Community Affairs
Legislation Committee

Examination of Additional Estimates 2003-2004

Additional Information Received

VOLUME 3

Outcomes: whole of portfolio, Outcomes 1 & 2

HEALTH AND AGEING PORTFOLIO

MAY 2004

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 ADDITIONAL EXPENDITURE FOR 2003-2004

Included in this volume are answers to written and oral questions taken on notice and tabled papers relating to the additional estimates hearing on 18 February 2004

HEALTH AND AGEING PORTFOLIO

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ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-160

OUTCOME: Whole of Portfolio

Topic: PERFORMANCE ASSESSMENT MECHANISMS

Written Question on Notice

Senator Carr asked:

(a) Please provide full details of each of the performance assessment mechanisms linked to the pay outcomes or other financial reward of individual employees, including;
   (i) What are the current process/es of performance assessment within the portfolio agency? If more than one, please provide details of each, and the employee category it applies to.
   (ii) For each of the performance assessment process/es identified in (i), please list the range of outcome results an employee can achieve from each of the performance assessment processes identified in (i);
   (iii) For each of the performance assessment process/es identified in (i), what pay or other financial change is linked to each outcome or result for the employee from the performance assessment [ie, the pay increase or one-off bonus or classification or level change];
   (iv) For each of the performance assessments identified in (i), what is the classification level of employees subject to this performance assessment (eg SES, EL1, EL2 or APS and equivalent);
   (v) What is the principal industrial or other instrument governing each of the performance assessment mechanism/s (eg, the certified agreement or AWA);
   (vi) Does the performance assessment operate over a common cycle? Please provide the commencement and dates of the most recent full cycle of each of the assessment process/es.

(b) For each performance assessment mechanism in (a), advise the number of male and the number of female employees at each possible outcome, by classification level for the most recent full cycle (if the performance mechanism does not operate over a common cycle – aggregate outcomes using the 2002-03 financial year).

Answer:

(a)(i) Department response: Performance Development Scheme (PDS). The PDS Guidelines are attached for your information – Attachment A.
CRS Australia response: Performance Achievement System (PAS) - applies to all CRS Australia staff employed under the PS Act 1999 - remuneration progression on individual development plans linked to PAS, incorporates a performance plan and a development plan. Business, operational and individual plans linked in logical sequence (cascading planning). The PAS Guidelines are attached for your information – Attachment B.

(a)(ii) Both the Department and CRS Australia use a five point rating system. The Department's ratings are:
A – Outstanding
B – Superior
C – Fully Effective
D – Partially Effective
E – Unsatisfactory
CRS Australia's rating system is linked to Key Result Areas and competencies. Ratings and descriptors are:
Exceptional – all or most objectives were consistently exceeded and all competency behaviours were demonstrated to an exceptional level (Rating 5).
Exceeds Expectations – the majority of objectives were exceeded and competency behaviours were demonstrated to a consistently high level (Rating 4).
Fully Effective – objectives were achieved and all competencies demonstrated consistently (Rating 3).
Development Need Indicated – some but not all objectives were achieved and/or some but not all competencies were demonstrated. Specific goals (as appropriate) to be included in the Development Plan (Rating 2).
Unsatisfactory – few, if any, objectives were achieved and few, if any, competencies demonstrated. Performance counselling is indicated and should have already commenced if this rating is allocated. Significant improvement is required (Rating 1).

(a)(iii) Department response: if rated C or above and if not already at the top of the salary range, salary advancement for APS1 to EL2 and equivalent staff. Performance pay for EL2 and equivalent staff with an AWA and SES Bands 1 – 3 through an AWA if rated C or above. For the last cycle ended 30/6/03, rates were:
SES A - 15%, B - 10%, C – 5% and non SES A – 12%, B – 7%, C – 3.5%.
CRS Australia response:
Possible base salary increase for those rated 3 or higher and not already at the top of salary range, and/or
Possible one-off bonus for those rated 3 or higher
Performance management procedures for those ranked 2 or 1
A rating of 3 or above does not automatically give rise to a set percentage increase in pay. The exact percentage is determined on a case by case basis
A rating of 5 allows the employee to receive a pay increase up to 5%
A rating of 4 allows the employee to receive a pay increase up to 4%
A rating of 3 allows the employee to receive a pay increase up to 3%

(a)(iv) Department response: APS1 to SES Band 3 and equivalents inclusive.
CRS Australia response: APS1 up to and including EL2.

(a)(v) Department response: Certified Agreement for APS1 through to EL2 and equivalent staff without an AWA. Australian Workplace Agreements for SES Band 1 – SES Band 3 staff and EL2 and equivalent staff.
CRS Australia response: CRS Australia Certified Agreement 2002 – 2005.

(a)(vi) Department response: Yes, 1 July to 30 June, with last cycle completed 1 July 2002 to 30 June 2003.
CRS Australia response: Yes, 1 July to 30 June, with last cycle completed 1 July 2002 to 30 June 2003.

(b) Department response: APS1 to EL2 in respect of salary advancement outcome. Numbers of males / females by classification level is available in the annual report, however only staff who are not at the top of the salary range are eligible for advancement - no further detail is available. EL2 and SES for performance pay as per annual report.
CRS Australia response:

CRS Australia					
Level	**Number**	**Aggregated amount $**	**Average $**	**Minimum $**	**Maximum $**
Executive Level 2A & 2B	14	38322	2240	803	4814
Executive Level 1	76	144125	1896	578	5309
APS 6	32	44615	1394	508	2636
APS 5	62	63246	1020	189	3171
APS 4	65	53468	823	118	1596
APS 3	89	83177	935	290	3083
APS 2	145	93413	644	117	1788
APS 1	34	17912	527	119	978
Rehabilitation Consultant 1	89	72150	811	110	2949
Rehabilitation Consultant 2	824	947958	1150	110	4584
	1430	**1558386**			

Note:

- Figures have been aggregated to preserve employees' privacy
- These figures are based on performance pay as at 30 June 2003
- SES details have not been included
- 244 males received a performance bonus for 2002/2003
- 1187 females received a performance bonus for 2002/2003

[Note: the attachments have not been included in the electronic/printed volume]

Please Note: The TGA have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-099

OUTCOME Whole of Portfolio

Topic: ADMINISTERED PROGRAMMES

Written Question on Notice

Senator Forshaw asked:

Could you provide a list of all administered programmes in the Department, including:

- A description of the programme;
- number of people directly receiving funds/assistance under the programme;
- a breakdown on those receiving funds/assistance under the programme by electorate;
- the policy objective of the programme;
- whether the programme is ongoing
- the funding in each financial year of the forward estimates for the programme (with a breakdown of administered and departmental expenses), including:
  - how much funding was allocated for the programme;
  - how much is committed to the programme; and
  - how much is unspent.
- indication of whether an evaluation of the programme effectiveness has been conducted:
  - if so, when that evaluation occurred; and
  - if so, the conclusion of that evaluation

Answer:

There is no standing definition or list of 'administered programmes'. Therefore, in formulating an answer to the question, we have adopted a meaning for ‘administered programmes’ to best fit the range and nature of the specific data requested, and consistent with the question’s reference to ‘administered’, alluding to the level of activity reported in the portfolio budget statements. The ‘administered programmes’ identified in the attached table are the portfolio’s outcomes, administered items and special appropriations which are in the nature of a programme. All of these are reported in the portfolio budget statements and annual reports, which is the level of external reporting that the Government has prescribed in its outcome and output budgeting and reporting framework, and guidelines to annual reports.

Attached (refer Attachment A) is the list of administered programmes in the Department including:

- description
- policy objective
- whether the programme is ongoing
- the current year appropriation per programme and the expected spend
- an indication of whether an evaluation of the programme effectiveness has been conducted, and, if so, when the evaluation occurred and, if available, the conclusion of that evaluation.

The Government's policy is that forward estimates by programme are not published beyond the budget year and that commitments are not published at all. An indication of the forward estimates, however, can be seen at the sub-function level, in Budget Paper No.1, 2003-04 on page 6-24 (Table 8) for health, and page 6-29 (Table 9) for ageing. The figures for 'Assistance to the aged' in Table 9 include a range of items including pensions. The tables have been reproduced below. A graph of the forward estimates for each outcome is also published in each outcome chapter of the Portfolio Budget Statement.

Table 8: Summary of expenses – Health Function

	2002-03 $m	2003-04 $m	2004-05 $m	2005-06 $m	2006-07 $m
Medical services and benefits(a)	11,776	12,491	13,052	13,486	13,893
Hospital services	1,577	1,639	1,766	1,940	2,116
Health care agreements	7,244	7,539	7,966	8,384	8,828
Hospital services and health care agreements	*8,820*	*9,178*	*9,732*	*10,324*	*10,944*
Pharmaceutical services and benefits	5,704	5,825	6,294	6,687	7,091
Aboriginal and Torres Strait Islander health	231	258	266	277	289
Health services	674	900	920	897	946
Other health services	963	1,054	1,113	1,141	1,187
Other health services	*1,636*	*1,954*	*2,033*	*2,039*	*2,133*
General administration	1,329	1,402	1,373	1,404	1,429
Health assistance to the aged(b)	69	75	80	86	93
Total health	**29,566**	**31,183**	**32,830**	**34,303**	**35,872**

a The financial impact of premium growth on the forward estimates for the 30 per cent Private Health Insurance Rebate have been allocated to the Contingency Reserve.

b The bulk of Department of Health and Ageing and Department of Veterans' Affairs expenses for assistance to the aged are now classified to the Assistance to the Aged Sub-Function (Social Security and Welfare Function).

Table 9: Summary of expenses - Social Security and Welfare Function

	2002-03 $m	2003-04 $m	2004-05 $m	2005-06 $m	2006-07 $m
Assistance to the aged(a)	24,851	26,323	27,767	29,310	30,950
Assistance to veterans and dependants	5,578	5,734	5,834	5,931	6,002
Assistance to people with disabilities(b)	9,625	10,117	10,405	10,883	11,448
Assistance to families with children	19,464	20,474	21,338	22,297	23,253
Assistance to the unemployed	5,569	5,695	6,382	6,497	6,440
Assistance to the sick	85	90	105	119	124
Assistance to the unemployed and sick	*5,655*	*5,785*	*6,487*	*6,617*	*6,564*
Common Youth Allowance	2,239	2,295	2,368	2,427	2,473
Other welfare programmes	325	337	340	360	366
Aboriginal advancement nec	1,297	1,408	1,439	1,470	1,507
General administration	2,280	2,403	2,426	2,449	2,460
Total social security and welfare	**71,313**	**74,875**	**78,404**	**81,743**	**85,022**

a The bulk of Department of Health and Ageing and Department of Veterans' Affairs expenses relating to assistance to the aged are classified to this sub-function.

b Assistance to People with Disabilities now includes CRS Australia administrative costs. Previously CRS Australia (formerly the Commonwealth Rehabilitation Service) was classified under General Administration.

Departmental estimates are split only to outcome level, and so estimates of departmental resourcing for an administered program is available only when an administered program aligns wholly with an outcome (refer Attachment A). This is the case for six of the thirteen administered programmes in the attached table. Estimates of departmental resourcing are available only for current/budget year, as for administered estimates.

Data on numbers of people receiving funds/assistance per electorate per programme is not maintained.

The attached table includes details of evaluations of an administered programme as a whole wherever these have occurred. The response does not include evaluations of the sub-components of administered programmes.

There is a nil response to the question from the Health Insurance Commission (HIC), Commonwealth Rehabilitation Service (CRS) and the Therapeutics Goods Authority (TGA) as these agencies have no administered programmes. Administered funds administered by the HIC are included in the attached Health response (refer Attachment A)

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-100

OUTCOME: Whole of Portfolio

Topic: SENIOR EXECUTIVE OFFICERS

Written Question on Notice

Senator Forshaw asked:

How many Senior Executive Officers (or equivalent) were employed in the Department in 1996-97, 1997-98, 1998-99, 1999-2000, 2000-01, 2001-02, 2002-03, 2003-04?

Answer:

The table below lists the total number of Senior Executive and equivalent officers as at 30 June.

Financial Year	**02/03 ^^**	**01/02 ^**	**00/01 ^**	**99/00 ^**	**98/99 ^**	**97/98 #**	**96/97***
Total	107	101	77	98	90	98	88

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

Figures have not been provided for 2003-04 as these will be published as part of the forthcoming annual report, to ensure consistency of reporting period comparison.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-101

OUTCOME: Whole of Portfolio

Topic: WAGES

Written Question on Notice

Senator Forshaw asked:

What was the base and top (including performance pay) wages of APS 1, 2, 3, 4, 5, 6 (or equivalent), Executive Level 1 and 2 (or equivalent), and SES band 1, band 2 and band 3 (or equivalent) in the Department in 1996-97, 1997-98, 1998-99, 1999-2000, 2000-01, 2001-02, 2002-03, 2003-04?

Answer:

Wage ranges and performance pay details have been provided in each year's annual report. Pay ranges have only been provided in the past three annual reports, however performance pay details have been provided in all annual reports.

The Department is unable to provide a response to this question as the considerable work involved would require a significant diversion of resources from other Departmental operations.

Figures have not been provided for 2003-04 as these will be published as part of the forthcoming annual report to ensure consistency of reporting period comparison.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-102

OUTCOME: Whole of Portfolio

Topic: AVERAGE SALARY

Written Question on Notice

Senator Forshaw asked:

What was the average salary for an SES (or equivalent) in the Department in 1996-97, 1997-98, 1998-99, 1999-2000, 2000-01, 2001-02, 2002-03, 2003-04?

Answer:

The average SES (or equivalent) salary in the Department in 2002-03 was $123,740.

The Department is unable to provide a full response to this question as the considerable work involved would require a significant diversion of resources from other Departmental operations.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: EO4-103

OUTCOME: Whole of Portfolio

Topic: MOBILE TELEPHONES

Written Question on Notice

Senator Forshaw asked:

How many staff had mobile phones issued by the Department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

Health & Ageing - Number of Mobile Telephones

Sourced from Optus

Year	Total
1996	877
1997	766
1998	864
1999	758
2000	775
2001	836
2002	823
2003	849

Sourced from Telstra

Year	Total
2001/2002	211
2002/2003	191

It should be noted that, the questions could not be answered using Departmental records, so both Optus and Telstra, the Department's mobile suppliers, were approached.

Optus could only provide a 'snapshot' response over the period. Telstra were only able to provide the two years' data shown.

CRS Australia

Year	Total
2002-2003	434
2003-2004 (to Feb 29th)	494

Please note CRS Australia joined the Department of Health and Ageing portfolio on 1 July 2002.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-104

OUTCOME: Whole of Portfolio

Topic: COST OF MOBILE TELEPHONES

Written Question on Notice

Senator Forshaw asked:

What was the total mobile phone bill for the Department in 1996-97, 1997-98, 1998-99, 1999-00,2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

Health & Ageing Calculated Mobile Costs

Optus	
1996	$225,700
1997	$227,400
1998	$266,300
1999	$225,500
2000	$279,200
2001	$267,000
2002	$239,600
2003	$363,200

Telstra	
2001/2002	$188,000
2002/2003	$136,000

It should be noted that, the questions could not be answered using Departmental records, so both Optus and Telstra, the Department's mobile suppliers, were approached.

Optus could only provide a 'snapshot' response over the period. Telstra were only able to provide the two years' data shown.

CRS Australia Mobile costs

Total mobile phone bill for CRS Australia in 2002-2003 was $167,329

Total mobile phone bill for CRS Australia in 2003-2004 (to 29th Feb) was $118,403

Please note CRS Australia joined the Department of Health Ageing portfolio on 1 July 2002.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-105

OUTCOME: Whole of Portfolio

Topic: SES CAR ISSUE

Written Question on Notice

Senator Forshaw asked:

How many SES (or equivalent) were issued with cars in the Department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04.

Answer:

Information for the years 1996-97 and 1997-98 is not readily available and the Department is unable to provide a response as the considerable work involved would require a significant diversion of resources from other Departmental operations.

A number of sources were cross-referenced to extract the required data for the years 1998-99 – 2003-04. The information is provided in table below.

Year	**Officers issued with car**
1998 – 99	92
1999 – 00	106
2000 – 01	94
2001 – 02	83
2002 – 03	89
2003 – 04	87

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-106

OUTCOME: Whole of Portfolio

Topic: MANAGEMENT RETREATS/TRAINING

Written Question on Notice

Senator Forshaw asked:

Could you please list all 'management retreats/training' conducted by the Department which were attended by employees during 2000-01, 2001-02, 2002-03, 2003-04 to date. For such meetings held off site (from the Department), could you please indicate:

- where (location and hotel) and when they were held;
- how much was spent in total;
- how much was spent on accommodation;
- how much was spent on food;
- how much was spent on alcohol/drinks; and
- how much was spent on transport?

Answer:

This information is not recorded centrally in the Department. Management retreats/training (eg planning days) are organised and funded at the local level.

As such, the Department is unable to provide a response to this question as the considerable work involved would require a significant diversion of resources from other Departmental operations.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-107

OUTCOME Whole of Portfolio

Topic: OVERSEAS TRIPS

Written Question on Notice

Senator Forshaw asked:

(a) How many overseas trips were taken by employees in your Department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2003-04 to date.

(b) What were the destinations of each of these overseas trips?

(c) What was the total costs of overseas trips of staff for the Department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2003-04 to date.

With breakdown on the cost of accommodation allowances, food allowances and airflights?

Answer:

(a) Data on the number of overseas trips taken by the Department's employees is not available prior to 1999-00. The data shown in the following table on the number of overseas trips by Departmental staff between financial years 1999-00 and 2003-04 to date has been drawn from the Department's ancillary overseas travel system.

Table of the Number of Overseas Trips Paid by the Department from 1999-00 through to 2003-04 (Financial year to date February 2004)

Financial Year	Number of Overseas Trips	Departmental Title and Function*
1999-00	272**	Department of Health and Aged Care
2000-01	290**	Department of Health and Aged Care
2001-02	263	Department of Health and Ageing
2002-03	213	Department of Health and Ageing
2003-04 to February 2004	234	Department of Health and Ageing

* When making comparisons between financial years, consideration should be given to changes in the Department's functions and responsibilities.
** Unable to separate the number of overseas trips for non-employees from employees.

(b) The Department is unable to provide a response to this question as the considerable

work involved would require a significant diversion of resources from other Departmental operations.

(c) The total costs of overseas trips paid by the Department, in the periods in question, are provided in the following table. This information is subject to a number of qualifications and these are as follows:

1. Travelling allowances include the cost of accommodation, meals and incidentals. It is not possible to separate the cost of each of these components.
2. The breakdown between the cost of airfares and the cost of travelling allowances is not available prior to 2001-02 without significant resource intensive analysis on the transactional data held in the Department's previous financial management information and ancillary overseas travel systems.
3. Non-employee travel costs paid by the Department cannot be separately identified without a trip by trip analysis in both the current and previous financial management information systems and the ancillary overseas travel system. The Department is not able to allocate the resources required to collect all this information.
4. CRS Australia has been included as part of the Department from 2002-03.

Table of the Costs of Overseas Trips Paid by the Department from 1996-97 through to Financial (Year to date February 2004)

Financial Year	Airfares $	Travelling Allowances $	Total Cost $	Departmental Title and Function*
1996-97	not available	not available	462,234	Department of Health and Family Services
1997-98	not available	not available	588,542	Department of Health and Family Services
1998-99	not available	not available	871,305	Department of Health and Aged Care
1999-00	not available	not available	923,657	Department of Health and Aged Care
2000-01	not available	not available	1,721,501	Department of Health and Aged Care
2001-02	1,559,755	830,795	2,390,550	Department of Health and Ageing
2002-03	1,034,031	588,262	1,622,293	Department of Health and Ageing
2003-04 to February 2004	1,170,784	425,704	1,596,488	Department of Health and Ageing

* When making comparisons between financial years, consideration should be given to changes over time in the Department's functions and responsibilities over time.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-108

OUTCOME Whole of Portfolio

Topic: DOMESTIC TRIPS

Written Question on Notice

Senator Forshaw asked:

What was the total costs of domestic trips of staff for the Department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2003-04 to date.

With breakdown on the cost of accommodation allowances, food allowances and airflights?

Answer:

The total costs of domestic travel by Departmental staff in the periods in question are provided in the following table. This information is subject to a number of qualifications and these are as follows:

1. Travelling allowances include the cost of accommodation, meals and incidentals. It is not possible to separately identify the cost of each of these components.
2. The breakdown between the cost of airfares and the cost of travelling allowances is not available prior to 2001-02 without considerable resource intensive analysis on the transactional data held in the Department's previous financial management information system.
3. Non-staff travel costs paid by the Department cannot be separated out without trip by trip analysis of data in both the current and previous financial management information systems. The Department is not able to allocate the resources required to collect this information.
4. The Total Travel Costs provided in the table exclude private vehicle allowances which cannot be separated between domestic travel and the reimbursement for the local use of private vehicles.
5. CRS Australia has been included as part of the Department from 2002-03. The CRS Australia expenditure for 2002-03 was $2,878,236 and financial year to date February 2004 is $2,349,501.

Table of the Costs of Domestic Trips Paid by the Department from 1996-97 through to 2003-04 (Financial year to date February 2004)

Financial Year	Airfares $	Other Fares $	Travelling Allowances $	Total Travel Costs $	Departmental Title and Function*
1996-97	not available	not available	not available	7,780,142	Department of Health and Family Services
1997-98	not available	not available	not available	9,153,519	Department of Health and Family Services
1998-99	not available	not available	not available	9,615,132	Department of Health and Aged Care
1999-00	not available	not available	not available	9,184,945	Department of Health and Aged Care
2000-01	not available	not available	not available	10,364,243	Department of Health and Aged Care
2001-02	7,203,095	781,916	3,122,238	11,107,249	Department of Health and Ageing
2002-03	8,965,325	901,060	4,170,213	14,036,598	Department of Health and Ageing
2003-04 to February 2004	6,183,411	577,705	2,798,166	9,559,282	Department of Health and Ageing

* When making comparisons between financial years, consideration should be given to changes over time in the Department's functions and responsibilities.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-109

OUTCOME Whole of Portfolio

Topic: OVERSEAS TRAVEL BY MINISTERIAL STAFF

Written Question on Notice

Senator Forshaw asked:

(a) How many overseas trips of Ministerial Staff were paid for by the Department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2003-04 to date.

(d) What was the total costs of overseas trips of Ministerial Staff paid for by the Department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2003-04 to date.

Answer:

(a) and (b)
These questions should be directed to the Department of Finance and Administration who approve and fund overseas trips by Ministerial Staff.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-110

OUTCOME Whole of Portfolio

Topic: ADVERTISING

Written Question on Notice

Senator Forshaw asked:

How much was spent on advertising by the department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

The Government Communications Unit's Central Advertising System provides the following information regarding the department's campaign advertising placement expenditure from 1996-97 to 2002-03:

$5.66M spent in 1996-97; $16.36M spent in 1997-98; $15.31M spent in 1998-99; $23.2M spent in 1999-00; $15.64 spent in 2000-01; $11.14M spent in 2001-02; $3.06M spent in 2002-03.

In 2003-04 to date, the department has spent $8,121, 268 on campaign advertising placement for the Pharmaceutical Benefits Campaign, the Meningococcal C Campaign and the National Tobacco Campaign. The Department's advertising for normal business such as recruitment and tender activities are not covered in these figures.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-111

OUTCOME: Whole of Portfolio

Topic: PUBLICATIONS THAT PROVIDED ELECTORATE BREAKDOWNS OF SPENDING

Written Question on Notice

Senator Forshaw asked:

Did the department produce publications that provided electorate breakdowns on spending on government programmes in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date?

Answer:

The Department produced annual electorate profile reports in the first four years in question. The reports were published in April 1997, April 1998, May 1999 and June 2000. Electorate profile reports have not been produced since this date.

The electorate profiles produced between 1996-97 and 1999-00 followed the same format as reports produced in 1992/93. The reports contained information about health and community services and spending in each electorate, including Medicare utilisation, hospital beds, GP numbers, aged care services, children's services, hearing services, supported accommodation assistance, disability programs, emergency relief, and home and community care.

Production of the electorate profiles was suspended in 2000 following the transfer of a range of functions to the Family and Community Services Portfolio. The reports were then dropped altogether in February 2002.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-112

OUTCOME Whole of Portfolio

Topic: ADVERTISING WHICH PROVIDED ELECTORATE BREAKDOWNS OF SPENDING

Written Question on Notice

Senator Forshaw asked:

How much was spent on advertising which provided electorate breakdowns of spending by the government on programmes within the department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

Spending on advertising by the Department is notified each year in the departmental annual report. There was no money spent on advertising which provided electorate breakdowns of spending by the Government on programmes within the department.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04 - 113

OUTCOME Whole of Portfolio

Topic: CONSULTANCIES

Written Question on Notice

Senator Forshaw asked:

How much was spent on consultancies by the Department in 1996-97, 1997-98, 1998-99,1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date?

Answer:

Expenditure on individual consultancies (valued at more than $10,000 each) is reported in the Department's annual report. The table below provides information on relevant consultancy costs with page number references from the relevant annual reports.

Information about relatively minor individual consultancies valued at less than $10,000 each is more difficult to obtain. This information could be obtained by reviewing every Purchasing and Disposals Gazette (the Gazette) issued during the periods in question. The Gazette holds information on all contracts valued at more than $2,000 – including consultancies.

However the Department is not able to devote the considerable resources needed to review all contract notifications in the Gazette over an eight year period and to identify consultancies valued at more than $2,000 but less than $10,000.

Departmental Title and Function*	Annual Report Financial Year	Location	Total
Department of Health and Family Services	1996 - 1997	Appendix 8 Pages 286 - 294	$14,852,372
Department of Health and Family Services	1997 - 1998	Appendix 8 Pages 272 – 282	$23,911,488
Department of Health and Aged Care	1998 - 1999	Appendix 8 Pages 325 – 338	$21,588,005
Department of Health and Aged Care	1999 - 2000	Appendix 8 Pages 427 - 439	$18,961,939
Department of Health and Aged Care	2000 - 2001	Appendix 12 Pages 515 – 540	$21,592,075
Department of Health and Ageing	2001 - 2002	Appendix 12 Pages 438 – 461	$22,987,345
Department of Health and Ageing	2002 - 2003	Appendix 8 Pages 450 - 469	$29,264,705

* When making comparisons between financial years, consideration should be given to changes over time in the Department's functions and responsibilities.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-114

OUTCOME: Whole of Portfolio

Topic: SURVEYS OF ATTITUDES TOWARDS PROGRAMMES

Written Question on Notice

Senator Forshaw asked:

(a) Did the department conduct any surveys of attitudes towards programmes run by their Department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date?

(b) On what programmes administered by the department were surveys conducted?

What were the findings of these surveys?

Answer:

The Department of Health and Ageing has carried out a total of 28 surveys of attitudes towards programmes run by the Department over the years in question.

Some of these surveys have been one-off studies, addressing specific issues of concern, while others have been parts of annual monitoring programmes.

The count of surveys conducted each year is:

Financial year	*Number*
2003-04	4
2002-03	5
2001-02	5
2000-01	5
1999-2000	4
1998-99	3
1997-98	2
1996-97	0

The attached tabulation provides the details of the individual surveys as requested.

Please Note: The TGA and CRS have been consulted in the development of this response and their information has been included where relevant.

ATTACHMENT

Details of Individual Surveys of Attitudes to Programmes

Year	**Name of survey [Q. (a)]**	**Related Departmental programmes [Q. (b)]**	**Major findings [Q. (c)]**
2003-04			
2003-04	Rural Australia Medical Undergraduate Scholarship Scholar and Mentor Survey (a survey regarding the Mentoring aspect of the program)	Rural Australia Medical Undergraduate Scholarship (RAMUS) Scheme	The results of this survey are currently not publicly available as they are part of current policy development processes.
2003-04	MRB Scholar Survey	Medical Rural Bonded (MRB) Scholarship Scheme	The results of this survey are currently not publicly available as they are part of current policy development processes.
2003-04	Survey of doctors working in rural and remote locations under Australia's Five-Year Overseas Trained Doctor Recruitment Scheme	Australian, State and Territory Five Year Overseas Trained Doctor Recruitment Schemes	The survey found that doctors participating on the scheme were generally satisfied with the program. The suggestion for improvement mainly related to ongoing support and education for doctors participating on the scheme.

2003-04 (and similar surveys 2002-03, 1999-00, 1997-98)	Yearly independent survey of samples of customers, clients and other stakeholders	- Government funded Vocational Rehabilitation programmes (funded by FaCS) - Government funded Career Planning (funded by DEST) - Services provided to other purchasers (being external to Australian Government)	Satisfaction with CRS Australia services to government funded program recipients remain very high. Key data from the 2003 survey is provided below on Government programs. • Key stakeholders indicated that CRS Australia offers a strong and solid partnership, being both proactive and responsive in satisfying the needs of FaCS and Centrelink • 95% of Centrelink referrers are confident that CRS has the ability to provide consistent high quality service to its clients (an increase from 91% in 2002) • 85% of clients are likely to recommend CRS to a friend with 72% being satisfied that their program is meeting their needs • 9% of clients were dissatisfied with CRS Australia service. • Key stakeholders suggested that CRS Australia should better communicate the good outcomes being achieved by clients and to keep referrers better informed regarding client progress. • 85 % of people receiving career planning assistance were satisfied with the service. FaCS and Centrelink considered CRS as being a very capable and professional organisation which performs very favourably against each of the objectives that are set. CRS has consolidated its position as both a worthy and leading supplier to FaCS and Centrelink.

2002-03			
2002-03	Service Charter survey CEO survey	NICNAS (National Industrial Chemicals Notification and Assessment Scheme)	• 86 % found staff to be helpful and courteous always or most of the time; • 83 % found their questions and inquiries were answered in 7-28 days always or most of the time; • 86 % found written explanations clear always or most of the time; • 85 % found that NICNAS provided accurate and consistent information always or most of the time; and • 82 % of organisation surveyed were aware of NICNAS web site. Of these 79 per cent found the web site easy to navigate. While the response rate was lower than the general customer survey, the results indicate a higher level of satisfaction with NICNAS's service. The issues CEOs identified as requiring attention by NICNAS were similar to those of the general customer survey.
2002-03	Client Satisfaction Survey	Commonwealth Hearing Services Program	92% of respondents were satisfied or very satisfied with the services provided under the Program.
2002-03	Complainant Satisfaction Survey	Aged Care Complaints Resolution Scheme	• 67% satisfied, 18% mostly satisfied, 7% minor, 4% not satisfied • 89% assisted to make their complaint • 73% found the Scheme very helpful • 75% were always kept informed • 73% wishes were always respected • 83% were informed about their rights.

