaking pre and post market testing related work.

(b) The current budget (2002-3) for the 76 staff that may be involved in product testing is estimated at $11 million.

The product testing budget can be further itemised as follows:

Salaries	$5.6m	
Suppliers	$0.7m	
Business support	$4.7m	(This includes equipment depreciation of about $600,000 and rent $2.5m; IT resources, accreditation and quality assurance activities; equipment and building maintenance)

(c) In order to answer the question how many products would an individual staff member test in a year, it is necessary to explain what happens in the laboratories. There is a range of activities undertaken by staff in relation to a broad range of products. Most staff are highly specialised in their skills base (e.g. in analytical chemistry, microbiology, immunobiology or biomaterials) and they therefore work only in their particular area of expertise. Products tested can include complex medical devices such as pacemakers, or more simply designed goods, such as condoms, for example. Medicine examples might range from a high technology vaccine product or recombinant growth replacement factor, to a simple tablet of an alternative brand to dissolvable aspirin. Just as the products are diverse, so the range of testing activities to assess them are diverse and some products may require multiple types of tests. At the high technology end of the scale there may be considerable time required to work with international collaborators to develop and then regularly set up and perform a test on a single complex product. At the other end of the scale, the laboratories can take advantage of automated testing equipment to rapidly analyse multiple specimens. It is therefore not possible to say how many products an individual staff member would test. Some staff members do many direct tests, some develop and perform complex tests and some support and assist those other staff.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 June 2003

Question: E03-271

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: AUSTRALIAN REGULATORY GUIDELINES FOR COMPLEMENTARY MEDICINES

Hansard Page: CA260

Senator Nettle asked:

Is it possible to get a list of the eight people who are involved in the first stage of the process of stakeholder consultation that is taking place in the development of the Guidelines?

Answer:

The 8 members on the TGA/Industry Consultation Group developing the Draft Australian Regulatory Guidelines for Complementary Medicines (ARGCM) for stakeholder consultation are:

1. Ms Val Johanson
   Executive Director
   Complementary Healthcare Council of Australia (CHC)

2. Mr Allan Crosthwaite
   Technical Director
   Complementary Healthcare Council of Australia (CHC)

3. Mr Jonathan Breach
   Regulatory & Technical Manager
   Australian Self-Medication Industry (ASMI)

4. Ms Sue Akeroyd
   Director
   Sue Akeroyd & Associates

5. Dr John Miller
   Divisional Regulatory & Industry Affairs Manager
   Mayne Consumer Health Ltd

6. Mr Michael Gepp
   Regulatory & Technical Affairs Manager - Complementary Medicines
   Herron Pharmaceuticals Pty Ltd

7. Ms Lynda McFarlane
   Regulatory Affairs Manager
   Blackmores Ltd

8. Dr Darryl Reed
   Medical Marketing Manager
   Roche Consumer Health Pty Ltd

Two further industry representatives were involved in the process in its earlier stages but have subsequently retired. They were:

1. Dr Richard Oppenheim
   R.P. Scherer

2. Dr Helena Dickenson
   Director
   Regulatory Concepts Pty Ltd

Dr Dickenson retired due to other commitments, and Dr Oppenheim because of a job change.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-126
Revised

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: RECALL OF PRODUCTS MANUFACTURED BY PAN PHARMACEUTICALS PTY LTD

Hansard Page: CA194, CA195, CA200, CA205, CA206

Senator Forshaw asked:

(a) Can you provide the Committee with the dates and numbers of products advertised in the recall of Pan Pharmaceuticals Pty Ltd manufactured products?

(b) Can you provide the Committee with a table of when the audits occurred and whether they were scheduled or unscheduled?

(c) Can you provide the Committee with a list of the 12 deficiencies identified in the audit of April 2002?

(d) Other than the Health Canada GMP auditor, have any other persons on TGA run training courses on auditing and testing been taken through Pan?

(e) Once finalised, can the Committee be provided with the findings of the Adverse Drug Reactions Advisory Committee in relation to Pan products that have had adverse drug reactions reports made in relation to them since the recall?

Answer:

(a)

- 29 April 2003 – 219 recalled products advertised in majority of national daily metropolitan papers;
- 30 April – advertisements appeared in remaining metropolitan papers;
- 1 May 2003 – list of additional 449 recalled products advertised in metropolitan papers;
- 2 May 2003 – lists of the 219 plus 449 products advertised in more than 360 regional papers;
- 2 May 2003 – list of additional 700 products advertised in metropolitan papers;

- 6 May 2003 – list of additional 386 recalled products, plus 40 products cancelled from the Australian Register of Therapeutic Goods, advertised in metropolitan papers; and
- 6 May 2003 – list of 700 plus 426 products advertised in regional papers.

Please note that advertisements appearing after this time were the responsibility of individual sponsors.

(b) Refer to Attachment 1.

(c) The 12 deficiencies identified at the 30 April – 1 May 2002 audit were:
- No Standard Operating Procedure (SOP) for investigations of out of specification laboratory results.
- No documented acceptance limits for duplicate results derived from routine analysis of a sample.
- No SOP relating to unanticipated deviations.
- The SOP for environmental monitoring did not provide for corrective/preventative actions in the event of discordant observations.
- Documentation Management procedures did not include a verifiable change over and recovery of superseded documents.
- Instances of inadequate recording.
- Instances of inadequate referencing.
- A source reference standard was not recorded when conducting an identification test.
- Refractometer was unsuitable for refractive index measurements.
- Status labels on processing equipment and rooms did not always appear to be used as intended.
- The label storeroom was not locked to prevent unauthorised access.
- No SOP for the training of laboratory staff.

Following this audit, the company rectified the deficiencies identified.

(d) No.

(e) Yes. See Attachment 2.

Attachment 1

GMP Audits of Pan Laboratories Pty Ltd and Pan Pharmaceuticals Limited from 1992

Audit Date	Company Name	Site	Scheduled
6-7/2/92	Pan Laboratories Pty Ltd	Villawood	Yes
21/9/92	Pan Laboratories Pty Ltd	Villawood	No
9-10/2/93	Pan Laboratories Pty Ltd	Villawood	Yes
15/2/94	Pan Laboratories Pty Ltd	Villawood	Yes
16-17/2/94	Pan Laboratories Pty Ltd	Villawood	No
14-15/2/95	Pan Laboratories Pty Ltd	Villawood	Yes
21-23/4/97	Pan Laboratories Pty Ltd	Villawood	Yes
16-18/11/98	Pan Laboratories Pty Ltd	Villawood	Yes
22-23/1/01	Pan Pharmaceuticals Limited	Villawood	Yes
12/12/01	Pan Pharmaceuticals Limited	Moorebank	Yes
30/4-1/5/02	Pan Pharmaceuticals Limited	Moorebank	Yes
30-31/1/03	Pan Pharmaceuticals Limited	Moorebank	No
24-25/2/03	Pan Pharmaceuticals Limited	Moorebank	No
7-14/4/03	Pan Pharmaceuticals Limited	Moorebank	No

Australian Government

Department of Health and Ageing

ADRAC report in relation to adverse reactions reported since 28 April 2003 to products manufactured by Pan Pharmaceuticals Ltd

August 2003

THERAPEUTIC GOODS ADMINISTRATION

Introduction

This report contains the findings of the Adverse Drug Reactions Advisory Committee (ADRAC) in relation to Pan products that have had adverse drug reaction reports made in relation to them since the recall.

The report consists of a tabulated listing of all reports to ADRAC implicating at least one Pan-manufactured product (Table 1). The products manufactured by Pan Pharmaceuticals are indicated in the table by putting the AUST L number in bold. Following the table are comments made by ADRAC on individual reports. The fact that ADRAC has commented on an individual report should not be taken to imply that ADRAC's feeling was that there was a causative link between the medicine(s) and the reaction(s) in any particular report.

This report does not contain the reports involving Travacalm products.

The ADRAC report is sent regularly to the Complementary Medicines Evaluation Committee, for that Committee's further discussion. Each individual reaction report is also discussed with the TGA's Office of Complementary Medicines, who may decide further action, perhaps including laboratory testing of products, to be necessary.

Table 1 – Reports implicating Pan-manufactured products since 28 April 2003

Report #	Suspected Medicine(s)	AUST L # +/- Batch #	Reaction(s)	Active ingredients
185291	Cenovis Men's multivitamin	**70825 B206034**	headache, dizziness, lethargy, constipation	Thiamine, Riboflavine, Pyridoxine, Nicotinamide Ascorbic acid, Manganese sulfate Calcium HPO_4, Betacarotene Cyanocobalamin, Cholecalciferol dl-alpha-Tocopheryl, Calcium pantothenate, Biotin, Folic acid Potassium sulfate, Zinc sulfate, *Eleutherococcus senticosus Serenoa serrulata*
185338	Cenovis valerian	**79856**	manic episode	*Valeriana officinalis*
185378	Co enzyme Q10	**70722 B81781**	AF, VT	Fish oil Ubidecarenone
185464	Nature's Own Omega 3	**82228 B206350**	palpitations, hypotension	Fish oil
185465	Nature's Own travel well	**45447 B00080**	sweating, nausea, disorientation	*Zingiber officinale,* Peppermint Oil, Cinnamon Bark Oil *Matricaria recutita*
185466	Nature's Own Omega 3	**82228 B206419**	stomach cramps	Fish oil
185482	Nature's Own travel well	**45447**	bleeding, miscarriage	*Zingiber officinale,* Peppermint Oil, Cinnamon Bark Oil *Matricaria recutita*
185520	Nature's Own Insomnia; Glucosamine; Lemsip	28566 **69947**	hepatitis	*Valeriana officinalis, Humulus lupulus, Scutellaria lateriflora Passiflora incarnata,* Calcium HPO_4, Magnesium phosphate*;* Glucosamine sulfate, *Vaccinium oxycoccus, Paullinia cupana Piper methysticum, Salix alba*
185521	Nature's Own Omega 3	**82228**	hallucinations	Fish oil
185540	Nature's Own Zinc lozenge	**28191 B203426**	hallucinations, vomiting	Ascorbic acid Zinc gluconate
185560	Bio-organics Nerve Relaxer	**30710**	amnesia, fatigue	*Valeriana officinalis Passiflora incarnata*
185597	Bio-organics Arthri-eze	**66228**	light-headed, disorientation	Celery Seed Oil, Evening Primrose Oil, Fish oil, d-alpha-Tocopherol, Cod-liver oil, *Salix alba, Harpagophytum procumbens*
185620	Nature's Own Anti-Stress	**28305**	fatigue, lethargy, anger	Ascorbic acid, Lecithin, Wheatgerm Oil, dl-Methionine, Thiamine hydrochloride, Riboflavine, Calcium pantothenate, Pyridoxine hydrochloride, Choline bitartrate, Aminobenzoic acid, Inositol, Cyanocobalamin, Folic acid, Biotin, Nicotinamide
185683	Bio-organics cranberry	**49054**	itchy rash	*Vaccinium oxycoccus* Ascorbic acid

Report #	Suspected Medicine(s)	AUST L # +/- Batch #	Reaction(s)	Active ingredients
185691	Natural Nutrition Multi-vitamin	**80098**	amnesia, hallucinations	Betacarotene, Retinyl palmitate Thiamine hydrochloride, Riboflavin, Nicotinamide, Nicotinic acid, Calcium pantothenate Pyridoxine hydrochloride, Cyanocobalamin, Calcium ascorbate, Colecalciferol, d-alpha-Tocopheryl acid succinate, Biotin, Choline bitartrate, Folic acid, Inositol, Calcium citrate hydrate, Chromium picolinate, Cupric sulfate pentahydrate, Potassium iodide, Ferrous fumarate, Magnesium oxide, Manganese amino acid chelate, Selenomethionine, Zinc sulfate monohydrate, *Ginkgo biloba, Silybum marianum, Bacopa monnieri, Vaccinium myrtillus, Vaccinium oxycoccus, Vitis vinifera, Cucurbita pepo, Equisetum arvense, Fucus vesiculosus, Carica papaya,* Bioflavonoids, Bromelains, Fish oil – natural, Glucosamine sulfate-potassium chloride, Glutamine, Lecithin, Taurine
185693	Natural Alternative Digestive Enzyme	**28224**	nausea, lightheadedness, weakness	Pancreatin, Papain, Pepsin Bromelains, Peppermint Oil, Whey powder
185724	Horny goat weed plus	**78808 B78577**	abdominal pain, diarrhoea, palpitations	*Epimedium sagittatum, Avena sativa, Liriosma ovata, Eleutherococcus senticosus, Tribulus terrestris, Turnera diffusa, Urtica dioica, Ginkgo biloba,* Zinc amino acid chelate, Nicotinic acid, Pyridoxine hydrochloride *Panax ginseng*
185759	Nature's Own Fish Oil	**60277 B202473**	Leg cramps, nausea, sweating, rash, inability to walk	Fish oil
185761	NW Pregnancy & Breastfeeding; HB paracetamol	**80784 B77701 64151 B45050**	miscarriage	Fish oil, Thiamine hydrochloride Riboflavin, Nicotinamide, Calcium pantothenate, Pyridoxine hydrochloride, Folic acid, Cyanocobalamin, d-alpha-Tocopherol, Ascorbic acid, Calcium HPO_4, Magnesium oxide, Ferrous fumarate, Zinc sulfate monohydrate, Potassium iodide, Betacarotene, *Zingiber officinale, Foeniculum vulgare*; Paracetamol

Report #	Suspected Medicine(s)	AUST L # +/- Batch #	Reaction(s)	Active ingredients
185762	Nature's Own Super Potency Evening Primrose Oil	**82254 B203250**	"internal shaking"	
185775	Herbal Nutrition Vitex 1000	**55290**	nausea, headache	*Vitex agnus-castus*
185776	Cenovis Women's Multi Vitamin; Cenovis Cod Liver Oil	**70990 33613**	nausea, vomiting, diarrhoea	multiple vitamins and minerals *Withania somnifera*; Cod-liver oil
185777	Natural Nutrition Mg mega	**62037**	seizure	Pyridoxine hydrochloride, Magnesium aspartate, Potassium citrate, *Equisetum arvense, Avena sativa,* d-alpha-Tocopheryl acid succinate, Lecithin, Calcium ascorbate, Magnesium oxide, Zinc gluconate, Calcium phosphate, Cholecalciferol
185779	Microgenics Mega B; Microgenics Zinc	**79037 B79566 28116 B78368**	"blank thinking"	Thiamine hydrochloride, Riboflavin, Pyridoxine hydrochloride Choline bitartrate, Inositol Cyanocobalamin, Folic acid Biotin, Calcium pantothenate Nicotinamide; Zinc citrate Magnesium amino acid chelate Manganese amino acid chelate Pyridoxine hydrochloride Betacarotene, Molybdenum trioxide, Chromium amino acid chelate, *Tabebuia serratifolia Arctium lappa*
185820	NN Herbiotic Health Guardian	**54869 B161**	syncope, confusion, dysuria, dark urine	*Echinacea purpurea, Echinacea angustifolia, Hydrastis canadensis, Astragalus membranaceus Tabebuia serratifolia, Lentinula edodes, Ligustrum lucidum, Schizandra chinensis, Allium sativum*
185874	Metagenics Fibroplex	**90373**	palpitations, insomnia	Magnesium amino acid chelate Chromium nicotinate, Selenomethionine, Thiamine nitrate Nicotinamide, Pyridoxine hydrochloride, Cyanocobalamin Ascorbic acid, Folic acid, Glutamine, Levocarnitine, Taurine
185889	Nature's Way breast feeding	**80784 B77700**	headaches	Fish oil, Thiamine hydrochloride Riboflavin, Nicotinamide, Calcium pantothenate, Pyridoxine hydrochloride, Folic acid, Cyanocobalamin, d-alpha-Tocopherol Ascorbic acid, Calcium HPO_4 Magnesium oxide, Ferrous fumarate, Zinc sulfate, Potassium iodide, Betacarotene, *Zingiber officinale, Foeniculum vulgare*

Report #	Suspected Medicine(s)	AUST L # +/- Batch #	Reaction(s)	Active ingredients
185957	Panlabs Shark Cartilage; Panlabs Omega-3 Fish Oil; Panlabs Evening Primrose Oil; plus others	**66383; 66392; 66926**	hair loss, headaches, hallucinations, weight loss	
186073	Fat terminator; Wyld for women; NN Acidophilus; ramipril, frusemide, slow K	82768; **69421 B80558**; 81109	oedema, interstitial nephritis, acute renal failure	multiple; *Garcinia quaesita, Gymnema sylvestre,* Chromium picolinate, *Paullinia cupana, Liriosma ovata, Turnera diffusa*; *Lactobacillus acidophilus Bifidobacterium lactis*
186074	Fat terminator; Wyld for women; NN Acidophilus; ramipril, frusemide, slow K	82768; **69421 B80558**; 81109	oedema, interstitial nephritis, acute renal failure	multiple; *Garcinia quaesita, Gymnema sylvestre,* Chromium picolinate, *Paullinia cupana, Liriosma ovata, Turnera diffusa*; *Lactobacillus acidophilus Bifidobacterium lactis*
185512	Natures Own Natural Antibiotic Herbal Olive Leaf Complex	**68076**	swelling, itch around IV site	*Olea europaea,Tabebuia serratifolia, Allium sativum*
185653	Cenovis Mens Multivitain	**70825**	diarrhoea, dizziness, stomach cramps, vomiting	thiamine, riboflavine, pyridoxine, nicotinamide, ascorbic acid, manganese sulfate, calcium hydrogen phosphate, magnesium sulfate, betacarotene, cyanocobalamin, cholecalciferol, dl-alpha-tocopheryl, talcium pantothenate, biotin, folic acid, potassium sulfate, zinc sulfate, *Eleutherococcus senticosus, Serenoa serrulata*
185799	Natural Nutrition Equisetum 2000 Fingerprint Botanicals Tablet	**55597 B101643**	myalgia, angina, angioplasty (2 blocked coronary arteries)	***Equisetum arvense***
185626	Natures Own Superlecithin; Evening Primrose Oil	**28314 B203090**; ??	headaches	lecithin, phosphatidyl choline; evening primrose oil

Report #	Suspected Medicine(s)	AUST L # +/- Batch #	Reaction(s)	Active ingredients
186002	Natures Own Supavim	**46145 B204187**	rash	cyanocobalamin, biotin, pyridoxine, thiamine, riboflavine, rutin, *Rosa canina*, yeast dried, ferrous fumarate, folic acid, nicotinamide inositol, choline bitartrate, manganese, *Fucus vesiculosus*, cholecalciferol, zinc sulfate, calcium pantothenate, dl-alpha tocopheryl acid succinate, lecithin, ascorbic acid, betacarotene, magnesium oxide, calcium hydrogen phosphate
186003	Natural Nutrition Mens Mega Vitamin with Selenium; Bio Organics Ultrasorb Brahmi Phytosome	73811 B00259; **72975 B00254**	increased sexual thoughts in mildly retarded 26 year-old male	*Dunaliella salina*, thiamine, riboflavin, nicotinamide, nicotinic acid, calcium pantothenate, pyridoxine, cyanocobalamin, calcium ascorbate, cholecalciferol, d-alpha-tocopheryl acid succinate, biotin, choline bitartrate, folic acid, inositol, calcium citrate, chromium picolinate, copper gluconate, ferrous fumarate, manganese amino acid chelate, magnesium oxide, potassium iodide, potassium gluconate, selenomethionine, zinc amino acid chelate, *Vitis vinifera, Serenoa serrulata, Silybum marianum, Panax ginseng, Tribulus terrestris, Centella asiatica, Ginkgo biloba, Crataegus monogyna, Avena sativa, Vaccinium myrtillus, Astragalus membranaceus, Zingiber officinale, Smilax officinalis, Berberis vulgaris, Camellia sinensis, Lycopersicon esculentum, Tagetes erecta*, bioflavonoids, tyrosine, lysine hydrochloride; *Bacopa monnieri, Ginkgo biloba*, lecithin
186005	Phil Alexander Formula Six Multivitamins with Vitamin C; Phil Alexander Formula Six Multivitamins with Calcium; Phil Alexander Formula Six Multivitamins with Zinc	61695 B80300; **64050 B80306; 61696 B80302**	headaches, dizziness, fatigue	betacarotene, thiamine, riboflavine, nicotinamide, pyridoxine, calcium pantothenate, cyanocobalamin, cholecalciferol, ascorbic acid, d-alpha-tocopheryl acid succinate, choline bitartrate, inositol, folic acid, biotin; d-alpha-tocopheryl acid succinate, dolomite, ascorbic acid, rutin, hesperidin; d-alpha-tocopheryl acid succinate, ferrous phosphate, calcium phosphate, dolomite, potassium sulfate, zinc sulfate, manganese sulfate, magnesium phosphate, chromic chloride
186008	Advanced Hair Studio Serenoa	**74807 B80687**	migraines, fever, nausea, vertigo	***Serenoa serrulata***