2002-03	Service Provider Satisfaction Survey	Aged Care Complaints Resolution Scheme	• 76% satisfied, 19% mostly satisfied, 2.5% minor, 2.5% not satisfied • 91% respondents had the opportunity to contribute to resolution of complaint • 77% found the Scheme very helpful • 68% were always kept informed • 67% needs were always respected • 86% were informed about their rights • 59% thought that their business would be improved as a result of the complaint resolution.
2001-02			
2001-02	Service Charter survey	NICNAS	• 91 % found the staff to be always helpful and courteous (93 % previous year); • 88 % found their questions and inquiries always answered within 7-28 days (83 % previous year); • 79 % found written explanation always clear (71 per cent previous year); • 70 % found that NICNAS always provided accurate and consistent information (new survey question); and • 93 % of companies surveyed were aware of the NICNAS web site: of these 58 % found the web site easy to navigate.
2001-02	Client Satisfaction Survey	Commonwealth Hearing Services Program	93% of respondents were satisfied or very satisfied with the services provided under the Program.
2001-02	Client Top-Up Survey	Commonwealth Hearing Services Program	36% of return clients reported using their Top–Up hearing aids for more than 8 hours a day whereas only 21% of new clients did so.

2001-02	Complainant Satisfaction Survey	Aged Care Complaints Resolution Scheme	• 67% satisfied, 22% mostly satisfied, 6% minor, 5% not satisfied • 89% assisted to make their complaint • 76% found the Scheme very helpful • 75% were always kept informed • 76% wishes were always respected • 84% were informed about their rights.
2001-02	Service Provider Satisfaction Survey	Aged Care Complaints Resolution Scheme	• 69% satisfied, 20% mostly satisfied, 7% minor, 3% not satisfied • 88% respondents had the opportunity to contribute to resolution of complaint • 71% found the Scheme very helpful • 66% were always kept informed • 60% needs were always respected • 79% were informed about their rights • 56% thought that their business would be improved as a result of the complaint resolution.
2000-01			
2000-01	Service Charter survey	NICNAS	• 93 % found staff to be always helpful and courteous (80 per cent previous year); • 83 % found their questions and enquiries always answered promptly (63 per cent previous year); • 71 % found written explanations always clear (79 per cent previous year); • 93 % of companies surveyed are aware of the NICNAS web site: of these, 82 %t found the web site easy to navigate.
2000-01	Client Satisfaction and Hearing Aid Use Survey	Commonwealth Hearing Services Program	• 30% of respondents reported using their hearing aid for more than 8 hours per day; • 92% of respondents were satisfied or very satisfied with the services provided under the Program.

2000-01	Complainant Satisfaction Survey	Aged Care Complaints Resolution Scheme	• 67% satisfied, 21% mostly satisfied, 4% minor, 8% not satisfied. • 86% assisted to make their complaint • 77% found the Scheme very helpful • 68% were always informed • 73% wishes were always respected • 83% were informed about their rights.
2000-01	Service Provider Satisfaction Survey	Aged Care Complaints Resolution Scheme	• 71% satisfied, 19% mostly satisfied, 5% minor, 5% not satisfied • 88% respondents had the opportunity to contribute to resolution of complaint • 62% found the Scheme very helpful • 57% were always kept informed • 60% needs were always respected • 80% were informed about their rights • 68% thought that their business would be improved as a result of the complaint resolution.

2000-01	Awareness And Attitudes Of Australian Health Professionals Towards Drug Safety Monitoring, Reporting and Feedback	Post-marketing Surveillance Program	That the existing "system" for reporting adverse drug reactions (ADRs) works fairly well, but could be better according to the health professionals surveyed. Partly, their own busy work lives act as a barrier, but a noticeable improvement in the whole ADR process could be achieved through: • electronic access to the ADR pieces and information (like the Blue Card, ADR Bulletin); • acknowledgment of ADR reports received and quite quickly; • feedback on ADR reported by the health professional (direct to them, not just indirectly through publications) – also quickly; • informing them of ADRs before the media hears; • promoting an ADR Hotline; • making the information on the back page of the ADR Bulletin more obvious through a front page summary and / or reference including contact details; and • focusing on significant ADRs only in reporting.
2000-1999			
1999-2000	Service Charter survey	NICNAS	• 80% finding staff to be helpful and courteous; • 95% finding staff helpful in resolving complex issues; • 63% finding the questions and enquiries always answered promptly; • 88% finding information material easy to read including the web; and • 79% finding written explanations always clear.
1999-2000	Client Satisfaction and Utilisation Survey	Commonwealth Hearing Services Program	• 52% of return clients reported using their hearing aids for more than 8 hours a day whereas only 21% of new clients did so; • 92% of respondents were satisfied or very satisfied with the services provided under the Program.

1999-2000	Evaluation of the CJD Support Group Network Inc. – Recipient Survey	Australian Human Pituitary Hormone Program	A total of 2,300 questionnaires were sent out to recipients and health care professions providing services to human pituitary hormone recipients and their families. The survey highlighted the need to refocus support group activities (particularly for human growth hormone recipients) and the need to improve the administrative arrangements for the management of the support group network. Another key finding was the importance of general practitioners (GPs) in the provision of clinical and support services to recipients.
1998-99			
1998-99	Service Charter survey	NICNAS	• 62% positive comments; • 12% sought further information; • 19% suggested areas where they required further clarification; and • 6% were critical.
1998-99	Client need and Hearing Services Survey	Commonwealth Hearing Services Program	30% of respondents felt that they did not need the hearing aid that had been provided for them whereas only 8% of their family members felt that the client did not need the aid.
1998-99	Client Satisfaction Survey	Commonwealth Hearing Services Program	95% of respondents reported satisfaction with the services provided under the Program.
1997-98			
1997-98	Client Satisfaction and Utilisation Survey	Commonwealth Hearing Services Program	• 37% of respondents reported using their hearing aid for more than 8 hours per day; • 91% of respondents reported satisfaction with the services provided under the Program.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-222

OUTCOME Whole of Portfolio

Topic: CODE OF CONDUCT

Hansard Page: CA 137

Senator McLucas asked:

To be provided with copies of Departmental guidance available to staff relating to the question of accepting hospitality.

Answer:

Relevant guidance available to officers of the Department is as follows:

- The APS Code of Conduct - Attachment A
- Procedural Rule 4.2 on Ethics and Fair Dealings - Attachment B
- Gifts and Benefits from the Audit and Fraud Control Workplace Ethics booklet - Attachment C
- Code of Ethics in Procurement from the Audit and Fraud Control Workplace Ethics booklet - Attachment D
- Hospitality guidelines from the Audit and Fraud Control Workplace Ethics booklet - Attachment E

Australian Public Service Code of Conduct

1. An APS employee must behave honestly and with integrity in the course of APS employment.
2. An APS employee must act with care and diligence in the course of APS employment.
3. An APS employee, when acting in the course of APS employment, must treat everyone with respect and courtesy, and without harassment.
4. An APS employee, when acting in the course of APS employment, must comply with all applicable Australian laws.
5. An APS employee must comply with any lawful and reasonable direction given by someone in the employee's Agency who has authority to give the direction.
6. An APS employee must maintain appropriate confidentiality about dealings that the employee has with any Minister or Minister's member of staff.
7. An APS employee must disclose, and take reasonable steps to avoid, any conflict of interest (real or apparent) in connection with APS employment.
8. An APS employee must use Commonwealth resources in a proper manner.
9. An APS employee must not provide false or misleading information in response to a request for information that is made for official purposes in connection with the employee's APS employment.
10. An APS employee must not make improper use of:
    a. inside information; or
    b. the employee's duties, status, power or authority; in order to gain, or seek to gain, a benefit or advantage for the employee or for any other person.
11. An APS employee must at all times behave in a way that upholds the APS Values and the integrity and good reputation of the APS.
12. An APS employee on duty overseas must at all times behave in a way that upholds the good reputation of Australia.
13. An APS employee must not, except in the course of his or her duties as an APS employee or with the Agency Head's express authority, give or disclose, directly or indirectly, any information about public business or anything of which the employee has official knowledge.

Extract from Procedural Rule 4.2

Ethics and Fair Dealing

32. The Commonwealth's dealings with its suppliers and potential suppliers must be above reproach.
33. This imposes obligations on officials with regard to both their relations with the Commonwealth and their dealings with suppliers. Public money must be used honestly and accountably for legitimate official purposes. Potential suppliers must be treated fairly and equitably.
34. For example, if information relevant to an invitation to quote or tender is provided to one potential supplier, it must also be made available to others who have been invited. Information about a supplier or its products must not be provided to its competitors.
35. No official is to derive personal benefit from his/her position. Most obviously, officials must not accept gifts, travel, meals, etc from suppliers, especially in circumstances where such generosity could be construed as an attempt to influence a purchasing decision (eg. the award of a contract) or a reward for a favourable decision.
36. This principle also requires the disclosure of any interest, financial or otherwise, in a potential supplier to the department.
37. For example, if an official recommending or deciding on the selection of a supplier is related to one of the competitors, the official should advise her/his supervisor. They should discuss means of ensuring that the decision is not influenced by the relationship, and the existence of the relationship is clearly identified in the record of any further involvement the official has in the decision. (The simplest solution is for the official to withdraw from the decision-making process, but this may not always be possible, eg. if the official has particular technical knowledge relevant to the decision).
38. In the interests of ethics and fair dealing (and obtaining value for money), Expenditure Approvers should ensure that officials are trained and competent in the responsibilities of their duties and are able to deal professionally with clients and suppliers.

Gifts and Benefits

(Extract from the Audit and Fraud Control Workplace Ethics booklet)

You must not take advantage of your official position to get a benefit for yourself or other people. You may only accept a gift or benefit in accordance with the PSC Guidelines on Official Conduct of Commonwealth Public Servants. In summary:

- you may accept unsolicited gifts or benefits of an inconsequential or trivial nature where there is no real or apparent conflict of interest or where refusal may give offence;
- you may accept prizes won as a result of conducting official business but the prizes become the property of the Commonwealth;
- you may accept invitations to local sporting or cultural functions though care is needed to ensure that your presence does not imply an inappropriately close or preferred relationship with the person offering the invitation;
- you can not accept personal travel or accommodation related to the attendance at sporting cultural events;
- you can not accept discounts or free services, goods, club memberships or magazine subscriptions that have been made available only to you. (If they are generally available to people such as public servants then they may be acceptable); and
- you can not accept any gift, benefit or hospitality during any period of contract negotiation or where it may give the appearance of undue influence.

For more information refer to PSMPC Publications, via PSMPC Website
http://www.psmpc.gov.au

Code of Ethics in Procurement

(Extract from the Audit and Fraud Control Workplace Ethics booklet)

With the current trend of government towards Competitive Tendering and Contracting for the provision of services, more APS Officers are being involved in the tendering process and management of contracts than ever before. The resultant exposure to commercial information and the potential for breaches of conduct and ethics are made clearer with the code of ethics for procurement activity.

Officers should conduct themselves in a manner which ensures that they maintain a reputation for fair dealing. The following precepts of ethical behaviour must be observed by all officers involved with purchasing/procurement.

1. Officers should perform their duties impartially, uninfluenced by fear or favour.
2. Officers should be frank and honest in their dealings with colleagues.
3. Officers should avoid situations in which their private interests, whether pecuniary or otherwise, conflict or might reasonably be thought to conflict with their public duty.
4. When officers possess, directly or indirectly, an interest which conflicts or might reasonably be thought to conflict with their public duty, or to have any improper influence on their conduct in the discharge of their responsibilities in respect of some matter with which they are concerned, they should disclose that interest in writing to their immediate supervisor according to the prescribed procedures. Should circumstances change after an initial disclosure has been made, so that new or additional facts become material, the further information should be disclosed.
5. When interests of members of their immediate family are involved, officers should disclose these interests, to the extent to which they are known.
6. When officers possess an interest which conflicts with their duties and such an interest is not prescribed as a qualification for their office, they should forthwith divest themselves of that interest, secure their removals from the duties in question, or obtain the authorisation of their superior or colleagues to continue to discharge the duties.
7. Officers should not use information obtained in the course of official duties to gain directly or indirectly a pecuniary advantage for themselves or for any other person.
8. Officers must not:
    - solicit or accept from any person any remuneration or benefit for the discharge of the duties of their office;
    - solicit or accept any benefit, advantage or promise of further advantage whether for themselves, their immediate family or any business concern or trust with which they are associated from persons who are in, or seek to be in, any contractual or special relationship with government;
    - except as may be permitted under the rules applicable to their office, accept any gift, Hospitality or concessional travel offered in connection with the discharge of the duties of their office.
9. Officers should be scrupulous in their use of public property and services and should not permit their misuse by other persons.
10. Officers should not allow the pursuit of their private interests to interfere with the proper discharge of their public duties.

11. Officers should first consider all of the interests of the Commonwealth in all transactions and second, carry out the Commonwealth's established policies.
12. Officers should deal fairly and consistently with suppliers and ensure that the confidentiality of sensitive material is maintained.
13. Officers should seek to develop and maintain levels of knowledge and skills commensurate with their responsibilities.

For more information please refer to "Pitfalls of Probity" Tendering and Purchasing Case Studies, Independent Commission Against Corruption.

Hospitality

(Extract from the Audit and Fraud Control Workplace Ethics booklet)

Hospitality given or received must be associated with the demands of work, for example, working meals or functions associated with discussing public business and meeting with persons because of their ability to provide advice or service, or because of their vocational or business interests.

Expenditure on hospitality must be publicly defensible and be able to withstand scrutiny on the grounds that it:

- Promotes or supports a government policy objective, service or program.
- Facilitates the conduct of public business.
- Ensures costs incurred are reasonable and appropriate.

What is Official Hospitality?

Official hospitality could include the following types of functions provided that their primary reason is to facilitate the conduct of public business:

- luncheons, dinners, etc;
- working lunches at conferences and seminars;
- provision of refreshments to visitors;
- official function such as the opening of new offices; and
- gifts of protocol to visiting dignitaries/officials.

- Commonwealth Government Officials should only receive benefit from Commonwealth funded functions when they are required to represent the Department at these functions.
- Public funds are not to provide hospitality for Commonwealth Government officials only.
- Official hospitality for the Minister and the Chief Executive Officer is funded from the Department's running costs.
- Officials receiving meals, which are charges against official hospitality, must not also receive travelling allowance in respect of those meals.
- Officials must not charge refreshment or meal cost associated with seminars, training courses or similar forums, to official hospitality funds - justifiable expenditure should be met from the funds provided for the event or function.
- With the exception of justifiable light working lunches, expenditure should not be authorised for hospitality associated with functions of an interdepartmental or intra-Commonwealth Government nature.

Basically you should avoid any possible perception of undue benefit or conflict of interest.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-203

OUTCOME Whole of Portfolio

Topic: EXCLUSION OF CDEP PARTICIPANTS FROM COMMONWEALTH FUNDED PROGRAMS

Hansard Page: CA129

Senator O'Brien asked:

What other Commonwealth funded programs are CDEP participants excluded from?

Answer:

The Community Development Employment Project (CDEP) is currently coordinated by Aboriginal and Torres Strait Islander Services (ATSIS), however it will transfer to the Department of Employment and Workplace Relations (DEWR) when ATSIS ceases to exist on 1 July 2004. Consequently, the Department recommends that this question be redirected to ATSIS or DEWR.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: EO4-200

OUTCOME Whole of Portfolio

Topic: AVERAGE TIME IN MINISTER'S OFFICE FOR QUESTIONS ON NOTICE

Hansard Page: CA 6

Senator McLucas asked:

What is the average time that questions were in the Minister's Office waiting for his approval?

Answer:

The Department's system for tracking Ministerial documents does not accurately report on the average time answers to Senate Estimates questions are held within a Minister's office. For example, the system does not record instances where documents are returned to the Department for further information.

FOOD STANDARDS Australia New Zealand
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Office of the Chief Executive Officer

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

Dear Mr Humphrey

SENATE ESTIMATES HEARING 18 FEBRUARY 2004: OUTCOME 1

I am writing to correct statements made by Food Standards Australia New Zealand (FSANZ) officers attending the Senate Community Affairs Legislation Committee - Senate Estimates hearings on 18 February 2004. The relevant statements appear on the Hansard transcript at pages CA133, CA134 and CA136.

During these committee hearings, Senator Forshaw sought information concerning the status, in Australia, of nitrofurans[1] in food.

Based on a long-standing and commonly held interpretation of Standard 1.4.2 of the *Australia New Zealand Food Standards Code* (the Code), Senator Forshaw was advised that the presence of nitrofurans in food is prohibited.

This interpretation has been shared by FSANZ (and its statutory predecessors), the State and Territory food enforcement agencies, and the food industry (including the Australian Food and Grocery Council).

However, a recent review by FSANZ of relevant food standards in the Code has revealed that this interpretation is legally incorrect and that the Code does not technically prohibit the presence of nitrofurans in the food. Legal advice of 30 April 2004 confirmed that Standard 1.4.2 of the Code, when closely scrutinised, contains a technical anomaly inconsistent with the intended effect of the Standard.

This anomaly has existed in the Standard since 1987 and is contrary to the common understanding and purpose of the Standard. It is not confined to nitrofurans, but effectively applies to any chemical in food except those chemicals currently listed in the Standard.

[1] Nitrofurans are synthetic broad-spectrum antimicrobial agents used in some countries in human and veterinary medicine. There are four main nitrofuran chemicals referred to in the scientific literature, namely, furazolidone, furaltadone, nitrofurantoine and nitrofurazone.

Once this technical anomaly was confirmed on 30 April 2004, FSANZ moved immediately to address this problem, taking the following action:

1. FSANZ confirmed with State and Territory enforcement agencies and the Australian Quarantine Inspection Service (AQIS) that an anomaly in Standard 1.4.2 does in fact legally exist.

2. The Board of FSANZ prepared a proposal under its statutory urgency provisions to amend Standard 1.4.2 to remove the anomaly. It is anticipated that this proposal will be finalised by Friday 14 May 2004.

3. FSANZ removed incorrect advisory material related to nitrofurans in food from its website.

4. FSANZ consulted with the States, Territories, New Zealand and AQIS on the broader regulatory implications of the anomaly.

Most State and Territory jurisdictions believe they can rely on provisions under their own legislation to address the presence of residues in food. Food law provisions concerning food containing chemical agents foreign to the nature of the food could potentially be used by enforcement agencies to take action against suppliers of foods containing these residues. However, these provisions are untested in legal proceedings, and an express prohibition in the Code provides enforcement agencies with greater enforcement certainty.

For imported food, AQIS believes that the *Imported Food Control Act 1992* can be used to adequately address nitrofurans in food.

Given the potential public health implications, FSANZ and the enforcement agencies consider that the urgent proposal to amend the Standard is necessary to ensure that enforcement agencies can take action necessary to protect public health and safety.

The urgent proposal being progressed by FSANZ is designed to restore the model regulatory approach for agricultural and veterinary chemicals adopted elsewhere in the Code. This model involves a regulatory formula that prohibits substances in food unless those substances are expressly permitted. Standard 1.3.1 regulating food additives and Standard 1.3.3 on processing aids provide specific examples of the regulatory formula applied in the Code. This approach establishes the mechanism by which FSANZ effectively monitors the safety of substances in the food supply, thus enabling FSANZ to meet its statutory objective of protecting public health and safety.

Yours sincerely

Graham Peachey
Chief Executive Officer
11 May 2004

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-162

OUTCOME 1: Population Health and Safety

Topic: Performance Assessment Mechanism

Written Question on Notice

Senator Carr asked:

(a) Please provide full details of each of the performance assessment mechanisms linked to the pay outcomes or other financial reward of individual employees, including:

i. What are the current process/es of performance assessment within the portfolio agency? If more than one, please provide details of each, and the employee category it applies to.

ii. For each of the performance assessment process/es identified in (i), please list the range of outcome results an employee can achieve from each of the performance assessment processes identified in (i);

iii. For each of the performance assessment process/es identified in (i), what pay or other financial change is linked to each outcome or result for the employee from the performance assessment [ie, the pay increase or one-off bonus or classification or level change];

iv. For each of the performance assessments identified in (i), what is the classification level of employees subject to this performance assessment (eg SES, EL1, EL2 or APS and equivalent);

v. What is the principal industrial or other instrument governing each of the performance assessment mechanism/s (eg, the certified agreement or AWA);

vi. Does the performance assessment operate over a common cycle? Please provide the commencement and end dates of the most recent full cycle of each of the assessment process/es.

(b) For each performance assessment mechanism described in (a), advise the number of male and the number of female employees at each possible outcome, by classification level for the most recent full cycle (if the performance mechanism does not operate over a common cycle - aggregate outcomes using the 2002-03 financial year).

Answer:

(a) Applicable assessment mechanism
1. ARPANSA Performance and Development System (APDS)
2. Individual performance assessment (Australian Workplace Agreement – AWA)

APDS

(i) Overview - The branch plan identifies the work goals/expectations of the branch. The staff member and his/her supervisor then set agreed work goals/expectations that the staff member can realistically achieve in their job/position during the coming twelve months. The identification of the agreed work goals/expectations is recorded in yearly and quarterly Work Agreements. The tasks and responsibilities of the staff member which contribute to meeting the agreed expectations are also recorded in the Work Agreements**.**

In addition, the APDS identifies the training and development that an individual requires to meet ARPANSA's core skills and skill expectations. It also identifies the training and development that an individual requires to meet their specific job/position skill expectations. The results are recorded in yearly and quarterly Work Support Agreements.

(ii) Both the Work Agreement and the Work Support Agreement must be consistent with ARPANSA's goals and objectives, and with the staff member's position description and classification level. The application of the APDS is an agreement between the supervisor and the staff member regarding the daily tasks, responsibilities and duties to be undertaken by the staff member to achieve specific goals. There is also a feedback component provides staff with formal feedback on their performance and achievements.

A three level assessment scale is used to summarise the achievement of both skill and work goals/targets
- Satisfactory Plus – S+ (Performance and skill levels exceed the standards expected at this classification level)
- Satisfactory – S (Performance and skills meet the standard expected at this classification level.)
- Not entirely satisfactory – NES (Performance indicates that the acceptable results has not been achieved by failing to meet some standard work requirements and/or not being able to demonstrate a satisfactory standard against some significant skills which are important and expected for this level. Remedial action is to be taken and performance monitored until a higher outcome is achieved.)

(iii) In general incremental pay advancement is linked to satisfactory assessment outcome.

(iv) The APDS applies to staff with classification ranging from APS2 to APS6, EL1 to EL2.

(v) Governing industrial document – ARPANSA Agreement 2002-04

(vi) Operating cycle – 12 months from 1 January to 31 December each year

AWA

(i) Overview – Workplace agreements have been made between the CEO of ARPANSA and his direct reports and a small number of other staff. The ARPANSA Corporate Plan establishes strategic corporate direction/objectives and branch plans identify the work goals/expectations of the branch. Staff members develop performance objectives with the CEO for the twelve months period. These are recorded in the AWA (individual) and approved by the Office of Employment Advocate. The CEO can offer an AWA to any staff in the agency where he deems relevant. Performance objectives are reviewed (and amended if necessary) 6 monthly and outcomes are assessed annually between the signatories.

The AWA also identifies individual remuneration and professional development requirements.

(ii) Individual AWA performance outcomes must be consistent with ARPANSA's goals and objectives, and with the staff member's position description and classification level. For senior staff members, outcomes include management of staff resources and budget, contributing to the leadership of the organisation and effective management of key corporate initiatives. To be eligible for a performance bonus, the performance of senior staff is assessed as satisfactory, highly satisfactory or outstanding.

(iii) See (ii) above.

(iv) The performance review process applies to staff on AWAs. Classifications of staff currently on AWA are APS6, EL1, EL2 and SES.

(v) Governing industrial document – Australian Workplace Agreement

(vi) Operating cycle – 12 months from 1 January to 31 December each year.

(b) As at 30 June 2003

Level	Male	Female	Total
SES	5	0	5
Executive Level 2	15	2	17
Executive Level 1	22	5	27
APS 6	29	9	38
APS 5	8	3	11
APS 4	1	3	4
APS 3	3	17	20
APS2	0	10	10
TOTAL	78	47	125

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-164

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: PERFORMANCE ASSESSMENT MECHANISMS

Written Question on Notice

Senator Carr asked:

(a) Please provide full details of each of the performance assessment mechanisms linked to the pay outcomes or other financial reward of individual employees, including;

i. What are the current process/es of performance assessment within the portfolio agency? If more than one, please provide details of each, and the employee category it applies to.

ii. For each of the performance assessment process/es identified in (i), please list the range of outcome results an employee can achieve from each of the performance assessment processes identified in (i);

iii. For each of the performance assessment process/es identified in (ii), what pay or other financial change is linked to each outcome or result for the employee from the performance assessment [ie, the pay increase or one-off bonus or classification or level change];

iv. For each of the performance assessments identified in (i), what if the classification level of employees subject to this performance assessment (e.g. SES, EL1, EL2 or APS and equivalent);

v. What is the principal industrial or other instrument governing each of the performance assessment mechanism's (e.g., the certified agreement or AWA);

vi. Does the performance assessment operates over a common cycle? Please provide commencement and dates of the most recent full cycle of each of the assessment process/es.

(b) For each performance assessment mechanism in (a), advise the number of male and the number of female employees at each possible outcome, by classification level for the most recent full cycle (if the performance mechanism foes not operate over a common cycle – aggregate outcomes using the 2002-03 financial year).

Answer:

(a) Performance Enhancement Scheme
  (i) Immediate supervisor conducts the assessment, the next level supervisor reviews the assessment, and the Chief Executive Officer moderates the assessment.
  (ii) The outcomes for an employee are Outstanding, Superior, Fully Effective, Acceptable and Unsatisfactory.
  (iii) Performance pay for those on AWA's, and incremental advancement for those employees not on the top of the salary range.
  (iv) All employees are subject to the Performance Enhancement Scheme, i.e. APS1, 2, 3, 4, 5, 6, EL1, 2, SES.
  (v) Certified Agreement.
  (vi) Yes. Most recent full cycle was 1 July 2002 to 30 June 2003.

(b) Employee break up as per 2002-03 Annual Report, Appendix 3, Table 1, page 100.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-037

OUTCOME 1: Population Health and Safety

Topic: TOTAL COST FROM RECALL OF PAN PHARMACEUTICALS PRODUCTS

Written Question on Notice

Senator Forshaw asked:

Can you provide an updated total cost, including advertising and legal costs, to the TGA from the recall of all Pan Pharmaceutical products?

Answer:

The total cost to the TGA of the recall of products manufactured by Pan Pharmaceuticals Limited as at 31 January 2004 was $14,863,434 (GST-inclusive). This amount includes $10,519,308 for advertising recall notices and $67,141 in legal expenses.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-038

OUTCOME 1: Population Health and Safety

Topic: INCREASE OF FEES AND CHARGES

Written Question on Notice

Senator Forshaw asked:

Since January 2003, have you increased any fees pertaining to registration and licensing or for over-the-counter and complementary medicines products? (If so, provide details of increases).

Answer:

The TGA introduced revised fees and charges on 1 July 2003. A general increase of 3.25% was applied to all manufacturing licence and inspection fees, and to all product application and evaluation fees applicable to over-the-counter and complementary medicines. Due to the under-recovery of costs in these sectors in recent years, annual charges for Registered Non-Prescription Medicines were increased by $160 to $690 and annual charges for Listed Medicines were increased by $115 to $505.

Further details of changes to fees and charges are provided in tabular form in response to question E04-039.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-039

OUTCOME 1: Population Health and Safety

Topic: CURRENT FEES/CHARGES AND TRAINING

Written Question ion Notice

Senator Forshaw asked:

Can you provide details of all your current fees and charges, including training, this financial year compared to last financial year?

Answer:

A table comparing fees and charges for 2002/03 and 2003/04 made in accordance with the Therapeutic Goods Regulations and the Therapeutic Goods (Charges) Regulations is at Attachment A.

Following consultation with industry representatives during 2002/03, the TGA varied the way in which evaluation fees were applied in the Prescription Medicines Program from the previous page-count approach to one based on the type of submission made. This new approach applied for new submissions received after 1 July 2003 and consequently, they are not directly comparable. Nonetheless, an extract from the relevant section of TGA fees and charges that applied to the Prescription Medicines Program in 2002/03 is included at Attachment B.

Course fees relating to training programs delivered by the TGA will vary, based on the cost of delivering a program and the number of persons attending a course. A copy of the 2004 International Training Program, including course fees, is at Attachment C.

Attachment A

TGA THERAPEUTIC GOODS ADMINISTRATION

Summary of Fees and Charges
Comparison: 2002/03 and 2003/04

ABN: 40 939 406 804

PRESCRIPTION MEDICINES:

From July 2003 a new fee structure applies to therapeutic goods evaluated by the Drug Safety and Evaluation Branch of TGA. Fees will vary according to the type of evaluation undertaken and are on a per submission basis. A submission is one or more applications from the same sponsor, with the same active ingredient, submitted at the same time. A concomitant application from, or on behalf of, another sponsor is a separate submission.