Report #	Suspected Medicine(s)	AUST L # +/- Batch #	Reaction(s)	Active ingredients
186037	Ginkgo biloba	**67379**	headache, rash	*Ginkgo biloba, Panax ginseng, Centella asiatica*, lecithin, tyrosine, glutamine, *Crataegus laevigata*
186041	Cenovis Cod Liver Oil; Ultrasorb Brahmi Phytosome	**33613 B205376; 72975 B00254**	generalised convulsion	cod liver oil; *Bacopa monnieri, Ginkgo biloba*, lecithin
186044	Natures Own Vitamin B6	**28403 BIV01533**	palpitations, tachycardia	pyridoxine hydrochloride
186048	Golden Glow Super One A Day	**81307 B205420**	rash, fatigue, itch, skin discolouration	thiamine, riboflavine, pyridoxine, nicotinamide, ascorbic acid, calcium amino acid chelate, cyanocobalamin, calcium pantothenate, biotin, folic acid, d-alpha-tocopherol, manganese amino acid chelate, zinc amino acid chelate, bioflavonoids, hesperidin, rutin, betacarotene, chromium picolinate, cysteine, inositol, potassium gluconate, selenomethionine, *Fucus vesiculosus*, *Equisetum arvense*, magnesium amino acid chelate
186051	Bio organics Glucosamine	**67706 B300026**	arthritis aggravated	glucosamine sulfate
186109	Omega 3 Fish Oil	**82228 206306**	weight loss, dyspnoea, bleeding problems	fish oil
186110	Omega 3 Fish Oil	**82228 206306**	weight loss, dyspnoea, bleeding problems	fish oil
186123	Metagenics Crotico B5 B6 tablets	**16436 B5060**	disorientated, hallucination	calcium pantothenate, ascorbic acid, pyridoxine, magnesium oxide, bioflavonoids
186154	Microgenics Natural Omega 3 Fish Oil	**55445 B78288,** B73979	palpitations	fish oil
186193	Natural Nutrition Immune Support	**75534**	fatigue, dizziness, amnesia	*Andrographis paniculata*, yeast dried, selenomethionine
186297	Natural Nutrition Immune Support	**75534**	fatigue, dizziness, amnesia	*Andrographis paniculata*, yeast dried, selenomethionine
186299	Natural Nutrition Immune Support	**75534**	fatigue, dizziness, amnesia	*Andrographis paniculata*, yeast dried, selenomethionine

Report #	Suspected Medicine(s)	AUST L # +/- Batch #	Reaction(s)	Active ingredients
186195	Naytura Mega Multivitamin	**79514 B14541**	vomiting	thiamine, riboflavin, nicotinamide, pyridoxine, cyanocobalamin, ascorbic acid, d-alpha-tocopheryl acid succinate, calcium pantothenate, ferrous fumarate, cupric sulfate, potassium iodide, magnesium oxide, manganese sulfate, potassium sulfate, zinc oxide, calcium hydrogen phosphate, biotin, folic acid, cholecalciferol, betacarotene
186442	Bio-organics Co-Enzyme 10; other medications	**69889 B206322**	*Aspergillus fumigatus* grown on sputum sample	ubidecarenone
186599	Brain and Memory Natural Care	**91022 B81116**	headache, nose bleeds, vomiting, impaired concentration	glutamine, tyrosine, pyridoxine, folic acid, cyanocobalamin, *Ginkgo biloba*, *Bacopa monnieri*
186675	Bioglan Evening Primrose Oil	**13680 B1843**	epigastric pain, bloating, oedema of hands and legs	Evening Primrose Oil, d-alpha-tocopherol
186731	Natures Own B6 100mg	**28403 B205166**	therapeutic inefficacy	pyridoxine
186835	Kordell's Advanced Nutrition Joint Pain Relief	**70179 B2046**	feeling faint, nausea, bloating	glucosamine sulfate, bioflavonoids, cupric sulfate, manganese sulfate, zinc oxide, ascorbic acid, shark cartilage
186987	Myadec Multivitamins and Minerals; Bio-organics Standard Valerian; Bio-organics Anxiety-Eze	43128 B75498; **59080 B7923701; 62824 Some**	rash, dyspnoea, itch	calcium hydrogen phosphate, cupric sulfate, ferrous sulfate, potassium iodide, magnesium sulfate, potassium sulfate, zinc sulfate, thiamine, riboflavine, pyridoxine hydrochloride, cyano-cobalamin, calcium ascorbate, cholecalciferol, dl-alpha-toco-pheryl acetate, nicotinamide, manganese sulfate; *Valeriana officinalis; Hypericum perforatum, Piper methysticum*, magnesium phosphate
187034	Zinc + C Lozenges	**28191 B101720**	pharyngitis, aphonia	ascorbic acid, zinc gluconate
187091	Bio-Organics Glucosamine Sulfate	**67706**	muscle ache, headache, depression, fatigue	glucosamine sulfate
187112	Dietary Fatblaster	**76107 B83276**	dizziness, ache, stomach cramps, change in bowel habit	*Garcinia quaesita, Paullinia cupna, Gymnema sylvestre, Salix alba,* chromium picolinate, chitosan, psyllium husk powder, *Citrus aurantium,*

Comments on individual reports

185338 *Cenovis Easy Sleep Valeriana officinalis* and manic episode

The wife of a 42 year old male reported by telephone that he had had a manic episode requiring hospitalisation one week after commencing *Cenovis Easy Sleep Valeriana officinalis* (AUST L 79856), containing *Valeriana officinalis.* The product was among those manufactured by Pan Pharmaceuticals which were recalled.

ADRAC has received 19 reports concerning single ingredient products containing valerian but there appears to be no pattern and there are no previous reports of mania.

Although the manic episode may have been unrelated to the valerian product, members considered it appropriate to designate the report "possible" for causality.

185378 Amcal Co-Enzyme Q10 *and atrial flutter, ventricular tachycardia*

The mother of a 17 year old male reported by telephone that he had developed atrial flutter and ventricular tachycardia 10 days after commencing *Amcal Co-Enzyme Q10* (AUST L 70722), containing ubidecarenone and fish oil. The patient was taking digoxin for a congenital heart defect of a single ventricle transposition. He required DC cardioversion, amiodarone and enalapril in an intensive care unit. The product was among those manufactured by Pan Pharmaceuticals which were recalled.

ADRAC has received 10 reports involving single ingredient products containing ubidecarenone (co-enzyme Q) including one that described atrial fibrillation and supraventricular tachycardia (report 161155) but in this report co-enzyme Q was one of 7 suspected drugs.

Members considered that the patient's adverse event was probably related to his congenital heart defect, but since a contribution from *Amcal Co-Enzyme Q10* could not be excluded it was agreed that a causality designation of "possible" was appropriate.

185464 Nature's Own Omega 3 Fish Oil *and palpitations, hypotension*

According to a consumer report, a 58 year old woman developed hypotension and palpitations after taking *Nature's Own Omega 3 Fish Oil* (AUST L 82228, B206419 manufactured by Pan) for 3 days. After discharge, she took the product again for one day and developed the same symptoms.

In the basis of the positive rechallenge, members agreed with the causality designation of "certain".

185465 *Nature's Own Travel Well* and sweating, shakes, nausea, disorientation

A 26 year old woman reported that she experienced sweating, shakes, nausea, and disorientation after taking *Nature's Own Travel Well* (containing ginger, German chamomile, peppermint oil, and cinnamon bark oil) on an airline flight. She had to be taken off the plane. Concomitant medications were celecoxib and hydralazine (both long-term). She had a past history of arthritis and chronic fatigue. *Nature's Own Travel Well* was manufactured by Pan Pharmaceuticals.

Because of the close temporal relationship between taking the product and developing the adverse effect, members considered that the report should have the designation "probable".

185482 *Nature's Own Travel Well* and miscarriage

A pharmacist reported that a 20 year old woman was '2 weeks pregnant' when she started taking *Nature's Own Travel Well* (containing ginger, German chamomile, peppermint oil, and cinnamon bark oil) for nausea. A few days after starting it, she developed cramping and bleeding, and had a miscarriage a few weeks later. She took the product for 3 weeks in total. *Nature's Own Travel Well* was manufactured by Pan Pharmaceuticals.

Although miscarriage is common in early pregnancy, members agreed that it was not possible to exclude a contribution from *Nature's Own Travel Well* and considered that a causal designation of "possible" was appropriate.

185520 *Nature's Own Insomnia*, a glucosamine product and severe acute hepatitis

A report from the gastroenterology unit, The Canberra Hospital described a 51 year old woman who commenced a glucosamine product sometime in 2002, and stopped it in January 2003. In March 2003 she took *Nature's Own Insomnia* (5 tablets only) and Lemsip, apparently for only one day. In mid April 2003 she developed severe acute hepatitis with jaundice. Liver biopsy revealed "liver cell apoptosis, lymphocyte infiltration consistent with drugs or virus". Viral serology was negative. The glucosamine product contained glucosamine sulphate, cranberry, guarana, kava, and white willow. *Nature's Own Insomnia* contains valerian, hops, skullcap, and passion flower.

Members commented that this may be another case of hepatitis with kava. Skullcap may also have contributed, but the time course is less convincing. Members agreed that *Nature's Own Insomnia,* Lemsip and the glucosamine product should all be designated "possible" for causality.

185521 Nature's Own Omega 3 Fish Oil *and hallucinations*

A general practitioner reported that a 73 year old woman had been using *Nature's Own Omega 3 Fish Oil* (AUST L not provided, but possibly 82228, which is a Pan product). When she increased the dose from daily to three times daily, she experienced 2 episodes of hallucination. She recovered on stopping the medication.

Members considered the causality designation of "probable" to be appropriate on the grands of the dose relationship and the recovery on withdrawal of the medication.

185540 *Nature's Own Zinc Lozenge* and auditory hallucinations, vomiting

A father reported that his 9 year old son experienced auditory hallucinations and vomiting after taking *Nature's Own Zinc Lozenge* (contains zinc gluconate and vitamin C) for 2 days for an upper respiratory tract infection. He recovered on stopping the medication. The product was manufactured by Pan.

The Committee considered the causality designation of "possible" to be appropriate for this report.

185759 Nature's Own Fish Oil *and leg cramps, vomiting, rash, inability to walk*

A pharmacist reported that a 57 year old male experienced leg cramps, nausea, vomiting, diarrhoea, sweating, rash and inability to walk 4-6 hours after taking one tablet of Nature's Own Fish Oil. He was observed in hospital overnight and had recovered the next day.

Because the event occurred soon after ingestion of the tablet, members considered that it was appropriate to give the report a causality designation of "probable".

185761..... *Paracetamol, Nature's Way Pregnancy & Breastfeeding* and miscarriage

In a consumer report, a 32 year old female had a miscarriage after taking Home Brand Paracetamol (6 tablets) and a single packet of *Nature's Way Pregnancy & Breastfeeding* (AUST L 80784). The duration of the pregnancy at miscarriage was not specified. The Nature's Way product contains fish oil, thiamine hydrochloride, riboflavin, nicotinamide, calcium pantothenate, pyridoxine hydrochloride, folic acid, cyanocobalamin, d-alpha-tocopherol, ascorbic acid, calcium HPO_4, magnesium oxide, ferrous fumarate, zinc sulfate monohydrate, potassium iodide, betacarotene, *Zingiber officinale*, and *Foeniculum vulgare.* Both products were manufactured by Pan Pharmaceuticals. The woman had had three previous live births and one miscarriage.

Members agreed that this report should be given a causality designation of "possible", even though miscarriages are common in early pregnancy.

185777 *Natural Nutrition Mg Mega* and seizure

A mother reported that her 30 year old son with a past history of surgically repaired (Sept 2000) left parietal arteriovenous malformation had been weaned off phenytoin post-surgery and was seizure-free since May 2001. In January 2003 he took a single tablet of *Natural Nutrition Mg Mega* (contains magnesium aspartate 145mg, magnesium oxide 450mg, other minerals and vitamins, horsetail and oats; Pan product) and suffered a grand mal seizure the following day and required intubation. The doctors who treated him considered that there was no association between the product taken and the seizure.

Members considered that the grand mal seizure may have been related to the patient's pre-disposition, but agreed that it was impossible to exclude a contribution from the product he had taken.

186073/186074 *Fat terminator*, *Wyld for Women*, *Natural Nutrition mega-acidophilus* and interstitial nephritis

A nephrologist reported that a 54 year old woman took *Fat terminator* (contains multiple herbs, vitamins, and minerals, including chromium picolinate 10mcg and chromic chloride 46.9mcg) 4 tablets daily for 2 weeks. She commenced *Wyld for Women* (contains brindleberry, *Gymnema*, guarana, muira puama, damiana, and chromium picolinate 195mcg) 2 tablets daily, and *Natural Nutrition mega-acidophilus* 3 months later. The following month, she developed oedema and was treated with ramipril, frusemide and potassium. The complementary medicine products were ceased. About 6 weeks later, she developed acute renal failure requiring dialysis. Renal biopsy showed mild interstitial nephritis and marked tubular changes. Two weeks after presentation with renal failure, her chromium level was 44 (normal range 6-26; units not stated).

The upper limit of the daily requirement for chromium is 200 mcg/day. Chromium salts are known to cause acute renal failure. *Wyld for Women* was a Pan product which had been recalled.

The Committee considered the causal designation of "possible" to be appropriate for both sequences (sequence 1 oedema; sequence 2 interstitial nephritis).

186041 *Cenovis Cod Liver Oil*, *Ultrasorb Brahmi Phytosome* and generalised seizures

A 35 year old female experienced new onset generalised seizures 2 months after starting *Cenovis Cod Liver Oil* and *Ultrasorb Brahmi Phytosome*. The patient is now on anticonvulsant medication.

The Committee agreed with the causality designation of "possible" for this report.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-127

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: RECALL OF PRODUCTS MANUFACTURED BY PAN PHARMACEUTICALS PTY LTD

Hansard Page: CA197

Senator Allison asked:

Why is it that when the advertisements went into the newspapers, they were listed by batch number instead of brand name?

Answer:

In recent advertisements recalled products were advertised according to their unique identifier the Aust L or Aust R number. The Aust L or Aust R number is issued for an individual product and cannot be used for any other product.

Brand and product names do not share the exclusivity of an Aust L or Aust R number. Brands can have two products with the same name but have different ingredients or different strengths. Even between different brands there can be a close similarity in the names, which can lead to confusion when trying to identify the product by brand or name.

The initial advertisement published on 29 April 2003 consisted solely of those products branded as Pan. That is those products were manufactured and sponsored by Pan Pharmaceuticals Ltd.

Subsequent advertisements for the recall of affected products manufactured by Pan included the unique identifier the Aust L or Aust R number, brand name, sponsor of product and where applicable which batches were affected.

Consumers could now search by sponsor, brand name or Aust L or Aust R number. For positive identification of a suspect product the Aust L/Aust R number, as the unique identifier needed to be confirmed.

Batch numbers were included in the recall list as Pan was also a contract manufacturer. Sponsors who use Pan as a contract manufacturer did not necessarily use Pan exclusively. It was therefore essential that all affected batches of a product be identified and recalled. Batch numbers were not used for the initial identification of products but to further clarify which batches needed to be recalled.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-128

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: LICENCES FOR DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

Hansard Page: CA209

Senator McLucas asked:

Since February 2003 how many inspections of trial sites have been undertaken for compliance?

Answer:

Since February 2003 the Office of the Gene Technology Regulator has inspected 36 trial sites for compliance with licence provisions.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-129

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: LICENCES FOR DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

Hansard Page: CA210, CA211

Senator McLucas asked:

(a) How many shipments and of what types and tonnage of grain has Hunter Grain Pty Ltd brought into Australia?

(b) Where was the spillage?

Answer:

(a) & (b) In January 2003 the Gene Technology Regulator issued two licences to Hunter Grains Pty Ltd in response to applications to import and process corn and soybeans from the USA.

As at 18 June 2003 there have been four shipments of soybean totalling 43, 520 tonnes and one shipment of 48,249 tonnes of maize.

There have been two instances of imported corn coming into contact with Australian grain in storage terminals. One instance occurred in Newcastle and the other in Melbourne. In both cases the corn was contained within the terminal facility and no release into the environment occurred. In both cases the Australian Quarantine Inspection Service (AQIS) ensured that grain that had come into contact with the imported grain was subject to the containment, transport security and treatment conditions that apply to the imported grain.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-145

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: POST-MARKETING MONITORING OF COMPLEMENTARY MEDICINE AND OVER-THE-COUNTER MEDICINE

Written Question on Notice

Senator McLucas asked:

(a) How many complementary medicine products have been tested per year since 1995/96?

(b) How many over-the-counter medicine products have been tested per year since 1995/96?

(c) How often does the TGA test each product?

(d) Do TGA staff ever buy complementary healthcare products off the shelves of pharmacies or health food stores for the purposes of undertaking product testing?

If so, please provide product name and manufacturer, total numbers of products tested and reasons why those particular products were selected. Please provide this information for the past 5 years.

(e) Do TGA staff ever buy over-the counter healthcare products off the shelves of pharmacy's or health food stores for the purposes of undertaking product testing?

If so, please provide product name and manufacturer, total numbers of products tested and reasons why those particular products were selected. Please provide this information for the past 5 years.

Answer:

(a) & (b)
The following number of complementary and over-the-counter medicine products have been tested:

Year	1995/6	1996/7	1997/8	1998/9	1999/0	2000/1	2001/2	2002/3 *
Number of complementary medicine products tested	191	73	367	261	114	275	182	303
Number over-the-counter medicine products tested	101	116	142	140	185	351	130	66

(c) The testing program involves the selection of both random and targeted samples for analysis. The selected product may be either tested once, or follow up testing on that particular product may occur if there are further quality assurance or safety concerns.

(d) & (e)

TGA staff do buy both complementary and over-the-counter healthcare products off the shelves of pharmacies or health food stores for the purposes of undertaking product testing. The attached sheets show the products, total numbers of products tested and reasons why those particular products were selected for the past 5 years and 2003/3 to date. Please note that the information does not show the name of the manufacturer. Sponsors may nominate several manufacturers for each product and this information is stored on the Australian Register for Therapeutic Goods (ARTG). Therefore, for any one batch of a product purchased, the TGA does not know, from their records, which particular manufacturer has produced that particular batch. If problems are detected through the laboratory-testing program, then follow up is initiated with the sponsor of the product to determine the manufacturer.