Evaluation Fees Category 1 and 2 Submissions	**2002/03 Fee $**	**2003/04 Fee $**
New Chemical Entity	Note 1	192,600
Extension of indications	Note 1	114,500
Major variations (new strength, new dosage form, new route of administration, change in patient group, change in dosage)	Note 1	74,650
New generic product	Note 1	65,000
Additional trade name	Note 1	12,100
Minor variations (change in formulation, composition, specifications or container) and variations to a Register entry involving the evaluation of chemistry, quality control and manufacturing information, and clinical, pre-clinical or bio-equivalence data, but not included in another fee category.	Note 1	4,300
Changes to Product Information involving the evaluation of data	Note 1	4,400
Changes to Product Information where no evaluation is required	Note 1	1,310
Changes to Consumer Medicine Information	Note 1	1,350
Evaluation Fees - Other Submissions	**2002/03 Fee $**	**2003/04 Fee $**
Variations to a Register entry involving the evaluation of only chemistry, quality control and manufacturing information	Note 1	4,300
Notification of Self Assessable Changes	560	1,310
Safety Related Notification	560	1,310
Testing and provision of advice, requested from Pharmaceutical Benefits Program, prior to listing on Pharmaceutical Benefits Listing Program	-	9,990
Administrative Charges	**2002/03 Fee $**	**2003/04 Fee $**
Withdrawal of submission prior to acceptance of the submission	10% of evaluation fee to maximum of $5,670	20% of evaluation fee to maximum of $5670
Withdrawal of submission after the evaluation process is taken to be complete	Full evaluation fee	Full evaluation fee
Correction of a Register entry	560	1,310
Annual Charges	**2002/03 Fee $**	**2003/04 Fee $**
Biologics	Note 2	2,300
Non-Biologics	Note 2	1,420
Clinical Trials	**2002/03 Fee $**	**2003/04 Fee $**
CTX 30 Days	1,240	1,240
CTX 50 Days	15,300	15,300
CTN	220	240

CTN-more than one trialing body	220	240

Note 1 – Evaluation fees in 2002/03 are detailed at Attachment B and were based on the page-count of an application and hence are not directly comparable.
Note 2 – In 2002/03, all prescription medicines were charged at the same rate of $1,070 for each entry on the ARTG

REGISTRATION OF NON-PRESCRIPTION MEDICINES (OTC & COMPLEMENTARY MEDICINES):	**2002/03 Fee $**	**2003/04 Fee $**
Application fee	730	755
Additional /concurrent application fee	310	325
Processing fee (variation to an existing registration)	730	755
Annual charge	530	690
EVALUATION FEES per submission if the documentation does not contain Clinical or Toxicological data	**2002/03 Fee $**	**2003/04 Fee $**
New product	4,870	5,030
Variation	1,750	1,810
New substance: CMEC, sunscreen excipients, all other	4,870	5,030
New product - **page count of Clinical or Toxicological data per submission**	**2002/03 Fee $**	**2003/04 Fee $**
1-50	4,870	5,030
51-250	6,230	6,435
251-500	8,510	8,790
501-1000	11,330	11,700
1001-2000	17,000	17,555
2001-3000	22,670	23,410
>3000	34,000	35,105
Variation ***- total page count of Clinical or Toxological data per submission***	**2002/03 Fee $**	**2003/04 Fee $**
1-50	1,750	1,810
51-250	6,230	6,435
251-500	8,510	8,790
501-1000	11,330	11,700
1001-2000	17,000	17,555
2001-3000	22,670	23,410
>3000	34,000	35,105
New Substance - *total page count of Clinical or Toxicological data per submission*	**2002/03 Fee $**	**2003/04 Fee $**
1-50	4,870	5,030
51-250	6,230	6,435
251-500	8,510	8,790
501-1000	11,330	11,700
1001-2000	17,000	17,555
2001-3000	22,670	23,410
>3000	34,000	35,105
Multiple new excipients in listed or registered good for dermal use	**2002/03 Fee $**	**2003/04 Fee $**
1-50	4,870	5,030

51-250	6,230	6,435
251-500	8,510	8,790
501-1000	11,330	11,700
1001-2000	17,000	17,555
2001-3000	22,670	23,410
>3000	34,000	35,105
EVALUATION FEES FOR SAFETY AND EFFICACY	**2002/03 Fee $**	**2003/04 Fee $**
– total page count of Clinical or Toxicological data per submission		
1-50	N/A	5,030
51-250	N/A	6,435
251-500	N/A	8,790
501-1000	N/A	11,700
1001-2000	N/A	17,555
20001-3000	N/A	23,410
>3000	N/A	35,105

LISTED MEDICINES:	**2002/03 Fee $**	**2003/04 Fee $**
Application fee	460	475
Processing fee (variation to an existing listing)	220	230
Annual charge	390	505
Evaluation fee for assessing information or documents relating to the safety of goods for the purposes for which they are to be used.	4,530	4,680

BLOOD & BLOOD PRODUCTS	**2002/03 Fee $**	**2003/04 Fee $**
EVALUATION FEES - per submission **Page counts**		
1 – 10	820	850
11 - 50	7,030	7,260
51 - 100	15,590	16,100
101 - 1000	20,970	21,655
1001 - 3000	32,860	33,930
3001 - 4000	43,630	45,050
> 4000	53,260	54,995
GMP Audit of Manufacturers of Blood & Blood Products	**2002/03 Fee $**	**2003/04 Fee $**
GMP certification of primary site	560	580
GMP certification of secondary site	400	415
Annual Licence Charge		
Metropolitan site	70,000	72,275
Additional fixed site	2,210	2,285

MEDICAL DEVICES: *The regulatory framework for medical devices changed with effect from 4 October 2002. Devices on the Australian Register of Therapeutic Goods (ARTG) at that date have a 5 year transitional period in which to transfer to the new arrangements. Fees for Registered and Listed Devices will gradually phase out as products make the transition to Included Devices.*

REGISTERED DEVICES – OLD SCHEME	**2002/03 Fee $**	**2003/04 Fee $**
Application fee - high level registration	2,720	2,810
Additional/concurrent - high level registration	1,360	1,405
Application fee - low level registration	900	930
Additional/concurrent - low level registration	460	475
Processing fee - high level registration (variation to an existing registration)	900	930
Processing fee - low level registration (variation to an existing registration)	460	475
Annual charge	1,020	1,850
Device Clinical Trials		
CTN	220	240
Clinical Trial – other	1,700	1,760
Clinical Trial – Sched 3 Pt1 Item 3	11,330	11,700

EVALUATION FEES	**Initial Application**		**Concurrent Application**		**Abridged Application**	
	02/03 Fee $	**03/04 Fee $**	**02/03 Fee $**	**03/04 Fee $**	**02/03 Fee $**	**03/04 Fee $**
High Level Registration -type of data						
Design/materials/testing	19,950	20,600	3,400	3,515	6,800	7,025
Manufacture/quality control	13,600	14,045	3,400	3,515	5,670	5,855
Biocompatibility/pre-clinical	13,600	14,045	3,400	3,515	5,670	5,855
Human clinical	22,670	23,410	3,400	3,515	22,670	23,410
Software	13,600	14,045	3,400	3,515	5,670	5,855
Confirmatory review of clinical information	N/A		N/A		5,670	5,855
Confirmatory review of overseas evaluation report	13,600	14,045	3,400	3,515	5,670	5,855
Low Level Registration -type of data						
Design/materials/testing	3,400	3,515	N/A		N/A	
Manufacture/quality control	3,400	3,515	N/A		N/A	
Biocompatibility/pre-clinical	3,400	3,515	N/A		N/A	

Registered Devices (cont):					
EVALUATION FEES	**Initial Application 02/03 Fee $**	**Initial Application 03/04 Fee $**	**Concurrent Application 02/03 Fee $**	**Concurrent Application 03/04 Fee $**	**Abridged Application Fee $**
Human clinical	3,400	3,515	N/A		N/A
Software	3,400	3,515	N/A		N/A
Diagnostic Goods Control Reagent	3,400	3,515	N/A		N/A
Disinfectants and diagnostic goods for in vitro use	11,330	11,700	N/A		N/A
Variation - High Level Registration – type of data					
Design/materials/testing	6,800	7,025	1,140	1,285	N/A
Manufacture/quality control	5,670	5,855	1,140	1,285	N/A
Biocompatibility/pre-clinical	5,670	5,855	1,140	1,285	N/A
Human clinical	22,670	23,410	1,140	1,285	N/A
Software	5,670	5,855	1,140	1,285	N/A
Confirmatory review of clinical information	5,670	5,855	N/A		N/A
Confirmatory review of overseas evaluation report	5,670	5,855	1,140	1,285	N/A
Variation – Low Level Registration – type of data					
Design/materials/testing	900	930	N/A		N/A
Manufacture/quality control	900	930	N/A		N/A
Biocompatibility/pre-clinical	900	930	N/A		N/A
Human clinical	900	930	N/A		N/A
Software	900	930	N/A		N/A
Diagnostic Goods Control Reagent	900	930	N/A		N/A
Disinfectants and diagnostic goods for in vitro use	2,270	2,345	N/A		N/A

LISTED DEVICES – OLD SCHEME	**2002/03 Fee $**	**2003/04 Fee $**
Application fee	280	290
Processing fee (variation to an existing listing)	280	290
Application for exemption under Section 14	280	290
Annual charge	510	930
Evaluation Fees		
Evaluation for assessing whether a listable or listed device is safe for the purposes for which it is to be used.	4,530	11,700

INCLUDED DEVICES – NEW SCHEME *Fees and charges for the new medical devices regulatory framework that came into effect on 4 October 2002	**2002/03 Fee $**	**2003/04 Fee $**
Application for Conformity Assessment Certificate – All Procedures	620	645
Medical Devices – Annual Charges	**2002/03 Fee $**	**2003/04 Fee $**
(a) Class AIMD medical device;	820	850
(b) Class III medical device;	820	850
(c) Class IIb medical device;	620	645
(d) Class IIa medical device;	620	645
(e) Class I medical device - sterile;	620	645
(f) Class I medical device - measuring function;	620	645
(g) Other Class I medical device	40	45
Conformity Assessment – Initial Assessment	**2002/03 Fee $**	**2003/04 Fee $**
(a) Schedule 3, Part 1- Full Quality Management System Audit; or	18,380	18,980
(b) Schedule 3, clause 1.6 - Design Examination; or	36,390	37,575
(c) Schedule 3, Part 2 - Type Examination (including management of testing, analysis, and reporting on examination of the type); or	25,320	26,145
(d) Schedule 3, Part 3 - Verification (including management of testing, analysis, and reporting on verification tests); or	17,690	18,265
(e) Schedule 3, Part 4 - Production Quality Management System Audit; or	16,130	16,655
(f) Schedule 3, Part 5 - Product Quality Management System Audit	13,900	14,355
Conformity Assessment – Changes	**2002/03 Fee $**	**2003/04 Fee $**
(a) Schedule 3, Part 1- Full Quality Management System Audit; or	11,030	11,390
(b) Schedule 3, clause 1.6 - Design Examination; or	21,830	22,540
(c) Schedule 3, Part 2 - Type Examination (including management of testing, analysis, and reporting on examination of the type); or	15,190	15,685
(e) Schedule 3, Part 4 - Production Quality Management System Audit; or	9,680	9,995
(f) Schedule 3, Part 5 - Product Quality Management System Audit	8,340	8,615
Conformity Assessment Surveillance Audits	**2002/03 Fee $**	**2003/04 Fee $**
(a) Schedule 3, Part 1 - Full Quality Management System Surveillance Audit; or	5,370	5,545
(b) Schedule 3, Part 4 - Production Quality Management System Surveillance Audit	5,370	5,545
(c) Schedule 3, Part 5 - Product Quality Management System Surveillance Audit	5,370	5,545
Conformity Assessment – Review of Certificate	**2002/03 Fee $**	**2003/04 Fee $**
(a) Schedule 3, clause 1.6 - Design Examination re-assessment	32,930	34,005
(b) Schedule 3, Part 2 - Type Examination re-assessment (including management of testing, analysis, and reporting on examination of the type)	25,320	26,145

Conformity Assessment – Components - Initial	**2002/03 Fee $**	**2003/04 Fee $**
(a) Schedule 3, Part 1- Full Quality Management System Audit; or	18,380	18,980
(b) Schedule 3, clause 1.6 - Design Examination; or	36,390	37,575
(c) Schedule 3, Part 2 - Type Examination (including management of testing, analysis, and reporting on examination of the type); or	25,320	26,145
(d) Schedule 3, Part 3 - Verification (including management of testing, analysis, and reporting on verification tests); or	17,690	18,265
(e) Schedule 3, Part 4 - Production Quality Management System Audit; or	16,130	16,655
(f) Schedule 3, Part 5 - Product Quality Management System Audit	13,900	14,355
Conformity Assessment – Components - Changes	**2002/03 Fee $**	**2003/04 Fee $**
(a) Schedule 3, Part 1- Full Quality Management System Audit; or	11,030	11,390
(b) Schedule 3, clause 1.6 - Design Examination; or	21,830	22,540
(c) Schedule 3, Part 2 - Type Examination (including management of testing, analysis, and reporting on examination of the type); or	15,190	15,685
(e) Schedule 3, Part 4 - Production Quality Management System Audit; or	9,680	9,995
(f) Schedule 3, Part 5 - Product Quality Management System Audit	8,340	8,615
Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate	**2002/03 Fee $**	**2003/04 Fee $**
Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate	4,380	4,525
Conformity Assessment – Additional Fees	**2002/03 Fee $**	**2003/04 Fee $**
Assessment of a medicinal component of a device	See Schedule 9 of the TG Regs Items 4(b),(c) or 5(b),(d)	See Schedule 9 of the TG Regs Items 5(b),(d)
Supplementary assessments to Items 1.2, 1.3, 1.9 or 1.10	$255 per assessor hour	$265 per assessor hour
Reasonable travel, accommodation and allowance costs including travel both in and outside Australia	At Cost	At Cost
Assessor preparation for assessments conducted outside Australia	$255 per assessor hour	$265 per assessor hour
Cost of testing incurred in purchasing, establishing and setting up the equipment to be used to conduct the tests and the direct costs of conducting the tests (including the cost of any consumables used to conduct the tests).	At Cost	At Cost
Conformity Assessment - Abridged Fee	**2002/03 Fee $**	**2003/04 Fee $**
Conformity assessment where assessment has already been undertaken by the TGA for the EU or EFTA Mutual Recognition Agreement and there is sufficient information to allow the assessment to be abridged.	2,500	2,585

INCLUSION IN THE ARTG – application for an inclusion in the Register	2002/03 Fee $	2003/04 Fee $
(a) Class AIMD medical device;	820	850
(b) Class III medical device;	820	850
(c) Class IIb medical device;	620	645
(d) Class IIa medical device;	620	645
(e) Class I medical device - sterile;	620	645
(f) Class I medical device - measuring function;	620	645
(g) Other Class I medical device	Nil	Nil
INCLUSION IN THE ARTG – Application Audit Assessment	**2002/03 Fee $**	**2003/04 Fee $**
(a) Level 1 — verification of sponsor's application and evidence of conformity	2,390	2,470
(b) Level 2 — Level 1 activities plus review of evidence of conformity	4,380	4.525
Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device from the Register	4,380	4.525
Variation to an ARTG inclusion entry if the entry is incomplete or incorrect	280	290
OTHER FEES	**2002/03 Fee $**	**2003/04 Fee $**
Application for consent of Secretary to importation into Australia, supply for use in Australia, or exportation from Australia of a medical device that does not conform to the Essential Principles.	280	290
Notification of intention to sponsor a clinical trial of a medical device to be used solely for experimental purposes in humans - Clinical Trial Notification Scheme (CTN)	220	230
Application for approval to use a specified kind of medical device solely for experimental purposes in humans - Clinical Trial eXemption Scheme (CTX)	11,330	11,700

GOOD MANUFACTURING PRACTICE:	2002/03 Fee $	2003/04 Fee $
Licence application fee	620	645
Annual License Charge (*)		
Single step/single medicine/type of device	3,970	4,100
In-vitro diagnostic products	3,970	4,100
Ingredients or components	3,970	4,100
Herbal/homoeopathic medicinal products	3,970	4,100
Other types of therapeutic goods manufacturer	7,710	7,965
Local GMP Audit Fee (previously Certification Fee) (*,#)	**2002/03 Hourly rate per auditor $**	**2003/04 Hourly rate per auditor $**
All types of therapeutic goods	400	415

Overseas GMP Audit Fee (previously Certification Fee)	2002/03 Hourly rate per auditor $	2003/04 Hourly rate per auditor $
All types of therapeutic goods	840	870
Overseas Manufacturers GMP Clearance Fees	**2002/03 Fee $**	**2003/04 Fee $**
Assessment of GMP evidence	-	240
Obtaining evidence from overseas regulatory agency	-	210
GMP approval reinstatement fee	-	750
GMP certification		
Certificate of GMP Compliance	75	80

MISCELLANEOUS	Fee $
Export Certificate	80
ARTG reinstatement application fee - registered medicines or devices - per invoice	645
ARTG reinstatement application fee - listed medicines or devices - per invoice	325
Application for Declaration that Turnover is Low Volume and Low Value – per product ($10,945 max.)	80
ARTG information - Freedom of Information (FOI) charges may apply	
The percentage of sales used in calculation of low volume and low value products for exemption from annual charges is 6.8%.	
The wholesale turnover level for reduction in the manufacturing licence charge is $62,985.	

ADVERTISING	2002/03 Fee $	2003/04 Fee $
Advertising processing time less than 1 hour and - not more than 100 words	130	135
- more than 100 words	160	170
- more than 300 words inc advertorial	290	300
- minor change	60	65
- classified ad	60	65
Each additional hour or part thereof	110	115

PRESCRIPTION MEDICINES: Fees based on assessable page-counts and are generally paid in full prior to assessment, or 75% in advance and 25% on completion. Fee scales apply for the year of application.

Clinical Evaluation		Toxicological Evaluation		Chemistry Evaluation	
Applications Received 1/7/02-30/6/03					
1 - 25 100%	6,120	1 - 25 100%	3,540	1 - 10 100%	820
1 - 25 75%	4,590	1 - 25 75%	2,655	1 - 10 75%	615
1 - 25 25%	1,530	1 - 25 25%	885	1 - 10 25%	205
26 - 300 100%	18,700	26 - 200 100%	12,070	11 - 50 100%	7,030
26 - 300 75%	14,025	26 - 200 75%	9,053	11 - 50 75%	5,273
26 - 300 25%	4,675	26 - 200 25%	3,017	11 - 50 25%	1,757
301 - 2000 100%	44,770	201 - 2000 100%	43,630	51 - 100 100%	15,590
301 - 2000 75%	33,578	201 - 2000 75%	32,723	51 - 100 75%	11,693
301 - 2000 25%	11,192	201 - 2000 25%	10,907	51 - 100 25%	3,897
2001 - 7000 100%	82,170	2001 - 7000 100%	64,600	101 - 1000 100%	20,970
2001 - 7000 75%	61,628	2001 - 7000 75%	48,375	101 - 1000 75%	15,728
2001 - 7000 25%	20,542	2001 - 7000 25%	16,225	101 - 1000 25%	5,242
7001 - 20000 100%	94,070	7001 - 20000 100%	70,840	1001 - 3000 100%	32,860
7001 - 20000 75%	70,553	7001 - 20000 75%	53,130	1001 - 3000 75%	24,645
7001 - 20000 25%	23,517	7001 - 20000 25%	17,710	1001 - 3000 25%	8,215
20001 - 40000 100%	100,300	> 20000 100%	76,500	3001 - 4000 100%	43,630
20001 - 40000 75%	75,225	> 20000 75%	57,375	3001 - 4000 75%	32,723
20001 - 40000 25%	25,075	> 20000 25%	19,125	3001 - 4000 25%	10,907
> 40000 100%	105,960			> 4000 100%	53,260
> 40000 75%	79,470			> 4000 75%	39,945
> 40000 25%	26,490			> 4000 25%	13,315
Applications Received 1/7/01-30/6/02					
1 - 25 100%	5,760	1 - 25 100%	3,330	1 - 10 100%	770
1 - 25 75%	4,320	1 - 25 75%	2,498	1 - 10 75%	578
1 - 25 25%	1,440	1 - 25 25%	832	1 - 10 25%	192
26 - 300 100%	17,590	26 - 200 100%	11,350	11 - 50 100%	6,610
26 - 300 75%	13,193	26 - 200 75%	8,513	11 - 50 75%	4,958
26 - 300 25%	4,397	26 - 200 25%	2,837	11 - 50 25%	1,652
301 - 2000 100%	42,110	201 - 2000 100%	41,040	51 - 100 100%	14,660
301 - 2000 75%	31,583	201 - 2000 75%	30,780	51 - 100 75%	10,995
301 - 2000 25%	10,527	201 - 2000 25%	10,260	51 - 100 25%	3,665
2001 - 7000 100%	77,290	2001 - 7000 100%	60,760	101 - 1000 100%	19,720
2001 - 7000 75%	57,968	2001 - 7000 75%	45,570	101 - 1000 75%	14,790
2001 - 7000 25%	19,322	2001 - 7000 25%	15,100	101 - 1000 25%	4,930
7001 - 20000 100%	88,480	7001 - 20000 100%	66,630	1001 - 3000 100%	30,910
7001 - 20000 75%	66,360	7001 - 20000 75%	49,973	1001 - 3000 75%	23,183
7001 - 20000 25%	22,120	7001 - 20000 25%	16,657	1001 - 3000 25%	7,728
20001 - 40000 100%	94,340	> 20000 100%	74,960	3001 - 4000 100%	41,040
20001 - 40000 75%	70,775	> 20000 75%	53,970	3001 - 4000 75%	30,780
20001 - 40000 25%	23,565	> 20000 25%	20,990	3001 - 4000 25%	10,260
> 40000 100%	99,670			> 4000 100%	50,100
> 40000 75%	74,753			> 4000 75%	37,575
> 40000 25%	24,917			> 4000 25%	12,525
Applications Received Pre 1/7/01					
1 - 25 25%	1,350	26 - 200 25%	2,662	1001 - 3000 25%	7,250
26 - 300 25%	4,125	201 - 2000 25%	9,625	3001 - 4000 25%	9,625
301 - 2000 25%	9,875	7001 - 20000 25%	15,625	> 4000 25%	11,750
2001 - 7000 25%	18,125				
7001 - 20000 25%	20,750				
20001 - 40000 25%	22,125				

Attachment C

TGA International Training Calendar in 2004

The following training programs are available for staff of overseas government regulatory organisations only. The programs will be presented at the Therapeutic Good Administration (TGA), Canberra, Australia in 2004.

General conditions and requirements. Please refer to the TGA policy statement for details.

Training program 1:

Practical Training In Vaccine Quality Assurance

Duration:	3 weeks
Dates:	Monday 10 – Friday 28 May 2004
Closing date:	Wednesday 10 March 2004
Feature of the course:	Practical demonstrations, with some "hands on" work as appropriate, involving manufacturing and quality assurance and control aspects of product licensing, lot release, laboratory testing and the inter-relationship between these important regulatory techniques.

Specific topics/activities would include:

- Potency testing of vaccines
  - Animal assays (eg. Tetanus, Diphtheria)
  - Immunological Assays [ELISA, SRID] (eg influenza, Hepatitis B, Acellular pertussis)
  - Biochemical assays [Lowry, Orcinol] (eg influenza, polysaccharide vaccines)
  - Live virus counts [Tissue culture] (eg Oral Polio, measles)
  - Live Bacterial counts (eg Oral typhoid, cholera)
- Potency testing of whole-cell Pertussis vaccines - a 2 day workshop on refinements to the widely used Kendrick assay.
- Lot release procedures
  - Use of specifications agreed during product licensing
  - Changes to product license/update of specifications
- Bacterial Endotoxin Test
  - practical testing
  - evaluation of company submissions for product licensing
- Viral & Prion Safety aspects of product licensing

Who should attend:	Regulatory agency staff with experience in regulation and quality control of vaccines. Qualifications and experience in biological science are required. Proficiency in English essential.
Training fees:	$13,690.00 (GST* inclusive)/per trainee

* GST - Australian goods and services tax

Training program 2:

Laboratory Testing And Evaluation of Manufacturing And Quality Control Data For Biologicals

Duration:	1 week
Dates:	Monday 7 – Friday 11 June 2004
Closing date:	Wednesday 7 April 2004
Feature of the course:	The course consists of lectures as well as laboratory sessions. The course will provide the trainees with an overview of the evaluation process for therapeutic proteins, from the format of applications through to the evaluation of manufacturing and quality control data. The course will also cover laboratory testing of these medicines.
Who should attend:	Regulatory agency staff with medical laboratory experience
Training fees:	$3,500.00 (GST inclusive)/per trainee

Training program 3:

Blood Safety And Quality -Includes Viral And Prion Safety

Duration:	1 week
Dates:	Monday 21 – Friday 25 June 2004
Closing date;	Wednesday 21 April 2004
Features of the course:	The course provides an introduction to blood regulation in Australia. The topics covered in the course will include quality and safety of blood and blood products, blood screening and donor population, cellular components and plasma fractionation, and interpretation of viral safety guidelines.
Who should attend:	Regulatory agency staff working in/as blood regulators, analysis of biological products or laboratory managers
Training fees:	$3,430.00 (GST inclusive)/per trainee

Training program 4:

Herbal Medicine - Analysis And Identification

Duration:	3 days
Dates:	Wednesday 25- Friday 27 August 2004
Closing date:	Friday 25 June 2004
Features of the course:	The course provides the trainee with an overview of regulation of herbal medicines in Australia. The course will comprise both lectures and laboratory work in standards and official requirements, GMP requirements for herbal manufacturers, chromatographic techniques used for analysis and identification of herbal medicines.
Who should attend:	Regulatory agency staff, particularly analysts dealing with herbal medicines, laboratory managers and quality control managers.
Training fees:	$6,610.00 (GST inclusive)/per trainee

Training program 5:

Regulation of Medical Devices

Duration:	2 weeks
Dates:	Monday 6 – Friday 17 September 2004
Closing date:	Tuesday 6 July 2004
Feature of the course:	The course will provide trainees with an understanding of the regulatory framework for regulation of medical devices in Australia which is based on the principles and processes of the Global Harmonisation Task Force on Medical Device Regulation. This includes the essential principles, classification rules, conformity assessment procedures, clinical requirements, quality systems harmonisation and quality auditing practices, post market surveillance, vigilance and GMP training.
Training fees:	$18,050.00 (GST inclusive)/per trainee

Training program 6:

Analytical Chemistry Method Development And Method Validation

Duration:	1 Week
Dates:	Monday 20 – Friday 24 September 2004
Closing date:	Tuesday 20 July 2004
Features of the course:	The course comprises lectures and laboratory sessions. The course provides the trainee with a good knowledge of how to develop and validate an analytical test procedure. Trainees will also be presented with examples of common deficiencies identified in analytical validation data.
Who should attend:	Laboratory staff and laboratory managers with sound experience in analytical techniques.
Training fees:	$4,190.00 (GST inclusive)/per trainee

Training program 7:

Prescription Medicine Regulation

Duration:	2 weeks
Dates:	Monday 27 September – Friday 8 October 2004
Closing date:	Tuesday 27 July 2004
Feature of the course:	Trainees will gain an understanding of Australia's approaches to the regulation of high-risk medicines. The course will outline the evaluation process from submission of an application through to approval and subsequent post-marketing regulation. Guidance on matters to be considered in regulating these products will also be provided.
Who should attend:	Staff involved in the regulation of medicines. Experience in clinical, pharmaceutical chemistry, pharmacology and/or toxicology fields is essential.
Training fees:	$11,950.00 (GST inclusive)/per trainee

Training program 8:

Bioavailability/Bioequivalence And Generic Medicines

Duration:	1 week
Dates:	Monday 11 – Friday 15 October 2004
Closing date:	Wednesday 11 August 2004
Feature of the course:	The course is offered as an intensive add on to the prescription medicine regulation course or as a stand alone course for participants with a particular interest in generic medicine evaluation. It will include lectures and practical workshops on how to assess generic medicines, particularly dealing with bioavailability and bioequivalence in depth.
Who should attend:	Staff involved in the regulation of medicines. Experience in clinical, pharmaceutical chemistry, pharmacology and/or toxicology fields is essential.
Training fees:	$2,920.00 (GST inclusive)/per trainee

Training program 9:

Counterfeit Medicine Control And Law Enforcement

Duration:	2 weeks
Dates:	Monday 18 – Friday 29 October 2004
Closing date:	Wednesday 18 August 2004
Feature of the course:	Trainees will be provided with up-to-date knowledge on the current internationally accepted best practice on counterfeit medicine control and law enforcement on medicine regulation. They will also get hands-on practice in laboratory testing with economic analytical techniques and in the field counterfeit medicines investigation.
Who should attend:	Officers of government regulatory agencies with responsibility on counterfeit medicine control, such as sample collection, lab testing and field investigation.
Training fees:	$6,820.00 (GST inclusive)/per trainee

Training program 10:

Medicinal Products Good Manufacturing Practice (GMP) Training

Duration:	1 week
Dates:	Monday 1 – Friday 5 November 2004
Closing date:	Wednesday 1 September 2004
Feature of the course:	To provide a workshop style training for GMP auditors/inspectors on medicinal products.
Who should attend:	Regulatory agency staff who have a good understanding of GMP audit with considerable working experience as GMP auditors/inspectors. Knowledge of pharmaceutical chemistry, microbiology and sterility is desirable.
Training fees:	$4,840.00 (GST inclusive)/per trainee

Training program 11:

Regulation Of Non-Prescription Medicines

Duration:	9 days
Dates:	Between September and November 2004 (to be confirmed)
Closing date:	People who are interested in this program should lodge their applications to the TGA **on or before 30 June 2004.** Once sufficient numbers of suitable applications have been received, the TGA will announce dates and other details about the program about 2 weeks of the closing date for application.
Feature of the course:	Trainees will gain an understanding of Australia's approaches to the regulation of low-risk medicines, including non-prescription (OTC) and complementary medicines.
Who should attend:	Staff involved in the regulation of medicines. Qualifications and experience in clinical, pharmaceutical chemistry, and/or pharmacology/toxicology fields are required.
Training fees:	TBA (To be announced by mid July 2004 once sufficient numbers of suitable applications have been received.)

Training program 12:

Pharmacovigilance – The Study Of Adverse Drug Reactions

Duration:	2 weeks
Preferred dates:	To be determined (more likely to be in late 2004)
Closing date:	
Feature of the course:	To be advised
Who should attend:	To be advised
Training fees:	To be advised

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-040

OUTCOME 1: Population Health and Safety

Topic: CRIMINAL CHARGES AGAINST PAN PHARMACEUTICALS

Written Question on Notice

Senator Forshaw asked:

As a result of Pan, where are you up to with the laying of criminal charges?