Attachment 1

NUMBER OF COMPLEMENTARY MEDICINES PURCHASED FOR TESTING OVER THE LAST FIVE YEARS

Year	1997/98	1998/99	1999/00	2000/01	2001/02	2002/03*
Number of complementary medicine products purchased for testing	93	19	12	12	25	46

* To Date

Description	Reason for test
OCTYL METHOXYCINNAMATE, OXYBENZONE SUNSCREEN JURLIQUE SPF15+	MAS INSPECTORATE ALERT SAMPLE
ECHINACEA PURPUREA ORAL LIQUID 1G/ML	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PALLIDA TABLET 300MG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA JUICE DRY TABLET ECHINACEA FORTE 3000	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA EXTRACT ORAL LIQUID 200MG/ML	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA TABLET ECHINAFORCE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA TINCTURE ORAL LIQUID ECHINACEAFORCE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA ROOT DRIED HERBS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA, ECHINACEA ANGUSTIFOLIA TABLET	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA TABLET CHEWABLE 5.6MG NATURAL NUTRITION	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA CAPSULE NATURE'S OWN ECHINACEA 500	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA, ECHINACEA ANGUSTIFOLIA ORAL LIQUID	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA, ASCORBIC ACID ORAL LIQUID TALLEBUDGERA HERBALS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA HERBAL ORAL LIQUID GREENRIDGE RELIEF	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA, LICORICE, MENTHOL, EUCALYPTUS OIL LOZENGE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GARLIC, ECHINACEA TABLET CHEWABLE BUG BUSTERS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA CAPSULE KORDEL'S SUPER ECHINACEA 3000	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA TABLET HERBS OF GOLD ECHINACEA 2000+	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA EXTRACT TABLET 1G HERB VALLEY	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA ROOT POWDER CAPSULE 450MG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA PURPUREA DRIED EXTRACT CAPSULE BIO-ORGANICS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA, CALCIUM ASCORBATE, ZINC TABLET PRETORIUS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GLYCEROL SUPPOSITORY ADULT 924MG/G	FOLLOW-UP TO ROUTINE TESTING
GLYCEROL SUPPOSITORY ADULT 924MG/G	FOLLOW-UP TO ROUTINE TESTING
GINSENG TABLET 500MG BLACKMORES	FOLLOW-UP A COMPLAINT
GINSENG CAPSULE 500MG NATURE'S OWN	FOLLOW-UP A COMPLAINT
GINSENG CAPSULE 500MG IL HWA	FOLLOW-UP A COMPLAINT

SENNA, FRANGULA, PSYLLIUM LIQUORICE, ANETHUM ORAL POWDER	SURVEILLANCE OF PAST DEFECTIVE PRODUCTS
GINSENG, AMERICAN DRIED HERB TEA	TESTING ASSOCIATED WITH A PRODUCT SURVEY
LIVER EXTRACT TABLET 550MG JOE WEIDERS' VICTORY LIVER	FOLLOW-UP TO ROUTINE TESTING
LIVER EXTRACT, FERROUS SULFATE, PROTEIN & B COMPLEX TABLET	FOLLOW-UP TO ROUTINE TESTING
LIVER EXTRACT, FERROUS SULFATE, PROTEIN & B COMPLEX TABLET	FOLLOW-UP TO ROUTINE TESTING
LIVER EXTRACT, PROTEIN, IRON, B COMPLEX TABLET WEIGHT GAIN	FOLLOW-UP TO ROUTINE TESTING
HERBS, VITAMINS & MINERALS TABLET HAIR SKIN & NAILS	FOLLOW-UP TO ROUTINE TESTING
LAVANDULA ANGUSTIFOLIA LAVENDER ESSENTIAL OIL 1ML/ML	TESTING ASSOCIATED WITH A PRODUCT SURVEY
LOW LACTOSE INFANT FORMULA ORAL POWDER DE-LACT	TESTING ASSOCIATED WITH A PRODUCT SURVEY
INFANT FORMULA ORAL POWDER S-26	TESTING ASSOCIATED WITH A PRODUCT SURVEY
LACTOSE-FREE INFANT FORMULA ORAL POWDER INFASOY	TESTING ASSOCIATED WITH A PRODUCT SURVEY
56189 HILDE HEMMES' HERBALS HERBAL LAXATIVE HERB, DRIED BAG	ROUTINE SAMPLE
HERBAL TOPICAL CREAME NPM THE SCARLESS HEALER BY ROSA	ROUTINE SAMPLE
THE GREEN MEDICINE A FREE BREATH GRANULES	ROUTINE SAMPLE
ELEUTHEROCOCCUS SENTICOSUS SIBERIAN GINSENG TABLET 1000MG	FOLLOW-UP A COMPLAINT
PANAX GINSENG CAPSULE PINE BRAND	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ELEUTHEROCOCCUS SENTICOSUS SIBERIAN GINSENG EXTRACT TABLET	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PANAX GINSENG EXTRACT CAPSULE BIO-ORGANICS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PANAX GINGSENG CAPSULE 100MG GINSANA G115	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PANAX GINSENG EXTRACT ORAL LIQUID HERBS OF GOLD	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ELEUTHEROCOCCUS SENTICOSUS SIBERIAN GINSENG TABLET FOREST	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PANAX GINSENG TABLET 260MG BLACKMORES TRADITIONAL HERBALS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ELEUTHEROCOCCUS SENTICOSUS SIBERIAN GINSENG ORAL LIQUID	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ELEUTHEROCOCCUS SENTICOSUS SIBERIAN GINSENG CAPSULE 410MG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PANAX GINSENG CAPSULE 334MG NATURAL NUTRITION	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PANAX GINSENG CAPSULE 1000MG MICROGENICS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
SIBERIAN GINSENG TABLET 500MG NATURE'S OWN	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PANAX GINSENG EXTRACT ORAL LIQUID 1:2	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ELEUTHEROCOCCUS SENTICOSUS, PANAX GINSENG CAPSULE 1G, 500MG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ROYAL JELLY CAPSULE BLACKMORES	TESTING ASSOCIATED WITH A PRODUCT SURVEY

ROYAL JELLY, HERBAL VITAMIN COMPLEX ORAL LIQUID	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ROYAL JELLY CAPSULE NATURE'S WAY	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GINSENG, ROYAL JELLY ORAL LIQUID 200MG, 1000MG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ROYAL JELLY ORAL LIQUID 2000MG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ECHINACEA, ASCORBIC ACID ORAL LIQUID LAWNCROFT	PRODUCT SURVEILLANCE BY MANUFACTURER
PAULLINIA CUPANA GUARANA CAPSULE NATURE'S OWN	TESTING ASSOCIATED WITH A PRODUCT SURVEY
SILYBUM MARIANUM ST MARY'S THISTLE HERBAL ORAL LIQUID	TESTING ASSOCIATED WITH A PRODUCT SURVEY
VALERIANA OFFICINALIS VALERIAN TABLET 1000MG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
SILYBUM MARIANUM ST MARY'S THISTLE CAPSULE NATURE'S SUNSHINE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
SILYBUM MARIANUM MILK THISTLE CAPSULE 70MG MICROGENICS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PAULLINIA CUPANA GUARANA SEED ORAL POWDER GUARANA NATURALE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
MATRICARIA RECUTITA CHAMOMILE DRIED HERB	TESTING ASSOCIATED WITH A PRODUCT SURVEY
VALERIANA OFFICINALIS VALERIAN DRIED HERB TEA BAG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PASSIFLORA SP. DRIED HERB	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HUMULUS LUPULUS HOPS DRIED HERB	TESTING ASSOCIATED WITH A PRODUCT SURVEY
VALERIANA OFFICINALIS VALERIAN ROOT POWDER CAPSULE 410MG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PASSIFLORA INCARNATA PASSIONFLOWER TABLET 125MG SEDACALM	TESTING ASSOCIATED WITH A PRODUCT SURVEY
VALERIANA OFFICINALIS VALERIAN ORAL LIQUID 1G/ML GREENRIDGE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
SILYBUM MARIANUM MILK THISTLE TABLET 84MG BLACKMORES	TESTING ASSOCIATED WITH A PRODUCT SURVEY
SILYBUM MARIANUM MILK THISTLE ORAL LIQUID 100MG/ML	TESTING ASSOCIATED WITH A PRODUCT SURVEY
VALERIANA OFFICINALIS VALERIAN TABLET EQUIV 560MG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
VALERIANA OFFICINALIS VALERIAN DRIED HERB HERBA-HEAL	TESTING ASSOCIATED WITH A PRODUCT SURVEY
VALERIANA OFFICINALIS VALERIAN DRIED HERB ROOT HILDE HEMMES	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PAULLINIA CUPANA GUARANA CAPSULE 500MG RIO AMAZON	TESTING ASSOCIATED WITH A PRODUCT SURVEY
VALERIANA OFFICINALIS VALERIAN DRY HERB ROOT BLOOMS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
VALERIANA OFFICINALIS VALERIAN ORAL LIQUID HILDE HEMMES	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PAULLINIA CUPANA GUARANA EXTRACT CAPSULE BIO-HEALTH	TESTING ASSOCIATED WITH A PRODUCT SURVEY
PAULLINIA CUPANA GUARANA CAPSULE HERBS OF GOLD GUARANA POWER	TESTING ASSOCIATED WITH A PRODUCT SURVEY
FERROUS SULFATE TABLET 350MG FERRO-GRADUMET	TESTING ASSOCIATED WITH A PRODUCT SURVEY
FERROUS SULFATE CAPSULE 270MG FEFOL	TESTING ASSOCIATED WITH A PRODUCT SURVEY

HUMULUS LUPULUS REFERENCE EXTRACT 085916	OTHER
VALERIANA OFFICINALIS REFERENCE EXTRACT 085201	OTHER
OCTYL METHOXYCINNAMATE, OXYBENZONE SUNSCREEN GEL SUN GUN	MAS INSPECTORATE ALERT SAMPLE
MUSSEL, HERBAL TABLET ARTHRITIS AND RHEUMATISM NATURE'S OWN	FOLLOW-UP TO ROUTINE TESTING
APIUM GRAVEOLENS CELERY SEED OIL AND EXTRACT TABLET	FOLLOW-UP TO ROUTINE TESTING
OCTYL METHOXYCINNAMATE, OXYBENZONE SUNSCREEN GEL SUN GUN	FOLLOW-UP TO ROUTINE TESTING

Total number of products purchased = 93

MAS = Manufacturing Assessment Section

Description	Reason for test
LAVANDULA ANGUSTIFOLIA LAVENDER OIL 1ML/ML SUNSPIRIT	FOLLOW-UP A COMPLAINT
HERBAL ORAL POWDER BLOOMS HERB-A-LAX	ROUTINE SAMPLE
LAVENDER OIL 1ML/ML	FOLLOW-UP A COMPLAINT
SKULLCAP, VALERIAN, HERB AND MINERAL TABLETS INSOMNIA	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERBAL CAPSULE MICROGENICS KAVA CALM	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERBAL ORAL LIQUID RAINBOW RESTFUL SLEEP REMEDY	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERBAL CAPSULE MICROGENICS SOUND-A-SLEEP	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GOLDEN SEAL HYDRASTIS CANADENSIS CAPSULE 535MG	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GOLDEN SEAL HYDRASTIS CANADENSIS CAPSULE NATURE'S SUNSHINE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GOLDEN SEAL HYDRASTIS CANADENSIS CAPSULE 500MG NATURE'S OWN	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GOLDEN SEAL HYDRASTIS CANADENSIS ORAL LIQUID	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GOLDEN SEAL HYDRASTIS CANADENSIS DRIED HERB	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GOLDEN SEAL HYDRASTIS CANADENSIS CAPSULE 500MG NATURE'S OWN	TESTING ASSOCIATED WITH A PRODUCT SURVEY
DEHYDROEPIANDROSTERONE TABLET 3MG PRETORIUS HOMOEPATHIC DHEA	ROUTINE SAMPLE
TRIBULUS TERRESTRIS TABLET 125MG TRIBULUS 1000	ROUTINE SAMPLE
MULTI VITAMIN & MINERALS TABLET SUSTAINED RELEASE BLACKMORES	FOLLOW-UP A COMPLAINT
MULTI VITAMIN & MINERALS TABLET SUSTAINED RELEASE BLACKMORES	FOLLOW-UP A COMPLAINT
MULTI VITAMIN & MINERALS TABLET SUSTAINED RELEASE BLACKMORES	FOLLOW-UP A COMPLAINT
MULTI VITAMIN & MINERALS TABLET SUSTAINED RELEASE BLACKMORES	FOLLOW-UP A COMPLAINT

Total number of products purchased = 19

Description	Reason for test
HERBAL TABLET COGENT DB	FOLLOW-UP TO ROUTINE TESTING
HERBAL TABLET COGENT DB	FOLLOW-UP TO ROUTINE TESTING
SWEET ALMOND PRUNUS DULCIS OIL COLD PRESSED SUNSPIRIT	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ALMOND OIL 100% THE OIL GARDEN	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ALMOND OIL 100% BIOGENIC	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ALMOND OIL 100% HEALTHERIES	TESTING ASSOCIATED WITH A PRODUCT SURVEY
APRICOT OIL 100% BIOGENIC	TESTING ASSOCIATED WITH A PRODUCT SURVEY
D-ALPHA-TOCOPHERYL ACID SUCCINATE TABLET 82.64MG CENOVIS	FOLLOW-UP A COMPLAINT
DL-ALPHA-TOCOPHERYL ACETATE TABLET 100MG (100IU)	FOLLOW-UP A COMPLAINT
LAVANDULA ANGUSTIFOLIA; LAVANDULA INTERMEDIA LAVENDER OIL	COMPLAINT CONTROL/COMPARISON
HERB, VITAMIN TABLET BLACKMORES TRANQUIL NIGHT	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERBS, MINERAL TABLET FASTING ACTING SLEEP EZY	TESTING ASSOCIATED WITH A PRODUCT SURVEY

Total number of products purchased = 12

Description	Reason for test
HERB DRIED MALVA VERTICILLATA TEA BAG DIETERS' DELITE	FOLLOW-UP TO ROUTINE TESTING
HERB DRIED MALVA VERTICILLATA TEA BAG DIETERS' DELITE	FOLLOW-UP TO ROUTINE TESTING
ASCORBIC ACID; MINERAL; HERBAL TABLET GINKGO 7500 PLUS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GINKGO BILOBA ORAL LIQUID 37.5MG/ML GINKGO 7500	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GINKGO BILOBA TINCTURE ORAL LIQUID 505MG/ML GINKGOFORCE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GINKGO BILOBA TABLET 40MG GINKGOFORTE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
GINKGO BILOBA; CRATAEGUS MONOGYNA; ALLIUM SATIVUM CAPSULE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
URTICA DIOICA NETTLE DRIED HERB 1G/G MARNI'S	FOLLOW-UP TO ROUTINE TESTING
COD LIVER OIL CAPSULE 160MG NATURE'S OWN	FOLLOW-UP A COMPLAINT
HERBAL ORAL LIQUID BLUE COHOSH CAULOPHYLLUM THALICTROIDES	TESTING ASSOCIATED WITH A PRODUCT SURVEY
MULTIVITAMINS; MINERALS TABLET CENTRUM	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERBS DRIED TEA OJETA NATURAL LAXATIVE TEA	FOLLOW-UP TO ROUTINE TESTING

Total number of products purchased = 12

Description	Reason for test
LACTOBACILLUS ACIDOPHILUS; BIFIDUS CAPSULE BIO ORGANICS	VALIDATION OF REFERENCE STANDARDS
LACTOBACILLUS ACIDOPHILUS CAPSULE CENOVIS ACIDOPHILUS	VALIDATION OF REFERENCE STANDARDS
ACIDOPHILUS CAPSULE NATURE'S OWN ACIDOPHILUS PLUS	VALIDATION OF REFERENCE STANDARDS
PIPER METHYSTICUM KAVA TABLET 300MG KAVA RELAX 3000	REPORTED PROBLEM FROM OVERSEAS
PIPER METHYSTICUM KAVA TABLET 1.8G KAVA FORTE	REPORTED PROBLEM FROM OVERSEAS
PIPER METHYSTICUM KAVA CAPSULE 100MG HILDE HEMMES	REPORTED PROBLEM FROM OVERSEAS
LACTOBACILLUS ACIDOPHILUS ORAL POWDER SUPERDOPHILUS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
MICROGENICS ACIDOPHILUS PLUS ENTERIC COATED CAPSULE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
LACTOBACILLUS ACIDOPHILUS ORAL POWDER MEGA ACIDOPHILUS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
LACTOBACILLUS ACIDOPHILUS; BIFIDOBACTERIUM LACTIS CAPSULE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
LACTOBACILLUS ACIDOPHILUS; BIFIDOBACTERIUM LACTIS CAPSULE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
LACTOBACILLUS ACIDOPHILUS ORAL POWDER INNER HEALTH	TESTING ASSOCIATED WITH A PRODUCT SURVEY
MICROGENICS PROBIOTIC 8 CAPSULE	TESTING ASSOCIATED WITH A PRODUCT SURVEY
LACTOBACILLUS ACIDOPHILUS TABLET CHILD CHEW	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ASCORBIC ACID TABLET 250MG SUGAR FREE VITAMIN C	ROUTINE SAMPLE
PIPER METHYSTICUM KAVA CAPSULE 200MG NATURE'S SUNSHINE	REPORTED PROBLEM FROM OVERSEAS
HERBAL CAPSULE HYDROXYCUT	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ACIDOPHILUS CAPSULE PROBIOTIC	TESTING ASSOCIATED WITH A PRODUCT SURVEY
LACTOBACILLUS ACIDOPHILUS; BIFIDUS CAPSULE BIO ORGANICS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
ACIDOPHILUS CAPSULE NATURE'S OWN ACIDOPHILUS PLUS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
CALCIUM (AS CARBONATE) TABLET 600MG SUPER CALCIUM	FOLLOW-UP TO ROUTINE TESTING
CALCIUM (AS CARBONATE) TABLET 600MG SUPER CALCIUM	FOLLOW-UP TO ROUTINE TESTING
HERBAL TOPICAL LINIMENT SPORTS ZHENG GU SHUI	FOLLOW-UP RECALLED PRODUCT
HERBAL TOPICAL LINIMENT ZHENG GU SHUI	FOLLOW-UP RECALLED PRODUCT
HERBAL TOPICAL LINIMENT SPRAY ZHENG GU SHUI	FOLLOW-UP RECALLED PRODUCT

Total number of products tested = 25

Purchased Samples 2002-2003

Description	Reason for test
AMINO ACIDS; MINERALS; VITAMINS TABLET ONE-A-DAY	FOLLOW-UP TO ROUTINE TESTING
FOLIC ACID TABLET 0.5MG NATURE'S OWN	FOLLOW-UP TO ROUTINE TESTING
MINERALS; HERBAL TABLET INSOMNIA NATURE'S OWN	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERBAL; MINERAL TABLET SLEEP-EZY NATURAL NUTRITION	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERB; MINERAL TABLET ENERVITE SLEEPAID	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERB; MINERAL TABLET ENERVITE SLEEPAID	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERBS; MINERALS; VITAMINS TABLET EXECUTIVE STRESS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERBS DRIED HERBA-HEAL NO. 9 CONSTIPATION HERBS	ROUTINE SAMPLE
ZEA MAYS CORN SILK DRIED HERB	ROUTINE SAMPLE
HERBS DRIED HERBA-HEAL NO. 9 CONSTIPATION HERBS	ROUTINE SAMPLE
HERBS DRIED HERBA-HEAL TEA NO. 4 SEDATIVE HERBS	ROUTINE SAMPLE
HERB; VITAMINS TABLET 30 PLUS	COMPLAINT CONTROL/COMPARISON
MULTIVITAMINS; MINERALS TABLET ONE-A-DAY IRON FORMULA PLUS	FOLLOW-UP TO ROUTINE TESTING
CASSIA SENNA LEAF ORAL POWDER NUTRI-HERBAL	ROUTINE SAMPLE
OPHTHALMIC SOLUTION OPTREX ORIGINAL EYE LOTION	ROUTINE SAMPLE
MALVA VERTICILLATA CHINESE HIGH MALLOW DRIED HERB BAG	ROUTINE SAMPLE
CASSIA ANGUSTIFOLIA SENNA LEAF DRIED HERB BLOOMS HERBAL TEA	ROUTINE SAMPLE
NEPETA HEDERACEA GROUND IVY LIQUID EXTRACT	COMPLAINT CONTROL/COMPARISON
AVENA SATIVA OATS TINCTURE 1:5 EXTRACT	COMPLAINT CONTROL/COMPARISON
FOLIC ACID TABLET 500UG BLACKMORE'S	FOLLOW-UP TO ROUTINE TESTING
FOLIC ACID TABLET 0.5MG MEGAFOL 0.5	FOLLOW-UP TO ROUTINE TESTING
FOLIC ACID TABLET 5MG MEGAFOL 5	FOLLOW-UP TO ROUTINE TESTING
TRIGONELLA FOENUM-GRAECUM FENUGREEK DRIED HERB MARNI'S	ROUTINE SAMPLE
SLIPPERY ELM ULMUS RUBRA BARK POWDER CAPSULE 360MG	ROUTINE SAMPLE
SLIPPERY ELM ULMUS RUBRA CAPSULES 400MG HERBS OF GOLD	ROUTINE SAMPLE