(a) Do you expect that criminal charges will be laid?

(b) If not, why not?

(c) If yes, is it typical for such delays in prosecution to occur, when do you anticipate prosecutions to commence? And does the TGA think this is an acceptable timeframe?

(d) If there is an ongoing investigation how many TGA resources, as at Feb 2004, are committed to the investigation.

Answer:

(a) Yes.

(b) Not applicable.

(c) This is a major criminal investigation with a significant amount of information and evidence to be collected and analysed prior to consideration by the Commonwealth Director of Public Prosecutions (DPP) of what charges should be laid. It will be for the DPP to decide when and against whom charges are laid in relation to breaches of the Therapeutic Goods Act 1989. The investigation is ongoing and progress to date is considered satisfactory.

(d) Four TGA Surveillance Unit investigators are committed to these investigations on a full time basis with other internal and external resources allocated as required.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-041

OUTCOME 1: Population Health and Safety

Topic: OVERSEAS PRE-CLEARANCE CERTIFICATES

Written Question.

Senator Forshaw asked:

(a) Given that Brian Corcoran raised with the TGA, in his review of the status of sponsors pre-clearances certificates, as a serious problem in 2002, why did the TGA have to ask the sponsors in 2003 to indicate the status of their GMP per-clearance?
   (i) Is there a database or 'alert system' that monitors the status of all O/S manufactures?
   (ii) If yes then why didn't this pick up on outdated pre-clearance certificates?
   (iii) If no, why has such a system not been implemented?

(b) For each sponsor please provide the following information:
   (i) When was a letter sent requesting information on pre-clearance.
   (ii) What date was the requested response date and when did each company respond.
   (iii) How many didn't reply by the requested response date.
   (iv) What is the status of the ones that have not replied?

Answer:

(a)
   (i) Yes, the TGA has a GMP pre-clearance database.
   (ii) The GMP pre-clearance database did pick up those overseas manufacturers due for reassessment, and hence the TGA wrote to 497 Australian sponsors.
   (iii) Not applicable.

(b)
   (i) The letters were sent over a period between May and June 2003.
   (ii) Each sponsor was requested to respond within 30 days of the date of the letter.
   (iii) 299 sponsors did not respond by the due date.
   (iv) The TGA followed up all non-respondents and has taken the necessary action to finalise their GMP preclearance status.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-042

OUTCOME 1: Population Health and Safety

Topic: REVIEW OF TGA CONSULTATIVE PROCESS

Written Question on Notice

Senator Forshaw asked:

(a) Over the past 12 months (Feb 2003-Feb 2004) what consultancies, or external reviews or reports, has the TGA commissioned?
(b) Please provide names of each consultancy, the name of the company or individual commissioned to do the consultancy and the cost.

Answer:

(a) & (b)
In relation to reviews of TGA consultative processes, the TGA engaged Strategic Consulting Services (Holdings) Pty Ltd (ABN 36 103 293 983) on 13 June 2003 to undertake a consultancy entitled "A Review of TGA Consultative Arrangements". The purpose of the review was to consider formal consultative arrangements for the TGA, and to examine the membership, roles and responsibilities of the TGA-Industry Consultative Committee (TICC).

The estimated cost of the consultancy is $34,500 (plus approved travel expenses). No costs have been invoiced against the consultancy to date.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-043

OUTCOME 1: Population Health and Safety

Topic: REVIEW OF TGA CONSULTATIVE PROCESS

Written Question on Notice.

Senator Forshaw asked:

In the past 12 months did the TGA commission a consultant (Alan Evans) to review the TGA consultative process? If yes please provide a copy of the review outcomes?

Answer:

In June 2003 the Therapeutic Goods Administration (TGA) engaged Strategic Consulting Services (Holdings) Pty Ltd, (Mr Alan Evans is a Principal) to undertake a review of its stakeholder consultative arrangements.

A final draft report has not yet been provided to the TGA.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-122

OUTCOME 1: Population Health and Safety

Topic: MELATONIN

Written Question on Notice

Senator Forshaw asked:

In Parliament on 14 May 2003, Martyn Evans MP, raised a number of concerns about melatonin products marketed by vitaminsaustralia.com. Mr Evans raised the issue of Melatonin not being licensed to be sold over the counter and that this meant if the advertised product actually contained Melatonin it would be illegal for sale in Australia.

Conversely, Mr Evans believes that if the company is advertising that the product does not contain Melatonin then there is a clear case that this is in breach of both TGA advertising requirements and the Trade Practices Act 1974.

To date Mr Evans is yet to receive a response to his concerns about the melatonin products marketed by vitaminsaustralia.com.au. Mr Evans has also just written to Ms Worth about another Melatonin product marketed by Johnson & Banara [sic] Pty Ltd.

Could the TGA please provide the following information:

(a) Has the TGA investigated any products sold by vitaminsaustralia.com.au? If yes please provide details of product name and outcomes of investigations.
(b) Has the TGA investigated any other products that claim to contain Melatonin? If yes please provide details of product names and outcomes of investigations.
(c) Does the TGA believe that such melatonin products are either illegal or misleading? If yes, what is the TGA doing to ensure that these products are removed from sale and appropriate action taken against the manufacturers and promoters? If no, why not?

Answer:

Mr Evans raised a number of concerns about homoeopathic products in Parliament on 14 May 2003, and these were acknowledged by the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth MP, in the debate on the same day. On 15 May 2003, Ms Worth announced the establishment of the Expert Committee on Complementary Medicines in the Health System and their terms of reference. These, and other concerns associated with the national system of regulatory controls for complementary medicines, were addressed in the Expert Committee's terms of reference. The Expert Committee released their report in October 2003 which included a recommendation that the regulation of homoeopathic medicines be reviewed and that the review take into account the need to clearly differentiate these medicines from other complementary medicines. The Government has widely consulted on the Expert Committee's report and is currently preparing its response to the report.

Mr Evans submitted a formal complaint to Ms Worth on 18 February 2004, regarding one homoeopathic melatonin product (J&B Melatonin). A response was provided on 2 March 2004.

(a), (b) & (c)

Vitamin Australia's web site www.vitaminsaustralia.com.au no longer exists, but is forwarded to another web site http://www.thexton.com.au, which appears to be operated by another organisation.

There are two homoeopathic melatonin products currently included on the web site www.thexton.com.au about which complaints have been made to the TGA.

J&B Melatonin, sponsored by Johnson & Barana Pty Ltd, was referred to the TGA for investigation by the Hon Trish Worth MP, Parliamentary Secretary to the Minister for Health and Ageing, when it was drawn to her attention by Mr Martin Evans MP. Ms Worth wrote to Mr Evans in March 2004 advising that the product was under investigation by the TGA. The TGA is currently working with the sponsor of this product to address deficiencies related to the advertising and labelling of this product.

The second homoeopathic product on the Thexton web site is Pretorius Melatonin. Pretorius Melatonin and a similar product, Bioglan Melatonin, have been the subject of numerous complaints to the TGA. The principal concern is that it might not be generally appreciated that these products were homoeopathic.

The TGA has reviewed these products and sought advice from the Complementary Medicines Evaluation Committee (CMEC) about these products and issues related to the regulation of these homoeopathic products generally. The CMEC recommended that homoeopathic medicines should be required to be more readily distinguished from their conventional counterparts. The CMEC was also of the view that these products did not appear to meet the definition of a homoeopathic preparation included in the Therapeutic Goods Regulations 1990, and that the evidence provided by the sponsor of these products was not sufficient to support the indications/claims made. However, the current definition of homoeopathic preparation was insufficiently robust to ensure a successful outcome in any action to be taken on these products.

Given the above, the TGA has been working internally on a review of the regulation of homoeopathic medicines. In addition, these and other concerns associated with the national system of regulatory controls for complementary medicines were addressed in the terms of reference of the Expert Committee on Complementary Medicines in the Health System.

The report of the Expert Committee included a recommendation that the regulation of homoeopathic medicines be reviewed and that the review take into account the need to clearly differentiate these medicines from other complementary medicines. The Government has widely consulted on the Expert Committee's report and is currently preparing its response to the report.

In addition to the homoeopathic melatonin products, the TGA has also received one complaint related to the sale of Bioactive Healthcare's Volcomin Forte suspension through the Vitamins Australia web site. The TGA was advised that this product was manufactured in Brisbane and is only intended for sale in Queensland, so is not subject to regulation by the TGA under the current legislative framework. The TGA was advised that reference to this product would be removed from the Vitamins Australia web site. The web site to which the Vitamins Australia web site is now directed is currently under active investigation by the TGA

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-033

OUTCOME 1: Population Health and Safety

Topic: COMPANIES MANUFACTURING/SPONSORING THERAPEUTIC GOODS

Written Question on Notice

Senator Forshaw asked:

For each of the companies or individuals that manufacture or sponsor, or have in the past manufactured or sponsored, therapeutic goods, devices or medicines either in Australia or overseas since you last provided this information in November 2003?

Please provide the information in the following way:

(a) Name of company.
(b) Types of product manufactured.
(c) Address of the company.
(d) Size of the company.
(e) Date of visit/audit/inspection.
(f) Reason for visit/audit/inspection and what type of visit/audit or inspection took place.
(g) The duration of the visit/audit/inspection.
(h) The number and type of TGA officials, including any outside consultants or contractors, that carried out the visit/audit inspection.
(i) The outcomes of visit/audit/inspection.
(j) The recommended follow up action by the TGA.
(k) Any change in GMP license or pre-clearance certificates following a TGA visit/audit/inspection - for this please provide any changes in licenses such as suspensions or cancellations for the period of six months after the TGA visit/audit or inspection.

Answer:

As a result of discussions to clarify the information required, it has been agreed that the following information about GMP audits in relation to medicines for each company audited would be provided:

(a) The name of company.
(b) The date of the audit.
(c) The reason for the audit and type of audit (ie. scheduled or unscheduled).
(d) Whether the audit was conducted by the TGA or a contracted agency.
(e) Any change in the GMP licence or pre-clearance certificates following the audit, such as suspension or cancellation.

(a), (b) & (c)
Refer to Attachment A for the details of manufacturer audits undertaken by the TGA from 1 November 2003 to 29 February 2004.

(d) All manufacturers listed on Attachment A were audited by the TGA. No contracted authorities were used for these audits.

(e) The release of company GMP licence action is generally treated as commercial-in-confidence. In summary, during this period, the manufacturing licences of two manufacturers were suspended at the request of the manufacturers.

Manufacturers audited by TGA from 1 November 03 to 29 Febuary 04		Attachment A
MANUFACTURER	**Audit date**	**Unscheduled**
Australian Manufacturers		
3M Pharmaceuticals Pty Limited	03/11/03	
Agen Biomedical Ltd	12/01/04	
Aloe Vera Industries Pty Ltd	13/01/04	yes
Analytical Laboratories	25/02/04	
APS Medical (Hirlhead) *ceased trading	04/12/03	
Australian Red Cross Blood Service (ARCBS) Brisbane North Region	11/12/03	
ARCBS - NSW Clarence St	23/02/04	
ARCBS - NSW Kingswood	26/02/04	
ARCBS- NSW Parramatta	06/11/03	
ARCBS - QLD Southport Mobile	18/12/03	
ARCBS - QLD Cairns	17/12/03	yes
ARCBS - QLD Mackay	16/12/03	yes
ARCBS - SA Adelaide	27/11/03	
ARCBS - VIC Geelong	21/11/03	
ARCBS - VIC Bundoora	20/11/03	
ARCBS - VIC Euroa	25/11/03	
ARCBS - VIC Frankston	18/11/03	
ARCBS - VIC Horsham	18/02/04	
ARCBS - VIC Ringwood Door Centre	14/11/03	
Aussie Tucker Tecknik Pty Ltd	12/12/03	
Baldwin Medical Australia	27/11/03	
Better Sachets Pty Ltd	15/12/03	
Biopharm Australia Pty Ltd	17/12/03	
Biotech Pharmaceuticals Pty Ltd	16/02/04	yes
Brisbane North Regional Health Authority T/A Royal Brisbane hospital Nuclear medical	11/12/03	
Bullivants Natural Health Products Pty Limited	19/11/03	
Cardinal Health Australia 200 Pty Ltd T/A Allegiance	13/11/03	
Centre for Phytochemistry Lismore	06/11/03	
Cockatoo Blue Medical Products Pty Ltd	11/02/04	
ConsulChem Laboratories Pty Ltd	11/12/03	yes
Contract Manufacturing and Packaging Services Pty Ltd	11/02/04	yes
Cryosite	23/02/04	
CSL Ltd Broadmeadows	18/12/03	
CSL Ltd Parkville	08/12/03	
Custom Medical Products Pty Ltd	02/02/04	
Draeger Medical Australia Pty Ltd	25/11/03	
Ecolab Pty Ltd	20/01/04	
Ellex Medical Pty Ltd	23/02/04	
Faulding Healthcare Pty Ltd	19/11/03	
Global Manufacturing Technology Pty Ltd	04/02/04	
GMP Pharmaceuticals Pty Limited	18/12/03	
Health World Limited	03/11/03	
Healthvision Pty Ltd trading as Medication Packaging Systems	05/12/03	
Hirlhead Pty Ltd (Trading as APS Medical) *ceased trading	04/12/03	
House with no steps Hunter Valley Region	11/12/03	
Hunter Area Pathology Service	08/12/03	
Imthage Pty Ltd	21/01/04	
Institute of Medical and Veterinary Science	18/12/03	
Jalco Cosmetics Pty Limited	23/02/04	
Labmark Pty Ltd	15/12/03	

Laboratories Pharm-a-care	09/02/04	
Lingard Private Hospital Bone Bank	09/12/03	
LIPA Pharmaceuticals Pty Ltd	20/01/04	
Matchlands Pty Ltd T/A New Products Development	19/02/04	yes
Mater Health Services Pathology	16/12/03	
Mater Misericordiae Health Services trading as Qld cord blood bank	04/12/03	
Mayne Health care Ptd Ltd	19/11/03	
Medi - Redi Pty Ltd	04/12/03	
Medical Access Pty Ltd T/A Custom Medical Products	02/02/04	
Mega Products Australia Pty Ltd	03/12/03	
Melba Products Australia Metropolitan Melbourne	03/12/03	
Melbourne Cord Bank	10/12/03	yes
Melrose Laboratories Pty Ltd	05/02/04	
Mercy Tissue Engineering Pty Ltd	25/11/03	
Milpharma Pty Ltd	10/02/04	yes
MonashUniversity Tissue culture Laboratory	28/01/04	
Narwhal Pty Ltd trading as Ramprie Laboratories	06/11/03	yes
Natures Care Manufacture Pty Ltd trading as Leimei Natures Care	16/12/03	yes
Norseld Pty Ltd	26/02/04	
Novogen Laboratories Pty Ltd	11/12/03	
Orielton Laboratories Pty Ltd	20/01/04	yes
Orielton Laboratories Pty Ltd	05/02/04	
Orion Laboratories Pty Ltd	03/11/03	yes
Orion Laboratories Pty Ltd	06/01/04	
Portland Orthopaedics Pty Ltd	11/11/03	
Proudex Australia Pty Ltd	15/12/03	
Queensland Institute of Medical Research T/A as Q-GEN	02/12/03	
Queensland Cord Bank	04/12/03	
Sentry Medical Pty Ltd	19/01/04	
Sigma Pharmaceuticals Pty Ltd	26/02/04	
South Pack Laboratories Pty Ltd	06/11/03	yes
St Vincents Hospital Pathology	05/11/03	
Steritech (Brisbane) Pty Ltd	02/12/03	
Sydney Adventist Hospital Limited	10/12/03	
Tabco Pty Ltd	24/02/04	
The University of Melbourne T/A Lions Corneal Donation Service	30/01/04	
Wholistic Traders Pty Ltd trading as In Essence aromatherapy	12/11/03	yes
William A. Cook Australia Pty Ltd	08/12/03	
Overseas Manufacturers		
Grindeks - Latvia	06/11/2003	
Lanzhou Taibao Pharmaceutical Factory Co Ltd - China	27/11/2003	
Lemery S A de C V - Mexico	24/11/2003	
Metagenics Manufacturing Plant - USA	24/11/2003	
Poly Implants Prostheses S.A. - France	17/11/2003	
Rhodia Quxi Parmaceuticals Co Ltd - China	24/11/2003	
Shanghai Harvest Pharmaceutical Limited - China	24/11/2003	
Shenzhen Taitai Pharmaceutials Industry Co Limited - China	10/11/2004	
Sicor Biotech UAB -Lithuania	17/11/2003	
Smith & Nephew Wound Management - USA	18/11/2003	
Tianjin Lisheng Pharmaceutical Co Ltd - China	03/12/2003	
Tissue Science Laboratories plc UK	24/11/2003	
Unilever - Home and Personal Care - USA	17/11/2003	
Unilever de Mexico - Mexico	20/11/2003	
Zhejiang Huahai Pharmaceutical Co Ltd- China	17/11/2003	
Total (Aust and overseas manufacturers) = 103		

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-034

OUTCOME 1: Population Health and Safety

Topic: COMPLAINTS REGARDING COMPLEMENTARY AND OTC MEDICINES

Written Question on Notice

Senator Forshaw asked:

In respect to all complaints or queries received by the TGA regarding complementary and OTC medicines since Estimates answer E03-106 was provided please provide the following information:

(a) The name and sponsor of the product.
(b) The nature of the complaint or query.
(c) The date the complaint or query was received.
(d) What investigation or follow up that the TGA made into the complaint or query.
(e) The outcome of any complaint or query.
(f) Any follow up action as a result of the complaint or query.
(g) The time taken to finalise the complaint or query.

Answer:

In the period 3 December 2003 to and including 1 March 2004, the TGA Surveillance Unit received 47 complaints relating to the supply of registered or unregistered non-prescription medicines (including complementary medicines) of which investigation into 21 complaints is not yet completed. The details are summarised in the attached papers.

[Note: the attachment has not been included in the electronic/printed volume]

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-035

OUTCOME 1: Population Health and Safety

Topic: UNRESOLVED/OUTSTANDING COMPLAINTS

Written Question on Notice

Senator Forshaw asked:

How many unresolved or outstanding complaints or queries does the TGA currently have and what is the nature of those complaints or queries?

Answer:

Further to the response provided to questions E03-106 and E03-107 from the Supplementary Estimates hearing in November 2003, the following information is provided.

During the period 1 January 2002 to and including 1 March 2004, the TGA Surveillance Unit received 456 complaints relating to the supply of registered or unregistered non-prescription medicines (including complementary medicines) of which investigation into 125 are not yet completed. Details of these unresolved investigations are summarised in the attached papers.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-036

OUTCOME 1: Population Health and Safety

Topic: PAN PHARMACEUTICALS

Written Question on Notice

Senator Forshaw asked:

Did the TGA ascertain what other products, excluding listed TGA regulated products, were manufactured or packaged at Pan Pharmaceuticals in the 12 months prior to January 2003.

(a) If yes, please provide a list of these products.
(b) In respect to these products did the TGA refer this information to any other regulators, companies or individuals for appropriate action such as recalling them.
(c) If yes, please provide details of the referrals

Answer:

(a), (b), and (c)

The TGA obtained Pan's records of batch production dating back to August 2002. The records included medicines, food and veterinary products.

The TGA worked closely with the Food Standards Australia and New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) following the decision to recall products manufactured by Pan Pharmaceuticals Ltd. This included the provision of available documentation (batch production records dating back to August 2002) to FSANZ in June 2003. The TGA, in May 2003, also provided documentation to the APVMA.

Representatives from State/Territory Health Departments were also briefed on and were involved in the recall process through their participation on the National Coordinating Committee for Therapeutic Goods, through the involvement of the State/Territory Recall Coordinators, and through active monitoring of compliance by retailers in their jurisdictions.

The TGA also advised overseas regulatory authorities of countries to which Pan products were exported for appropriate action. A list of these countries is at Attachment A.
In addition to those listed, the regulatory authorities of the following countries were notified through the international recall rapid alert notification network even though Pan Products were not exported to these countries: Austria, Bulgaria, Denmark, Estonia, Finland, Germany, Hungary, Iceland, Italy, Liechtenstein, Luxembourg, Norway, Slovak Republic, Spain, and the United Kingdom.

Attachment A - Exported countries advised by the TGA in relation to Pan products	
No	**Country**
1	Belgium
2	Brazil
3	Brunei
4	Cambodia
5	Canada
6	China
7	Cyprus
8	Czech Republic
9	Egypt
10	England
11	Fiji
12	France
13	French Polynesia
14	Greece
15	Hong Kong
16	Indonesia
17	Iran
18	Ireland
19	Israel
20	Japan
21	Jordan
22	Kuwait
23	Latvia
24	Lebanon
25	Macau
26	Malaysia
27	Mauritius
28	Myanmar
29	Netherlands
30	New Zealand
31	Philippines
32	PNG
33	Poland
34	Portugal
35	Qatar
36	Republic of Lithuania
37	Samoa
38	Singapore
39	Solomon Island
40	South Africa
41	South Korea
42	Spain
43	Sri Lanka
44	State of Bahrain
45	Sweden
46	Switzerland
47	Syria
48	Taiwan
49	Thailand
50	United Arab Emirates
51	United States
52	Vanuatu
53	Vietnam

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-154

OUTCOME 1: Population Health and Safety

Topic: PAN-MANUFACTURED PRODUCTS NOT REGULATED BY THE TGA

Hansard Page: CA 80

Senator Forshaw asked:

In relation to Pan-manufactured products not regulated by the TGA:

(a) Are you able to tell me what products you became aware of that were not regulated by the TGA that were manufactured by Pan of which you then informed the state authorities?

(b) Could you provide me with a list of all the products of which the state authorities were alerted?

(c) Did this include advising Food Standards Australia New Zealand?

Answer:

(a) (b) and (c)

Refer to answers to question E04-036.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-044

OUTCOME 1: Population Health and Safety

Topic: TGA AUDITS

Written Question on Notice

Senator Forshaw asked:

(c) Can you update the Committee on how many audits - either scheduled or unscheduled - the TGA conducted since we last spoke in November 2003?

(d) Which manufacturers were audited and what was the result of these audits?

Were any products recalled following unscheduled audits? (please provide details)

Answer:

(a) During the period 1 November 2003 – 29 February 2004, 103 manufacturers were audited by the TGA.

(b) The information has been included in Attachment A of Question E04-033. The results of the audits are commercial-in-confidence information.

(c) There were no consumer level recalls following unscheduled audits undertaken during the above mentioned period. There were two retail level recalls (‘A Stop’ and ‘Glycerin BP’) and one wholesale level recall (‘Black and Gold Cough Syrup’). All three were manufactured by Narwhal Pty Ltd (trading as Ramprie Laboratories).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-045

OUTCOME 1: Population Health and Safety

Topic: AUSTRALIAN GUIDELINES FOR THE REGULATION OF COMPLEMENTARY MEDICINES

Written Question on Notice

Senator Forshaw asked:

(a) Provide an update on the formulation of the Australian Guidelines for the Regulation of Complementary Medicines?

(b) Have the Guidelines been made available to stakeholder and industry groups yet?

(c) What feedback have you received from the Complementary medicines community about these guidelines?

(d) If the Guidelines have not been finalised, why not?

Answer:

(a), (b) & (d)

The Therapeutic Goods Administration (TGA), in consultation with the complementary medicines industry peak bodies – the Australian Self-Medication Industry (ASMI) and the Complementary Healthcare Council of Australia (CHC), are developing the Australian Regulatory Guidelines for Complementary Medicines (ARGCM). The development of regulatory guidance for complementary medicines is being undertaken for the first time in Australia.

Timelines for the completion of the ARGCM have been agreed by the TGA/Industry ARGCM Consultation Group. The ARGCM is structured in five parts. In consultation with ASMI and the CHC the TGA prioritised the development of the parts.

The Evaluation of Complementary Medicines Substances (Part III) was identified as the first priority. A draft of the Part III has already undergone stakeholder consultation and is currently in the final stages of revision. An electronic copy of the draft Part III guidance document remains on the TGA web site.

The Registration of Complementary Medicines (Part I) was identified as the second priority in the development of the ARGCM. A draft of the Part I document is available for stakeholder consultation on the TGA's web site.

The guidelines for Listed Complementary Medicines (Part II) have been drafted and were considered by the TGA/Industry ARGCM Consultation Group during their meetings in March 2004. They will be considered further at their meeting in May 2004. It is anticipated that Part II will be available for public consultation in late May 2004.

The remaining Parts IV and V will be considered for the first time at the TGA/Industry ARGCM Consultation Group in May 2004.

Following extensive stakeholder consultation, it is anticipated that the development of the ARGCM will be complete by the end of August 2004.

(c) The development of regulatory guidelines for complementary medicines has been well received by the complementary medicines industry.

To date, the peak industry representative bodies (ASMI and CHC) have provided comments on behalf of their members on the documents which have already undergone stakeholder consultation. ASMI's comments were technical in nature (and were subsequently addressed by the TGA/Industry ARGCM Consultation Group). The CHC advised that its members "fully support [the] documents and consider them a positive measure to clearly articulating the regulatory requirements for complementary medicines".

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-046

OUTCOME 1: Population Health and Safety

Topic: THE COMPLEMENTARY HEALTHCARE CONSULTATIVE FORUM

Written Question on Notice

Senator Forshaw asked:

(e) Are you planning to reconvene the Complementary Healthcare Consultative Forum at any stage?
(f) Has the Forum been officially disbanded? If so, why is still accessible and apparently active on the TGA website.

Answer:

(a) & (b)

No. The Complementary Healthcare Consultative Forum (CHCF) was established in 1999, at a time when complementary medicine regulation in Australia was undergoing significant reform. The CHCF has not been formally disbanded. However, the recent report of the Expert Committee on Complementary Medicines in the Health System recommended that the CHCF be formally disbanded as it had fulfilled its initial purpose and was no longer required. The Expert Committee recognised that there were other forums in which matters related to complementary medicines could be more appropriately considered.

As the CHCF has not yet been formally disbanded, its meeting records remain on the TGA's web site as an historical reference. The status of these documents will be reviewed following the release of the Government's response to the Expert Committee's report.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-047

OUTCOME 1: Population Health and Safety

Topic: ECHINACEA PRODUCTS

Written Question on Notice

Senator Forshaw asked:

(a) The Complementary Medicines Evaluation Committee has recommended the TGA that it conduct a review of the current scientific literature relating to echinacea to identify optimal marker compounds for herbal quality and efficacy - has the TGA commenced this review? If yes, please provide details.

(b) When did the TGA begin investigating the CHOICE magazine complaints about echinacea? What did these investigations include?

Answer:

(a) & (b)

The TGA referred the Echinacea article in *Choice* to the Complementary Medicines Evaluation Committee (CMEC), and it was reviewed at its meeting on 28 November 2003. At that meeting, the CMEC made the following recommendations:

- *that the TGA incorporates into its post-market monitoring program the testing of the quality of a random sample of listed Echinacea products based on currently accepted markers for herbal quality and/or efficacy, and against appropriate quality standards.*

- *that the TGA conducts a literature survey on the actions of Echinacea with a view to determining any risks associated with its immunomodulatory effects in immune function disorders or conditions.*

The Therapeutic Goods Administration (TGA) includes Echinacea products in its routine testing program and has sampled a significant number of Echinacea products since 1997. The focus has been to ensure the correct species of the herb is in the product.

Since the release of the *Choice* article and following CMEC's recommendation on 28 November 2003, the TGA has tested samples of 15 Echinacea products, as part of its ongoing monitoring program. Results indicate that all products contain the species listed on the product labels.

The TGA has commenced a comprehensive review of the scientific literature in accordance with the CMEC recommendation.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-048

OUTCOME 1: Population Health and Safety

Topic: SUNSCREEN LOTION

Written Question on Notice

Senator Forshaw asked:

(a) In December 2003, it was reported in the media (Herald Sun 31/12/03) that the TGA has requested that a number of sunscreen products be tested to ensure they met Australian national standards and to stamp out false claims – is this report correct?

(b) Over the past 2 years have any sunscreen manufacturers or sponsors provided the TGA with incorrect documentation regarding product testing or the standard to which the sunscreen was tested to? If yes what action was taken.

Answer:

(a) Yes. At a meeting with the Australian Self Medication Industry's Sunscreen Special Team in July 2003, an industry representative observed that the number of SPF tests performed through his testing facility did not appear to correlate with the number of sunscreen products on the Australian Register of Therapeutic Goods (ARTG).

Following this discussion, the Therapeutic Goods Administration (TGA) decided to survey a representative sample of sunscreens to determine the level of regulatory compliance. The ARTG was searched and 54 sunscreen products that had been listed since 1997 were chosen for review. Products were selected to include a range of product types from regular sunscreens to moisturisers with a sunscreen and a range of sponsors from small to major companies.

(b) Since 1997, sponsors of listable sunscreens have been required to provide a statutory declaration at the time of listing that the "goods have had the SPF rating established by testing as described in AS/NZS 2604:1998 or as currently in force".

There are around 1,200 sunscreens currently listed in the ARTG. On 15 August 2003, a letter was sent to those sponsors selected in the sample for review, requesting documentary evidence of testing of the nominated products according to AS/NZS 2604:1998.

The responses showed that all products had been tested according to the method given in AS/NZS 2604:1998 and in every case the SPF found at testing was equal to or higher than the label claim. Seven products had been tested according to the method in the US Sunscreens Monograph, but it was determined that this testing fitted within the method specified in AS/NZS 2604:1998. To confirm this, the data were re-analysed by the original testing laboratory using the statistical method specified in AS/NZS 2604:1998 and the SPF found in each case to be equivalent to the original result.

The results of this survey indicated that the level of regulatory compliance for sunscreens is high. The TGA will continue to monitor compliance of individual products.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-049

OUTCOME 1: Population Health and Safety

Topic: ABSTINENCE

Written Question on Notice

Senator Harradine asked:

(a) Does the Department agree that the only 100 per cent effective way of avoiding pregnancy and sexually transmitted disease is abstinence from sexual intercourse?

(b) How much money has the Department spent in each of the last five years on abstinence-based programs?

(c) How much money has the Department spent in each of the last five years on other programs that have the aim of reducing the incidence of unplanned pregnancy and sexually transmitted disease? What in broad terms is the nature of these other programs?

Answer:

(a) The Department agrees that for fertile couples, abstinence is the only 100% effective way of avoiding pregnancy. However, this is not the case for sexually transmitted infections (STIs). STIs can also be transmitted by blood transfusion, perinatal transmission (mother to child), non-sexual contact (such as contact with abraded skin, contact with infectious lesions or through clothing or linen) as well as sexual activity other than intercourse.

(b) The Department does not differentiate funding for specific strategies. In 2003-04, the Government will contribute approximately $14.3 million through the Family Planning Program to a range of sexual and reproductive health approaches, abstinence being one approach.

(c) The Government directly funds the Family Planning Program to provide a balanced approach to the range of family planning philosophies and promotes choice of service models. Additionally, the Family Planning Program also provides training and education of Australia's medical workforce. This dual approach promotes responsible sexual and reproductive health behaviours, rather than a focus on one particular strategy or program.

The overall funding allocations for the Family Planning Program for the financial years 1999-2004 is as follows:

	1999-00	**2000-01**	**2001-02**	**2002-03**	**2003-04**
Total	12,352,761	12,855,973	13,365,793	14,057,207	14,380,523

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-050

OUTCOME 1: Population Health and Safety

Topic: SEXUAL HEALTH INFORMATION NETWORKING AND EDUCATION SOUTH AUSTRALIA

Written Question on Notice

Senator Harradine asked:

(a) Does the Department provide any funding to the Sexual Health Information Networking and Education South Australia Inc? If so, please provide a breakdown of funding to that organisation for the past five years.

(b) Did the Department provide any specific funding for the "Which Wheels Do You Want?" campaign targeted to Aboriginal and Torres Strait Islander youth?

(c) Is the Department familiar with that campaign?

(d) Does the Department know whether this campaign will be run in other States? Would the Department support this campaign being run in other States? Has the Department been approached to fund the South Australian campaign or similar campaigns elsewhere?

(e) Does the Department have a view on the depictions used in the campaign which feature a couple with a crying baby in a pram looking longingly and sadly at another happy couple with no baby seated on an expensive looking car under the heading "Which Wheels do You Want?"

(f) Is the Department concerned at all by the message conveyed by this campaign that young people can have fun and be free of unplanned pregnancy through contraceptive choices when statistics show that contraception of any kind is not 100 per cent effective? Does such a message mislead young people?

Answer:

(a) The Australian Government contributes towards the capacity of individual States and Territories to maintain and improve the general level of Australia's health through the Public Health Outcome Funding Agreements (PHOFAs). These Agreements generally provide broadbanded funding to assist in the achievement of nationally agreed outcomes in a number of public health programs. Agreements with some States also provide specific funds for particular services, including the Family Planning Program in South Australia.

The Australian Government provided funding to the South Australian Government for the past five years to implement family planning activities. This funding is provided by the South Australian Government to the Sexual Health Information Networking and Education South Australia (SHine SA) to develop and implement family planning activities. Funding to the South Australian Government from the Australian Government, is as follows:

Actual Expenditure				Allocation
1999/2000	2000/2001	2001/2002	2002/2003	2003/2004
$1,420,000	$1,463,000	$1,495,000	$1,554,000	$1,593,000

(b) No. The Australian Government provides the funding at (a) above to the South Australian Government which is responsible for making local funding decisions in line with local needs.

(c) The "Which Wheels do you Want?" campaign is mentioned in the SHine SA Annual Report. A copy of that report was provided to the Australian Government by the South Australian Government as part of its 2002-2003 annual performance report on the PHOFAs. Under the PHOFA performance requirements, SHine SA is required to collect and supply data on the clinic and education and training activities to the National Family Planning Database, and to publish an annual report. The Department is aware of the "Which Wheels do you Want?" campaign through this process.

(d) The Department is not aware of any other States and Territories intending to run the "Which Wheels do you Want?" campaign. The Department has not been approached by any organisation to fund a similar campaign.

(e) The Department cannot provide an opinion on this matter.

(f) The Department cannot provide an opinion on this matter.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-051

OUTCOME 1: Population Health and Safety

Topic: ABORTION STATISTICS

Written Question on Notice

Senator Harradine asked:

Has the Department noted the latest South Australian abortion statistics report, tabled in November 2003, which shows that there has been an increase in the abortion rate for 18 and 19 year old women and that 37.7 per cent of women undergoing an abortion had already had one or more abortions? Does the Department consider that current approaches to preventing unplanned pregnancies are failing?

Answer:

The Department is not aware of the South Australian report tabled in 2003 that showed an increase in abortion rates for 18 and 19 year olds.

The Department considers that current approaches to preventing unplanned pregnancies are having some impact, but recognises there is always scope for improvement.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-052

OUTCOME 1: Population Health and Safety

Topic: ADVERSE MEDICINE EVENTS LINE

Written Question on Notice

Senator Harradine asked:

A report in The Australian on 14 February 2004 gave details of the new Adverse Medicine Events line, which has been in operation since October. The report said that doctors and pharmacists are phoning the AME line regarding the drug Postinor-2, because they are "not adequately informed on the new rules governing the supply of the drug and [recommend] further information be distributed." Please provide details of the number of calls and details of the concern expressed in each call in relation to Postinor-2. Please also provide details of the number and nature of calls regarding Ibuprofen.

Answer:

For the period 1 January 2004 to 11 March 2004, the Adverse Medicines Events (AME) Line had no calls about adverse reactions to Postinor-2. There were three calls from consumers who claimed to have had problems accessing Postinor-2 from pharmacists. No calls were received from doctors and pharmacists about Postinor-2, as suggested in *The Weekend Australian* on 14 February 2004.

For the same period, while there were a number of general calls on the AME Line regarding ibuprofen, only four of these were in relation to its safety. These calls involved consumer concerns about potential interactions between ibuprofen and other medicines. Only one of the four enquiries related to an actual event which had occurred. It was an enquiry about whether the adverse event was due to an interaction between ibuprofen and the anti-coagulant medicine warfarin. In the other three enquiries, the ibuprofen product of concern was a combination product containing ibuprofen. (Note that combination products containing ibuprofen were not rescheduled on 1 January 2004 and are not available from supermarkets and similar outlets).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-053

OUTCOME 1: Population Health and Safety

Topic: ADRAC - POSTINOR-2 ADVERSE REACTIONS

Written Question on Notice

Senator Harradine asked:

How many reports has ADRAC received to date as to adverse reactions from levonorgestrel (Postinor-2)? Please provide details.

Answer:

The Adverse Drug Reaction Advisory Committee (ADRAC) has received 13 reports of adverse reactions to Postinor-2, including 11 reports of unintended pregnancy, 1 report of vaginal bleeding, and 1 report of nausea and vomiting. None of these are unexpected reports for Postinor-2.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-063

OUTCOME 1: Population Health and Safety

Topic: REVIEW OF UNIFORM PROCEDURES FOR PRODUCT RECALL

Written Question on Notice

Senator Forshaw asked:

(c) Please provide an update on the current state of play with respect to the Review of the Uniform Procedures for Product Recall?

(d) Has the review been completed and if not, when are you expecting it to be? [The committee was told in June 2003 that the review was already underway].

(e) Have you updated the TGA website to explain when the 2001 edition will be superseded? If not, why not?

(f) What has been the process of consultation with stakeholders and industry? (please provide details).

(g) When do you expect the review to be publicly available?

Answer:

(a) and (b)
The final draft report of the Review of the Uniform Recall Procedure for Therapeutic Goods was issued for stakeholder consultation in late November 2003. The consultation period concluded in April 2004 and stakeholder comments will be considered by the States and Territories at the next meeting of the National Coordinating Committee for Therapeutic Goods (NCCTG) on 29-30 April 2004. The NCCTG, a subcommittee of the Australian Health Ministers Advisory Council, oversights the national recall procedure.

(c) No. The 2001 edition of the URPTG will be revised once the Review has been finalised by the NCCTG.

(d) The Review interviewed stakeholders involved in the recall of therapeutic goods. These included State/Territory Health Department recall co-ordinators, industry associations (manufacturers, importers, consumers and wholesalers), the Pharmacy Guild, government departments in both Australia and New Zealand and TGA staff. Comments were sought from these stakeholders on the final draft report of the Review in late 2003.

(e) The Review will be available on the TGA website when the recommendations have been accepted by the States and Territories.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-064

OUTCOME 1: Population Health and Safety

Topic: COMPLEMENTARY MEDICINES (EXPERT COMMITTEE'S REPORT)

Written Question on Notice

Senator Forshaw asked:

(a) In a previous answer on notice, the cost of the Expert review was 'estimated' at $207,000 - is this the exact figure for the review or is there an amended total cost?

(b) If the Government proceeds to implement the Expert Committee's recommendations - how will this be paid for?

(c) What progress has been made to work with stakeholders to review the way information on labels can better assist with product identification and recalled medicines?

(d) Will there be regulatory impact statements on any proposed regulatory changes emanating from the Expert Committee's report?

Answer:

(a) The final cost of preparation, publication and distribution of the report of the Expert Committee on Complementary Medicines in the Health System was $315,483. This includes the cost of an additional meeting which was found to be necessary, and the cost of additional secretariat support required by the Expert Committee.

(b) The development of a Government response to the recommendations of the Expert Committee will need to be completed before any assessment of the cost of implementation can be made.

(c) The TGA has requested the Therapeutic Goods Committee (TGC), the expert committee established under the Therapeutic Goods Regulations 1990, to advise the Minister on standards for therapeutic goods, including labelling matters, to develop a discussion paper for stakeholder consultation on medicine label improvements that will assist in product identification and recall.

To assist in developing this discussion paper, the TGC convened a Subcommittee on Medicine Labelling, with representation and expertise from all medicine industry sectors, the pharmacy profession, consumers, and medicines regulation.

The discussion paper, which will include a range of proposals for improvements to medicine labels, is nearing completion.

Stakeholder responses to the discussion paper will be considered by the TGA and the TGC, in order to provide recommendations to the Government for consideration.

(d) In the event that regulatory changes are proposed, the Government's requirements for preparation of Regulation Impact Statements will be followed.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-120

OUTCOME 1: Population Health and Safety

Topic: THE NATIONAL DRUG STRATEGY ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES' COMPLEMENTARY ACTION PLAN

Written Question on Notice

Senator Stephens asked:

(a) Are you aware of "The National Drug Strategy Aboriginal and Torres Strait Islander Peoples' Complementary Action Plan"?

(b) Do you know how much money has been allocated to it?

(c) If so, can you tell us how much has been distributed and which of the recommended programs have been initiated?

Answer:

(a) The Complementary Action Plan requires a whole of government cross jurisdictional response to indigenous substance abuse.

(b) Implementation of the key action areas identified in the Complementary Action Plan is the responsibility of the Australian, State and Territory governments who are currently working together to develop an Implementation Plan.

(c) Funding has not yet been allocated as governments are currently considering the application of existing resources and the possible requirement for any new resources to implement the key action areas under the Complementary Action Plan.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-125

OUTCOME 1: Population Health and Safety

Topic: PROTECTING AUSTRALIA FROM COMMUNICABLE DISEASES: EVERYBODY'S BUSINESS

Written Question on Notice

Senator McLucas asked:

(a) When was work on this report first commenced?

(b) When was work on this report concluded?

(c) What were the terms of reference (or the proposed purpose or scope) of this report?

(d) When were all the written contributions from individuals/working groups received?

(e) When was the collated version of this report first received on the desk of the Minister of the day?

(f) Were there any delays – in finalising, in printing, in releasing?

(g) Why does this report contain no recommendations to improve the detection and management of communicable diseases in Australia?

(h) How much did this report cost?

(i) How much were the consultant costs for this report?

(j) What were the printing and distribution costs?

(k) When was the decision to release this report on 11 February made?

Answer:

(a) Work on this report was initiated by the (then) Chief Medical Officer, Professor Richard Smallwood late in 2000.

(b) Work on this report concluded in January 2004.

(c) The report was intended to inform the public and Government of communicable diseases control in Australia. The report seeks to place the emergence of new infectious diseases, such as Severe Acute Respiratory Syndrome (SARS) and the re-emergence of old threats, such as tuberculosis, in a historical and contemporary context. By promoting greater community understanding of the issues involved, it seeks to assist future disease control efforts.

(d) Written contributions were received from external contributors during 2001 and 2002.

(e) A final copy of the report was forwarded to the Minister's Office on 9 February 2004.

(f) There were some delays in finalising, as lengthy contributions from external contributors needed editing at a time when the Department was responding to Bovine Spongiform Encephalopathy (BSE), anthrax threats from white powders and Severe Acute Respiratory Sydnrome (SARS). These episodes then informed the final version of the report. There was not an external due-by-date for the report and the management of these health events took precedence.

(g) The report is intended to be educational and not a policy review.

(h) The total cost of the report including the production, launch, printing and distribution (to date) is $44,690.

(i) The consultant costs for this report were $19,800.

(j) The printing costs were $23,900 and the distribution costs to date are $1000.

(k) The date of 11 February 2004 was decided on 30 January 2004 as it was available in the diaries of key participants for the launch.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-126

OUTCOME 1: Population Health and Safety

Topic: STRATEGY FOR MANAGEMENT OF COMMUNICABLE DISEASES IN AUSTRALIA

Written Question on Notice

Senator McLucas asked:

(a) What is in place to manage a disease outbreak such as avian flu or dengue fever?

(b) Some countries have activated their National Influenza Pandemic Plans as a precaution. What is the status of Australia's national plan? Has it been activated?

(c) The Government has said that it has a stockpile of drugs against a flu epidemic. What drugs? How many doses? Who would get these as a priority?

Answer:

(a) State and Territory Health Departments are primarily responsible for the control of communicable diseases and managing localised disease outbreaks, and the response is guided by public health legislation in each jurisdiction.

The Australian Government takes a lead role in outbreak investigations of national significance or when there are issues that relate to human quarantine. The Communicable Diseases Network Australia (CDNA) which includes the Australian Government and all States and Territories, is the main network involved in communicable disease control.

The National Arbovirus and Malaria Advisory Committee (NAMAC) reporting through the CDNA makes recommendations on arbovirus surveillance, strategic arbovirus disease management and vector control. NAMAC provides expert technical advice on dengue fever to assist in the detection, management and control of real or potential outbreaks. Dengue fever currently occurs only in north Queensland.

The Dengue Fever Management Plan prepared by Queensland Health outlines prevention and control strategies. The Dengue Action Response Team in north Queensland is responsible for implementing control measures, including spraying known mosquito breeding sites with insecticide and advising the public to minimise the opportunity for mosquitoes to breed by eliminating stagnant water in and around their homes.

The Australian Action Plan for Pandemic Influenza provides direction for the development of actions at the Australian Government, State and Territory and local levels including avian flu. In addition, the Action Plan provides guidance to health service providers and other groups at the local level, whose services may be critically important during an influenza pandemic.

The Action Plan aims to increase awareness of national pandemic preparedness during the period between pandemics and to provide information to facilitate an organised and effective response. The lead agency and main actions to be undertaken at different levels of alert are described within the Action Plan.

The Action Plan describes co-ordination activities, prevention measures, steps to reduce the rate of spread of influenza in health care and non health care settings, surveillance activities, communication strategies and animal influenza policy.

(b) The National Influenza Pandemic Action Committee (NIPAC) has developed the Australian Action Plan for Pandemic Influenza. Australia has activated the Action Plan, however, while there is no evidence of person-to-person transmission of avian influenza, we remain in the at Influenza Pandemic Phase 0 Preparedness, Level 2 (ratings as per the World Health Organisation guidelines). Whilst this phase does not declare the onset of a pandemic, it does call for heightened global awareness and vigilance.

(c) The national drug stockpile contains a range of antivirals and some antibiotics, which may be used during an influenza epidemic. The number of doses held varies according to the drug. In accordance with the Australian Action Plan for Pandemic Influenza, the Australian Government will make decisions for allocation of these drugs as required, with expert advice from relevant agencies, including State and Territory Health Departments and expert committees.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-127

OUTCOME 1: Population Health and Safety

Topic: INFLUENZA VACCINE TENDER

Written Question on Notice

Senator McLucas asked:

(a) The tender for influenza vaccine over 65's was released on June 27, 2003. When did the Department notify tenderers that the process has been changed significantly, resulting in the national tender being postponed for at least another year?

(b) When did the Department notify the States and Territories that they would be responsible for tendering for vaccines for 2004?

(c) Why did the Department decide to postpone the tender?

(d) What explanation has been provided to tenderers for the postponement of the tender? Please provide copies of correspondence to tenderers. Has the Department denied requests from tendering companies for a description of the tender evaluation process? Would you describe the tender process as being transparent?

(e) Has the Department had to appoint a new tender evaluation committee? If so, why?

(f) What contingencies have been put in place to ensure that Australians, particularly those aged 65 and over have access to an assured supply of influenza vaccine in 2004 given the reported supply shortage of vaccine in the Northern hemisphere?

(g) How will the assessment of the new national flu tender be undertaken?

(h) Has the Department done any analysis of the efficient use of the vaccine?

(i) What is the cost of the vaccine which is unused?

(j) What procedures is the Department putting in place to ensure that the wastage is minimised?

(k) Who will be in charge of assessing what vaccines are chosen to be a part of the tender?

(l) Will this tender allow for any new or improved vaccines that may be available to the Government over the course of this tender to also be provided to those at risk (ie from 2005 to 2007)?

Answer:

(a) 19 November 2003.

(b) 19 November 2003.

(c) The Department decided to set aside the initial evaluation of tenders on the basis of legal and probity advice.

(d) On 19 November 2003, tenderers were advised that the initial evaluation of responses to Request for Tender (RFT) 158/0203 (*National Influenza Vaccine Supply for Existing Influenza Immunisation Programs and for use in the event of an Influenza Pandemic*) had been set aside. Tenderers were also advised that an amendment to the RFT would be issued and would apply for the 2005-2007 influenza seasons. Tenderers were subsequently invited to an industry briefing on 2 December 2003, at which they were informed that the decision to set aside the original RFT was based on legal and probity advice due to issues arising during the evaluation process.

Release of the correspondence with companies about the suspension of the tender evaluation would require the agreement of the relevant companies.

Tenderers have been referred to the evaluation process and criteria set out in the RFT and Addendum No 1 to the RFT (issued on 28 November 2003) which gives a clear description of the process.

The tender process has been consistent with Departmental and Australian Government procurement guidelines.

(e) Yes. Following the decision to set aside the original evaluation process it was decided to appoint a new Tender Evaluation Committee to assess the modified tenders.

(f) All States and Territories have advised that they have completed their purchase of influenza vaccine for government funded programs in 2004.

(g) The Tender Evaluation Committee will assess tenders received against the evaluation process set out in the RFT and Addendum No 1 to the RFT, and in accordance with the approved Tender Evaluation Plan.

(h) Yes.

(i) For the 2003 influenza season, the Australian Government allocated $26.2 million for the purchase of influenza vaccine by States and Territories under the National Influenza Vaccine Program for Older Australians. Of this allocated funding, approximately $0.9 million was not used by the States and Territories to purchase vaccine, and remained with the Australian Government.

(j) States and Territories are accountable for wastage under the performance indicators of the Public Health Outcome Funding Agreements (PHOFAs) with the Australian Government. Measures to reduce wastage include limiting the amount of vaccine general practitioners can order at any one time. This measure reduces the amount of vaccine that remains unused at the end of the influenza season and must be discarded.

To minimise wastage due to vaccine being lost, destroyed or stored inappropriately, the publication *Keep it Cool: the Vaccine Cold Chain. Guidelines for Immunisation Providers on Maintaining the Cold Chain* is being updated and new protocols to decrease vaccine wastage due to cold chain failure are being developed.

(k) A Tender Evaluation Committee has been appointed to assess tenders received.

(l) Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-128

OUTCOME 1: Population Health and Safety

Topic: IMMUNISATION SCHEDULE

Written Question on Notice

Senator McLucas asked:

(a) Is the Department aware of a recent recommendation from A/Prof Peter McIntyre, acting director of the National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases, regarding the inclusion of pertussis in any tetanus or diphtheria-tetanus boosters they receive?

(b) What would be the additional cost of providing adults with the free Boostrix vaccine that is available to teenagers from January 2004?

(c) Of the current cases of pertussis in Australia, what percentage is in adults? What percentage is in young, unprotected children who have potentially been exposed to an adult with pertussis?

Answer:

(a) Yes. Associate Professor McIntyre has been quoted in the media as supporting the use of the vaccine containing pertussis when adults consider having tetanus or diphtheria-tetanus boosters.

(b) Adults are free at any time to purchase Boostrix in place of tetanus or diphtheria-tetanus boosters when required or recommended. The price of the vaccines are determined by the supplier and individual pharmacies. The Australian Technical Advisory Group on Immunisation has not made any recommendations to Government for the introduction of an adult diphtheria-tetanus-acellular pertussis vaccination program under the National Immunisation Program. The cost of such a program has therefore not been calculated.

The National Centre for Immunisation Surveillance of Vaccine Preventable Diseases is currently undertaking research on the epidemiology of pertussis in Australia. The report will be publicly released by the Centre when completed.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-129

OUTCOME 1: Population Health and Safety

Topic: SALE OF PRESCIPTION MEDICINES OVER THE INTERNET

Written Question on Notice

Senator McLucas asked:

(a) Is the Department aware of a recent article published in the Medical Journal of Australia which highlighted problems with online pharmacies in Mexico and Asia providing prescription medications without a prescription?

(b) To what extent are these imported drugs addictive or subject to abuse?

(c) What is the Department doing to address this problem?

(d) What is the Department is doing to work with other departments on this issue.

Answer:

(a) Yes.

(b) Medicines such as tranquilisers and sleeping pills are potentially addictive and can be subject to misuse.

(c) Due to such risks, in Australia, such medicines are regulated as "prescription-only" items, in the interests of public health and safety ie. they can only be lawfully supplied to consumers who have a doctor's prescription.

With regard to importation, Australian law allows an individual to import limited quantities of most prescription medicines into Australia, provided they are for use by themselves or immediate family members, and they have a prescription for those medicines which has been provided by an Australian doctor. Personal importation medicines may not be on-sold.

Certain medicines, such as benzodiaepines and steroids, cannot be imported under the personal importation provisions without an import permit issued by the Therapeutic Goods Administration (TGA) in addition to an Australian prescription.

The TGA also cautions people buying medicines over the Internet that they should be aware that the product they are buying is not of guaranteed quality or even identity. Medicines available over the Internet may not be subject to the same level of quality control as medicines approved for sale in Australia. In some cases they may contain little or no active ingredients. They may even contain different medicine ingredients to those expected from the labelling or promotion over the Internet.

(d) The TGA works closely with other agencies on this issue, namely the Australian Competition and Consumer Commission (ACCC) and the Australian Customs Service (ACS).

The ACS undertakes surveillance of packages imported into Australian to ensure they comply with relevant requirements.

With regard to the promotion of on-line pharmacies, the TGA is not able to regulate a company and/or its Internet site, which is based in, or on a server in, another country. Where there is concern that such websites are in breach of Australian legislation and relevant legislation in the originating country, the TGA refers such matters to the ACCC, and in some instances to other national regulatory agencies.

The ACCC has the ability to then progress such matters, in its capacity as a member of the International Consumer Protection Enforcement Network (ICPEN).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-131

OUTCOME 1: Population Health and Safety

Topic: STDS- GOVERNMENT'S RESPONSE TO THE REVIEW PANEL'S RECOMMENDATION

Written Question on Notice

Senator McLucas asked:

Recommendation 37 (HIV) was that the Commonwealth revitalise its national Leadership role.

(a) Will there be increased funding for the new national strategy for HIV/AIDS?

(b) Will there be increased funding for research?

(c) Will there be greater focus on the Commonwealth's coordination role? Recommendations 40 and 55 re Parliamentary Liaison Group

(d) Will the Commonwealth Parliamentary Liaison Group be re-established?

(e) What is the timeframe for doing this? Recommendation 41

(f) Is the Nationally Sexually Transmissible Infection Surveillance Plan completed?

(g) When will it be funded?

(h) When will it be implemented?

Answer:

(a) The previous National HIV/AIDS Strategies, like the new one being developed, are strategic documents which set out the goals, principles and directions for Australia's response to these infections. As such, it is not a funding Strategy. Rather, it operates to inform decisions about HIV/AIDS. This includes funding and resource allocation decisions made at the State and Territory level.

(b) As stated in the Government Response to the Reviews, the Australian Government is committed to HIV Research. The Government has committed to continuing the current level of core funding to the National Centres in HIV Research until 2006, a financial commitment of some $8 million per annum.

(c) As stated in the Government Response, the Government is committed to retaining its current leadership role for HIV/AIDS.

(d) Consideration is being given to recommencing this forum.

(e) See above.

(f) In 2002 the Intergovernmental Committee on HIV/AIDS, Hepatitis C and Related Diseases' subcommittee on Sexually Transmitted Infections Surveillance identified a number of steps required to inform the development of a national sexually transmissible infections (STI) surveillance plan. The first step, a review of current procedures for STI surveillance at the State and Territory level, has been completed. The second step, a review of published papers and reports on STI occurrence in Australia, is well underway and reports are expected to be completed in 2004. The remaining steps, including a review of overseas methods for STI surveillance and an assessment of national needs in STI surveillance, will then be undertaken. Guided by the above information, the subcommittee will then develop and prioritise a national STI surveillance plan for consideration by the Communicable Diseases Network Australia.

(g) This project is part of the workplan of the National Centre in HIV Epidemiology and Clinical Research and is funded through their core funding from the Department of Health and Ageing.

(h) The timeline for finalising the plan and implementing it has not yet been decided.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-132

OUTCOME 1: Population Health and Safety

Topic: STD'S - GOVERNMENTS RESPONSE TO THE REVIEW PANEL'S RECOMMENDATIONS

Written Question on Notice

Senator McLucas asked:

On page 19 of the Government's response it states "The Government has endorsed an implementation strategy for the introduction of retractable needle and syringe technology into Australia" –

(a) Can we have a copy of the strategy?

(b) What is the target group for this strategy?

(c) How will the $17.5 million allocated be spent?

(d) When will this implementation strategy commence?

(e) Since 1999 how many research projects into Hepatitis C have been funded by the NH&MRC?

(f) Will there be additional resources provided to analyse and monitor the economic benefits and costs to government and the community of HIV programs?

Answer:

(a) In the 2002-03 Federal Budget the Government committed $27.5 million to a Retractable Needle and Syringe Technology Initiative. The Initiative arose to address community concerns about the risk of injury from discarded needles and syringes in public places. A formal Implementation Strategy document was not produced.

The Initiative was revised through the 2003-04 Federal Budget, committing $17.5 million over three years. The revised Initiative will continue to address community concerns about the risk of injury from needles and syringes inappropriately discarded in public places through a range of activities including:

- A Implementation Reference Group (IRG) to provide independent advice to the Department on the implementation of the Initiative;
- Mapping community disposal facilities nationally to identify areas where insufficient disposal facilities exist;
- Pilot studies of retractable needle and syringe technology through selected Needle and Syringe Programs (NSPs); and
- An economic analysis to determine the costs of introducing retractable needles and syringes into NSPs nationally.

(b) To address community concerns about the risk of injury from needles discarded in public places, the initiative is targeted at injecting illicit drug users.

(c) The allocation of $17.5 million will be spent over three years on activities identified in answer (a).

2003-04 $m	**2004-05 $m**	**2005-06 $m**
2.8	2.6	12.1

(d) The implementation of the 2003-04 Initiative commenced in July 2003.

(e) NHMRC funded research projects into Hepatitis C since 1999 are listed in the table below:

(Start Year)	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Hepatitis C research	17	8	8	4	5	6
Grants that involve both Hepatitis B and C research	0	0	2	1	1	0
Non specific Hepatitis research	5	4	5	1	6	0
Total Number of Projects	**22**	**12**	**15**	**6**	**12**	**6**

(f) The Government addressed this issue in its response to recommendation 44 of the 2002 Reviews of the National HIV/AIDS and Hepatitis C Strategies. There are currently no plans to increase funding for these activities.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-133

OUTCOME 1: Population Health and Safety

Topic: TIMEFRAME TOWARD NEW STRATEGIES

Written Question on Notice

Senator McLucas asked:

(a) What is the progress towards the development and funding of new national strategies for HIV/AIDS and Hepatitis C?

(b) Will these new strategies be ready for implementation in July 2004?

(c) Will they be fully funded from July 2004?

Answer:

(a) The Australian Government is currently developing new National HIV/AIDS and Hepatitis C Strategies that will refocus Australia's response to these infections in light of emerging priorities.

(b) The new National HIV/AIDS and Hepatitis C Strategies will now take effect as from 1 January 2005. The current Strategies will be extended until 31 December 2004. This decision will allow extra time for further consideration and development of the new Strategies, and will also allow for further consultation about the Strategies with stakeholders.

(c) The National HIV/AIDS and Hepatitis C Strategies, like all previous HIV/AIDS and Hepatitis C Strategies, will be high level strategic documents which set out the goals, principles and directions for Australia's response to these infections. As such, they are not funding initiatives. Rather, they operate to inform decisions about HIV/AIDS and hepatitis C. This includes funding and resource allocation decisions made through existing national and State and Territory level programs.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-134

OUTCOME 1: Population Health and Safety

Topic: CERVICAL CANCER SCREENING

Written Question on Notice

Senator McLucas asked:

(a) When will the new Guidelines for cervical cancer be completed?

(b) How will the issue regarding the recommendations for low grade squamous abnormalities (CIN1) be resolved?

(c) Given that these new recommendations place a heavy reliance on cytology as a diagnostic test, what additional procedures will be put in place to ensure that women are not put at risk?

(d) If women with possible CIN1 are not to have any follow up other than another repeat smear 12 months later, how will this follow up be ensured?