VITAMINS; AMINO ACID TABLET NUTRA-LIFE SUPER FAT MOBILISER	TESTING ASSOCIATED WITH A PRODUCT SURVEY
SLIPPERY ELM ULMUS FULVA; LICORICE CAPSULE 400MG; 50MG	ROUTINE SAMPLE
SLIPPERY ELM ULMUS RUBRA TABLET 350MG BLACKMORES	ROUTINE SAMPLE
HERBAL CAPSULE VALERIAN 2500 COMPLEX MICROGENICS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
FOLIC ACID TABLET 0.5MG SIGMA	ROUTINE SAMPLE
FOLIC ACID TABLET 0.5MG SIGMA	FOLLOW-UP TO ROUTINE TESTING
FOLIC ACID TABLET 5MG MEGAFOL 5	FOLLOW-UP TO ROUTINE TESTING
MELATONIN HOMEOPATHIC TABLET 3MG 6X BIOGLAN	COMPLAINT CONTROL/COMPARISON
AMINO ACIDS; MINERALS; VITAMINS TABLET NATURE'S OWN HAIR	TESTING ASSOCIATED WITH A PRODUCT SURVEY
CAPSULE BIOGLAN AMINO ACID COMPLEX	TESTING ASSOCIATED WITH A PRODUCT SURVEY
HERB; MINERAL CAPSULE ACETABOLAN II	COMPLAINT SAMPLE
VITAMINS MINERALS HERBS TABLET WOMEN'S FORMULA 1	FOLLOW-UP TO ROUTINE TESTING
L-METHIONINE ORAL POWDER MUSASHI	TESTING ASSOCIATED WITH A PRODUCT SURVEY
AMINO ACID ORAL POWDER HUAN THE DISPERSION MUSASHI	TESTING ASSOCIATED WITH A PRODUCT SURVEY
VITAMIN TABLET DETOXIMET	TESTING ASSOCIATED WITH A PRODUCT SURVEY
N-ACETYL-5-METHOXY-TRYPTAMINE TABLET 5MG (6X) MELATONIN	TESTING ASSOCIATED WITH A PRODUCT SURVEY
SAM E HOMEOPATHIC TABLE SAM E PLUS	TESTING ASSOCIATED WITH A PRODUCT SURVEY
TABLET HOMEOPATHIC ARTHRI CALM	TESTING ASSOCIATED WITH A PRODUCT SURVEY
DEHYDRO-EPI-ANDROSTERONE HOMEOPATHIC TABLET 3MG (6X)	TESTING ASSOCIATED WITH A PRODUCT SURVEY
OMEGA-3 FISH OIL CAPSULE 1000MG CENOVIS NATURAL FISH OIL	COMPLAINT CONTROL/COMPARISON
HERBAL TABLET XIN YI SAN MAGNOLIA FLOWER FORMULA HAYFEVER	TESTING ASSOCIATED WITH A PRODUCT SURVEY

Total number of products purchased = 46

Attachment 2

NUMBER OF OVER-THE-COUNTER MEDICINES PURCHASED FOR TESTING OVER THE LAST FIVE YEARS

Year	1997/98	1998/99	1999/00	2000/01	2001/02	2002/03*
Number of over-the-counter medicine products purchased for testing	11	14	28	45	21	50

* To Date

Description	Reason test	SU
PARACETAMOL, CODEINE PHOSPHATE, DOXYLAMINE SUCCINATE CAPSULE	MAS Inspectorate Alert Sample	PURCHASED FROM FARMER'S MARKET CAPITAL CHEMIST WODEN
PARACETAMOL, CODEINE PHOSPHATE TABLET 500MG, 8MG	MAS Inspectorate Alert Sample	PURCHASED FROM FARMER'S MARKET CAPITAL CHEMIST WODEN
PARACETAMOL, CODEINE PHOSPHATE TABLET 500MG, 8MG	MAS Inspectorate Alert Sample	PURCHASED FROM FARMER'S MARKET CAPITAL CHEMIST WODEN
CHLORPHENIRAMINE, PARACETAMOL, PSEUDOEPHEDRINE TABLET	MAS Inspectorate Alert Sample	PURCHASED FROM FARMER'S MARKET CAPITAL CHEMIST WODEN PLAZA
PANADOL SINUS DAY/NIGHT TABLET COMBINATION PACK	MAS Inspectorate Alert Sample	PURCHASED FROM FARMER'S MARKET CAPITAL CHEMIST WODEN PLAZA
CODEINE PHOSPHATE, PSEUDOEPHEDRINE HYDROCHLORIDE ORAL LIQUID	MAS Inspectorate Alert Sample	PURCHASED FROM FARMER'S MARKET CAPITAL CHEMIST WODEN PLAZA
PARACETAMOL, PSEUDOEPHEDRINE HYDROCHLORIDE TABLET 500MG,30MG	MAS Inspectorate Alert Sample	PURCHASED FROM FARMER'S MARKET CAPITAL CHEMIST WODEN PLAZA
DEXTROMETHORPHAN, PARACETAMOL, PSEUDOEPHEDRINE TABLET	MAS Inspectorate Alert Sample	PURCHASED FROM FARMER'S MARKET CHEMIST
PARACETAMOL TABLETS 500MG PANADOL	Complaint control/comparison	PURCHASED FROM GRIFFITH PHARMACY GRIFFITH ACT

Description	Reason for test
GLYCEROL SUPPOSITORY ADULT 924MG/G	Follow-up to routine testing
GLYCEROL SUPPOSITORY ADULT 924MG/G	Follow-up to routine testing
OCTYL METHOXYCINNAMATE, OXYBENZONE SUNSCREEN GEL SUN GUN	Follow-up to routine testing
OCTYL METHOXYCINNAMATE, OXYBENZONE SUNSCREEN JURLIQUE SPF15+	MAS Inspectorate Alert Sample
OCTYL METHOXYCINNAMATE, OXYBENZONE SUNSCREEN GEL SUN GUN	MAS Inspectorate Alert Sample
SUN WIPES SPF 15+	Test newly approved product
LOW LACTOSE INFANT FORMULA ORAL POWDER DE-LACT	Testing associated with a product survey
INFANT FORMULA ORAL POWDER S-26	Testing associated with a product survey
LACTOSE-FREE INFANT FORMULA ORAL POWDER INFASOY	Testing associated with a product survey
FERROUS SULFATE TABLET 350MG FERRO-GRADUMET	Testing associated with a product survey
FERROUS SULFATE CAPSULE 270MG FEFOL	Testing associated with a product survey

Total number of products purchased = 11

MAS = Manufacturing Assessment Section

Description	Reason for test
IPECACUANHA SYRUP ORAL LIQUID 0.12%	Follow-up a Complaint
MALDISON SHAMPOO 1% K.P. 24 MEDICATED FOAM	Follow-up to routine testing
MALDISON SHAMPOO 1% K.P. 24 MEDICATED FOAM	Follow-up to routine testing
MEBENDAZOLE CHEWABLE TABLET 100MG CHEMISTS' OWN DE WORM	Routine Sample
MALDISON SHAMPOO 1% K.P. 24 MEDICATED FOAM	Testing associated with a product survey
MALDISON TOPICAL LOTION 0.5% K.P. 24 MEDICATED LOTION	Testing associated with a product survey
MALDISON TOPICAL LOTION 0.5% K.P. 24 MEDICATED LOTION	Testing associated with a product survey
MALDISON FOAM 10MG/ML HLT MEDICATED FOAM	Testing associated with a product survey
PSEUDOEPHEDRINE HYDROCHLORIDE TABLETS 50MG	Testing associated with a product survey
CLOTRIMAZOLE CREAM 10MG/G CHEMISTS' OWN	Testing associated with a product survey
CHLORPHENIRAMINE, PARACETAMOL, PSEUDOEPHEDRINE TABLET	Testing associated with a product survey
DOXYLAMINE SUCCINATE, CODEINE PHOSPHATE, PARACETAMOL TABLET	Testing associated with a product survey
PARACETAMOL TABLET 500MG CHEMISTS' OWN	Product Surveillance at Retail Level
PARACETAMOL TABLET 500MG CAPITAL CHEMIST	Product Surveillance at Retail Level

Total number of products purchased = 14

Description	Reason for test
PARACETAMOL ORAL SUSPENSION 24MG/ML DYMADON 1-4 YEARS	Follow-up a Complaint
PARACETAMOL ORAL SUSPENSION 24MG/ML COLOURFREE PANADOL 1-5	Follow-up a Complaint
PARACETAMOL ORAL SUSPENSION 48MG/ML PANADOL 5-12 YEARS	Follow-up a Complaint
PARACETAMOL ORAL SUSPENSION 50MG/ML DYMADON 5 YEARS PLUS	Follow-up a Complaint
PARACETAMOL ORAL LIQUID 100MG/ML CHEMADOL COLOUR FREE DROPS	Follow-up a Complaint
PARACETAMOL ORAL LIQUID 100MG/ML CHEMISTS' OWN	Follow-up a Complaint
PARACETAMOL ORAL LIQUID 100MG/ML COLOURFREE DROPS	Follow-up a Complaint
PARACETAMOL ORAL LIQUID 100MG/ML PHARMACIST INFANT DROPS	Follow-up a Complaint
PARACETAMOL ORAL LIQUID 100MG/ML PANADOL COLOURFREE DROPS	Follow-up a Complaint
PARACETAMOL ORAL LIQUID 100MG/ML DYMADON COLOUR FREE DROPS	Follow-up a Complaint
ATTAPULGITE; PECTIN; SIMETHICONE ORAL SUSPENSION DIAREZE	Follow-up a Complaint
ATTAPULGITE; PECTIN; SIMETHICONE ORAL SUSPENSION DIAREZE	Follow-up a Complaint
PARACETAMOL TABLET 500MG PANADOL TAMPON LIBRA FLEUR KIT	Routine Sample
BROMPHENIRAMIME MALEATE PHENYLEPHRINE HCL ORAL LIQUID	Testing associated with a product survey
BROMPHENIRAMIME MALEATE PHENYLEPHRINE ORAL LIQUID	Testing associated with a product survey
BROMPHENIRAMINE DEXTROMETHORPHAN PHENYLEPHRINE ORAL LIQUID	Testing associated with a product survey
BROMPHENIRAMINE DEXTROMETHORPHAN PHENYLEPHRINE ORAL LIQUID	Testing associated with a product survey
DEXTROMETHORPHAN PARACETAMOL PSEUDOEPHEDRINE ORAL LIQUID	Testing associated with a product survey
BROMPHENIRAMINE MALEATE PHENYLEPHRINE HCL ORAL LIQUID	Testing associated with a product survey
DEXTROMETHORPHAN PSEUDOEPHEDRINE ORAL LIQUID LOGICIN	Testing associated with a product survey
DEXTROMETHORPHAN PSEUDOEPHEDRINE ORAL LIQUID ROBITUSSIN DM-P	Testing associated with a product survey
BROMPHENIRAMINE MALEATE PHENYLEPHRINE HCL ORAL LIQUID	Testing associated with a product survey
BROMPHENIRAMINE MALEATE PHENYLEPHRINE HCL ORAL LIQUID	Testing associated with a product survey
CHLORPHENIRAMINE MALEATE PHENYLEPHRINE HCL ORAL LIQUID	Testing associated with a product survey
CHLORPHENIRAMINE MALEATE PHENYLEPHRINE HCL ORAL LIQUID	Testing associated with a product survey
KETOCONAZOLE SHAMPOO 2% SEBIZOLE	Testing associated with a product survey

MICONAZOLE SHAMPOO 20MG/G HAIRSCIENCE	Testing associated with a product survey
ACICLOVIR CREAM 5% ZOVIRAX COLD SORE CREAM	Testing associated with a product survey

Total number of products purchased = 28

Description	Reason for test
BROMHEXINE; GUAIPHENESIN ORAL LIQUID SOUL PATTINSON	Complaint control/comparison
BROMHEXINE; GUAIPHENESIN ORAL LIQUID SOUL PATTINSON	Complaint control/comparison
OCTYL METHOXYCINNAMATE; ZINC OXIDE; OCTOCRYLENE LOTION	Complaint control/comparison
POTASSIUM NITRATE; SODIUM MONOFLUOROPHOSPHATE TOOTHPASTE	Complaint control/comparison
ASPIRIN TABLET 300MG ASPRO CLEAR	Complaint control/comparison
PERMETHRIN LOTION 10MG/G PYRIFOAM HEAD LICE TREATMENT	Sample tested at end of expiry period
PARACETAMOL TABLET 500MG HERRON TABSULE	Follow-up a Complaint
PARAFFIN GEL TOPICAL VASELINE PETROLEUM JELLY	Follow-up a Complaint
SUNSCREEN TOPICAL LOTION GREATBLOC SPF30+ (COMPARISON)	Follow-up a Complaint
CHOLINE SALICYLATE; CETALKONIUM CHLORIDE ORAL GEL BONJELA	Follow-up a Complaint
CHOLINE SALICYLATE; CETALKONIUM CHLORIDE ORAL GEL BONJELA	Follow-up a Complaint
ASPIRIN TABLET 300MG SOLUBLE HOMEBRAND CLEAR ASPIRIN	Follow-up to routine testing
ASPIRIN TABLET 300MG SOLUBLE HOMEBRAND CLEAR ASPIRIN	Follow-up to routine testing
ASPIRIN TABLET 300MG SOLUBLE GUARDIAN ASPIRIN CLEAR	Routine Sample
KETOCONAZOLE SHAMPOO 1% NIZORAL	Testing associated with a product survey
KETOCONAZOLE SHAMPOO 2% NIZORAL	Testing associated with a product survey
INDOMETHACIN TOPICAL SPRAY 1% W/W INDOSPRAY	Testing associated with a product survey
INDOMETHACIN TOPICAL SPRAY 1% W/W INDOSPRAY	Testing associated with a product survey
MALDISON SHAMPOO 1% K.P. 24 MEDICATED FOAM	Testing associated with a product survey
MALDISON SHAMPOO 1% K.P. 24 MEDICATED FOAM	Testing associated with a product survey
MALDISON TOPICAL LOTION 0.5% K.P. 24 MEDICATED LOTION	Testing associated with a product survey
MALDISON TOPICAL LOTION 0.5% K.P. 24 MEDICATED LOTION	Testing associated with a product survey
MALDISON SHAMPOO 1% K.P. 24 MEDICATED FOAM	Testing associated with a product survey
ASPIRIN TABLET 300MG SOLUBLE HOMEBRAND ASPIRIN CLEAR	Testing associated with a product survey
ASPIRIN TABLET 300MG EFFERVESCENT SOUL PATTINSON	Testing associated with a product survey
ASPIRIN TABLET 300MG SOLUBLE GUARDIAN ASPIRIN CLEAR	Testing associated with a product survey
ASPIRIN TABLET 300MG SOLUBLE GUARDIAN ASPIRIN CLEAR	Testing associated with a product survey
PYRETHRINS; PIPERONYL BUTOXIDE AEROSOL FOAM BANLICE	Testing associated with a product survey

PERMETHRIN TOPICAL LOTION 1% ORANGE MEDIC PLUS	Testing associated with a product survey
PIPERONYL BUTOXIDE; PYRETHRINS LOTION AMCAL HEAD LICE FOAM	Testing associated with a product survey
PIPERONYL BUTOXIDE; PYRETHRINS TOPICAL LOTION PYRENEL FOAM	Testing associated with a product survey
PERMETHRIN TOPICAL APPLICATION QUELLADA FOR SHORT HAIR	Testing associated with a product survey
PERMETHRIN TOPICAL APPLICATION QUELLADA FOR SHORT HAIR	Testing associated with a product survey
PERMETHRIN TOPICAL LOTION 1% ORANGE MEDIC PLUS	Testing associated with a product survey
PIPERONYL BUTOXIDE; PYRETHRINS TOPICAL LOTION PYRENEL FOAM	Testing associated with a product survey
PERMETHRIN LOTION 10MG/ML QUELLADA CREME RINSE FOR LONG HAIR	Testing associated with a product survey
BROMHEXINE; GUAIPHENESIN ORAL LIQUID ROBITUSSIN ME	Testing associated with a product survey
BROMHEXINE; GUAIPHENESIN ORAL LIQUID PHARMACIST EXPECTORANT	Testing associated with a product survey
BROMHEXINE; GUAIPHENESIN ORAL LIQUID CHEMWORLD EXPECTORANT	Testing associated with a product survey
ASPIRIN TABLET 300MG SOLUBLE HOMEBRAND CLEAR ASPIRIN	Testing associated with a product survey
ASPIRIN TABLET 300MG SOLUBLE HOMEBRAND CLEAR ASPIRIN	Testing associated with a product survey
ASPIRIN TABLET 300MG SOLUBLE HOMEBRAND CLEAR ASPIRIN	Testing associated with a product survey
ASPIRIN TABLET 300MG SOLUBLE HOMEBRAND CLEAR ASPIRIN	Testing associated with a product survey
ASPIRIN TABLET 300MG SOLUBLE HOMEBRAND CLEAR ASPIRIN	Testing associated with a product survey
ASPIRIN TABLET 300MG SOLUBLE HOMEBRAND CLEAR ASPIRIN	Testing associated with a product survey

Total number of products purchased = 45

Description	Reason for test
CODEINE; DOXYLAMINE; PARACETAMOL TABLET RAPIDEINE PLUS	Follow-up to routine testing
CAFFEINE; NICOTINIC ACID; THIAMINE TABLET DYNAMO	Follow-up to routine testing
ALUMINIUM HYDROXIDE; ATTAPULGITE; PECTIN TABLET DIAREZE	Follow-up to routine testing
CODEINE; PARACETAMOL TABLET RAPIDEINE CLEAR	Follow-up to routine testing
ASPIRIN TABLET 300MG HOME BRAND SOLUBLE ASPIRIN	Follow-up to routine testing
CAFFEINE TABLET 100MG NO DOZ AWAKENERS	Follow-up to routine testing
CAFFEINE; NICOTINIC ACID; THIAMINE TABLET NO DOZ PLUS	Follow-up to routine testing
ASPIRIN; DIHYDROCODEINE TARTRATE TABLET SOLUBLE CODOX	Follow-up to routine testing
PARACETAMOL TABLET EFFERVESCENT 500MG CLEAR PARACETAMOL	Follow-up to routine testing
PERMETHRIN TOPICAL LOTION 1% ORANGE MEDIC PLUS	Follow-up to routine testing
PARACETAMOL ORAL LIQUID 100MG/ML CHEMISTS' OWN COLOUR FREE	Complaint sample
PARACETAMOL ORAL LIQUID 100MG/ML COLOURFREE DROPS	Follow-up a Complaint
CHLORPHENIRAMINE; PHENYLEPHRINE ORAL LIQUID DURO-TUSS INFANT	Follow-up Product Evaluation
CHLORPHENIRAMINE; PHENYLEPHRINE ORAL LIQUID DURO-TUSS	Follow-up Product Evaluation
CHLORPHENIRAMINE; PHENYLEPHRINE ORAL LIQUID DECONGESTANT	Follow-up Product Evaluation
CHLORPHENIRAMINE; PHENYLEPHRINE ORAL LIQUID DECONGESTANT	Follow-up Product Evaluation
CHLORPHENIRAMINE; PHENYLEPHRINE ORAL LIQUID DECONGESTANT	Follow-up Product Evaluation
CHLORPHENIRAMINE; PHENYLEPHRINE ORAL LIQUID DURO-TUSS	Follow-up Product Evaluation
CHLORPHENIRAMINE; PHENYLEPHRINE ORAL LIQUID PHARMACY HEALTH	Follow-up Product Evaluation
CHLORPHENIRAMINE; PHENYLEPHRINE ORAL LIQUID NYAL PLUS	Follow-up Product Evaluation
CHLORPHENIRAMINE; PHENYLEPHRINE ORAL LIQUID COLD & ALLERGY	Follow-up Product Evaluation

Total number of products purchased = 21

Description	Reason for test
ATROPINE; HYOSCYAMINE; HYOSCINE TABLET DONNATAB	Follow-up a Complaint
HYOSCINE BUTYLBROMIDE TABLET 10MG BUSCOPAN	Follow-up a Complaint
HYOSCINE HYDROBROMIDE TABLET 0.3MG KWELLS	Follow-up a Complaint
HYOSCINE HYDROBROMIDE TABLET 0.3MG KWELLS	Follow-up a Complaint
ATROPINE; HYOSCYAMINE; HYOSCINE TABLET ATROBEL	Follow-up a Complaint
ATROPINE; HYOSCYAMINE; HYOSCINE TABLET ATROBEL FORTE	Follow-up a Complaint
CLOTRIMAZOLE 10MG/G CREAM	Follow-up Product Evaluation
CLOTRIMAZOLE 10MG/G CREAM	Follow-up Product Evaluation
PSEUDOEPHEDRINE HYDROCHLORIDE TABLET 60MG SINUS RELIEF	Follow-up Product Evaluation
CHLORPHENIRAMINE; PARACETAMOL; PSEUDOEPHEDRINE TABLET	Follow-up Product Evaluation
CHLORPHENIRAMINE; PARACETAMOL TABLET CHEMISTS' OWN COLDEZE	Follow-up Product Evaluation
DOLASED DAY/NIGHT PAIN RELIEF TABLET	Follow-up Product Evaluation
CODEINE; PARACETAMOL TABLET CHEMISTS' OWN PAIN TABSULES	Follow-up Product Evaluation
PARACETAMOL; PSEUDOEPHEDRINE TABLET SINUS-PAIN RELIEF	Follow-up Product Evaluation
COLD AND FLU DAY/NIGHT TABLET CHEMISTS' OWN	Follow-up Product Evaluation
CODEINE; DOXYLAMINE; PARACETAMOL TABLET DOLASED	Follow-up Product Evaluation
CODEINE; PARACETAMOL TABLET CHEMISTS' OWN PAIN TABLETS	Follow-up Product Evaluation
CODEINE; PARACETAMOL; PSEUDOEPHEDRINE TABLET COLD & FLU	Follow-up Product Evaluation
CHLORPHENIRAMINE; PSEUDOEPHEDRINE ORAL LIQUID AMCAL INFANT	Follow-up to routine testing
CHLORPHENIRAMINE; PSEUDOEPHEDRINE ORAL LIQUID AMCAL INFANT	Follow-up to routine testing
CETRIMIDE; CHLORHEXIDINE TOPICAL LIQUID SAVLON ANTISEPTIC	Routine Sample
CHLOROXYLENOL TOPICAL LIQUID 48MG/ML DETTOL ANTISEPTIC	Routine Sample
BENZALKONIUM CHLORIDE TOPICAL LIQUID DETTOL SPRAY	Routine Sample
IBUPROFEN ORAL SUSPENSION 20MG/ML CHEMISTS' OWN	Testing associated with a product survey
IBUPROFEN ORAL SUSPENSION 20MG/ML NUROFEN FOR CHILDREN	Testing associated with a product survey
POVIDONE-IODINE TOPICAL LIQUID 100MG/ML SOUL PATTINSON	Testing associated with a product survey
POVIDONE-IODINE TOPICAL OINTMENT 100MG/G SOUL PATTINSON	Testing associated with a product survey
ACICLOVIR CREAM 5% ZOLATEN	Testing associated with a product survey

ACICLOVIR CREAM 5% ZOVIRAX WITH MAC-P PUMP	Testing associated with a product survey
ACICLOVIR CREAM 5% ZOVIRAX WITH MAC-P TUBE	Testing associated with a product survey
ACICLOVIR CREAM 5% BIOCHEMIE COLD SORE CREAM	Testing associated with a product survey
ACICLOVIR CREAM 5% ACIHEXAL	Testing associated with a product survey
ACICLOVIR CREAM 5% ACIHEXAL	Testing associated with a product survey
ACICLOVIR CREAM 5% ACIHEXAL	Testing associated with a product survey
POVIDONE-IODINE ORAL SOLUTION 75MG/ML BETADINE SORE THROAT	Testing associated with a product survey
POVIDONE-IODINE; ETHANOL TOPICAL SOLUTION BETADINE COLD SORE	Testing associated with a product survey
POVIDONE-IODINE TOPICAL OINTMENT 100MG/ML BETADINE COLD SORE	Testing associated with a product survey
POVIDONE-IODINE TOPICAL POWDER 140MG/G SAVLON	Testing associated with a product survey
POVIDONE-IODINE TOPICAL POWDER 145MG/G EDP	Testing associated with a product survey
POVIDONE-IODINE TOPICAL CREAM 100MG/ML BETADINE FIRST AID	Testing associated with a product survey
POVIDONE-IODINE TOPICAL OINTMENT 100MG/ML BETADINE	Testing associated with a product survey
POVIDONE-IODINE TOPICAL SOLUTION BETADINE COLD SORE PAINT	Testing associated with a product survey
POVIDONE-IODINE TOPICAL OINTMENT 100MG/ML BETADINE LIQUID	Testing associated with a product survey
POVIDONE-IODINE TOPICAL OINTMENT 100MG/ML BETADINE LIQUID	Testing associated with a product survey
POVIDONE-IODINE ORAL SOLUTION 25MG/G MINIDINE SORE THROAT	Testing associated with a product survey
POVIDONE-IODINE TOPICAL OINTMENT 100MG/ML BETADINE COLD SORE	Testing associated with a product survey
POVIDONE-IODINE TOPICAL SOLUTION 75MG/ML SURGICAL SCRUB	Testing associated with a product survey
ACICLOVIR CREAM 5% AMCAL COLD SORE CREAM	Testing associated with a product survey
ACICLOVIR CREAM 5% ANTIVIRAL COLD SORE TREATMENT	Testing associated with a product survey

Total number of products purchased = 50

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 June 2003

Question: E03-146

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: POST-MARKETING MONITORING OF COMPLEMENTARY MEDICINE AND OVER-THE-COUNTER MEDICINE

Written Question on Notice

Senator McLucas asked:

(a) With regards to the TGA budget for testing complementary healthcare medicines:

(i) What is the dollar amount and the proportion of the yearly budget that has been devoted to post-market auditing, since 1995/96?

(ii) What is the dollar amount and the proportion of the yearly budget that has been devoted to post-market testing, since 1995/96?

(iii) What is the dollar amount and the proportion of the yearly budget that has been devoted to purchasing products 'off the shelf' for testing since 1995/96?

(b) With regards to the TGA budget for testing over-the-counter medicines:

(i) What is the dollar amount and the proportion of the yearly budget that has been devoted to post-market auditing, since 1995/96?

(ii) What is the dollar amount and the proportion of the yearly budget that has been devoted to post-market testing, since 1995/96?

(iii) What is the dollar amount and the proportion of the yearly budget that has been devoted to purchasing products 'off the shelf' for testing since 1995/96?

Answer:

(a)(i) & (b)(i) Post market auditing functions other than product testing are not part of the TGA testing budget for complementary or over the counter medicines. Post-market testing information is covered below.

(a)(ii) & (b)(ii) The following table summarises the TGA laboratories expenditure on post-market testing of complementary and over-the-counter medicines. All figures are in dollar amounts.

Year	Post-market OTC Medicines testing	Post-market Complementary. Medicines -testing
1995/6	$814,718	$748,795
1996/7	$876,607	$805,675
1997/8	$926,728	$851,741
1998/9	$967,983	$889,658
1999/0	$832,209	$764,870
2000/1	$669,020	$774,820
2001/2	$839,127	$1,079,039

Pre-market product testing of OTC and complementary medicines is not routinely undertaken. Essentially, 100% of the testing budget for these products is allocated to post-market testing.

(a)(iii) & (b)(iii) Generally, the TGA pays for about 36% of all samples tested. However, the current accounting database does not differentiate the costs of purchases of OTC and complementary medicine samples from all samples purchased by the Branch. Neither does it distinguish between samples which have been purchased "off-the-shelf" from those purchased from sponsors. In order to collate expenditure on sample purchases for the OTC and complementary testing programs, a large number of individual paper account records would have to be examined and this process would take several weeks because of the extraordinarily labour-intensive nature of this work.

However, the following table gives the numbers of samples purchased from all sources for the past three years, compared with 1995/6.

Financial Year	**Samples purchased**	**Total samples tested**
2002-2003	556	1544
2001-2002	464	1326
2000-2001	645	1654
1995-1996	683	1107

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-147

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: POST-MARKETING MONITORING OF COMPLEMENTARY MEDICINE AND OVER-THE-COUNTER MEDICINE

Written Question on Notice

Senator McLucas asked:

(a) Does the TGA use instruments with multiple-sample introduction systems? If so how many samples would you analyse in a single analytical run?

(b) If the TGA's instruments have 100- or 50-unit auto samplers, what proportion of their capacity is used?

(c) What is the value of the TGA's asset base in terms of analytical equipment?

Answer:

(a) & (b) TGA has a large number of instruments with multi-sample introduction capacity. The capacities are based on the standard units supplied with each instrument and range from 16 - 120 samples for different types of analytical instrument. The usage of the autosampler capacity is variable, and depends on the type of assay being run at the time, the number of sample replicates and standards needed for each assay, and the number of products available for assay at the particular point of time.

(c) The written down book value is $ 2,314,877 at the end of this financial year. The replacement value is $7,783,124 for this equipment.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-149

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: POST-MARKETING MONITORING OF COMPLEMENTARY MEDICINE AND OVER-THE-COUNTER MEDICINE

Written Question on Notice

Senator McLucas asked:

Does the post-market monitoring regime differ for prescription and non-prescription medicinal products?

If so, in what ways exactly are there differences, and on what general grounds is there a difference?

Answer:

The post market monitoring regimes for both prescription and non-prescription medicinal products are the same in that they comprise the following activities:

- Product surveys on specific substances, products or product groups;
- Testing for the Pharmaceutical Benefits Scheme (PBS)
- Problem/complaint/recall/quality alert investigation;
- Adverse Drug Reactions Unit (ADRU) investigation;
- Consultation and problem resolution with sponsors/manufacturers;
- Follow-up on intelligence from surveillance activities and audits of Good Manufacturing Practice;
- Laboratory testing.

Laboratory testing is carried out on both prescription and non-prescription medicines to determine:

- quantitative and qualitative characterisation of ingredients (including active and excipient ingredients);
- drug release profiles;
- determination of impurities and degradation products;
- testing for the presence of heavy metals, residues, and contaminants, including microbiological contaminants;
- potential adulteration by prescription and/or other restricted substances in non-prescription medicines.

The different risk profiles for prescription and non-prescription medicines may result in different weightings being given to the above factors in determining the testing priorities.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 June 2003

Question: E03-148
Revised

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: UNSCHEDULED SITE AUDITS

Written Question on Notice

Senator McLucas asked:

In relation to unscheduled or random manufacturing site audits:

(a) How many of these audits have occurred in the last 10 years?

(b) Where did these audits take place?

(c) When did these audits occur?

(d) Why were these audits considered necessary?

(e) Have TGA auditors ever been refused entry to a manufacturer when they have arrived for an unscheduled audit? If yes, how many times has this occurred, and when did these instances occur?

Answer:

(a) There have been 36 unscheduled GMP audits of manufacturers of therapeutic goods in the last 10 years.

(b) & (c)
The names, addresses and dates of these unscheduled audits are as follows:

Pan Laboratories, Villawood, NSW	21/9/92
Meditube Extrusions, Epping, VIC	15/7/93
Bega Blood Bank, NSW	16/11/93
Pan Laboratories, Villawood, NSW	16-17/4/94
Sydney Blood Bank, NSW	21/4/94
Canberra Blood Bank, ACT	6/11/96
Parramatta Blood Bank, NSW	24/4/97
MJ & AE Barber, Beaconsfield, NSW	29/8/97
CSL Bioplasma, Broadmeadows, VIC	24/11/98
Positive Healthcare, Parramatta, NSW	8-9/12/98

Aura Pharmaceuticals, Seaforth, VIC	3/2/99
Aura Pharmaceuticals, Seaforth, VIC	29/4/99
Aura Pharmaceuticals, Seaforth, VIC	1/9/99
CSL Bioplasma, Broadmeadows, VIC	1/7/99
North Sydney mobile blood collection site, NSW	20/7/99
CSL Bioplasma, Broadmeadows, VIC	23/11/99
Sydney Blood Bank, NSW	26/11/99
Townsville Blood Bank, QLD	22/6/00
Cairns Blood Bank, QLD	23/6/00
CSL Bioplasma, Broadmeadows, VIC	25-27/7/00
CSL Bioplasma, Broadmeadows, VIC	26-27/2/01
Sydney Blood Bank, NSW	30/5/01
CSL Bioplasma, Broadmeadows, VIC	6-8/6/01
Soul Pattinson Manufacturing, NSW	11/12/01
Afford Packaging, Mayfield, NSW	6/6/02
CSL Bioplasma, Broadmeadows, VIC	1-3/7/02
CSL Bioplasma, Broadmeadows, VIC	21-22/1/03
Pan Pharmaceuticals, Moorebank, NSW	30-31/1/03
Pan Pharmaceuticals, Moorebank, NSW	24-25/2/03
Gosford Blood Bank, NSW	17/3/03
Southbank Blood Bank, VIC	19/3/03
Pan Pharmaceuticals, Moorebank, NSW	7-14/4/03
CSL Bioplasma, Broadmeadows, VIC	5-7/5/03
Sigma, Clayton, VIC	8-9/5/03
Alphapharm, Carole Park, QLD	16/5/03
Lipa, Minto, NSW	11-13/6/03

(d) Unscheduled audits are carried out based upon the risk profile of the manufacturer. The TGA has a sophisticated system for monitoring manufacturers, which draws upon adverse reaction reports; previous audit history; targeted and random laboratory testing of products in the marketplace; results of surveillance activities, including investigation of complaints and tip-offs from competitors, consumers and employees. Unscheduled audits are carried out when information becomes available to the TGA which requires immediate investigation and/or where an assessment of true GMP compliance could not be assured otherwise.

(e) TGA auditors were refused entry to a manufacturer of therapeutic goods on two occasions when they have arrived to conduct an unscheduled audit. This occurred at audits that were to commence on 24 February 2003 and on 7 April 2003.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-150

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: COST OF PAN PHARMACEUTICALS RECALL

Written Question on Notice

Senator McLucas asked:

What was the cost of the following in relation to the recall of Pan Pharmaceuticals:

(a) Cost of advertising the recall in both print and broadcasting media.

(b) Total costs of call centre operation.

(c) Additional staffing costs to the TGA.

(d) Additional administrative costs.

(e) Legal advice.

(f) External advice, eg any consultancies.

(g) Cost of communicating the recall to the complementary healthcare industry.

(h) The cost of communicating the recall to the broader international industry.

(i) Any other associated costs.

Answer:

(a) The cost of advertising in metropolitan and regional newspapers to ensure the national dissemination of important public health and safety information was $11.6 million. No advertising was undertaken in the broadcast media.

(b) Call centre costs have been estimated to be $2.98 million.

(c) No additional staff have been engaged by TGA to manage the recall of Pan Pharmaceutical products.

(d) As part of its ongoing regulatory role, the TGA redirected resources to undertake additional Good Manufacturing Practice audits and undertake surveillance and investigation activities at an estimated cost of $2.2 million.

(e) Costs for legal advice associated with the Pan Pharmaceuticals Ltd recall has been estimated at $100,000 with a further $27,300 for legal services from the Department of Health and Ageing to assist with Freedom of Information Act applications.

(f) The TGA has estimated the cost of obtaining external advice from the Expert Committee on Complementary Medicines at approximately $17,000.

(g) The cost of printing and distributing materials to the complementary health care industry has been estimated at $135,505 with a further $3,840 incurred to update the TGA website with product recall information. The TGA also estimates costs of $177,000 for additional telecommunications expenses.

(h) Minimal costs were incurred in notifying international regulatory agencies of the recall of products manufactured by Pan Pharmaceuticals.

(i) Nil.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-151

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: COMPLEMENTARY HEALTH CARE INDUSTRY

Written Question on Notice

Senator McLucas asked:

Will there be an increase in next year's fees and charges for the complimentary heath care industry as a result of the extra costs incurred this year?

Answer:

There will not be an increase in fees and charges for complementary medicines as a result of the extra costs incurred this year. There will, however, be an increase of $115 in the annual charge for a listed complementary medicine being approved for marketing to reflect a projected short fall in TGA revenues from this sector in 2003/2004.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-152

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: PAN PHARMACEUTICALS RECALL LIST INFORMATION

Written Question on Notice

Senator McLucas asked:

Regarding the 2 June 2003 advertisement (Daily Telegraph) of 166 Pan products which were subsequently added to the recall list can you please provide the following:

(a) Full details for which companies were responsible for the recalled products, in respect to these companies please also provide the number of products per company, the names and batch numbers of the each product per company.

(b) For each of the companies please provide details as to these products and any other products they were responsible for, including when information was provided regarding the products the company was responsible for.

(c) Copies of any correspondence in whichever manner it was received whether that be by fax, email, post or otherwise and including proof of when it was received - such as fax confirmation receipts, date received stamps, and/or e-mail logs.

Answer:

There was no recall advertisement related to Pan products published in the Daily Telegraph on 2 June 2003. However, an advertisement for 166 additional Pan products was published in a number of papers on 3 June 2003. This advertising was the responsibility of individual sponsors, not the Therapeutic Goods Administration (TGA). The following responses refer to this advertisement.

(a) & (b)

A full list of product names and product batches for each sponsor is included as Attachment 1. This document also contains information on the date of documents received from sponsors and additional comments, where relevant.

Please note that in the advertisement some of the products are not listed under sponsor name as per the entry in the Australian Register of Therapeutic Goods (ARTG), eg products advertised as sponsored by Medicines from Nature are listed as sponsored by Health Promotions International Pty Ltd in the ARTG.

In summary, each sponsor had the following number of products advertised:

- AMCAL – 3;
- Bullivants Natural Health Products – 25;
- Guardian Pharmacies Australia Pty Ltd – 5;
- Health Promotions International Pty Ltd – 8;
- Herbs of Gold Pty Ltd – 19;
- Laboratories Pharm-A-Care Pty Ltd – 4;
- Lanopearl Pty Ltd – 4;
- Natural Remedies Pty Ltd – 2;
- Nutralife Health And Fitness Australia Pty Ltd – 1;
- Pharm-A-Care Laboratories Pty Limited – 1;
- Queensland Biochemics Pty Ltd – 3;
- Wagner Pro Biotics Pty Ltd –1; and
- Weider Health & Fitness Pty Ltd – 3.

(c) The documents requested contain information that was provided in confidence by sponsors. Before these documents could be released publicly, the TGA would need to seek advice from each sponsor as to whether these documents may be released.