Answer:

(a) It is anticipated that following an external review of the Guidelines they will be considered by the NHMRC in August 2004 and then submitted to NHMRC Council for consideration for approval in September 2004.

(b) The *Guidelines for the Management of Women with Screen Detected Abnormalities* have been developed in accordance with the NHMRC's guidelines for the development of Clinical Practice Guidelines. All recommendations, including those for low grade squamous abnormalities, have been based on a detailed assessment of the latest published literature and an analysis of the data on all Australian women held in all state cytology registries except Northern Territory. The Guideline Review Group Executive met on 23 February 2004 to consider the submissions received during the consultation process. A number of amendments have been made in response to the submissions. A final draft will be considered by the entire Guideline Review Group prior to being sent to the NHMRC for consideration.

(c) The National Cervical Screening Program does not rely on cytology as a diagnostic test. The Pap smear is a screening test.

The Pap Test Registers will send reminders to women to ensure they have a repeat Pap smear 12 months later.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-171

OUTCOME 1: Population Health and Safety

Topic: TREATMENT SERVICES

Hansard Page: CA99

Senator Denman asked:

The minimum data collection shows that treatment episodes have been increasing. Can I have a State by State breakdown?

Answer:

The number of "open treatment episodes" provided by agencies funded under the Australian Government's Non-Government Treatment Grant Program for 1999-2000 and 2000-2001 by State and Territory is provided below.

STATE/TERRITORY	OPEN TREATMENT EPISODES	
	1999-2000	**2000-2001**
New South Wales	2,655	11,089
Victoria	2,191	2,232
Queensland	1,955	1,854
Western Australia	1,450	1,858
South Australia	9,473	10,225
Tasmania	1,018	1,033
Australian Capital Territory	11	99
Northern Territory	358	1,825
TOTAL	**19,111**	**30,215**

The *Alcohol and other drug treatment services in Australia 2001-02: Report on the National Minimum Data Set* released by the Australian Institute of Health and Welfare (AIHW) in November 2003 provides a more comprehensive record of alcohol and drug treatment episodes.

The following table presents number of "closed treatment episodes" provided by the agencies that contributed data to the Alcohol and Other Drug Treatment Services National Minimum Data Set by State and Territory in 2001-2002.

STATE/TERRITORY	CLOSED TREATMENT EPISODES
New South Wales	39,348
Victoria	44,824
Queensland	4,151[2]
Western Australia	15,232
South Australia	7,164[3]
Tasmania	2,015
Australian Capital Territory	2,824
Northern Territory	2,405
TOTAL	**117,963**

[2] Police diversion data only.

[3] For the 2001-02 period, South Australia supplied client registration data for the first treatment episode only. Therefore data from South Australia is likely to be an undercount of all treatment episodes in comparison to other states and territories.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-172

OUTCOME 1: Population Health and Safety

Topic: TOUGH ON DRUGS NATIONAL STRATEGY

Hansard Page: CA99

Senator Denman asked:

Can I have a breakdown of funding committed by the Government to curb the supply and effect of illicit drugs? Could it be broken down by supply, control and prevention and treatment in harm reduction?

Answer:

A breakdown of total funding committed by the Government since 1997 under the National Illicit Drug Strategy 'Tough on Drugs' is provided in the attached table.

FUNDING TO THE NATIONAL ILLICIT DRUG STRATEGY 1997-2007

BUDGET MEASURES	AGENCY	FUNDING AS ANNOUNCED $m
DEMAND REDUCTION MEASURES		
NIDS 1 (1997/1998)		
Non-Government Organisation Treatment Grants Programme	DHA	29.271
Community Partnerships Initiative	DHA	4.812
Australian Drug Information Network	DHA	1.833
Training Frontline Workers Initiative	DHA	3.002
Evaluation of Trials of Alternative Pharmacotherapies	DHA	1.303
NHMRC Research	DHA	3.962
National School Drug Education Strategy	DEST	7.494
Sub-Total		**51.677**
NIDS 2 (1998/1999)		
Non-Government Organisation Treatment Grants Programme	DHA	21.384
National Illicit Drugs Campaign	DHA	17.557
Australian National Council on Drugs & Supporting Structures	DHA	3.640
Australian Drug Information Network	DHA	0.700
Illicit Drug Reporting and Information	DHA	3.635
Best Practice & Evaluation in Illicit Drug Dependence	DHA	4.434
Sub-Total		**51.350**
NIDS 3 (1998 Election Commitments)		
Non-Government Organisation Treatment Grants Programme	DHA	10.200
National School Drug Education Strategy	DEST	10.200
Sub-Total		**20.400**
NIDS 4 COAG Diversion Initiative (1999/2000)		
National Illicit Drug Diversion Initiative	DHA	111.536
Cannabis Cessation Strategies for Adults and Adolescents	DHA	1.179
National Illicit Drugs Campaign	DHA	10.621
Increased Education Counselling and Referrals	DHA	17.615
Community Partnerships Initiative	DHA	4.041
Increased Support for Needle and Syringe Programmes	DHA	12.962
Research into Barriers to Treatment	DHA	0.252
Strengthening & Supporting Families	FACS	11.337
School Protocol Development	DEST	1.171
School Information and Education Resources	DEST	2.048
Local School and Community Summits	DEST	6.109
Evaluation	DOFA	0.681
Sub-Total		**179.552**
NIDS 5 (2001 Election Commitments)		
Non-Government Organisation Treatment Grants Programme	DHA	65.100
Community Partnerships Initiative	DHA	14.000
Croc Festivals	DHA	1.200
Retractable Needle and Syringe Technology	DHA	17.500
Illicit Drug reporting and Information	DHA	2.727
ANCD and Supporting Structures	DHA	2.730
Sub-Total		**103.257**

BUDGET MEASURES	AGENCY	FUNDING AS ANNOUNCED $m
DEMAND REDUCTION MEASURES CONTINUED		
NIDS 6 (2003 Election Commitments)		
COAG Illicit Drug Diversion Initiative	DHA	215.900
Increased Education Counselling and Referrals	DHA	22.400
Increased Support for Needle and Syringe Programmes	DHA	16.300
National Comorbidity Initiative	DHA	4.400
National Psychostimulants Initiative	DHA	2.000
National Illicit Drug Strategy Rural and Regional Initiative	DHA	4.000
National Illicit Drug Strategy Research Fund	DHA	2.800
Australian Drug Information Network	DHA	1.000
Strengthening & Supporting Families	FACS	3.300
National School Drug Education Strategy	DEST	5.300
Sub-Total		**277.400**
DEMAND REDUCTION TOTAL		**683.636**

BUDGET MEASURES	AGENCY	FUNDING AS ANNOUNCED $m
SUPPLY REDUCTION MEASURES		
NIDS 1 (1997/1998)		
Mobile Strike Teams	AFP	19.887
Thursday Island	AFP	0.899
Heroin Signature Programme	AFP	1.200
Informants and Witness Handling	AFP	4.070
Transaction Monitoring	AUSTRAC	1.761
Torres Strait Initiatives	ACS	7.770
Cargo Profiling and Examination	ACS	4.300
Covert Examination Facility	ACS	6.245
Communications and IT Capability	ACS	9.203
Intelligence Analysts	ACS	2.560
Research into Drug-Crime Links	AIC	0.200
Sub-Total		**58.095**
NIDS 2 (1998/1999)		
AFP Posts	AFP	6.122
Law Enforcement Cooperation Programme	AFP	5.749
Mobile Strike Teams	AFP	12.099
Money Laundering	APG	1.000
Blade Enhancement	NCA	21.598
ACS Analysts	ACS	4.392
DUMA Project	AIC	1.648
Sub-Total		**52.608**
NIDS 3 (1998 Election Commitments)		
Mobile Strike Teams	AFP	24.232
X-Ray Technology	ACS	12.295
Moblie Search Teams	ACS	9.860
Additional Marine Crew	ACS	3.891
Capital Expenditure	ACS	9.344
Sub-Total		**59.622**
NIDS 4 COAG (1999/2000)		
Law Enforcement Cooperation Programme	AFP	8.082
Enhanced Telephone Intercept Capacity	AFP	4.371
Overseas Liaison Network	AFP	6.036
Connection to AFP Computer	AFP	4.804
Enhanced Telephone Intercept Capacity	NCA	7.326
High-Risk Cash Dealer Strategy	AUSTRAC	7.443
Intensive Training and Support Programme	AUSTRAC	2.007
Research into Drug-Crime Links	AGD	1.524
Sub-Total		**41.593**
NIDS 5 (2001 Election Commitments)		
Cocaine and ATS Signature Programme	AFP	4.700
Sub-Total		**4.700**
NIDS 6 (2003 Election Commitments)		
Prevent Diversion of Precursor Chemicals	AGD	4.300
Drug Use Monitoring in Australia	AIC	4.300
Financial Intelligence Capability	AUSTRAC	3.400
Sub-Total		**12.000**

BUDGET MEASURES	AGENCY	FUNDING AS ANNOUNCED $m
2003-04 to 2006-07 Ongoing Measures		
Law Enforcement Cooperation Programme	AFP	8.700
Enhanced Telephone Intercept Capacity	AFP	4.000
Overseas Liaison Network	AFP	5.900
Connection to AFP Computer	AFP	5.100
Enhanced Telephone Intercept Capacity	ACC	8.000
High-Risk Cash Dealer Strategy	AUSTRAC	1.800
Intensive Training and Support Programme	AUSTRAC	0.500
Mobile Strike Teams	AFP	57.944
Thursday Island	AFP	0.832
Heroin Signature Programme	AFP	6.002
Informants and Witness Handling	AFP	4.988
Transaction Monitoring	AUSTRAC	0.646
Torres Strait Initiatives	ACS	4.358
Cargo Profiling and Examination	ACS	2.098
Covert Examination Facility	ACS	5.126
Communications and IT Capability	ACS	4.982
Intelligence Analysts	ACS	8.292
Blade Enhancement	ACC	23.104
X-ray Technology	ACS	14.878
Mobile Search Teams	ACS	11.372
Additional Marine Crew	ACS	6.671
APG Secretariat	ACC	2.082
Sub-Total		**187.375**
SUPPLY REDUCTION TOTAL		**415.993**
COMBINED SUPPLY AND DEMAND REDUCTION TOTAL		**1099.629**

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-121

OUTCOME 1: Population Health and Safety

Topic: TOUGH ON DRUGS

Written Question on Notice

Senator Stephens asked:

(a) The Government's "Tough on Drugs" Indigenous Community Initiative was announced in August 2003. Are you familiar with this Initiative?

(b) Do you know how much money has been allocated to this Initiative?

(c) If so, do you know how much has been distributed?

Answer:

(a) and (b)
The Australian Government has committed $10.5 million over four years to the Tough on Drugs Indigenous Community Initiative.

(c) Funding from the Tough on Drugs Indigenous Community Initiative has not yet been distributed.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-173

OUTCOME 1: Population Health and Safety

Topic: AMPHETAMINE USE

Hansard Page: CA 100

Senator Denman asked:

Can you provide figures on the use of amphetamines, if there is any, for the last two years by State if possible?

Answer:

The National Drug Strategy Household Survey is conducted triennially. The results from the 2001 Survey are the most recent and reliable source of trend data on amphetamine use amongst the general population in Australia.

The findings from the 2001 National Drug Strategy Household Survey showed a slight decrease in the proportion of Australians aged 14 years and over who had used amphetamines in the 12 months preceding the Survey (from 3.7 per cent in 1998 to 3.4 per cent).

However, the 2001 National Drug Strategy Household Survey also showed a slight increase in the proportion of Australians aged 14 years and over who had used amphetamines at some time in their lives (from 8.8 per cent in 1998 to 8.9 per cent in 2001).

The table below provides a summary comparison of amphetamine use by State and Territory in 1998 and 2001.

Table 1. Recent use (last 12 months) of amphetamines: proportion of the population aged 14 years and over, States and Territories, 1998 and 2001 (source: 1998 and 2001 National Drug Strategy Survey State and Territory Findings)

STATE/TERRITORY	1998	2001
NSW	3.8	3.4
Vic	3.4	2.4
Qld	3.0	2.9
WA	6.0	5.8
SA	3.5	4.3
Tas	1.6	2.1
ACT	3.1	4.5
NT	7.2	6.3

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-174

OUTCOME 1: Population Health and Safety

Topic: PSYCHOSTIMULANT RESEARCH

Hansard Page: CA 100

Senator Denman asked:

Can I have the figures for planned research on psychostimulants, and the issues that are being researched?

Answer:

The table below provides an overview of planned research on psychostimulants that is funded by the Australian Government Department of Health and Ageing.

Research Centre	**Study Details**	**Funding Source**
NDARC	Estimating the number of methamphetamine users in Sydney, Australia	UNSW John Yu Fellowship and the Australian Government Department of Health and Ageing *
NDARC	Developing appropriate interventions for methamphetamine users	Australian Government Department of Health and Ageing *
NDARC	The emergence of more potent forms of methamphetamine in Sydney: Developing our understanding of Australia's dynamic methamphetamine market	National Drug Law Enforcement Research Fund - $245,781
Drug & Alcohol Services Council	A trial of assertive community follow-up treatment for methamphetamine-induced psychosis.	Australian Government Department of Health and Ageing - $218,494

Note: NDARC – National Drug and Alcohol Research Centre, University of New South Wales, Sydney.

* This project is not costed separately and is undertaken as part of the Funding Agreement to facilitate NDARC's core research programme.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-175

OUTCOME 1: Population Health and Safety

Topic: NATIONAL DRUG RESEARCH STRATEGY RESEARCH

Hansard Page: CA103

Senator Allison asked:

Is it possible to get a list of the research programs currently being funded or in the pipeline to proceed in relation to research funding? Also to provide names of organisations receiving funding this financial year and draft workplans of the National Drug Research Centres.

Answer:

The Australian Government Department of Health and Ageing funds three National Drug Strategy Research Centres – the National Drug and Alcohol Research Centre; the National Drug Research Institute; and the National Centre for Education and Training on Addiction.

A list of the current research activities being undertaken by the National Drug Strategy Research Centres is attached.

NATIONAL DRUG RESEARCH INSTITUTE

- National Alcohol Indicators Project
- NAIP Component Study: Analysis of trends in drinking patterns 1983-2003
- Illicit Drugs Reporting System
- Monitoring of alcohol-related violence and crime in NSW
- Australian Drug Information Network (ADIN)
- Database on Indigenous Australian alcohol and other drug intervention projects.
- Bibliographic data base on Indigenous Australian alcohol and other drug use.
- Grief and alcohol misuse among Indigenous people in Central Australia.
- Evaluation of the 'Makin Tracks' substance misuse intervention project.
- Heavy cannabis use in two remote Aboriginal communities: prospects for a population based intervention.
- The policy response to Indigenous petrol sniffing.
- Indigenous Australian drug and alcohol projects: elements of best practice.
- Volatile substance misuse in an urban area.
- Building Indigenous research capacity.
- Survey of the attitudes of Aboriginal Town Campers to the Alice Springs liquor licensing restrictions.
- The impact of reducing criminal penalties for cannabis use on serious road injury in Australia
- Driving after drinking on licensed premises
- An evaluation of the impact of changes to law in WA on cannabis use, the drug market, law enforcement, knowledge and attitudes and cannabis-related harms.
- Preventing Alcohol Related Violence
- NAIP Component Study: Re-evaluation of the public health impact of the Northern Territory's Living With Alcohol program
- Laboratory pilot study of efficacy of cleansing needles to prevent spread of Hep C
- School Health and Alcohol Harm Reduction Project (SHAHRP) 2000
- SHAHRP Dissemination Project
- Evaluation of the School Drug Education Project's In Touch Program.
- Formative research on National Approaches and Strategies for School Illicit Drug Education
- Formative investigation of the potential for early intervention of multiple adolescent problem behaviours
- Carnarvon Health and Men Project (CHAMP) – Second Phase
- WHO International comparative study of emergency room data on alcohol and injury
- Development of the evidence base to inform National Drug Strategy prevention agenda (Prevention Monograph)
- Developmental risk and protection factors and adolescent substance use.
- The relationship between non-fatal drug overdose, suicidality and depression
- Do some drug users have less to live for? Examining the role of perceived life wealth in the extent to which young adults' drug use controlled or excessive
- Does moderate drinking prevent heart disease? A meta-analysis
- Social, cultural and economic processes in illicit drug markets and their public health consequences

NATIONAL DRUG AND ALCOHOL RESEARCH CENTRE

- National Illicit Drug Indicators Project
- Estimating the number of methamphetamine users in Sydney, Australia
- Patterns of use and experiences of recreational pharmaceutical drug use amongst 'party drug' users
- Rural Injector Project
- Substance use, dependence and treatment seeking in the United States and Australia: A cross-national comparison
- Pharmacotherapies for nicotine dependence: economic considerations
- Pharmacotherapies for excessive alcohol use: economic considerations
- The Illicit Drug Reporting System (IDRS)
- Party Drugs Initiative (PDI)
- Structural determinants of drug abuse
- Drug information needs, sources and credibility among 'party drug' users
- Developing appropriate interventions for methamphetamine users
- Self-efficacy, expectancy and abstinence acceptance: outcomes of a community-based forensic drug relapse intervention
- Assessment of the psychometric properties of the adult and adolescent versions of the Cannabis Problems Questionnaires
- The Australian Treatment Outcome Study (ATOS): Heroin
- The development of an Adolescent Cannabis Check-up and Intervention Trial
- The Prison Opiate Dependence Treatment Trial
- Australian methamphetamine interventions research forum
- Disseminating and implementing the Guidelines for the Treatment of Alcohol Problems
- Program of International Research and Training (PIRT)

NATIONAL CENTRE FOR EDUCATION AND TRAINING ON ADDICTION

- Alcohol and Other Drug Treatment Agencies – A National Workforce Development Survey
- Attitudes Towards Illicit Drug Users: Development of a Psychological Model of Attitude Formation and Change
- Updating the Handbook for Medical Practitioners and Other Health Care Workers on Alcohol and Other Drug Problems, and Developing a National Training Package for Medical Practitioners on Illicit Drug Issue

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-176

OUTCOME 1: Population Health and Safety

Topic: ALCOHOL PREVALANCE

Hansard Page: CA 106

Senator Allison asked:

Can I get a copy of the findings of the report issued by the National Drug Research Institute at Curtin University?

Answer:

A copy of "*Australian Alcohol Indicators: patterns of alcohol use and related harms for Australian states and territories 1990-2001*" is attached.

The report may be accessed at: http://www.nationaldrugstrategy.gov.au/pdf/naip.pdf

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-177

OUTCOME 1: Population Health and Safety

Topic: ALCOPOPS RESEARCH

Hansard Page: CA 107

Senator Allison asked:

Is it possible to provide the terms of reference for the research commissioned on alcopops?

Answer:

The Australian Government has recently commissioned research to determine –

i. if "ready to drinks" are preferred by teenagers compared to other alcoholic beverages;
ii. whether this pattern changes with age; and
iii. the extent to which packaging and marketing affects these likes and dislikes.

A steering committee will be convened including representatives from the Department of Health and Ageing, peak youth organisations, the police service and a clinician with expertise in taste and smell in children, an expert in youth marketing and liquor industry representatives from the spirit, wine and brewing sectors.

It is anticipated that the preliminary results from this research will be available towards the end of 2004 and that final results will be available in the first quarter of 2005.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question:E04-017

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: ADMINISTERED PROGRAMMES

Written Question on Notice

Senator Forshaw asked:

Could you provide a list of all administered programmes in FSANZ, including:

- A description of the programme;
- number of people directly receiving funds/assistance under the programme;
- a breakdown of those receiving funds/assistance under the programme by electorate;
- the policy objective of the programme;
- whether the programme is ongoing;
- the funding in each financial year of the forward estimates for the programme (with a breakdown of administered and departmental expenses), including:
  - how much funding was allocated for the programme;
  - how much is committed to the programme; and
  - how much is unspent.
- indication of whether an evaluation of the programme effectiveness has been conducted:
- if so, when that evaluation occurred; and
- if so, the conclusion of that evaluation.

Answer:

FSANZ does not have administered programmes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-018

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: SENIOR EXECUTIVE OFFICERS

Written Question on Notice

Senator Forshaw asked:

How many Senior Executive Officers (or equivalent) were employed in FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04.

Answer:

1996-97:	FSANZ cannot provide information for 1997-97 as this information has been archived	
1997-98:	Annual Report, Appendix 3, Table 8, (page 100)	Total 5
1998-99:	Annual Report, Appendix 3, Table 4, (page 116)	Total 4
1999-00:	Annual Report, Appendix 3, Table 3, (page 104)	Total 5
2000-01:	Annual Report, Appendix 3, Table 1, (page 142)	Total 5
2001-02:	Annual Report, Appendix 3, Table 1, (page 138)	Total 5
2002-03:	Annual Report, Appendix 3, Table 1, (page 100)	Total 5

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-019

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: WAGES

Written Question on Notice

Senator Forshaw asked:

What was the base and top (including performance pay) wages of APS 1, 2, 3, 4, 5, 6 (or equivalent), Executive Level 1 and 2 (or equivalent), and SES band 1, band 2 and band 3 (or equivalent) in FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04.

Answer:

Performance pay is covered by individual AWA's.

1996-97, 1997-98: APS pay rates applicable at the time.

1998-99
APS1: $24,903 – 27,932
APS2: $28,183 – 31,717
APS3: $32,101 – 35,161
APS4: $35,777 – 39,423
APS5: $39,905 – 42,942
APS6: $43,100 – 50,244
EL1: $55,252 – 60,549
EL2: $63,726 – 77,063
SESB1 $77,841

1999-00
APS1: $24,903 – 27,932
APS2: $28,183 – 31,717
APS3: $32,101 – 35,161
APS4: $35,777 – 39,423
APS5: $39,905 – 42,942
APS6: $43,100 – 50,244
EL1: $55,252 – 60,549
EL2: $63,726 – 77,063
SESB1 $85,818

2000-01
APS1: $26,049 – 29,217
APS2: $29,479 – 33,176
APS3: $33,578 – 36,778
APS4: $37,423 – 41,236
APS5: $41,741 – 44,917
APS6: $45,083 – 52,555
EL1: $57,794 – 64,380
EL2: $66,657 – 80,608
SESB1 $91,042

2001-02
APS1: $26,883 – 30,152
APS2: $30,422 – 34,238
APS3: $34,652 – 37,955
APS4: $38,621 – 42,556
APS5: $43,077 – 46,354
APS6: $46,526 – 54,237
EL1: $59,643 – 66,440
EL2: $68,790 – 83,187
SESB1 $96,230

2002-03
APS1: $28,039 – 31,449
APS2: $31,730 – 35,710
APS3: $36,142 – 39,587
APS4: $40,282 – 44,386
APS5: $44,929 – 48,347
APS6: $48,527 – 56,569
EL1: $62,208 – 69,297
EL2: $71,748 – 86,764
SESB1 $102,200

2003-04
APS1: $29,217 – 32,770
APS2: $33,063 – 37,210
APS3: $37,660 – 41,250
APS4: $41,974 – 46,250
APS5: $46,816 – 50,378
APS6: $50,565 – 58,945
EL1: $64,821 – 72,207
EL2: $74,761 – 90,408
SESB1 $107,200

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-020

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: AVERAGE SALARY

Written Question on Notice

Senator Forshaw asked:

What was the average salary for an SES (or equivalent) in FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04.

Answer:

1996-97, 1997-98: APS pay rates applicable at the time.
1998-99: $77,841
1999-00: $85,818
2000-01: $91,042
2001-02: $96,230
2002-03: $102,200
2003-04: $107,200

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question:E04-021

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: MOBILE PHONES

Written Question on Notice

Senator Forshaw asked:

How many staff had mobile phones issued by FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

1996-97	FSANZ cannot provide information for 1996-97 as this information has been archived.
1997-98	FSANZ cannot provide information for 1997-98 as this information has been archived
1998-99	30
1999-00	33
2000-01	51
2001-02	53
2002-03	52
2003-04	51

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question:E04-022

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: TOTAL MOBILE PHONE BILL

Written Question on Notice

Senator Forshaw asked:

What was the total mobile phone bill for FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

1996-97	FSANZ cannot provide information for 1996-97 as this information has been archived.
1997-98	FSANZ cannot provide information for 1997-98 as this information has been archived
1998-99	$20,952.60
1999-00	$17,631.06
2000-01	$21,520.43
2001-02	$18,989.77
2002-03	$17,481.57
2003-04	$11,791.55

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question:E04-023

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: SES CAR ISSUE

Written Question on Notice

Senator Forshaw asked:

How many SES (or equivalent) were issued with cars in FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04.

Answer:

1996-97	FSANZ cannot provide information for 1996-97 as this information has been archived.
1997-98	FSANZ cannot provide information for 1997-98 as this information has been archived
1998-99	5
1999-00	6
2000-01	5
2001-02	5
2002-03	6
2003-04	5

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-024

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: MANAGEMENT TRAINING/RETREATS

Written Question on Notice

Senator Forshaw asked:

Could you please list all 'management retreats/training' conducted by FSANZ which were attended by employees during 2000-01, 2001-02, 2002-03, 2003-04 to date. For such meetings held off-site (from the FSANZ), could you please indicate:

- where (location and hotel) and when they were hold;
- how much was spent in total;
- how much was spent in accommodation;
- how much was spent on food;
- how much was spent on alcohol/drinks; and
- how much was spent on transport.

Answer:

This information is not recorded centrally in the Agency.

As such, the Agency is unable to provide a response to this question as the considerable work involved would require a significant diversion of resources from other Agency operations.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-025

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: OVERSEAS TRIPS

Written Question on Notice

Senator Forshaw asked:

(a) How many overseas trips were taken by employees in FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

(b) What were the destinations of each of these overseas trips.

(c) What was the total cost of the overseas trips of staff for by FANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

With a breakdown on the cost of accommodation allowances, food allowances and airflights.

Answer:

(a)

1996-97	FSANZ cannot provide information for 1996-97 as this information has been archived.
1997-98	FSANZ cannot provide information for 1997-98 as this information has been archived
1998-99	52
1999-00	103
2000-01	114
2001-02	125
2002-03	120
2003-04	67

(b)

1996-97	FSANZ cannot provide information for 1996-97 as this information has been archived.
1997-98	FSANZ cannot provide information for 1997-98 as this information has been archived
1998-99	New Zealand – 30 USA – 4 Berlin – 1 Paris – 1

Geneva – 1
London – 4
Amsterdam – 7
Jakarta – 3
Rome – 1

1999-00 New Zealand – 70
Rome – 2
Amsterdam – 4
Beijing – 3
USA – 3
Paris – 2
Netherlands – 1
Bangkok – 5
Rio De Janeiro – 2
Vancouver – 2
London – 3
Tokyo – 2
Hanoi – 3
Berlin – 1

2000-01 New Zealand – 82
Kuala Lumpur – 3
Hong Kong – 1
Tokyo – 1
Vienna – 1
USA – 2
Brunei – 1
India – 1
Canada – 3
Narita – 2
Manila – 1
Rio De Janeiro – 2
Geneva – 3
London – 1
Paris – 4
Singapore – 4
Hanoi – 1
Bangkok – 1

2001-02 New Zealand – 72
Geneva – 5
USA – 6
Manila – 2
China – 1
Singapore – 5
London – 4
Belgium – 1
Bangkok – 3
Vancouver – 2
Berlin – 1
Dubai – 1

Tokyo – 2
Amsterdam – 3
Halifax – 1
Hanoi – 8
Paris – 2
Suva – 1
Jakarta – 1
Rome – 1
Nadi – 1
Mexico – 2

2002-03 New Zealand – 76
Singapore – 3
Rome – 2
Bangkok – 8
Mexico – 1
Jakarta – 1
Hong Kong – 1
USA – 8
Hanoi – 2
London – 1
Dubai – 2
Kuala Lumpur – 2
Lisbon – 1
China – 1
Barcelona – 1
Nadi – 1
Tokyo – 1
Frankfurt – 1
Geneva – 3
Amsterdam – 1
Bali – 1
Calgary – 1

2003-04 New Zealand – 38
USA – 5
Bangkok – 10
Calgary – 2
Kuala Lumpur – 1
Geneva – 3
Paris – 1
Rome – 1
Beijing – 1
Jakarta – 1
Taipei – 2
Singapore – 1
India – 1

(c)

1996-97	FSANZ cannot provide information for 1996-97 as this information has been archived.
1997-98	FSANZ cannot provide information for 1997-98 as this information has been archived
1998-99	Airfares $150,393.71 Travel Expenses (includes accommodation and food allowances) $34,960.99
1999-00	Airfares $164,979.96 Travel Expenses $58,174.31
2000-01	Airfares $302,662.91 Travel Expenses $51,844.02
2001-02	Airfares $375,750.69 Travel Expenses $162,667.12
2002-03	Airfares $279,012.65 Travel Expenses $150,935.95
2003-04	Airfares $168,150.54 Travel Expenses $57,046.81

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-026

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: DOMESTIC TRIPS

Written Question on Notice

Senator Forshaw asked:

What was the total cost of domestic trips of staff for by FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

- with a breakdown on the cost of accommodation allowances, food allowances and airflights.