SPONSOR	AUST L NUMBER	PRODUCT NAME (as per ARTG entry)	BATCH NUMBER	DOCUMENT TYPE	DATE OF DOCUMENT	COMMENTS
ALLIED MASTER CHEMISTS OF AUSTRALIA LIMITED (AMCAL)	70720	AMCAL GLUCOSAMINE 1000 MG TABLETS Glucosamine sulfate 1g Tablet - film coated bottle	77436	Product Questionnaire	05/05/2003	Unable to determine date when the documents were received as document was not date stamped.
ALLIED MASTER CHEMISTS OF AUSTRALIA LIMITED (AMCAL)	70720	AMCAL GLUCOSAMINE 1000 MG TABLETS Glucosamine sulfate 1g Tablet - film coated bottle	81414	Product Questionnaire	05/05/2003	Unable to determine date when the documents were received as document was not date stamped.
ALLIED MASTER CHEMISTS OF AUSTRALIA LIMITED (AMCAL)	70720	AMCAL GLUCOSAMINE 1000 MG TABLETS Glucosamine sulfate 1g Tablet - film coated bottle	81664	Product Questionnaire	05/05/2003	Unable to determine date when the documents were received as document was not date stamped.
ALLIED MASTER CHEMISTS OF AUSTRALIA LIMITED (AMCAL)	70720	AMCAL GLUCOSAMINE 1000 MG TABLETS Glucosamine sulfate 1g Tablet - film coated bottle	81665	Product Questionnaire	05/05/2003	Unable to determine date when the documents were received as document was not date stamped.
ALLIED MASTER CHEMISTS OF AUSTRALIA LIMITED (AMCAL)	70722	AMCAL EO CO-ENZYME Q10	84217	Product Questionnaire	05/05/2003	Unable to determine date when the documents were received as document was not date stamped.
ALLIED MASTER CHEMISTS OF AUSTRALIA LIMITED (AMCAL)	72911	AMCAL ACIDOPHILUS COMPLEX CAPSULES Capsule, hard bottle	80499	Product Questionnaire	05/05/2003	Unable to determine date when the documents were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	27072	NATURAL ALTERNATIVE Vitamin C 500mg Natural Orange Flavour Tablets 100	201938	Letter	29/04/2003	Only product name listed - no AUSTL/R to positively identify, and no batch numbers. Facsimiles dated 29/04/03 received on the same day.
BULLIVANTS NATURAL HEALTH PRODUCTS	27072	NATURAL ALTERNATIVE Vitamin C 500mg Natural Orange Flavour Tablets 100	2V01938	Letters	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28177	NATURE'S OWN Valerian 500mg Capsules 200	204776	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28177	NATURE'S OWN Valerian 500mg Capsules 200	206195	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28177	NATURE'S OWN Valerian 500mg Capsules 90	204761	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28177	NATURE'S OWN Valerian 500mg Capsules 90	204879	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28177	NATURE'S OWN Valerian 500mg Capsules 90	205912	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28177	NATURE'S OWN Valerian 500mg Capsules 90	206286	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28294	NATURE'S OWN Raspberry Leaf 500mg Tablets 90	204593	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28294	NATURE'S OWN Raspberry Leaf 500mg Tablets 90	205840	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28294	NATURE'S OWN Raspberry Leaf 500mg Tablets 90	300284	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28324	NATURE'S OWN Vitamin C Natural Orange Flavour 1000mg Tablets 150	205530	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28324	NATURE'S OWN Vitamin C Natural Orange Flavour 1000mg Tablets 150	206269	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28324	NATURE'S OWN Vitamin C Natural Orange Flavour 1000mg Tablets 60	203626	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28324	NATURE'S OWN Vitamin C Natural Orange Flavour 1000mg Tablets 60	204403	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28324	NATURE'S OWN Vitamin C Natural Orange Flavour 1000mg Tablets 60	204576	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28327	NATURE'S OWN Vitamin C Natural Orange Flavour 500mg Tablets 100	202919	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28327	NATURE'S OWN Vitamin C Natural Orange Flavour 500mg Tablets 100	203029	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28327	NATURE'S OWN Vitamin C Natural Orange Flavour 500mg Tablets 100	203545	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28327	NATURE'S OWN Vitamin C 500mg Natural Orange Flavour Trial Size 20	203509	No documents		
BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	202116	Letter	29/04/2003	Only product name listed - no AUSTL/R to positively identify, and no batch numbers. Documents received on the same day.
BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	203082	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	203548	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	204091	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	204108	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	204745	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	205467	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	206272	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	300526	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	300780	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28449	NATURE'S OWN Colds & Flu Tablets 75	2V02116	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28462	NATURE'S OWN Hair Tablets 75	101852	Letter	29/04/2003	Only product name listed - no AUSTL/R to positively identify, and no batch numbers. Documents received on the same day.
BULLIVANTS NATURAL HEALTH PRODUCTS	28462	NATURE'S OWN Hair Tablets 75	203579	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28462	NATURE'S OWN Hair Tablets 75	204839	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28462	NATURE'S OWN Hair Tablets 75	1V01852	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 50	10237	Letter	29/04/2003	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 50	203762	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 50	204204	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 50	205269	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 50	205852	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 50	206593	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 50	300074	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 50	1V02377	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 150	203763	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 150	204205	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 150	204780	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 150	206300	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 150	206594	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28464	NATURE'S OWN Vitamin C 1000mg + RoseHips Tablets 150	300073	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28478	NATURE'S OWN Dolomite (Micro Refined) 1000mg Tablets 50	206755	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28478	NATURE'S OWN Dolomite (Micro Refined) 1000mg Tablets 50	300408	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28509	NATURE'S OWN Betacarotene 6mg Capsules 75	204389	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28526	NATURE'S OWN Vitamin B5 250mg (Pantothenic Acid) Tablets 50	300438	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28535	NATURE'S OWN Golden Seal 500mg Capsules 50	205839	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28535	NATURE'S OWN Golden Seal 500mg Capsules 50	206574	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28535	NATURE'S OWN Golden Seal 500mg Capsules 50	300671	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28547	NATURE'S OWN Celery Seed 250mg Tablets 100	204249	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28557	NATURE'S OWN Cold Sores Tablets 60	204838	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28557	NATURE'S OWN Cold Sores Tablets 60	206185	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28557	NATURE'S OWN Cold Sores Tablets 60	300201	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28563	NATURE'S OWN Digestive Enzymes Tablets 100	203899	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28563	NATURE'S OWN Digestive Enzymes Tablets 100	204964	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28563	NATURE'S OWN Digestive Enzymes Tablets 100	205534	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28563	NATURE'S OWN Digestive Enzymes Tablets 100	300392	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28563	NATURE'S OWN Digestive Enzymes Tablets 50	204251	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	28563	NATURE'S OWN Digestive Enzymes Tablets 50	205272	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	28563	NATURE'S OWN Digestive Enzymes Tablets 50	205835	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	30623	NATURE'S OWN Vitamin B6 250mg Tablets 50	203243	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	30623	NATURE'S OWN Vitamin B6 250mg Tablets 50	205465	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	30623	NATURE'S OWN Vitamin B6 250mg Tablets 50	206241	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	30623	NATURE'S OWN Vitamin B6 250mg Tablets 50	300075	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	30700	NATURE'S OWN Silica (Silica Oxide) Tablets 200	204649	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	30700	NATURE'S OWN Silica (Silica Oxide) Tablets 200	205279	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	30700	NATURE'S OWN Silica (Silica Oxide) Tablets 200	205924	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	30700	NATURE'S OWN Silica (Silica Oxide) Tablets 200	300349	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	56771	NATURE'S OWN Vitamin B3 250mg Tablets 100	204512	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	56771	NATURE'S OWN Vitamin B3 250mg Tablets 100	205165	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	56771	NATURE'S OWN Vitamin B3 250mg Tablets 100	205441	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	56771	NATURE'S OWN Vitamin B3 250mg Tablets 100	300174	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	62820	NATURE'S OWN Evening Primrose Oil 1500mg Capsules 90	201794	Letter	29/04/2003	Only product name listed - no AUSTL/R to positively identify, and no batch numbers. Documents received on the same day.
BULLIVANTS NATURAL HEALTH PRODUCTS	62820	NATURE'S OWN Evening Primrose Oil 1500mg Capsules 90	204856	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	62820	NATURE'S OWN Evening Primrose Oil 1500mg Capsules 90	205960	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	62820	NATURE'S OWN Evening Primrose Oil 1500mg Capsules 90	206766	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	62820	NATURE'S OWN Evening Primrose Oil 1500mg Capsules 90	2V01794	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 100	202631	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as documents not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 100	204136	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 100	205173	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 100	205442	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 100	206097	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 100	300199	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 100	300489	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 300	203322	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 300	203739	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 300	204514	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 300	205443	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.

BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 300	206108	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 300	300489	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	64752	NATURE'S OWN Cod Liver Oil Capsules 300	300523	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	66386	NATURE'S OWN Chromium Picolinate 400mcg Tablets 200	203590	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents

						dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	66386	NATURE'S OWN Chromium Picolinate 400mcg Tablets 200	203630	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	66386	NATURE'S OWN Chromium Picolinate 400mcg Tablets 200	203828	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	66386	NATURE'S OWN Chromium Picolinate 400mcg Tablets 200	205032	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	66386	NATURE'S OWN Chromium Picolinate 400mcg Tablets 200	205895	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents

						dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	68123	NATURE'S OWN Triple Strength ChitoSan 750mg Tablets 60	205416	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers. Facsimiles dated 29/04/03 and 30/4/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as documents not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	68123	NATURE'S OWN Triple Strength ChitoSan 750mg Tablets 60	206595	Letter	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Second letter (30/4/03) listed AUSTL numbers, but no batch numbers.
BULLIVANTS NATURAL HEALTH PRODUCTS	72686	NATURE'S OWN L-Tyrosine 500mg Tablets 30	205311	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72686	NATURE'S OWN L-Tyrosine 500mg Tablets 30	206246	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents

						dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72686	NATURE'S OWN L-Tyrosine 500mg Tablets 30	204681	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72686	NATURE'S OWN L-Tyrosine 500mg Tablets 60	205551	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72686	NATURE'S OWN L-Tyrosine 500mg Tablets 60	206535	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72686	NATURE'S OWN L-Tyrosine 500mg Tablets 60	300376	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents

						dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72687	NATURAL NUTRITION L-Lysine 1000mg Tablets 30	204137	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72687	NATURAL NUTRITION L-Lysine 1000mg Tablets 30	204906	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72687	NATURAL NUTRITION L-Lysine 1000mg Tablets 30	206058	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72687	NATURAL NUTRITION L-Lysine 1000mg Tablets 30	206673	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents

						dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72687	NATURAL NUTRITION L-Lysine 1000mg Tablets 30	206758	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	72687	NATURAL NUTRITION L-Lysine 1000mg Tablets 30	300354	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	90415	BIO-ORGANICS UltrasorbTM - Ginkgo Biloba Capsules 30	277	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	90415	BIO-ORGANICS UltrasorbTM - Ginkgo Biloba Capsules 30	311	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents

						dated 09/05/03 were received as document was not date stamped.
BULLIVANTS NATURAL HEALTH PRODUCTS	90415	BIO-ORGANICS UltrasorbTM - Ginkgo Biloba Capsules 30	355	Letter	29/4/03; 9/5/03	First letter listed product names only - no AUSTL/R numbers and no batch numbers. Facsimiles dated 29/04/03 received on the same day. Unable to determine the date when the documents dated 09/05/03 were received as document was not date stamped.
GUARDIAN PHARMACIES AUSTRALIA PTY LTD	50357	GUARDIAN VITAMIN C 1000 COMPLEX tablet bottle	80357	Product Questionnaire	05/05/2003	Unable to determine date when the documents were received as document was not date stamped.
GUARDIAN PHARMACIES AUSTRALIA PTY LTD	50357	GUARDIAN VITAMIN C 1000 COMPLEX tablet bottle	83434	Product Questionnaire	30/04/2003	Unable to determine date when the documents were received as document was not date stamped.
GUARDIAN PHARMACIES AUSTRALIA PTY LTD	58953	GUARDIAN WOMEN'S VITAMIN-MINERAL & HERBAL FORMULA capsule bottle	76823	Product Questionnaire	30/04/2003	Unable to determine date when the documents were received as document was not date stamped.
GUARDIAN PHARMACIES AUSTRALIA PTY LTD	58953	GUARDIAN WOMEN'S VITAMIN-MINERAL & HERBAL FORMULA capsule bottle	83648	Product Questionnaire	30/04/2003	Unable to determine date when the documents were received as document was not date stamped.
GUARDIAN PHARMACIES AUSTRALIA PTY LTD	61734	GUARDIAN VITAMIN C 500MG	79020	N/A	N/A	No documents listing this product received.
GUARDIAN PHARMACIES	61735	GUARDIAN VITAMIN C 250MG ORANGE	80356	Product Questionnaire	30/04/2003	Unable to determine date when the documents were received as document

AUSTRALIA PTY LTD		FLAVOUR Tablet - chewable bottle				was not date stamped.
GUARDIAN PHARMACIES AUSTRALIA PTY LTD	61735	GUARDIAN VITAMIN C 250MG ORANGE FLAVOUR Tablet - chewable bottle	84176	Product Questionnaire	05/05/2003	Unable to determine date when the documents were received as document was not date stamped.
GUARDIAN PHARMACIES AUSTRALIA PTY LTD	61735	GUARDIAN VITAMIN C 250MG ORANGE FLAVOUR Tablet - chewable bottle	84186	Product Questionnaire	30/04/2003	Unable to determine date when the documents were received as document was not date stamped.
GUARDIAN PHARMACIES AUSTRALIA PTY LTD	71264	GUARDIAN PHARMACY GLUCOSAMINE SULFATE 1000 Glucosamine sulfate 1g Tablet - film coated bottle	77436	Product Questionnaire	05/05/2003	Unable to determine date when the documents were received as document was not date stamped.
GUARDIAN PHARMACIES AUSTRALIA PTY LTD	71264	GUARDIAN PHARMACY GLUCOSAMINE SULFATE 1000 Glucosamine sulfate 1g Tablet - film coated bottle	81316	Product Questionnaire	30/04/2003	Unable to determine date when the documents were received as document was not date stamped.
GUARDIAN PHARMACIES AUSTRALIA PTY LTD	71264	GUARDIAN PHARMACY GLUCOSAMINE SULFATE 1000 Glucosamine sulfate 1g Tablet - film coated bottle	82810	Product Questionnaire	30/04/2003	Unable to determine date when the documents were received as document was not date stamped.

HEALTH PROMOTIONS INTERNATIONAL PTY LTD	72118	PROMAXIN FOR MEN MEDICINES FROM NATURE BY ROSS GARDINER Capsule, soft bottle	78171	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	72118	PROMAXIN FOR MEN MEDICINES FROM NATURE BY ROSS GARDINER Capsule, soft bottle	80359	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	77377	ROSS GARDINER FLORA MAX PRO CAPSULES ENTERIC COATED Capsule, enteric bottle	76757	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	77377	ROSS GARDINER FLORA MAX PRO CAPSULES ENTERIC COATED Capsule, enteric bottle	78085	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	77377	ROSS GARDINER FLORA MAX PRO CAPSULES ENTERIC COATED Capsule, enteric bottle	78845	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	77377	ROSS GARDINER FLORA MAX PRO CAPSULES ENTERIC COATED Capsule, enteric bottle	80581	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.

HEALTH PROMOTIONS INTERNATIONAL PTY LTD	77377	ROSS GARDINER FLORA MAX PRO CAPSULES ENTERIC COATED Capsule, enteric bottle	82807	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	79163	ROSS GARDINER MAXI-FERRIN PRO PLUS Capsule, hard bottle	78000	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	79163	ROSS GARDINER MAXI-FERRIN PRO PLUS Capsule, hard bottle	84323	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	80943	ROSS GARDINER LIVER PRO PLUS LIVER TONIC Capsule, hard Information not provided	77097	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	80943	ROSS GARDINER LIVER PRO PLUS LIVER TONIC Capsule, hard Information not provided	77096	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	80944	ROSS GARDINER LIVER PRO PLUS POWDER Powder - oral Information not provided	77097	Product Questionnaire	01/05/2005	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	80944	ROSS GARDINER LIVER PRO PLUS POWDER Powder - oral Information not provided	77096	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	82330	MFN PROFESSIONALS GHF Powder - oral jar/can	80496	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.

HEALTH PROMOTIONS INTERNATIONAL PTY LTD	90327	Flexi-Nol Medicines from nature by Ross Gardiner	79903	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HEALTH PROMOTIONS INTERNATIONAL PTY LTD	90423	Lacto-Max Pro Medicine from Nature by Ross Gardiner	80241	Product Questionnaire	01/05/2003	Documents received on 02/5/2003.
HERBS OF GOLD P/L	17169	HERBS OF GOLD Eco Herbs Calendula Cream	All batches	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	17170	HERBS OF GOLD "Eco Herbs" Chickweed Cream	All batches	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	17171	HERBS OF GOLD Eco Herbs Comfrey Cream	All batches	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	17173	HERBS OF GOLD "Eco-Herbs" Arnica Cream	All batches	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	68565	EXTRA STRENGTH ARTHRICIN PLUS GLUCOSAMINE	20788	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	68565	EXTRA STRENGTH ARTHRICIN PLUS GLUCOSAMINE	20897	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	77822	GINKGO BILOBA 2500 Ginkgo biloba 50mg Tablet - film coated bottle	19957	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	77822	GINKGO BILOBA 2500 Ginkgo biloba 50mg Tablet - film coated bottle	19962	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	77822	GINKGO BILOBA 2500 Ginkgo biloba 50mg Tablet - film coated bottle	20270	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	77822	GINKGO BILOBA 2500 Ginkgo biloba 50mg	20298	Letter	01/05/2003	Document received 2/5/03

		Tablet - film coated bottle				
HERBS OF GOLD P/L	77822	GINKGO BILOBA 2500 Ginkgo biloba 50mg Tablet - film coated bottle	20319	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	77822	GINKGO BILOBA 2500 Ginkgo biloba 50mg Tablet - film coated bottle	20643	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	77822	GINKGO BILOBA 2500 Ginkgo biloba 50mg Tablet - film coated bottle	20785	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	77822	GINKGO BILOBA 2500 Ginkgo biloba 50mg Tablet - film coated bottle	20792	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	77822	GINKGO BILOBA 2500 Ginkgo biloba 50mg Tablet - film coated bottle	20826	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78044	CARDIO CARE Tablet - film coated blister pack	20540	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78044	CARDIO CARE Tablet - film coated blister pack	20660	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78044	CARDIO CARE Tablet - film coated blister pack	20688	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78044	CARDIO CARE Tablet - film coated blister pack	20795	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78044	CARDIO CARE Tablet - film coated blister pack	20829	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78049	CHOLESTEROL CARE Capsule, soft blister pack	20834	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78049	CHOLESTEROL CARE Capsule, soft blister pack	20836	Product Questionnaire	01/05/2003	Document received 2/5/03

HERBS OF GOLD P/L	78049	CHOLESTEROL CARE Capsule, soft blister pack	20913	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78049	CHOLESTEROL CARE Capsule, soft blister pack	20915	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78322	GINSENG 4 ENERGY Tablet - film coated blister pack	20076	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78322	GINSENG 4 ENERGY Tablet - film coated blister pack	20256	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78322	GINSENG 4 ENERGY Tablet - film coated blister pack	20406	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78322	GINSENG 4 ENERGY Tablet - film coated blister pack	20599	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78322	GINSENG 4 ENERGY Tablet - film coated blister pack	20696	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78322	GINSENG 4 ENERGY Tablet - film coated blister pack	20869	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	78891	COD LIVER OIL 1000 Cod-liver oil 1g Capsule, soft bottle	20868	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79084	HERBS OF GOLD VITAMIN B1 Thiamine hydrochloride 100mg Tablet - uncoated bottle	20704	Product Questionnaire	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79084	HERBS OF GOLD VITAMIN B1 Thiamine hydrochloride 100mg	20800	Product Questionnaire	01/05/2003	Document received 2/5/03

		Tablet - uncoated bottle				
HERBS OF GOLD P/L	79090	HERBS OF GOLD MAGNESIUM COMPLEX Tablet - film coated bottle	20335	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79090	HERBS OF GOLD MAGNESIUM COMPLEX Tablet - film coated bottle	20507	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79090	HERBS OF GOLD MAGNESIUM COMPLEX Tablet - film coated bottle	20641	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79090	HERBS OF GOLD MAGNESIUM COMPLEX Tablet - film coated bottle	20791	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79090	HERBS OF GOLD MAGNESIUM COMPLEX Tablet - film coated bottle	20852	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20061	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20162	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20163	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20353	Product Questionnaire	01/05/2003	Document received 5/5/03

HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20354	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20485	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20512	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20562	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20593	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20653	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20799	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20881	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79136	WOMEN'S MULTI Tablet - film coated bottle	20882	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79137	ODOURLESS GARLIC 2000 Capsule, soft bottle	20630	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79137	ODOURLESS GARLIC 2000 Capsule, soft bottle	20819	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79139	ZINC COMPLEX Tablet - film coated bottle	20570	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79139	ZINC COMPLEX Tablet - film coated bottle	20765	Product Questionnaire	01/05/2003	Document received 5/5/03
HERBS OF GOLD P/L	79140	FOLIC ACID COMPLEX Tablet - film coated bottle	20499	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79140	FOLIC ACID COMPLEX Tablet - film	20631	Letter	01/05/2003	Document received 2/5/03

		coated bottle				
HERBS OF GOLD P/L	79141	CYSTITIS RELIEF Tablet - film coated bottle	20862	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79141	CYSTITIS RELIEF Tablet - film coated bottle	20888	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79142	ULTRA OMEGA Capsule, soft bottle	20278	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79142	ULTRA OMEGA Capsule, soft bottle	20321	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79142	ULTRA OMEGA Capsule, soft bottle	20408	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79142	ULTRA OMEGA Capsule, soft bottle	20528	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79142	ULTRA OMEGA Capsule, soft bottle	20561	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79142	ULTRA OMEGA Capsule, soft bottle	20768	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79305	HERBS OF GOLD STRESS RELIEF - MEGA B Tablet - film coated bottle	20534	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79305	HERBS OF GOLD STRESS RELIEF - MEGA B Tablet - film coated bottle	20633	Letter	01/05/2003	Document received 2/5/03
HERBS OF GOLD P/L	79305	HERBS OF GOLD STRESS RELIEF - MEGA B Tablet - film coated bottle	20706	Letter	01/05/2003	Document received 2/5/03

HERBS OF GOLD P/L	79305	HERBS OF GOLD STRESS RELIEF - MEGA B Tablet - film coated bottle	20873	Letter	01/05/2003	Document received 2/5/03
LABORATORIES PHARM-A-CARE PTY LTD	58262	ODOURLESS GARLIC 5mg capsule bottle	81451	Facsimile	14/05/2003	Document received 14/5/03
LABORATORIES PHARM-A-CARE PTY LTD	75968	GLUCOSAMINE PLUS Capsule bottle	77680	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	75968	GLUCOSAMINE PLUS Capsule bottle	81988	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	75968	GLUCOSAMINE PLUS Capsule bottle	84917	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81085	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81086	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81087	Email	1/5/03 (4:58pm)	Document received 1/5/03

LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81088	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81968	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81969	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81970	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81971	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81972	Email	1/5/03 (4:58pm)	Document received 1/5/03

LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81973	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	77129	NATURES WAY SUPER CALCIUM COMPLEX WITH HYDROXYAPATITE Tablet bottle	81974	Email	1/5/03 (4:58pm)	Document received 1/5/03
LABORATORIES PHARM-A-CARE PTY LTD	78636	NATURES WAY GARLIC + C & HORSERADISH WITH FENUGREEK & MARSHMALLOW Tablet	78973	Facsimile	09/05/2003	Document received 9/5/03
LABORATORIES PHARM-A-CARE PTY LTD	78636	NATURES WAY GARLIC + C & HORSERADISH WITH FENUGREEK & MARSHMALLOW Tablet	78974	Facsimile	09/05/2003	Document received 9/5/03
LABORATORIES PHARM-A-CARE PTY LTD	78636	NATURES WAY GARLIC + C & HORSERADISH WITH FENUGREEK & MARSHMALLOW Tablet	78975	Facsimile	09/05/2003	Document received 9/5/03
LABORATORIES PHARM-A-CARE PTY LTD	78636	NATURES WAY GARLIC + C & HORSERADISH WITH FENUGREEK & MARSHMALLOW Tablet	78976	Facsimile	09/05/2003	Document received 9/5/03

LABORATORIES PHARM-A-CARE PTY LTD	78636	NATURES WAY GARLIC + C & HORSERADISH WITH FENUGREEK & MARSHMALLOW Tablet	79950	Facsimile	09/05/2003	Document received 9/5/03
LABORATORIES PHARM-A-CARE PTY LTD	78636	NATURES WAY GARLIC + C & HORSERADISH WITH FENUGREEK & MARSHMALLOW Tablet	79951	Facsimile	09/05/2003	Document received 9/5/03
LABORATORIES PHARM-A-CARE PTY LTD	78636	NATURES WAY GARLIC + C & HORSERADISH WITH FENUGREEK & MARSHMALLOW Tablet	81949	Facsimile	09/05/2003	Document received 9/5/03
LABORATORIES PHARM-A-CARE PTY LTD	78636	NATURES WAY GARLIC + C & HORSERADISH WITH FENUGREEK & MARSHMALLOW Tablet	81950	Facsimile	09/05/2003	Document received 9/5/03
LABORATORIES PHARM-A-CARE PTY LTD	78636	NATURES WAY GARLIC + C & HORSERADISH WITH FENUGREEK & MARSHMALLOW Tablet	83096	Facsimile	09/05/2003	Document received 9/5/03
LABORATORIES PHARM-A-CARE PTY LTD	78636	NATURES WAY GARLIC + C & HORSERADISH WITH FENUGREEK & MARSHMALLOW Tablet	83097	Facsimile	09/05/2003	Document received 9/5/03

LANOPEARL PTY LTD	73103	LIFE SPRING BIO-C Tablet - film coated bottle	81388	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	73103	LIFE SPRING BIO-C Tablet - film coated bottle	82878	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	73103	LIFE SPRING BIO-C Tablet - film coated bottle	83368	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	73103	LIFE SPRING BIO-C Tablet - film coated bottle	81388A	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	73103	LIFE SPRING BIO-C Tablet - film coated bottle	82878A	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	73139	LIFE SPRING ANTIOXIDANTS WITH GRAPESEED Capsule, soft bottle	81514	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.

LANOPEARL PTY LTD	73139	LIFE SPRING ANTIOXIDANTS WITH GRAPESEED Capsule, soft bottle	82905	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	73139	LIFE SPRING ANTIOXIDANTS WITH GRAPESEED Capsule, soft bottle	83357	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	73139	LIFE SPRING ANTIOXIDANTS WITH GRAPESEED Capsule, soft bottle	81514A	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	73139	LIFE SPRING ANTIOXIDANTS WITH GRAPESEED Capsule, soft bottle	82905A	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	75539	LIFE SPRING CALCIUM CHILDREN CHEWABLE COMPLEX PLUS LECITHIN Tablet - chewable bottle	82742	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	75539	LIFE SPRING CALCIUM CHILDREN CHEWABLE COMPLEX PLUS LECITHIN Tablet - chewable bottle	82742A	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.

LANOPEARL PTY LTD	76365	LIFE SPRING VITAMIN C 500MG CHEWABLE Tablet - chewable bottle	82790	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
LANOPEARL PTY LTD	76365	LIFE SPRING VITAMIN C 500MG CHEWABLE Tablet - chewable bottle	82790A	Copy of Recall Letter sent to customers	?/5/03, 14/5/03	Information first provided in the undated letter in response to TGA's letter dated 7/5/03. Additional information received on 14/5/03, adding this product to the recall list.
NATURAL REMEDIES PTY LTD	90422	Spirulina Energy Plus	81511	Product Questionnaire	30/04/2003	Document received 5/5/03
NATURAL REMEDIES PTY LTD	90808	Joint Active Liquid Glucosamine	81603	Product Questionnaire	30/04/2003	Document received 5/5/03
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	F2056	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	F2061	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	G2022	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	G2023	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.

NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	H2035	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	H2082	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	J2029	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	J2031	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	J2212	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	K2077	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	M2065	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	M2085	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.

NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	M2243	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	M2344	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
NUTRALIFE HEALTH AND FITNESS AUSTRALIA PTY LTD	79603	MAGNESIUM COMPLETE tablets	P2025	Product Questionnaire	30/04/2003	Batch number was linked to AUSTL 79604, not to AUSTL 79603. Unable to determine the date when document was received as document not date stamped.
PHARM-A-CARE LABORATORIES PTY LIMITED	18854	ADACOL ANESTHETIC THROAT LOZENGES Strip pack	80162	Facsimile	14/05/2003	Facsimile received on 14/5/03 adding this product to the list of products to be recalled.
QUEENSLAND BIOCHEMICS PTY LTD	81676	GOLDEN GLOW CHONDROITIN COMP	300561	Letter; facsimile	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Facsimile (30/4/03) listed AUSTL numbers, but no batch numbers.
QUEENSLAND BIOCHEMICS PTY LTD	82012	GG FIBRO MUSCLE SMOOTHE	76401	Facsimile	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Facsimile (30/4/03) listed AUSTL numbers, but no batch numbers.
QUEENSLAND BIOCHEMICS PTY LTD	79082	Natural Vit E 1000iu Caps 50	206540	Facsimile	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Facsimile (30/4/03) listed AUSTL numbers, but no batch numbers.

QUEENSLAND BIOCHEMICS PTY LTD	79082	Natural Vit E 1000iu Caps 50	300537	Facsimile	29/4/03; 30/4/03; 9/5/03	First letter (29/4/03) listed product names only - no AUSTL/R numbers and no batch numbers. Facsimile (30/4/03) listed AUSTL numbers, but no batch numbers.
WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	C3073	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	F2066	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	F2067	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	H2008	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	H2021	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.

WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	K2047	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	K2048	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	M2031	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	M2057	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	M2234	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	P2017	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.

WAGNER PRO BIOTICS P/L	49248	WAGNER PROBIOTICS OMEGAFLAX 369 CAPSULE BOTTLE Linseed Oil 1g Capsule - soft bottle	P2108	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	18029	JOE WEIDER'S VICTORY LIVER 10000mg tablet bottle	D3151	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	18029	JOE WEIDER'S VICTORY LIVER 10000mg tablet bottle	F2038	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	18029	JOE WEIDER'S VICTORY LIVER 10000mg tablet bottle	F2039	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	18029	JOE WEIDER'S VICTORY LIVER 10000mg tablet bottle	K2097	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	18029	JOE WEIDER'S VICTORY LIVER 10000mg tablet bottle	M2189	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	18032	JOE WEIDER'S VICTORY RECOVERY AMINOS (Branch-Chain Amino Acids) Plus Mineral Succinates tablet bottle	A3007	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	18032	JOE WEIDER'S VICTORY RECOVERY AMINOS (Branch-Chain Amino Acids) Plus Mineral Succinates tablet bottle	A3107	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.

WEIDER HEALTH & FITNESS PTY LTD	18032	JOE WEIDER'S VICTORY RECOVERY AMINOS (Branch-Chain Amino Acids) Plus Mineral Succinates tablet bottle	F2048	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	18032	JOE WEIDER'S VICTORY RECOVERY AMINOS (Branch-Chain Amino Acids) Plus Mineral Succinates tablet bottle	G2310	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	18032	JOE WEIDER'S VICTORY RECOVERY AMINOS (Branch-Chain Amino Acids) Plus Mineral Succinates tablet bottle	K2058	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	18032	JOE WEIDER'S VICTORY RECOVERY AMINOS (Branch-Chain Amino Acids) Plus Mineral Succinates tablet bottle	M2232	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	35995	JOE WEIDER'S "VICTORY" AMINO POWER 10/30 10gram amino acids 30% BCAA formula tablet bottle	C3049	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.

WEIDER HEALTH & FITNESS PTY LTD	35995	JOE WEIDER'S "VICTORY" AMINO POWER 10/30 10gram amino acids 30% BCAA formula tablet bottle	G2301	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.
WEIDER HEALTH & FITNESS PTY LTD	35995	JOE WEIDER'S "VICTORY" AMINO POWER 10/30 10gram amino acids 30% BCAA formula tablet bottle	K2119	Product Questionnaire	01/05/2003	Unable to determine date when the documents were received as document was not date stamped.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-153

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: TGA FEES AND CHARGES FOR COMPLEMENTARY MEDICINE AND OVER-THE-COUNTER PRODUCTS

Written Question on Notice

Senator McLucas asked:

What methods does the TGA have in place for the potential costs that may arise in a subsequent year for unforeseen and unpredictable monitoring/auditing/testing? Are these costs factored into industry fees?

Answer:

The Therapeutic Goods Administration (TGA) is required to fully recover its operating costs. It collects its revenue primarily through annual charges, evaluation and assessment fees and licence fees. The TGA also has a reserve fund which is intended to have the capacity to meet contingent liabilities and unexpected expenses.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-154

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: TGA FEES AND CHARGES FOR COMPLEMENTARY MEDICINE AND OVER-THE-COUNTER PRODUCTS

Written Question on Notice

Senator McLucas asked:

(a) What is the role of the complementary healthcare industry in discussing and agreeing the TGA's schedule of fees?

(b) Does this process allow room for industry disagreement or negotiation about proposed fees or methods for their determination?

(c) If so, what weight has typically been given to industry concerns or interests in setting fees?

Answer:

(a) The Therapeutic Goods Administration (TGA) is required to fully recover its operating costs. The TGA's fees and charges are usually determined after consultation with peak industry associations, including the Australian Self Medication Industry and the Complementary Healthcare Council of Australia for complementary medicines. Generally, bilateral negotiation with industry commences early in the year, with ad hoc meetings being called as required. Fees and charges are also formally presented to the TGA-Industry Consultative Committee (TICC), which is a consultative forum that meets twice a year to facilitate consultation between the TGA, industry representatives and consumers.

(b) Yes.

(c) Industry concerns and comments are taken into account to enable the TGA to make informed forecasts of industry growth (eg in relation to the expected number of new applications and expected product life cycles), import and export activities and the overall economic outlook for the industry sector to determine the appropriate structuring of fees and charges to achieve cost recovery.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-155

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: REPORTING OF ADVERSE DRUG REACTIONS OF PRODUCTS MADE BY PAN PHARMACEUTICALS

Written Question on Notice

Senator McLucas asked:

(a) What products made by Pan Pharmaceuticals (subject to the recall and excluding Travacalm) have had an adverse drug reaction report made about them in the period after the recall?

(b) Have those ADR reports been validated? If yes please provide details including the name of the product and its' manufacturer.

Answer:

(a) Following the Pan recall, excluding reports for Travacalm, 65 reports clearly implicated a recalled batch of product manufactured by Pan Pharmaceuticals have been received by the Adverse Drug Reactions Unit (ADRU) of TGA. In a further 28 reports, the product used may have been manufactured by Pan, but insufficient information is available to confirm this. It is clear that the number of reports to ADRU involving products confirmed to be manufactured by Pan is decreasing - in the 6 weeks to mid-August, only six such reports were received.

A further eight reports implicating Travacalm Natural, which is a different product to Travacalm Original and Travacalm HO were received over the same period. Travacalm Original and Travacalm HO was the subject of an earlier recall in January 2003.

(b) A list of the 65 reports in which it has been confirmed that the suspected product was manufactured by Pan Pharmaceuticals is attached (Appendix 1).

APPENDIX 1 - ADRs to Pan Manufactured Products

Report no.	Suspected Medicine(s)	AUST L no. +/- Batch no.
185291	Cenovis Men's multivitamin	**70825 B206034**
185338	Cenovis valerian	**79856**
185378	Co enzyme Q10	**70722 B81781**
185464	Nature's Own Omega 3	**82228 B206350**
185465	Nature's Own travel well	**45447 B00080**
185466	Nature's Own Omega 3	**82228 B206419**
185482	Nature's Own travel well	**45447**
185520	Glucosamine	**69947**
185521	Nature's Own Omega 3	**82228**
185540	Nature's Own Zinc lozenge	**28191 B203426**
185560	Bio-organics Nerve Relaxer	**30710**
185597	Bio-organics Arthri-eze	**66228**
185620	Nature's Own Anti-Stress	**28305**
185683	Bio-organics cranberry	**49054**
185691	Natural Nutrition Multi-vitamin	**80098**
185693	Natural Alternative Digestive Enzyme	**28224**
185759	Nature's Own Fish Oil	**60277 B202473**
185761	NW Pregnancy & Breastfeeding; HB paracetamol	**80784 B77701; 64151 B45050**
185762	Nature's Own Super Potency Evening Primrose Oil	**82254 B203250**
185775	Herbal Nutrition Vitex 1000	**55290**
185776	Cenovis Women's Multi Vitamin; Cenovis Cod Liver Oil	**70990; 33613**
185777	Natural Nutrition Mg mega	**62037**
185779	Microgenics Mega B; Microgenics Zinc	**79037 B79566; 28116 B78368**
185820	NN Herbiotic Health Guardian	**54869 B161**
185874	Metagenics Fibroplex	**90373**
185889	Nature's Way breast feeding	**80784 B77700**
185957	Panlabs Shark Cartilage; Panlabs Omega-3 Fish Oil; Panlabs Evening	**66383; 66392;**

	Primrose Oil; plus others	**66926**
186074	Wyld for women	**69421 B80558**
186073	Wyld for women	**69421 B80558**
185512	Natures Own Natural Antibiotic Herbal Olive Leaf Complex	**68076**
185653	Cenovis Mens Multivitain	**70825**
185799	Natural Nutrition Equisetum 2000 Fingerprint Botanicals Tablet	**55597 B101643**
185626	Natures Own Superlecithin	**28314 B203090**
186002	Natures Own Supavim	**46145 B204187**
186003	Bio Organics Ultrasorb Brahmi Phytosome	**72975 B00254**
186005	Phil Alexander Formula Six Multivitamins with Calcium; Phil Alexander Formula Six Multivitamins with Zinc	**64050 B80306; 61696 B80302**
186008	Advanced Hair Studio Serenoa	**74807 B80687**
186037	Ginkgo biloba	**67379**
186041	Cenovis Cod Liver Oil; Ultrasorb Brahmi Phytosome	**33613 B205376; 72975 B00254**
186044	Natures Own Vitamin B6	**28403 BIV01533**
186048	Golden Glow Super One A Day	**81307 B205420**
186051	Bio organics Glucosamine	**67706 B300026**
186109	Omega 3 Fish Oil	**82228 B206306**
186110	Omega 3 Fish Oil	**82228 B206306**
186123	Metagenics Crotico B5 B6 tablets	**16436 B5060**
186154	Microgenics Natural Omega 3 Fish Oil	**55445 B78288**
186193	Natural Nutrition Immune Support	**75534**
186297	Natural Nutrition Immune Support	**75534**
186299	Natural Nutrition Immune Support	**75534**
186195	Naytura Mega Multivitamin	**79514 B14541**
186442	Bio-organics Co-Enzyme 10	**69889 B206322**
186599	Brain and Memory Natural Care	**91022 B81116**

186675	Bioglan Evening Primrose Oil	**13680** **B1843**
186731	Natures Own B6 100mg	**28403** **B205166**
186835	Kordell's Advanced Nutrition Joint Pain Relief	**70179** **B2046**
186987	Bio-organics Standard Valerian	**59080** **B7923701**
187034	Zinc + C Lozenges	**28191** **B101720**
187091	Bio-Organics Glucosamine Sulfate	**67706**
187112	Dietary Fatblaster	**76107** **B83276**
186249	Bioglan Lysine	**27274** **B1847**
187094	Golden Glow Vitamin A	**61333**
187103	Metagenics Brahmi	**71342**
188101	Golden Glow Prosta-Guard	**57562** **B206327**
188385	Nature's Own Travel Well	**45447**
189187	Super Calcium Complete	**71296** **BA3127**

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ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-156

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: CONTENT OF ISOFLAVONES IN MENOPAUSE PRODUCTS

Written Question on Notice

Senator McLucas asked:

(a) Did the TGA refer the issue of 'truth-in-labelling' of isoflavones in menopause products to the Australian Competition and Consumer Commission (ACCC) for investigation as a potential breach of the Trade Practices Act 1974.

(b) If yes, when was the issue referred to the ACCC, and what was their response.

If no, why didn't the TGA refer the issue to the ACCC.

Answer:

(a) No.

(b) Isoflavones are found in foods, particularly soy based foods, and the amounts in herbal menopause products are well within safe levels of intake. The isoflavone content of the products is drawn from the herbal material they contain. What is required in these products is not isoflavones but the specified content of herbal material. The herbal material in these products was there in the stated quantities. Therefore the TGA does not have specific evidence that these products were not true to their labeling claims and thus did not have grounds to refer the issue to the ACCC.

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ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-157

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: CORCORAN REVIEW OF THE TGA AUDIT AND LICENSING OF GOOD MANUFACTURING PRACTICE

Written Question on Notice

Senator McLucas asked:

(a) During the Corcoran review how many stakeholder consultation meetings were held, who were they held with and when were they held.

(b) In respect to issue 3.1 of the Corcoran review has the TGA reviewed the GMPALS computer management information systems? Have new information systems been put in place, if yes what was the cost of the new systems?

(c) In respect to the complaints received by the TGA about TGA auditors and audit outcomes does the TGA keep a record of any such complaints?

If yes, please provide details of how many complaints have been received each year over the past five years and brief summary of the nature and outcome of each complaint.

(d) Please provide details of the TGA's complaint handling processes.

Answer:

(a) Consultation took place over the period October 2001 to February 2002 with TGA officers, overseas regulatory authorities (Canada, Sweden, UK and USA) and various industry associations. The report of the Review does not list all stakeholders consulted during the review process. Only the following industry associations consulted are listed and the timing of these consultations was not recorded by the consultant.

- Australian Pharmaceutical Manufacturers Association (now known as Medicines Australia)
- Medical Industry Association of Australia Inc
- The Australian Self Medication Industry Association
- Complementary Healthcare Council of Australia
- Association of Therapeutic Goods Consultants Inc.

(b) Yes, the TGA has implemented the recommendations contained in issue 3.1 by reviewing the GMPALS computer management information systems and commencing the redevelopment of a new management information system for the Good Manufacturing Practice program. It is expected that the new system will be operational by 1 July 2004. The cost of developing the new system, including business needs analysis, detailed design and development and implementation, has been estimated at $0.75 million.

(c) All complaints about TGA auditors are recorded and investigated. A total of 9 formal complaints against GMP auditors were received over the past 5 years. A brief summary of the nature and outcome of each of these complaints is appended as Attachment 1.

(d) The TGA's GMP program operates a Quality System in compliance with ISO 9002. As part of this Quality System, a written Standard Operating Procedure (SOP) is in place describing how complaints are to be handled. The SOP requires the complaint to be recorded and investigated, and for appropriate corrective action to be implemented if necessary. The SOP requires the Chief Auditor to ensure that corrective action is effective.