Answer:

1996-97	FSANZ cannot provide information for 1996-97 as this information has been archived.
1997-98	FSANZ cannot provide information for 1997-98 as this information has been archived
1998-99	Airfares $162,003.66 Travel Expenses (includes accommodation and food allowances) $82,393.01
1999-00	Airfares $128,430.63 Travel Expenses $65,482.34
2000-01	Airfares $200,142.71 Travel Expenses $83,601.83
2001-02	Airfares $182,989.44 Travel Expenses $82,233.79
2002-03	Airfares $159,060.35 Travel Expenses $85,886.82
2003-04	Airfares $114,613.81 Travel Expenses $67,890.90

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question:E04-027

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: OVERSEAS TRIPS FOR MINISTERIAL STAFF

Written Question on Notice

Senator Forshaw asked:

(a) How many overseas trips of Ministerial Staff were paid for by FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

(b) What was the total cost of overseas trips of Ministerial Staff paid for by FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

(a) & (b)
No.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-028

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: ADVERTISING

Written Question on Notice

Senator Forshaw asked:

How much was spent on advertising by FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

Nil.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question:E04-029

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: PUBLICATIONS WITH ELECTORATE BREAKDOWNS ON SPENDING ON GOVERNMENT PROGRAMMES

Written Question on Notice

Senator Forshaw asked:

Did FSANZ produce publications that provided electorate breakdowns on spending on government programmes in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

No.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-030

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: ADVERTISING THAT PROVIDED ELECTORATE BREAKDOWNS ON SPENDING ON GOVERNMENT PROGRAMMES

Written Question on Notice

Senator Forshaw asked:

How much was spent on advertising which provided electorate breakdowns of spending by government on programmes within FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

Nil.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-031

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: CONSULTANCIES

Written Question on Notice

Senator Forshaw asked:

How much was spent on consultancies by FSANZ in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

Answer:

1996-97	$232,210
1997-98	$459,766
1998-99	$640,415
1999-00	$396,799
2000-01	$136,772
2001-02	$708,445
2002-03	$437,121
2003-04	$123,843

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question:E04-032

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: SURVEYS OF ATTITUDES TOWARDS PROGRAMMES

Written Question on Notice

Senator Forshaw asked:

(a) Did FSANZ conduct any surveys of attitudes towards programmes run by their department in 1996-97, 1997-98, 1998-99, 1999-00, 2000-01, 2001-02, 2002-03, 2003-04 to date.

(b) On what programmes administered by FSANZ were surveys conducted.

(c) What were the findings of these surveys.

Answer:

(a), (b) & (c)

FSANZ does not administer any programmes and therefore no surveys were conducted.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-152

OUTCOME 1: Population Health and Safety

Topic: LEGAL ACTION AGAINST PAN

Hansard Page: CA 85

Senator Forshaw asked:

Are you able to confirm whether you have referred any matters to either the New South Wales Health Department or the Australian Federal Police?

Answer:

Legal action against Pan Pharmaceuticals has been investigated by the Therapeutic Goods Administration (TGA) in consultation with the Commonwealth Director of Public Prosecutions (DPP). The TGA is not aware of any legal matters being referred to the NSW Health Department or the Australian Federal Police.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-155

OUTCOME 1: Population Health and Safety

Topic: PUBLIC COMMENTS ABOUT A DIRECTOR OF PAN

Hansard Page: CA 85

Senator Allison asked:

There has been the necessity for your public relations person, Ms McNiece, to offer an apology for statements made to the press at one stage. Can you enlighten us as to what has transpired since that time?

Answer:

A complaint was made to the TGA about comments allegedly made by Ms McNiece to a television news journalist. The allegation has been investigated and there is no evidence to support the claim. Both Ms McNiece and the journalist concerned deny making the alleged comments.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-183

OUTCOME 1: Population Health and Safety

Topic: CONTROL OF DENGUE FEVER IN THE TORRES STRAIT

Hansard page: CA135

Senator O'Brien asked:

Last night, Senator Crossin and I asked the Torres Strait Regional Authority (TSRA) about Commonwealth resources devoted to the control of dengue fever in the Torres Strait. We were told that no Commonwealth resources are dedicated to this task. That was the view the TSRA put to the legal and constitutional committee. Is that correct?

Answer:

State and Territory Governments are responsible for managing localised disease outbreaks. The National Arbovirus and Malaria Advisory Committee reporting through the Communicable Diseases Network Australia makes recommendations on arbovirus surveillance, strategic arbovirus disease management and vector control. The Committee provides expert technical advice on arboviruses such as dengue to assist in the detection, management and control of real or potential outbreaks of arboviral disease.

The Dengue Fever Management Plan prepared by Queensland Health outlines prevention and control strategies. The Dengue Action Response Team in north Queensland is responsible for implementing control measures, including spraying known mosquito breeding sites with insecticide and advising the public to minimise the opportunity for mosquitoes to breed by eliminating stagnant water in and around their homes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-065

OUTCOME 1: Population Health and Safety

Topic: REFERRALS TO ACCC

Hansard Page: CA 88, CA 89

Senator Forshaw asked:

(h) How many cases has the TGA come across of alleged or apparent incorrect or misleading labelling that it has referred to the ACCC or other Offices of Fair Trading?

(i) Can you provide details of what has been referred to the ACCC or other agencies and what the ACCC or other agencies have referred to you?

(j) What is the TGA's process and procedures when it comes across therapeutic goods that have misleading or incorrect labelling?

Answer:

(a-b) Since January 2000, the TGA has referred 41 cases of alleged or apparent misleading claims for products making therapeutic claims to the Australian Competition and Consumer Commission (ACCC).

It is not possible to separate those referrals that relate only to 'truth in labelling' issues from other advertising issues as the breaches typically involve issues that may cover a number of aspects of a product promotion including labels, leaflets, point of sale material and/or Internet sites.

The regulation/monitoring of these types of breaches is shared by the Therapeutic Goods Administration (TGA) and the ACCC under the *Therapeutic Goods Act 1989* and Regulations, and the *Trade Practices Act 1974*.

Where misleading claims are made for a therapeutic good that lead to misuse or potential for misuse of that product or create a public health and safety concern, the TGA will use its powers under the Therapeutic Goods legislation to stop the breaches. However, in the instances where the claims for a product do not create a public health and safety concern, nor encourage misuse of a product but do create false or misleading statements about the product, these issues may also be referred to the ACCC for action.

Complaints about products making therapeutic claims that are not therapeutic goods, foods, pesticides or veterinary medicines are also referred to the ACCC for action under Trade Practices legislation.

Since 1 January 2000, the TGA has received approximately 8 referrals from the ACCC or other consumer protection agencies. These referrals have involved therapeutic goods, which are subject to the *Therapeutic Goods Act 1989*.

In its dealings with other agencies, since 1 January 2000, the TGA has –

- Referred five complaints about agricultural chemicals or veterinary medicines to the Australian Pesticides and Veterinary Medicines Authority (APVMA), formerly the National Registration Authority (NRA);

- Received 1 complaint about therapeutic goods from the NRA;

- Referred 12 complaints about food products to Food Standards Australia New Zealand (FSANZ), formerly the Australian New Zealand Food Authority (ANZFA); and

- Received 2 complaints about therapeutic goods from Food Standards Australia New Zealand (FSANZ).

(c) Where there is no obvious public health or safety concern, the alleged misleading or incorrect labelling is initially referred to the product sponsor, drawing the complaint to their attention and seeking their comment in relation to the allegations/s raised, including the provision of evidence which does substantiate the claims in question. Upon receipt, the TGA assesses the validity of the information and makes a judgement as to any further action which may be required.

In cases where the labelling is found to be misleading or incorrect, the sponsors are then afforded the opportunity to initiate appropriate remedial action in the first instance. However, where sponsors fail to do so, the TGA has a range of regulatory responses open to it, from requesting publication of corrections to the cancelling of the listing or registration of the product from the Australian Register of Therapeutic Goods. If cancelled, the product's marketing authorisation is effectively revoked. In more serious cases, consideration can also be given to initiating a prosecution of the parties involved.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-151

OUTCOME 1: Population Health and Safety

Topic: TGA STAFFING AND ADMINISTRATIVE CHANGES

Hansard Page: CA 86, CA 92

Senator Forshaw asked:

Can you outline all the staffing and administrative changes to the TGA since January 2003, including details of where there have been movements in senior staff within the TGA, not identifying individuals.

Answer:

Overall staffing numbers in the TGA, including the Office of Chemical Safety (OCS) of which the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is a part, varied between January and December 2003 as demonstrated by the staffing numbers below:

Full time equivalent staff as at 1 January 2003

Ongoing (permanent)	450
Non-ongoing	34
Casual	0
Total	484

Full time equivalent staff as at 31 December 2003

Ongoing (permanent)	457
Non-ongoing	45
Casual	0
Total	502

Since January 2003 three senior executives have left the TGA and three senior executive staff transferred into the TGA. There was one internal promotion. In addition, one new Executive Professional position (senior executive equivalent) was established to address the growing requirement for specialist expertise in the area of blood regulation. An Executive Professional position (senior executive equivalent) was created to provide specialist knowledge and expertise to the Project Team currently developing the new regulatory framework for the Trans Tasman Regulatory Agency.

A number of internal structural changes have also been made:

- The Conformity Assessment Branch has changed its name to the Office of Devices, Blood and Tissues to more accurately reflect the majority of its functional responsibilities. As part of this change, one work team was transferred to the new Office from the TGA Laboratories Branch.
- The Business and Services Branch has been amalgamated with the Trans Tasman Group to form the Trans Tasman and Business Management Group. This will facilitate ongoing business support for the TGA and a coordinated approach to the development of the new regulatory framework for the new Agency together with the establishment of the associated business support infrastructure needed to enable the new Agency to operate on a day to day basis.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-153

OUTCOME 1: Population Health and Safety

Topic: PAN-MANUFACTURED CAPSULES CONTAINING EMU OIL

Hansard Page: CA 81, CA82, CA83

Senator Forshaw asked:

In relation to Pan-manufactured capsules containing emu oil:

(d) Do you know if any other capsules manufactured by Pan containing emu oil were recalled, either listed or unlisted?

(e) Can you recall any instance where you gave advice to any of the state authorities, or any other authority for that matter, that Pan was manufacturing emu oil in capsule form that was not listed by the TGA?

(f) Following the recall of the emu oil product manufactured by Pan for Emu Spririt and that company, was the TGA advised of the fact that other products were being sold openly as a food and what did the TGA do in response to that advice?

Answer:

(a) The recall of therapeutic products applied only to products manufactured by Pan Pharmaceuticals (Pan) in the period since 1 May 2002. Emu oil products manufactured by Pan prior to that date, or manufactured by other manufacturers were not subject to the recall.

In April 2003 there were 5 listed medicines on the Australian Register of Therapeutic Goods (ARTG) approved for supply in Australia, that had both Emu oil as an ingredient and Pan as a nominated manufacturer. The sponsor of each product was asked to provide a declaration to the TGA to confirm whether or not any batches of their product had been manufactured by Pan in the period May 2002/April 2003 inclusive. Emu Research Corporation of Australia Pty Ltd (Emu Spirit) sponsored four of the five products and declared that Pan had manufactured three batches of their emu oil product. These were recalled. The sponsor of the fifth product declared that no batches of their product were manufactured during the period in question. This product was not, therefore, subject to recall.

Notwithstanding these declarations the TGA reviewed Pan manufacturing records provided to the TGA on 29 July 2003. The TGA identified two additional companies for which Pan had manufactured emu oil products although neither company had emu oil products listed or registered on the ARTG as at 28 April 2003. One of these companies advised the TGA that it still has possession of product manufactured by Pan and therefore no recall action was required. In June 2003 this company listed a new product on the ARTG nominating a new manufacturer. The second company advised that its food product manufactured by Pan had been destroyed.

(b) The TGA investigated all instances where records indicated Pan had manufactured emu oil products in the period after 1 May 2002 including those where the product was not included in the ARTG (see (a) above). As a result, there was no additional investigative or other action required of any State/Territory and so it was not necessary to provide specific separate advice in relation to emu oil products.

(c) A number of complaints were received by the TGA alleging emu oil products manufactured by Pan and subject to recall, continued to be sold after the recall. All such allegations received to date have been investigated but none have been substantiated (see answer to (a) above.

Emu oil products may be sold as either a food or a therapeutic product, depending on its presentation and any claims made on labels and in promotional material. Those presented as a therapeutic product must comply with all of the provisions of the *Therapeutic Goods Act 1989*, while those presented as a food must comply with the Food Standards Code and any other relevant State or Territory legislation.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-141

OUTCOME 1: Population Health and Safety

Topic: UF6

Written Question on Notice

Senator McLucas asked:

On the 29th of November 1999 Mr John Bellinger of ANSO informed the US Nuclear Regulatory Committee that ANSO had been informed by SILEX of the impending delivery of 15kg of UF6. US Nuclear Regulatory Commission export license XSNM3113 and ASNO license number PN144 are referred to.

(a) Has ARPANSA issued a license to either ANSTO or SILX SYSTEMS LTD to possess UF6?

(b) How many separate transports of UF6 for use by either SILEX SYSTEMS LTD or ANSTO for use in laser enrichment experiments are ARAPSNA aware of?

(c) What methods of transportation (ship or aircraft) have been used to import UF6 for use by either SILEX SYSTEMS LTD or ANSTO on the laser enrichment research?

(d) If a ship was used, at which Australian port(s) UF6 been unloaded and on what date

(e) If an aircraft was used, at which airport(s) in Australia was it landed and on what date(s).

(f) Was ARPANSA consulted by ASNO to provide advice on the safe transportation of this material?

(g) Were NSW emergency services informed on this transport(s)?

(h) Was the NSW Environmental Protection Agency informed of this transport(s)?

(i) In the event of an accident during transportation of UF6, resulting in property or personal damage, which government agency or public corporate entity would be liable for providing compensation to affected parties?

Answer:

(a) ARPANSA has issued a Facility Licence to ANSTO under Section 32 of the *ARPANS Act 1998* that covers the possession and use of various isotopes of Uranium in specified activities. This material may be in various chemical forms, and the licence covers the storage, but not the use, of uranium isotopes in the form of UF6. These materials are of low radiological hazard.

SILEX is a private company dealing with sensitive 'associated technologies' as defined in the *Nuclear Non-Proliferation (Safeguards) Act 1987*. The Safeguards Act is administered by ASNO and implements Australia's obligations under the Convention on the Physical Protection of Nuclear Material. Section 82 of the *ARPANS Act 1998* obliges ARPANSA to comply with the relevant sections of the ASNO Act.

SILEX is located within the Lucas Heights Research Laboratories site and under the tenancy terms must comply with the ANSTO safety arrangements.

Pursuant to the definition of a "controlled person" in the ARPANS Act which includes a "person in a prescribed Commonwealth place" and following amendment in 2000 of the ARPANSA Regulations 1998 that prescribed the site occupied by SILEX (Regulation 6A of the ARPANS Regulations), a Source Licence was issued to SILEX in August 2001.

The SILEX licence was issued under Section 33 of the *ARPANS Act 1998* that allows SILEX to deal with certain small quantities of the various isotopes of Uranium, including in the form of UF6, for the purposes of research.

(b) ARPANSA officers are designated delegates of the Minister for Health under the Customs Prohibited Imports Regulations 1956 and, as such, ARPANSA officers may give import permissions for the importation of radioactive material. Since February 1999 (the commencement of the ARPANS Act) ARPANSA officers has given, to SILEX, three import permissions for three shipments of small quantities of various uranium isotopes, including in the form of UF6. The import permissions were issued on 25 January 2001, 12 August 2002 and 27 August 2002.

No import permissions have been issued by ARPANSA officers under the Customs Prohibited Import Regulations 1956 to ANSTO for UF6 imports.

(c) It is a condition of licence set out in the ARPANS Regulations (Regulation 48) that all licence holders (including ANSTO and SILEX) must comply with the Australian *Code of Practice for the Safe Transport of Radioactive Materials*. As mentioned above, only SILEX has sought and obtained importation permissions from ARPANSA officers in the period from February 1999. The mode of transportation for the small quantities of UF6 imported is by aircraft.

(d) N/A.

(e) This information is unknown to ARPANSA.

(f) This information is unknown to ARPANSA.

(g) This information is unknown to ARPANSA.

(h) No. The import permissions under the Customs Prohibited Imports Regulations 1956 were for small quantities of material for research purposes. The *Code of Practice for the Safe Transport of Radioactive Materials* does not require notification of the shipment of such small quantities of UF6.

(i) The material imported by SILEX is small quantities of low radiological hazard. The determination of liability is a matter for the courts.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-142

OUTCOME 1: Population Health and Safety

Topic: Silex Systems Ltd

Written Question on Notice

Senator McLucas asked:

(a) Does ARPANSA conduct regular inspections of the operations of SILEX SYSTEMS LTD to ensure that the conditions of licenses issued by ARPANSA are not breached?

(b) Provide dates and results of inspections

The ASNO 2002-2003 report states "To assist with reporting to the IAEA, a separate 'material balance area' was created this year for Silex Systems Ltd's laboratories."

(c) Has ARPANSA inspected the newly created material balance area? If so, provide report on inspection.

The ASNO 2001-2003 report states "Tests to produce small (gram quantity) samples marginally enriched or depleted were planned for the second half of 2002. However, equipment problems delayed these tests to early 2003."

The ASNO 2002-2003 report states "During the year the company announced a successful demonstration of the process, achieving a measurable assay change in a gram-sized sample."

A presentation given by SILEX SYSTEMS LTD at their 2003 Annual General Meeting included the line "technical feasibility demonstrated efficient – enrichment."

(d) Does ARPANSA consider it technically possible to prove enrichment "feasibility" without actually enriching uranium?

(e) Would the actual enrichment of uranium be in breach of the license issued to SILEX SYSTEMS LTD?

(f) Is the enrichment of uranium illegal under the ARPANS Act?

(g) Provide all licenses held by SILEX SYSTEMS LTD issued by ARPANSA.

Answer:

(a) ARPANSA monitors compliance with licence conditions through quarterly and annual reporting by the licence holder, and site visits and inspections. ARPANSA reports compliance matters in its quarterly and annual reports to Parliament.

(b) ARPANSA undertook site visits prior to a licence being issued and an inspection was conducted on 16 May 2002, after the licence was issued. The frequency of inspections of licence holders, including SILEX, is planned according to the hazard of the licensed dealing. The inspection concluded that SILEX was satisfactorily complying with all licence conditions and made some recommendations relating to the operations of the laser laboratories.

(c) 'Material balance area' is terminology used by ASNO, the responsible organisation for inventories of nuclear material for accounting purposes to assist with reporting to the IAEA. The terminology does not refer to a physical area as such, has no relevance to the licence issued by ARPANSA and ARPANSA has not inspected the 'material balance area'.

(d) ARPANSA understands that the research being undertaken by SILEX as being within a 'closed loop' process. That is, any enriched UF6 stream of material is recombined with the depleted UF6 stream so that no significant quantity of enriched uranium is accumulated. Analyses of the streams might prove the 'feasibility' of the process without accumulating enriched uranium.

(e) No, provided that the small quantities of the various isotopes of uranium resulting from the process do not exceed the maximum quantities specified in the licence schedules, and the quantities are used for the purposes of research in accordance with the licence.

(f) Paragraph 10(2)(c) of the ARPANS Act prohibits the CEO of ARPANSA from issuing a Section 32 Facility Licence authorising the construction or operation of an enrichment plant.

(g) The license issued to SILEX is attached. However, the inventories of Controlled Apparatus and Controlled Materials cannot be provided because it would be in contravention of section 82 of the *ARPANSA Act 1998* regarding associated technologies.

(5)

AUSTRALIAN RADIATION PROTECTION AND NUCLEAR SAFETY AGENCY

ARPANSA

S0090/01/D

Source Licence

Under Section 33 of the *Australian Radiation Protection and Nuclear Safety Act 1998*, I, John Loy, Chief Executive Officer of ARPANSA issue a Source Licence to:

Silex Systems Limited

that authorises the persons identified below to Deal With Controlled Apparatus or Controlled Material specified in Columns 2 and 3 of Schedule 1 and held by **Silex Systems Limited**, a person in a prescribed Commonwealth place, subject to the following:

1. Conditions, limitations or restrictions in Column 4 of Schedule 1
2. Special Licence Conditions in Schedule 2
3. Organisational Conditions in Part 2 of the Handbook[1]
4. Standard Conditions for Source Licences in Part 3.1 of the Handbook[1]

Persons covered by this Licence are the Licence Holder, employees of the Licence Holder, and all persons in the prescribed Commonwealth place.

ISSUED at SYDNEY, this Seventeenth day of August 2001.

Dr John Loy
CEO of ARPANSA

[1] *Handbook* means the document entitled "*Australian Radiation Protection and Nuclear Safety Agency – Licence Conditions Handbook*" published by ARPANSA and as amended from time to time.

Schedule 1

Kinds of Controlled Material and Controlled Apparatus and associated conditions

Column 1	Column 2 Kind of Controlled Apparatus or Controlled Material	Column 3 Source Details	Column 4 Conditions
Group 1	Laser products with accessible emission levels more than the accessible emission limit of a Class 3B (Restricted) laser product, set out in Australia/New Zealand Standard AS/NZS 2211.1:1997	Controlled Apparatus as specified in Source Inventory[2]	Handbook, Part 1 Handbook, Part 2 Handbook, Part 3, 3.1 Handbook, Part 3, 3.2, 3.2.4 Table H (Green)
Group 2	Unsealed source, or sources, in a laboratory or premises, having nuclides such that when the maximum activity of each nuclide in the source, or sources, is divided by the amount mentioned in column 4 of Part 2 of Schedule 2 of the Regulations for that kind of nuclide, the total of the results for all nuclides in the source, or sources, is more than 10^4, but not more than 10^4, as specified in Source Inventory[2]	Unsealed Controlled Material in one location as specified in Source Inventory[3]	Handbook, Part 1 Handbook, Part 2 Handbook, Part 3, 3.1 Handbook, Part 3, 3.2, 3.2.2 Table G (Blue)

2 *Source Inventory* means the Licence Holder's current inventory of Controlled Apparatus and Controlled Material as amended from time to time in compliance with Special Licence Condition 1 in Schedule 2.
3 *Source Inventory* means the Licence Holder's current inventory of Controlled Apparatus and Controlled Material as amended from time to time in compliance with Special Licence Condition 1 in Schedule 2.

Schedule 2
Special Licence Conditions

1. The Licence Holder must provide to the CEO on a quarterly basis and in a form acceptable to the CEO, an updated inventory of all Controlled Material and Controlled Apparatus held by Silex Systems Limited. The Licence Holder must also provide to the CEO a summary of all changes made to the inventory during the preceding quarter.

2. The Licence Holder must provide to the CEO the final version of the Memorandum of Understanding (MOU) with USEC, including copies of all documents referenced in the MOU.

3. The Licence Holder must ensure that all persons involved in the laboratory experiments associated with the project have successfully completed an accredited Laser safety course.

4. The Licence Holder must ensure compliance with the requirements of the SAC approval 1445/00 and other SAC approvals that may be issued by the Australian Nuclear Science and Technology Organisation from time to time.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-143

OUTCOME 1: Population Health and Safety

Topic: ANSTO

Written Question on Notice

Senator McLucas asked:

(h) Provide all licenses held by ANSTO for equipment and materials related to research into laser enrichment.

(i) ARPANSA monitors atmospheric radioactive discharges that result from the activities of ANSTO.

(j) Does ARPANSA have a similar monitoring system in place to detect atmospheric discharges from uranium enrichment research?

(k) Provide details of monitoring.

A presentation given by SILEX SYSTEMS LTD at 2003 Annual General Meeting in relation to the uranium enrichment projects states "economic feasibility underway – Pilot Plant Program, commission Pilot Plant Q1 '04."

(l) Has ARPANSA been consulted in relation to regulatory matters applicable to the construction of a pilot plant to continue the SILEX uranium enrichment research? If so, provide details of communications.

(m) Has ARPANSA inspected the waste storage facility operated by SILEX SYSTEMS LTD on the premises it leases from ANSTO at Lucas Heights?

(n) Provide details as to how the waste is stored, and the volume, form and isotopic content of the waste.

(o) Has SILEX SYSTEMS LTD or ANSTO provided ARPANSA with any proposals for the long-term storage or disposal of the waste generated during laser enrichment research? Provide details.

Answer:

(a) No licences have been issued to ANSTO for equipment and materials for research into laser enrichment.

(b) Yes.

(c) The atmospheric monitoring undertaken for the ANSTO site covers all radioactive materials, including uranium.

(d) Results of ANSTO air monitoring are reported in the ARPANSA quarterly reports to Parliament.

(e) No, there have been no consultations going beyond the activities currently licensed by the CEO of ARPANSA.

(f) There is no 'waste storage facility' operated by SILEX. The little radioactive waste generated by SILEX, is mainly lightly contaminated gloves which are stored in a sealed drum in a secure area within the SILEX facility. ANSTO does not accept radioactive waste arising from the operations at SILEX.

(g) The Waste Management Plan approved by ARPANSA requires the information on volume, form and isotopic content to be held by SILEX. ARPANSA does not maintain copies of the details on the waste, but requires the license holder to maintain such inventories and make them available to ARPANSA for audit.

(h) No.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-216

OUTCOME 1: Population Health and Safety

Topic: IAEA Report

Hansard Page: CA70

Senator Wong asked:

Who are the members of the team who are preparing the draft International Atomic Energy Agency Report

Answer:

The members of the team who are preparing the draft International Atomic Energy Agency report are as follows:

- Phil Metcalf – Head of Radioactive Waste Disposal Safety Section of the IAEA; former Deputy General Manager of the South African Nuclear Safety Regulator; Chair of the IAEA Waste Safety Standards Advisory Committee;

- Karoly Berci – Nuclear engineer, ETU Power Engineering and Contractor Company, Hungary; extensive experience with nuclear power plant and radioactive waste facility safety assessments;

- Gerard Bruno – French Institute for Radioprotection and Safety (IRSN). The IRSN is the technical adviser to the French radiation protection and nuclear safety agency;

- Ian Crossland – Independent consultant based in the UK; wide experience in nuclear safety issues having held senior positions with a UK nuclear electricity generator and the UK's radioactive waste disposal company, Nirex;

- Matthew Kozak – Principal consultant for Monitor Scientific, USA; served on the US National Academy of Sciences and the US National Council on Radiation Protection and Measurements committees on radioactive waste management.

ARPANSA issued a media release on 29 January about the visiting five-member IAEA peer review team and its mission and drew attention to the team member profiles posted on the ARPANSA Proposed National Radioactive Waste Repository webpage (www.arpansa.gov.au/reposit/nrwr.htm).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-217

OUTCOME 1: Population Health and Safety

Topic: ANSO and ARPANSA

Hansard Page: CA76

Senator McLucas asked:

Can you explain why there is a discussion between ASNO and ARPANSA about SILEX

Answer:

The CEO of ARPANSA and the Director General of Safeguards have overlapping responsibilities for safety and security under their respective enabling legislation, the Australian
Radiation Protection and Nuclear Safety Act 1998 and the Nuclear Non-Proliferation (Safeguards) Act 1987. Sections 9 and 82 of the ARPANSA Act 1998 requires the concurrent operation of the two Acts. Any discussions between ASNO and ARPANSA about SILEX have been to ensure that the powers and obligations of the two agencies, under the two Acts, are exercised coherently.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-218

OUTCOME 1: Population Health and Safety

Topic: Proposals for Storage and Disposal of Waste

Hansard Page: CA 77

Senator McLucas asked:

Have you received any communication about proposals for storage and disposal of waste generated by Silex Systems Ltd in their current or proposed operations?

Answer:

Other than the Waste Management Plan in the original application by SILEX for a licence, there has been no communication about proposals for SILEX to store or dispose of wastes.

The Medicare tables may be are accessed at:

http://www.health.gov.au/haf/medstats/#tabled

Expenditure and prescriptions twelve months to 31 December 2003 – Pharmaceutical Pricing Section, Pharmaceutical Benefits Branch may be accessed at:

http://www.health.gov.au/pbs/general/pubs/pbbexp/index.htm

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-165

OUTCOME 2: ACCESS TO MEDICARE

Topic: PERFORMANCE ASSESSMENT MECHANISMS

Written Question on Notice

Senator Carr asked:

(a) Please provide full details of each of the performance assessment mechanisms linked to the pay outcomes or other financial reward of individual employees, including:

i) What are the current process/es of performance assessment within the portfolio agency? If more than one, please provide details of each, and the employee category it applies to.

ii) For each of the performance assessment process/es identified in i), please list the range of outcome results an employee can achieve from each of the performance assessment processes identified in i);

iii) For each of the performance assessment process/es identified in i), what pay or other financial change is linked to each outcome or result for the employee from the performance assessment [ie, the pay increase or one-off bonus or classification or level change];

iv) For each of the performance assessment process/es identified in i), what is the classification level of employees subject to this performance assessment (eg SES, EL1, EL2 or APS and equivalent);

v) What is the principal industrial or other instrument governing each of the performance assessment mechanism/s (eg the certified agreement or AWA);

vi) Does the performance assessment operate over a common cycle? Please provide the commencement and dates of the most recent full cycle of each of the assessment process/es.

(b) For each performance assessment mechanism in (a), advise the number of male and the number of female employees at each possible outcome, by classification level for the most recent full cycle (if the performance mechanism does not operate over a common cycle, aggregate outcomes using the 2002-03 financial year).

Answer:

(a) i) The Health Insurance Commission (HIC) has a performance management framework for its employees. This determines the extent to which an employee does not meet, fully meets or exceeds expectations, in respect of performance goals and measures, and is established in a performance agreement.

The HIC's Performance Support Program requires managers and staff to develop an annual Performance Support Agreement (PSA). The PSA covers the performance goals to be achieved by the employee, how the goals will be achieved and what the supervisor and the HIC will do to support the employee to achieve the goals.

ii) The rating scales applying to senior executives and employees below the senior executive level are similar and provide for assessment outcomes based on the following:

Performance Assessment/Outcome	Rating
The employee has met and exceeded expectations in all essential performance goals.	5
The employee has met all essential performance goals and exceeded expectations in one or more, but not all.	4
The employee has met all essential performance goals.	3
One of the employee's essential performance goals is assessed as not met.	2
More than one of the employee's essential performance goals is assessed as not met.	1

iii) Senior executives are eligible, unless prescribed otherwise in an Australian Workplace Agreement (AWA), for the bonus payments outlined in the following table. Employees below the senior executive level (excluding those in Information Technology (IT) roles as outlined below) who are covered by an AWA, are also eligible for bonus payments as outlined in this table:

Rating	Bonus Payment (% of salary)
5	10 – 12%
4	6 – 9%
3	2 – 5%
2	Nil
1	Nil

Employees, below the senior executive level, in IT roles and covered by AWAs, are eligible for the following bonus amounts:

Non-Senior Executive (IT)

Rating	Team Leader	Technical Specialist
5	5 - 10%	4 - 8%
4	3 - 5%	2 - 4%
3	0 - 3%	0 - 2%
2	Nil	Nil
1	Nil	Nil

iv) See answer to iii) above.

v) The performance management framework for employees below the senior executive level is provided for under the *HIC (Managing Change) Certified Agreement 2003-2005*. Access to performance bonus payments is facilitated through individual AWAs for senior executives and those employees below the senior executive level who receive an AWA.

vi) Yes. The last completed performance cycle was for the period 1 July 2002 to 30 June 2003.