Attachment 1

Complaints About TGA Auditors over the past 5 years

Date	Nature of Complaint	Outcome
24/4/98	Auditor expressed negative comments about company	Complaint not justified. Complainant informed.
2/11/98	Attitude of auditor	Complaint not justified. Complainant informed.
6/5/99	Manner in which audit carried out	Complaint not justified. Complainant informed.
10/12/99	Delay in faxing response to company	Complaint justified. Corrective action implemented. Complainant informed.
15/11/00	Inconsistencies across 3 TGA audits	Complaint justified. Corrective action implemented. Complainant informed
5/2/01	Excessive time taken to process GMP preclearances	Complaint justified. Corrective action implemented. Complainant informed.
5/2/01	Unfair treatment at audit	Complaint partially justified. Corrective action implemented. Complainant informed
1/2/02	Poor telephone service	Not enough detail provided by complainant to permit an investigation.
2/10/02	Long time to issue licence	Complaint justified. Corrective action implemented. Complainant informed

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2, 3 & 5 June 2003

Question: E03-158

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: IMPORTATION OF BOVINE (ANIMAL) INSULIN INTO AUSTRALIA

Written Question on Notice

Senator McLucas asked:

(a) Has the TGA restricted or prohibited the importation of bovine (animal) insulin into Australia?

(b) If so:

(i) What is the basis for restricting or prohibiting the importation of bovine (animal) insulin into Australia?

(ii) How long will any such restrictions or prohibitions remain in force?

(iii) Has the TGA taken into account that some Australians who require insulin, are not able to use human insulin and are dependant on the availability of bovine (animal) insulin?

(iv) Is the TGA prepared to review to review its decision in the light of the dependency of a number of Australians on its availability?

(c) If not:

i) Is this likely to occur?

ii) When would this be likely to occur?

Answer:

(a) The TGA has not prohibited the importation of bovine insulin into Australia, but some restrictions on the source of bovine materials have been introduced based on an assessment of the Bovine spongiform encephalopathy (BSE or "mad cow disease") status of the country from which the bovine materials originated.

(b) (i) There is a general restriction on the sourcing of bovine materials sourced from countries reporting BSE, in order to protect the Australian community from contracting variant Creutzfeld-Jakob Disease (vCJD) through contamination of therapeutic goods. Where bovine ingredients used in the production of insulin have been identified as having been sourced from a country reporting BSE, the TGA has worked with sponsors to source the materials from a BSE-free country.

(i) The BSE-related restrictions will remain in force indefinitely.

(iii) Bovine insulin is considered an essential medicine to some patients unable to use human recombinant alternatives. The TGA has undertaken risk assessments which have shown that the theoretical risk of exposure to the BSE agent through the final product to be very low, even in the case where the bovine ingredients were sourced from a country reporting a high incidence of BSE. Such a risk assessment was reported in media releases from the Commonwealth Department of Health and Aged Care on 22nd March 2001 and the NHMRC on 5th April 2001. Canada is considered to be a low incidence country, based on the there having been only one recently reported case of BSE, so that the theoretical risk would be even lower for ingredients sourced from Canada.

(iv) The TGA makes a case-by-case decision regarding the importation of shipments of bovine insulin. In the case of a recent shipment of bovine insulin, where AQIS had suspended its import permit because of its Canadian origin, the TGA advised AQIS to release the shipment for use in Australia. This was because the TGA determined that the BSE risks were slight in comparison with the real health risks of denying access to an essential medicine with no readily available alternative source. To ensure best practice with regard to sourcing of bovine materials in therapeutic goods, the Sponsor of bovine insulin has been asked to re-source the bovine material from a country that has not reported BSE and to provide TGA with a timeframe in which alternative product will become available.

(c) There are no plans to prohibit the importation of bovine insulin. The measures described in (b) above are considered appropriate to manage the BSE risk.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-223

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: TRANS-TASMAN THERAPEUTIC PRODUCTS AGENCY

Written Question on Notice

Senator McLucas asked:

The Budget contains $8.1 million in funding for Australia's share of establishing the joint Australian - NZ agency to regulate therapeutic goods.

(a) What is the estimate for the total cost of establishing this agency?

(b) How much is the NZ Government contributing towards the cost?

(c) Where will the additional funding come from?

Answer:

(a) & (b) The costs of establishing the joint therapeutic products agency consist of infrastructure and implementation costs. Total infrastructure costs are A$5.8 million, which are being shared equally between the Australian and New Zealand Governments. In addition, the Australian implementation costs for the joint agency are $5.2 million. The New Zealand Government is paying for the costs of New Zealand officials engaged in the implementation process.

(c) The Government has allocated $8.1 million in the Budget to establish the joint agency. No further allocation is required. Once the agency commences, its ongoing operations will be funded by full cost recovery from Australian and New Zealand industry.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-224

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: TRANS-TASMAN THERAPEUTIC PRODUCTS AGENCY

Written Question on Notice

Senator McLucas asked:

The budget papers say that $7 million for set-up and implementation will be recovered from industry:

(a) Has industry been consulted about this?

(b) How has industry responded to this proposal?

Answer:

(a) & (b) The Government's decision to recover the set-up and implementation costs of establishing the trans-Tasman therapeutic products agency from industry was announced in the 2003-04 Budget and is based on the *Commonwealth's Cost Recovery Guidelines.* Consistent with past practice, the Government intends to consult industry about the proposed approach for recovering these monies.

No formal representations from industry have been made in response to this announcement.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-084

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: REVIEW OF GM FOOD LABELLING

Written Question on Notice

Senator Nettle asked:

(a) What is the purpose of the review of GM labelling requirements announced by the Australia and New Zealand Food Regulation Ministerial Council on 4 April 2003?
(b) Why is the review being conducted so early into the new labelling regime?
(c) What is the purpose of examining other countries' labelling laws?
(d) Who is conducting the review?
(e) What will the review cost?
(f) What are the plans for public consultation for developing the terms of reference of the review?
(g) If there is no public consultation planned for developing the terms of reference, why not?

Answer:

(a) When the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) met on 4 April 2003, Ministers decided to proceed with a review of the labelling requirements for GM food. The purpose of the review is to undertake a tightly focused examination of the regulatory environment for GM food labelling, and in particular, consideration of relevant international developments.

(b) ANZFRMC considered it important that the review go ahead at this time to honour the original commitment to undertake a review in the year 2003 and due to the importance of maintaining consumer confidence in the food standards system.

(c) Australia was one of the first countries to introduce mandatory labelling of GM foods. Therefore, it is important to examine international developments in GM food labelling regulation that have occurred since Australia's standard was put in place.

(d) ANZFRMC will decide who will conduct the review.

(e) The cost of the Review will depend on the scope of the terms of reference endorsed by Ministers.
(f) None.

(g) On the basis of the guidance provided by ANZFRMC, FRSC has developed advice on the terms of reference, but they are still draft at this point.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question:E03-085
revised

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: REVIEW OF GM FOOD LABELLING

Written Question on Notice

Senator Nettle asked:

(a) How will the review be conducted? Will it be a public review? If not, why not?
(b) Does the consultation process comply with the new Principles and Protocols for Stakeholder Consultation that the Ministerial Council approved in April 2003?
(c) What is the timeline for the review process, including the anticipated time for completion of the review?
(d) How will the negotiations for a Free Trade Agreement between Australia and the United States affect the review?
(e) Will the review include an analysis of the inadequacies of the current labelling laws in relation to consumer right to know, in particular, the issue of traceability and whether the traceability model being implemented by the EU is appropriate for Australia?
(f) What does the Ministerial Council intend to do with the findings of the review?

Answer:

(a) At the 1 August 2003 meeting of the Australia and New Zealand Food Regulation Ministerial Council, Ministers agreed that Food Standards Australia New Zealand (FSANZ) will conduct a Review of Labelling of Genetically Modified Foods and prepare a report for the Ministerial Council, governed by the following terms of reference:

1. Prepare a review of GM food labelling legislation or regulation internationally (proposed and existing), with particular focus on the European Union, United States of America, Canada, and the counties forming the Asia-Pacific Economic Cooperation (APEC).
2. Compare the current Australian/New Zealand requirements for GM food labelling with the requirements of countries listed in (1).
3. Examine consumer attitudes in relation to the labelling and acceptance of GM foods, where they have been publicly reported in Australia/New Zealand and those countries listed in (1).
4. Summarise developments in the *Codex Alimentarius* in respect of a standard for the labelling of GM food.

5. Prepare in association with New Zealand Food Safety Authority and Australian State and Territory authorities a summary of implementation of the GM food labelling standard in Australia and New Zealand and report on compliance and enforcement with the Standard to date.

Ministers agreed to a two pronged approach to consultation on the review. On 6 August 2003, key stakeholders were approached directly and invited to comment on a series of questions based on the terms of reference for the review. The terms of reference and consultation questions were also made available on the FSANZ website at **http://www.foodstandards.gov.au/whatsinfood/gmfoods/index.cfm**. The website includes an invitation to the general public to respond to the consultation questions. Submissions were due to FSANZ by 5 September 2003.

(b) The Principles and Protocols for Stakeholder Consultation document relates to consultation undertaken during the development of Ministerial policy guidelines and as such does not apply to this review. However, Ministers considered that it was important to ensure that stakeholder views are considered. Accordingly, Ministers agreed to incorporate targeted consultation with stakeholders into the review process. Members of the public were also able to provide input to the review via the FSANZ website.

(c) It is expected that FSANZ will provide a report on the outcomes of the review to the Australia and New Zealand Food Regulation Ministerial Council in the first half of 2004.

(d) Australia has made it clear to the United States of America that food regulation is a matter on which the Australian Commonwealth shares responsibility with the Australian States/Territories, and notably, New Zealand. The USA Free Trade Agreement negotiations are coordinated in Australia by the Department of Foreign Affairs and Trade with input from the Department of Health and Ageing to ensure priority is given to maintaining the integrity of the Australian food system.

(e) In accordance with its terms of reference, the Review will examine consumer attitudes in relation to the labelling and acceptance of GM foods. The EUs food labelling regulations will also be reviewed and compared to the current Australian/New Zealand requirements.

(f) Given that Australia was one of the first countries to introduce mandatory GM food labelling requirements, the Ministerial Council will use the outcomes of the review to compare the Australian GM labelling arrangements with current international practice. The terms of reference for the review include an examination of consumer attitudes in relation to the labelling and acceptance of GM foods internationally.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-263

OUTCOME 1 : POPULATION HEALTH AND SAFETY

Topic: REPLACEMENT RESEARCH REACTOR PIPE WELDS

Hansard Page: CA 142

Senator Carr asked:

(a) Did you find that any of the welds were faulty?
(b) As I understand it, we are talking about three separate sets of events. There is the question of the welds last year and your decision to have additional licensing requirements. Did you, during 2002, demand higher standards from ANSTO and INVAP in four critical pipe work areas in July, September and twice in November?

Answer:

(a) The reason for undertaking inspections of welds in any fabrication process is so that any defects can be repaired. In relation to the vessels and pipework fabrication for the replacement reactor, 100% of the weld length is inspected. About 0.7% of inspected length of weld was found not to comply with inspection criteria and was repaired. This demonstrates an extremely high standard of welding on reactor components. ARPANSA is satisfied with this standard of welding being achieved.
(b) Prior to commencement of construction of the items, the following additional Licence Conditions were imposed by the CEO of ARPANSA under Section 36(2)(a) of the *ARPANS Act 1998*

Condition RFA001-1 (11 July 2002)

The Licence holder must ensure that all factory and on-site butt welds for the Reactor Pool Tank, Services Pool Tank, Transfer Canal and Reactor and Services Tank Piping categorised as Safety Category 1 or 2 are subjected to:
(a) 100 percent radiographic or ultrasonic testing, and
(b) 100 percent dye-penetrant testing.

Condition RFA008-1 (30 September 2002)

The licence holder must ensure that all factory and on-site butt welds of the Primary Coolant System Decay Tank are subjected to 100 percent radiographic or ultrasonic inspection.

Condition RFA008-1 (related to RFA009) (5 November 2002)

The licence holder must ensure that all factory and on-site butt welds of the Reactor and Service Pool Cooling System Decay Tank are subjected to 100 percent radiographic or ultrasonic inspection.

Condition RFA027-1 (related to RFA027, RFA031, RFA032) (22 November 2002)

The licence holder must ensure that seamless piping is used within these systems [Primary Cooling System, Reactor & Service Pool Cooling System, Reactor Coolant Purification System] where the nominal diameter is not greater than 200 mm.

Condition RFA027-2 (related to RFA027, RFA031, RFA032) (22 November 2002)

The licence holder must ensure that all factory and on-site butt welds of piping that is greater than 25 mm nominal diameter, within these systems [Primary Cooling System, Reactor & Service Pool Cooling System, Reactor Coolant Purification System], are subjected to 100 percent volumetric radiographic inspection, unless the welds are both:

- butt welds of longitudinal seams made during the factory manufacture of piping, and
- not embedded within concrete

Condition RFA035-1 (14 January 2003)

The Licence holder must ensure that the minimum mission time for an individual redundancy of the Standby Power Supply [diesel generators] is 24 hours. The systems required to achieve this mission time shall be Safety Category 1.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-264

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: MARALINGA REHABILITATION AND THE MARTAC REPORT

Hansard Page: CA 151-2, 154 and 159

Senator Allison asked:

(a) Why is the department's health physics management document not attached to the MARTAC report?

(b) Pages 94 and 95 of the MARTAC Report show a project activity summary that lists work that is done with start and finish dates. Table 2.4 shows a heading 'Pit exhumation and restoration', but it does not say which pits it refers to. It shows exhumation of debris pits at Taranaki taking place in the period 27 July to 20 September 1997, but in fact, as I understand it, no pits were exhumed at Taranaki until the ISV project was cancelled in 1999. Can you explain why the report would indicate that?

(c) An area that you were responsible for under ARL was the area within which contaminated soil was to be removed for burial, and I understand that technicians from ARL delineated the boundaries. Page 189 describes how ARL set the boundaries. It says: 'The final soil removal boundary was set at least 30 m outside the last detected visible fragment or particle exceeding MARTAC criteria.' But isn't it the case that there were fragments beyond that boundary? Why is it that that did not appear in the report?

(d) Let us take the area which I understand to be about four metres outside the boundary. This area was contaminated with lead bricks between the Taranaki north-east and north plumes. When the health physicist went to remove this material, the lead bricks, after soil removal was complete they apparently had to dig down some 600 millimetres to retrieve it. So there is, firstly, the question of it being there and, secondly, that it was covered up by contaminated soil at some stage.

(e) On page 205 the report says that after soil removal was complete additional scanning was carried out. It says:
'*... scanning was carried out to a substantial distance beyond the outermost particle or fragment located.' Could you clarify what 'substantial distance' means and why it was not more precise?*

(f) Page 185 says that workers were required to sign the job safety analysis form. The job safety analyses were internal Thiess documents and part of an engineering design process, not part of a health physics regime, and that radiation workers were required to sign the radiological work permit after receiving suitable training.

(g) Isn't there another issue about the enormous quantities of soil that were removed through dust blowing onto other areas? Could you also check the lots which had been checked by ARL and given clearance certificates which subsequently had contaminated soil blown onto them at quite some depths.

Answer:

(a) There is no ARPANSA document that could reasonably be described as "the health physics management document". Attachment 5.3 to the MARTAC Report lists all the Health Physics Procedures including the Health Physics Strategy Statement M02. The procedures were developed by GHD and approved by ARPANSA and are not reproduced in the report. M02 outlines the health physics management system and a copy of this would be available from DEST or GHD. However, a DPIE "Health Physics Management document" is referred to in attachment 5.5, "Report On The Health Physics Regime" by the Health Physics Review Team and may be the document in question. DEST should be able to provide a copy of this.

(b) There were 25 debris pits in the forward area specifically designated by the British for the disposal of radioactive material. There were other pits at many places on the site, including Taranaki, where uncontaminated debris or debris contaminated to low-levels was buried, and these so-called "Category 2" pits were possibly exhumed during this time. (See section 3.7 and fig 3.19)

(c) The next sentence in the report at page 189 states:
'*It was envisaged that small areas of contamination, amenable to small-scale removal by hand or machinery without special safety modification, might well have existed outside this boundary and would need to be remediated individually.'*

(d) ARPANSA is aware of an incident concerning lead bricks at Taranaki. Lead bricks showing light contamination were discovered by ARL personnel while surveying the boundary of the soil removal boundary at Taranaki. The bricks were in between the north and north-east plumes and only a metre or so from a road that separated the blue area from the red area. During soil removal from the lots immediately to the south of this location a large amount of dust and sand raising was observed and some of this would have travelled the few metres to reach the bricks. The bricks were located at the foot of a hill as the land started to rise and wind-borne soil was trapped there over a relatively small area. The lots where the soil came from were only lightly contaminated and did not qualify for soil removal but were included in the soil removal area because of a few contaminated fragments, such as the lead bricks. The area nearby was surveyed after soil removal and found to meet MARTAC criteria.

(e) Scanning was generally carried out for 100 m beyond the boundary of the soil removal area. However, when particles of contamination were discovered during this procedure, additional scanning was performed. Attachment 4.3, "Maralinga Rehabilitation Project -Radiological Field Monitoring at Taranaki and at other Miscellaneous Sites ", p44 states "*This extra distance was dependent on the frequency of additional removals being detected and was at least 30 m, and up to 50 m if the particles removed were more sparsely scattered than 30 m intervals*." In the scanning of 850,000 square metres (85 Ha) at Taranaki, 23 particles exceeding 80 kBq were detected and removed.

(f) For radiological safety requirements each operator was required to sign on to a Radiological Work Permit. Other procedures that were required for general occupational health and safety following a job safety analysis were the responsibility of the project manager and the contractors.

(g) ARPANSA was continually monitoring cleared lots during the project and never recorded a case where wind borne contamination was detected on an adjacent lot. Extensive monitoring by the Health Physics Provider and by ARPANSA during and after the rehabilitation did not show that spread of contamination by airborne dust was a problem.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-265

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: MARALINGA REHABILITATION

Hansard Page: CA 152

Senator Carr asked:

This committee was advised by people who were quite intimately involved with the project and had occupied very senior positions within the project in a technical sense, of the following:

'*This section of the report shows how requirements changed, especially after the transition from ARL to ARPANSA It also makes spurious claims about the requirement to melt steel amongst the debris; melting to the bottom of individual pits; and the presence of debris and plutonium under the ISV blocks. Reference to other documents that are not appended show that MARTAC's claims are ill-founded. In at least one instance, MARTAC relates comments made by ARPANSA, but leaves out a vital sentence which denies the point they are attempting to make.'*

Could you have a look at the comments you made to see whether or not they have been edited in the report?

Answer:

The MARTAC report refers to a letter from the CEO of ARPANSA as requiring "a clear demonstration that ISV satisfactorily encapsulated the contaminated material in the melt matrix before it could approve the use of ISV in the hybrid option". (MARTAC Report, page 271, underlining added).

The letter from ARPANSA stated "For the ex situ vitrification to proceed there would also need to be a clear demonstration that ISV could incorporate the majority of plutonium contamination into the melt" (underlining added).

It may have been preferable for MARTAC to have used the same words as ARPANSA, but it is not clear that the difference between satisfactory encapsulation and encapsulating the majority of the plutonium is material.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2-3 & 5 June 2003

Question: E03-266

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: INCIDENT AT ANSTO INVOLVING RELEASE OF NOBLE GASES

Hansard Page: CA 158

Senator Foreshaw asked:

There was a report again in the St George and Sutherland Shire Leader newspaper on 13 May regarding three workers at the Lucas Heights facility being 'contaminated' with radioactive noble gases. ANSTO disputes that. When was ARPANSA informed of this incident? Do you recall? And how were you informed?

Answer:

After contact between ARPANSA and ANSTO, the Acting Director of ANSTO's Safety Division advised ARPANSA of the incident, by telephone, on 9 May, outlining the circumstances of the incident, the actions taken by ANSTO and the reviews to be undertaken.

On 28 May 2003, the CEO of ARPANSA wrote to ANSTO seeking:

- details of the incident including the procedures and arrangements to deal with incidents and abnormal occurrences;
- dose records of the workers involved in the incident including the whole body counting results;
- area monitoring results during the week of the incident;
- details of countermeasures taken following the incident; and
- an assessment of any contribution of the modification of the ventilation system to the incident.