(b) For the last completed performance cycle (1 July 2002 to 30 June 2003) the number of male and female employees in the HIC covered by an AWA, aggregated by classification level and performance assessment rating, is shown in the attached tables:

Senior Executives and Medical Officers

(**Note:** To protect the privacy of individuals, all Executives have been grouped under the Senior Executive title.)

Classification/Rating	**Male**	**Female**
Senior Executive		
Rating: 5	5	0
4	20	15
3	9	2
2	1	1
Medical Officers		
Rating: 5	0	0
4	10	3
3	4	3
Total	49	24

Employees below the Senior Executive level

(Note: During the 2002-03 performance cycle, employees below the Senior Executive level were subject to a 4-point rating scale under the HIC's Performance Support Program. To protect the privacy of individuals, relevant employees below the Senior Executive level have been grouped together, according to gender).

Relevant employees below the Senior Executive level		
Classification/Rating	**Male**	**Female**
Rating: 4	59	47
3	41	30
2	1	1
Total:	101	78

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question:E04-167

OUTCOME 2 : ACCESS TO MEDICARE

Topic: Performance Assessment Mechanisms

Written Question on Notice

Senator Carr asked:

(a) Please provide full details of each of the performance assessment mechanisms linked to the pay outcomes or other financial reward of individual employees, including;
   i. What are the current process/es of performance assessment within the portfolio agency? If more than one, please provide details of each, and the employee category it applies to.
   ii. For each of the performance assessment process/es identified in (i), please list the range of outcome results an employee can achieve from each of the performance assessment processes identified in (i);
   iii. For each of the performance assessment process/es identified in (i), what pay or other financial change is linked to each outcome or result for the employee from the performance assessment [ie, the pay increase or one-off bonus or classification or level change];
   iv. For each of the performance assessments identified in (i), what is he classification level of employees subject to this performance assessment (eg SES, EL1, EL2 or APS and equivalent);
   v. What is the principal industrial or other instrument governing each of the performance assessment mechanism/s (eg, the certified agreement or AWA);
   vi. Does the performance assessment operates over a common cycle? Please provide the commencement and end dates of the most recent full cycle of each of the assessment process/es.

(b) For each performance assessment mechanism described in (a), advise the number of male and the number of female employees at each possible outcome, by classification level for the most recent full cycle (if the performance mechanism does not operate over a common cycle - aggregate outcomes using the 2002-03 financial year).

Answer:

(a)

(i) Professional Services Review (PSR) conducts a performance management and development system called the Performance Development Scheme, similar to that used in the Department of Health and Ageing. This is the foundation platform for assessing the performance of all staff within the agency.

(ii) 1. All employees who achieve a rating of fully effective, or higher, will progress to the next pay scale increment until they reach the top of the range, as outlined in the PSR Certified Agreement (CA).
2. In addition, any employee may negotiate an AWA which may include performance pay. All PSR staff are able to negotiate an AWA. Currently there are four staff who have negotiated their eligibility for a performance bonus (1 X SES Level 1, 2 X EL2 and 1 X EL1).

(iii) 1. Progression to the next increment level within the classification on the pay scale if the employee attains a rating of fully effective, or higher. The pay scales are detailed in Attachment A of the PSR CA.

2. For those staff who have negotiated a performance bonus into their AWA, they are paid at the following rates:

3-4% for staff with a rating of fully effective (4-6% for SES1);
6-8% for staff with a rating of superior (7-10% for SES1); and
11-13% for staff with a rating of outstanding (12-15% for SES1).

(iv) All staff participate in the Performance Development Scheme (including the SES Level).

(v) 1. The performance assessment mechanism is outlined in Attachment 3 of the PSR CA. Progression to the next pay scale increment for performance rated as fully effective, or higher, is outlined in section 3 Part B of the PSR CA.

2. The performance assessment mechanism is outlined in Attachment 3 of the PSR CA. The instrument governing the payment of a performance bonus is an individually negotiated AWA.

3. The SES level not being covered by the PSR CA abide by the SES Remuneration policy and an individually negotiated AWA.

(vi) A performance agreement is negotiated at the commencement of the cycle on 1 July of every year and concludes on 30 June of the next year. The most recent full cycle commenced on 1 July 2002 and concluded on 30 June 2003.

(b)

Aggregated Increment increases paid to male staff

Aggregated Classification Levels	Total Number of Staff	Aggregated Amount Paid
EL1 - SES1	7	$3,587
APS 3 - APS 6	5	$1,111

Aggregated Increment increases paid to female staff

Aggregated Classification Levels	Total Number of Staff	Aggregated Amount Paid
EL1 - EL2	4	$9,287
APS 4 - APS 6	11	$9,750

For the performance assessment period of July 2002 to June 2003, PSR paid a total of $22,211 in performance pay to three staff.

As PSR is a small agency of 27 staff, the above details have been aggregated so that specific payments cannot be associated with individual staff members.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-054

OUTCOME 2: Access to Medicare

Topic: ABORTIONS FUNDED BY MEDICARE - STATISTICS

Written Question on Notice

Senator Harradine asked:

In answer to question 45 at the budget estimates hearings in 2000-2001 the Department provided statistics on abortions funded by Medicare. Please provide an updated table to match the one provided earlier, including the number of services and benefits paid for 2000-01, 2001-02 and 2002-03.

Answer:

The definitions of medical services included in the Schedule to the Health Insurance Act which may result in the termination of pregnancy have not changed since 2000-2001.

A table showing the number of services and benefits paid, by item number and by the State in which the services were rendered in the period 2000-01 to 2002-03, is attached.

The attached data only relate to services rendered on a 'fee-for-service' basis for which Medicare benefits were paid. Excluded are details of services to public patients in hospital and through other publicly funded programs.

MEDICARE: ITEMS 16525 AND 35643									
NUMBER OF SERVICES AND BENEFITS PAID									
BY STATE/TERRITORY OF SERVICE PROVISION									
2000-01, 2001-02 AND 2002-03									
Item No/	**NSW**	**VIC**	**QLD**	**SA**	**WA**	**TAS**	**NT**	**ACT**	**AUST**
Year									
16525									
	Number of Services								
2000-01	200	247	125	55	45	10	(a) 10	(b)	692
2001-02	198	208	114	57	41	8	(a) 10	(b)	636
2002-03	243	171	135	54	31	8	(a) 18	(b)	660
	Benefits Paid ($)								
2000-01	34,368	42,079	21,551	9,503	7,737	1,716	(a) 1,714	(b)	118,668
2001-02	34,399	36,108	19,854	9,795	7,077	1,392	(a) 1,727	(b)	110,352
2002-03	43,110	30,290	24,065	9,580	5,553	1,430	(a) 3,207	(b)	117,235
35643									
	Number of Services								
2000-01	(c) 35,150	18,982	13,081	546	7,552	492	108	(d)	75,911
2001-02	(c) 35,368	18,360	13,124	667	8,001	544	144	(d)	76,208
2002-03	(c) 33,563	17,780	13,000	639	7,260	910	115	(d)	73,267
	Benefits Paid ($)								
2000-01	(c) 4,839,114	2,500,398	1,839,502	66,332	1,069,126	65,029	13,156	(d)	10,392,657
2001-02	(c) 4,946,965	2,396,950	1,867,044	82,622	1,140,691	74,287	18,093	(d)	10,526,652
2002-03	(c) 4,801,529	2,337,838	1,857,424	80,593	1,061,293	132,914	14,695	(d)	10,286,286
(a) Includes statistics for ACT.									
(b) Statistics included in NT.									
(c) Includes statistics for ACT.									
(d) Statistics included in NSW.									

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-055

OUTCOME 2: Access to Medicare

Topic: STATISTICS ON CONSUMER MEDICINE INFORMATION DOCUMENTS

Written Question on Notice

Senator Harradine asked:

The Department provided me with a range of statistics on Consumer Medicine Information (CMI) documents in response to Question E03-042 (Supplementary Budget Estimate 2003-2004). Please provide me with the equivalent statistics for Tasmania.

Answer:

The number of approved pharmacies (those approved to supply pharmaceutical benefits) in Tasmania for each of the past three financial years is:

Active approval (date of effect)	**Number of Pharmacies**
As at 30 June 2001	140
As at 30 June 2002	140
As at 30 June 2003	139

The amount paid to Tasmanian pharmacies under the Medicines Information to Consumers (MIC) Program for each of the last financial years is outlined below:

MIC Payments (date of effect)	**2000-01 (GST exclusive)**	**2001-02 (GST exclusive)**	**2002-03 (GST exclusive)**
Readiness Payment (August 2001)	nil	$420,000	nil
Registration Incentive (December 2002)	nil	nil	$124,000
Participation Allowance (from January 2003)	nil	nil	$138,738

The number of approved pharmacies in Tasmania which have received the MIC Readiness Payment and the MIC Registration Incentive, and this number as a proportion of the total Tasmanian pharmacies approved to supply pharmaceutical benefits, are outlined below:

MIC Payments (date of effect)	Pharmacies which received payment	Total number of approved pharmacies	Proportion
Readiness Payment (August 2001)	140	140	100%
Registration Incentive (December 2002)	124	140	88%

The number of approved pharmacies in Tasmania which have received the MIC Participation Allowance (payable every two months), and this number as a proportion of the total Tasmanian pharmacies approved to supply pharmaceutical benefits, are outlined below:

PHARMACIES	Jan – Feb 2003	Mar – Apr 2003	May – Jun 2003	Jul – Aug 2003	Sep – Oct 2003	Nov – Dec 2003
Number	13	77	101	112	107	98
Proportion	9%	55%	72%	80%	77%	70%

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-117

OUTCOME 2: Access to Medicare

Topic: MEDICAREPLUS AND THE NATIONAL STRATEGIC FRAMEWORK FOR ATSI HEALTH

Written Question on Notice

Senator Stephens asked:

(a) Was this Strategic framework taken into account in the formulation of the "**MedicarePlus**" package?

(b) What consultation took place with those who formulated the "**MedicarePlus**" package?

(c) Those in remote areas of Australia would often need to travel for health services; do you know if such travel-related expenses have been taken into account in determining the safety net subsidies?

Answer:

(a) **MedicarePlus** reflects key principles of *The National Strategic Framework for Aboriginal and Torres Strait Islander Health* (the *National Strategic Framework*). In particular, it contributes to addressing the strategic priority of **strengthening comprehensive primary health care.** Enhancements to the package announced by the Minister on 10 March 2004 strengthen its contribution to **improving social and emotional wellbeing** and **improving data availability and quality**.

MedicarePlus provides $2.85 billion over the next four years to protect and strengthen Medicare for all Australians, but especially for children, concession card holders and the chronically ill attending general practitioners for primary care. Compared to the general population, much higher proportions of the Aboriginal and Torres Strait Islander population fall into these categories, and so the changes in **MedicarePlus** are of particular relevance to Aboriginal and Torres Strait Islander people.

- **MedicarePlus** will help to ensure children under 16 and concession card holders are bulk billed by GPs, by providing an incentive payment to GPs to do this.

  - 75% of the Aboriginal and Torres Strait Islander population is estimated to be eligible for Commonwealth Concession Cards.

- more than 40% of the Aboriginal and Torres Strait Islander population are children aged 16 years or younger.

- In regional, rural and remote areas and in all of Tasmania, the incentive payment will be $7.50 for each bulk billed MBS service provided to an eligible patient. In the rest of Australia it will be $5 for each bulk billed MBS service provided to an eligible patient.

  - More than a third of Aboriginal and Torres Strait Islander people live in regional, rural and remote areas, compared to 6 per cent of the general population, and many of those living in regional, rural and remote areas access services through Aboriginal Medical Services.

  - Under particular arrangements, the services of GPs working in Aboriginal Medical Services (AMSs) are generally eligible for Medicare rebates and so consultations with eligible patients will attract the $7.50 or the $5 incentive depending on where the service is provided.

- The **MedicarePlus** safety net reimburses 80% of out of pocket costs for medical services provided outside hospital once an annual threshold is reached. For Commonwealth Concession Card holders and families who receive Family Tax Benefit (A), the safety net will apply once annual costs reach $300 per individual or family. For all other Australians, an annual threshold of $700 per individual or family applies.

  - As around 75% of our Aboriginal and Torres Strait Islander population is estimated to be eligible for Commonwealth Concession Cards, many will be eligible for the lower threshold.

- The availability of a doctor is central to accessing affordable medical services. **MedicarePlus** invests over $1 billion in increasing and supporting the medical workforce, with a focus on areas with the greatest need for a doctor or nurse. Areas of need often align with rural and remote localities and the outskirts of major cities. Workforce measures of particular note include:

  - Grants to support employment of practice nurses and allied health professionals (including Aboriginal health workers) in general practice. 457 full time positions will be supported focussed on urban areas of workforce shortage.

  - Measures that will see more overseas trained doctors practising in areas of need.

  - 246 new additional medical school places, bonded to areas of workforce shortage for 6 years, to help meet the health care needs of growing rural and regional areas.

- The *National* Strategic *Framework* calls for support for immunisation services provided by nurses in order to promote preventive health and the provision of culturally appropriate care.

  - New MBS items are available to enable practice nurses to provide immunisation and wound management services to patients on behalf of a GP.

  - Medicare payments will also be available for up to five allied health consultations delivered to patients with chronic conditions and complex needs who are being managed under an Enhanced Primary Care (EPC) multidisciplinary care plan.

  - These services, which will be provided for and on behalf of the patient's GP, are particularly relevant to Aboriginal people and Torres Strait Islanders who, on average, suffer a higher burden of chronic disease than the non-Indigenous population. Aboriginal health workers are amongst the eligible allied health providers.

- Overcoming the shortcomings of data and information is another key focus of the *National Strategic Framework.*

  - Under **MedicarePlus**, the Government is investing in the roll out of a national information network that will provide secure electronic health records for people wherever they go in the health system. This means that people will no longer need to recall their medical history and medication regime when they attend the doctor – doctors and health providers will be able to access information through a secure records system wherever people present for care.

MedicarePlus will help to make Medicare more relevant to the needs of Aboriginal and Torres Strait Islander people by improving affordability, and increasing the range of services supported through Medicare.

The Government will also continue to implement other measures targeted specifically towards improving access for Indigenous Australians, including improving rates of Medicare enrolment, and the provision of Indigenous specific services to complement the availability of primary health care services.

(b) The Government's proposed changes to Medicare have been the subject of two Senate Committee inquiries. As part of this process, organisations and individuals were invited to express their views through submissions to, and appearances before, the Committee. The Government considered the views of the community and parliamentarians during this period of debate.

(c) No. As is the case with the existing safety net, only fees charged for out of hospital services on the Medicare Benefits Schedule will qualify for the new **MedicarePlus** safety net.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-144

OUTCOME 2: Access to Medicare

Topic: BULK BILLING RATES BY ELECTORATE

Written Question on Notice

Senator McLucas asked:

Please provide Medicare bulk billing rates by electorate for December 03 and March 04.

Answer:

Medicare statistics by electorate are no longer produced on a quarterly basis. Statistics by electorate are available on a calendar year basis.

The percentage of non-referred (GP) attendances bulk billed by electorate for the 12 months ending December 2003, is as follows:

MEDICARE: NON-REFERRED (GP) ATTENDANCES
PERCENTAGE OF SERVICES BULK BILLED BY ELECTORATE
TWELVE MONTHS ENDING DECEMBER 2003

Federal Electorate	
Adelaide	60.8%
Aston	71.1%
Ballarat	43.2%
Banks	84.5%
Barker	39.9%
Barton	91.2%
Bass	43.6%
Batman	83.3%
Bendigo	48.2%
Bennelong	80.0%
Berowra	70.0%
Blair	71.8%
Blaxland	95.5%
Bonython	87.1%
Boothby	52.1%
Bowman	66.1%
Braddon	48.9%

Bradfield	59.7%

MEDICARE: NON-REFERRED (GP) ATTENDANCES
PERCENTAGE OF SERVICES BULK BILLED BY ELECTORATE
TWELVE MONTHS ENDING DECEMBER 2003

Federal Electorate	
Brand	59.8%
Brisbane	59.2%
Bruce	76.0%
Burke	59.1%
Calare	59.4%
Calwell	81.5%
Canberra	39.8%
Canning	54.2%
Capricornia	45.7%
Casey	59.6%
Charlton	56.0%
Chifley	98.3%
Chisholm	72.7%
Cook	74.3%
Corangamite	41.8%
Corio	57.9%
Cowan	73.2%
Cowper	51.9%
Cunningham	81.0%
Curtin	55.6%
Dawson	63.6%
Deakin	64.6%
Denison	47.4%
Dickson	48.2%
Dobell	57.8%
Dunkley	47.6%
Eden-Monaro	37.9%
Fadden	68.7%
Fairfax	56.1%
Farrer	41.0%
Fisher	62.1%
Flinders	44.5%
Forde	76.9%
Forrest	53.6%
Fowler	97.5%
Franklin	51.5%
Fraser	35.0%
Fremantle	64.6%
Gellibrand	85.0%
Gilmore	60.4%
Gippsland	46.1%

Goldstein	55.7%
Grayndler	90.6%
Greenway	94.4%
Grey	67.5%

MEDICARE: NON-REFERRED (GP) ATTENDANCES
PERCENTAGE OF SERVICES BULK BILLED BY ELECTORATE
TWELVE MONTHS ENDING DECEMBER 2003

Federal Electorate	
Griffith	59.5%
Groom	51.0%
Gwydir	64.4%
Hasluck	69.2%
Herbert	61.0%
Higgins	60.5%
Hindmarsh	62.5%
Hinkler	44.5%
Holt	76.1%
Hotham	76.4%
Hughes	75.7%
Hume	59.1%
Hunter	49.4%
Indi	29.8%
Isaacs	65.1%
Jagajaga	68.1%
Kalgoorlie	61.3%
Kennedy	59.3%
Kingsford-Smith	88.1%
Kingston	56.7%
Kooyong	58.3%
La Trobe	62.4%
Lalor	77.2%
Leichhardt	75.9%
Lilley	60.6%
Lindsay	87.1%
Lingiari	68.5%
Longman	70.7%
Lowe	91.3%
Lyne	57.7%
Lyons	65.9%
Macarthur	89.5%
Mackellar	71.5%
Macquarie	71.1%
Makin	60.8%
Mallee	54.1%
Maranoa	54.0%
Maribyrnong	82.4%
Mayo	49.0%

McEwen	60.9%
McMillan	67.6%
McPherson	70.2%
Melbourne	79.9%
Melbourne Ports	70.5%
Menzies	70.0%

MEDICARE: NON-REFERRED (GP) ATTENDANCES
PERCENTAGE OF SERVICES BULK BILLED BY ELECTORATE
TWELVE MONTHS ENDING DECEMBER 2003

Federal Electorate	
Mitchell	80.6%
Moncrieff	66.8%
Moore	64.1%
Moreton	67.0%
Murray	31.5%
New England	48.2%
Newcastle	61.8%
North Sydney	60.1%
O'Connor	50.1%
Oxley	73.9%
Page	46.9%
Parkes	66.5%
Parramatta	90.7%
Paterson	53.5%
Pearce	70.4%
Perth	72.2%
Petrie	57.1%
Port Adelaide	80.1%
Prospect	96.9%
Rankin	81.3%
Reid	97.1%
Richmond	62.9%
Riverina	46.3%
Robertson	61.8%
Ryan	49.1%
Scullin	84.8%
Shortland	51.3%
Solomon	55.7%
Stirling	73.2%
Sturt	51.8%
Swan	72.4%
Sydney	83.0%
Tangney	61.4%
Throsby	94.2%
Wakefield	44.1%
Wannon	42.2%
Warringah	69.2%

Watson	95.5%
Wentworth	71.4%
Werriwa	95.3%
Wide Bay	60.5%
Wills	79.0%
Total	67.7%

Notes to the Statistics

These statistics relate to non-referred (general practitioner) attendances that were rendered on a 'fee-for-service' basis and for which benefits were processed by the Health Insurance Commission in the 12 months to December 2003. Excluded are details of non-referred attendances to public patients in hospital, to Department of Veterans' Affairs patients and some compensation cases.

The statistics were compiled from Medicare data by patient enrolment (mailing address) postcode. Where a postcode overlapped electoral boundaries, the statistics were allocated to electorate using a concordance file derived from Population Census data, showing the proportion of the population of each postal area, in each electorate.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-145

OUTCOME 2: Access to Medicare

Topic: OUT OF POCKET EXPENSES

Written Question on Notice

Senator McLucas asked:

Please provide information on out of pocket costs by electorate for December 03 and March 04.

Answer:

Medicare statistics by electorate are no longer produced on a quarterly basis. Statistics by electorate are available on a calendar year basis.

The average patient contribution per service (patient billed non-hospital services only) for non-referred general practitioner attendances, by electorate, in the 12 months ending December 2003, is as follows:

MEDICARE: NON-REFERRED (GP) ATTENDANCES
AVERAGE PATIENT CONTRIBUTION PER SERVICE
PATIENT BILLED NON-HOSPITAL SERVICES
BY ELECTORATE, 2003 (YEAR OF PROCESSING)

Federal Electorate	*Gap/Service*
Adelaide	$11.84
Aston	$15.10
Ballarat	$11.33
Banks	$12.01
Barker	$10.88
Barton	$14.84
Bass	$12.16
Batman	$13.69
Bendigo	$11.68
Bennelong	$16.15
Berowra	$15.80
Blair	$10.56
Blaxland	$11.13
Bonython	$9.01
Boothby	$11.47

Bowman	$13.59

MEDICARE: NON-REFERRED (GP) ATTENDANCES
AVERAGE PATIENT CONTRIBUTION PER SERVICE
PATIENT BILLED NON-HOSPITAL SERVICES
BY ELECTORATE, 2003 (YEAR OF PROCESSING)

Federal Electorate	*Gap/Service*
Braddon	$8.91
Bradfield	$20.00
Brand	$10.67
Brisbane	$14.57
Bruce	$14.78
Burke	$13.63
Calare	$12.75
Calwell	$12.06
Canberra	$18.11
Canning	$11.65
Capricornia	$12.24
Casey	$14.39
Charlton	$12.68
Chifley	$15.49
Chisholm	$15.65
Cook	$13.85
Corangamite	$12.65
Corio	$11.87
Cowan	$12.30
Cowper	$12.07
Cunningham	$11.01
Curtin	$16.95
Dawson	$16.57
Deakin	$14.57
Denison	$10.44
Dickson	$13.35
Dobell	$11.23
Dunkley	$13.36
Eden-Monaro	$13.53
Fadden	$13.62
Fairfax	$10.05
Farrer	$12.46
Fisher	$11.01
Flinders	$11.97
Forde	$11.98
Forrest	$13.47
Fowler	$12.69
Franklin	$10.69

Fraser	$17.41
Fremantle	$15.76
Gellibrand	$13.52
Gilmore	$12.65
Gippsland	$10.46
Goldstein	$17.36

MEDICARE: NON-REFERRED (GP) ATTENDANCES
AVERAGE PATIENT CONTRIBUTION PER SERVICE
PATIENT BILLED NON-HOSPITAL SERVICES
BY ELECTORATE, 2003 (YEAR OF PROCESSING)

Federal Electorate	*Gap/Service*
Grayndler	$19.21
Greenway	$18.16
Grey	$9.96
Griffith	$14.93
Groom	$12.77
Gwydir	$12.83
Hasluck	$12.89
Herbert	$15.85
Higgins	$18.85
Hindmarsh	$10.79
Hinkler	$12.18
Holt	$12.10
Hotham	$12.91
Hughes	$13.51
Hume	$14.94
Hunter	$12.70
Indi	$11.21
Isaacs	$12.72
Jagajaga	$14.43
Kalgoorlie	$15.77
Kennedy	$13.95
Kingsford-Smith	$16.57
Kingston	$9.78
Kooyong	$18.36
La Trobe	$14.86
Lalor	$12.08
Leichhardt	$14.50
Lilley	$14.65
Lindsay	$13.23
Lingiari	$18.00
Longman	$10.67
Lowe	$19.06
Lyne	$10.50
Lyons	$10.90

Macarthur	$13.56
Mackellar	$19.46
Macquarie	$13.51
Makin	$10.78
Mallee	$12.12
Maranoa	$13.14
Maribyrnong	$12.89
Mayo	$11.86
McEwen	$12.66
McMillan	$11.52

MEDICARE: NON-REFERRED (GP) ATTENDANCES
AVERAGE PATIENT CONTRIBUTION PER SERVICE
PATIENT BILLED NON-HOSPITAL SERVICES
BY ELECTORATE, 2003 (YEAR OF PROCESSING)

Federal Electorate	*Gap/Service*
McPherson	$14.74
Melbourne	$17.87
Melbourne Ports	$18.43
Menzies	$15.78
Mitchell	$19.20
Moncrieff	$15.84
Moore	$12.91
Moreton	$14.41
Murray	$13.65
New England	$12.06
Newcastle	$13.63
North Sydney	$20.16
O'Connor	$13.20
Oxley	$11.35
Page	$11.83
Parkes	$13.56
Parramatta	$14.76
Paterson	$13.19
Pearce	$13.00
Perth	$13.23
Petrie	$12.34
Port Adelaide	$10.41
Prospect	$13.65
Rankin	$13.41
Reid	$13.34
Richmond	$10.88
Riverina	$13.72
Robertson	$11.30
Ryan	$15.31
Scullin	$12.59

Shortland	$11.69
Solomon	$20.99
Stirling	$13.01
Sturt	$11.94
Swan	$14.09
Sydney	$21.44
Tangney	$16.62
Throsby	$12.50
Wakefield	$10.59
Wannon	$10.58
Warringah	$21.03
Watson	$14.20
Wentworth	$22.46
Werriwa	$12.61

MEDICARE: NON-REFERRED (GP) ATTENDANCES
AVERAGE PATIENT CONTRIBUTION PER SERVICE
PATIENT BILLED NON-HOSPITAL SERVICES
BY ELECTORATE, 2003 (YEAR OF PROCESSING)

Federal Electorate	*Gap/Service*
Wide Bay	$10.55
Wills	$12.79
Total	$13.48

Notes to the Statistics

These statistics relate to non-referred (general practitioner) attendances that were rendered on a 'fee-for-service' basis and for which benefits were processed by the Health Insurance Commission in 12 months to December 2003 (year of processing). Excluded are details of non-referred attendances to public patients in hospital, to Department of Veterans' Affairs patients and some compensation cases.

Average out of pocket costs relate to non-hospital patient billed services, and are the difference between aggregate fees charged and aggregate benefits paid, divided by the number of services. It is not possible to compute accurate statistics on the average patient contribution per service for patient billed services in hospital, since the Medicare system does not record gap payments under private health insurance arrangements.

The statistics were compiled from Medicare data by patient enrolment (mailing address) postcode. Where a postcode overlapped electoral boundaries, the statistics were allocated to electorate using a concordance file derived from Population Census data, showing the proportion of the population of each postal area, in each electorate.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-187

OUTCOME 2: Access to Medicare

Topic: MBS QUARTERLY STATISTICS

Hansard Page: CA 8

Senator McLucas asked:

(a) How statistically relevant are these so-called distortions?

(b) What is the cost of providing the statistics each quarter? Mr Abbott has said that it costs $100,000 for the Department to comply with the request. Is that annually? (This is to include ASL and computer time).

(c) Did the Department advise Mr Abbott of the cost of producing these quarterly figures? I want to know when the information was requested and when it was provided, if in fact it was, or whether this is just a figure that Mr Abbott made up?

(d) The point that comes to mind is that in some electorates there are only individual specialists. Could it be produced by State?

Answer:

(a) The accuracy of Medicare statistics depends on:
(i) whether the statistics are based on period of service or period of processing data;
(ii) the time period in respect of which the statistics are compiled;
(iii) the geographic region for which the statistics are compiled; and
(iv) the underlying method used in compiling the statistics.

In combination, these factors create a level of distortion which is greater for a shorter time period or a smaller area.

In regard to (i), (ii) and (iii) above, where Medicare bulk billing statistics are compiled by electorate by quarter, there can be very minor movements in bulk billing rates in successive quarters. For example, between the June and September quarters 2003, 28 per cent of electorates (42 out of 150) experienced variations of plus or minus 0.4 of a percentage point. Minor variations between quarters in volumes of services and in bulk billing rates may not reflect the true underlying rate in the region in the quarter. In part, this will relate to the timing of lodgement of claims.

Approximately 81 per cent of Medicare claim records for a quarter of service are processed in that quarter, with approximately 98 per cent of claim records for the quarter of service being processed within 6 months. To avoid delays in release of statistics, most statistics are compiled on a period of processing basis. Statistics compiled for short time periods can reflect rates of processing by the Heath Insurance Commission for different bill types, rather than what actually happened in the period.

The rate of bulk billing for non-referred (general practitioner) attendances for Australia in the March quarter 2003, at 68.5 per cent, was down 1.1 percentage point on the December quarter 2002. However, the bulk billing rate remained unchanged at 68.5 per cent in the June quarter and fell by 1.1 percentage points to 67.4 per cent in the September quarter 2003. Despite this, the trend in approximately 26 per cent of electorates (39 out of 150) did not follow the overall trend - ie. they moved up or down against this trend.

In regard to (iii) and (iv) above, Medicare statistics are clearly more accurate at national and State/Territory level. The finer the level of geography for which statistics are compiled, the less accurate the resultant statistics will be, having regard to the method of compilation of the statistics.

Medicare statistics are not captured by electorate. Most bulk billing statistics by electorate are compiled from Medicare data by patient enrolment (mailing address) postcode. Where a postcode overlaps electoral boundaries, the statistics are allocated to electorate using a concordance file derived from Population Census data showing the proportion of the population of each postal area in each electorate. In using this methodology it is assumed that Medicare service use by postcode is proportional to population by postal area. Where pockets of a postcode have residents of an older age range (with high Medicare service usage) and that postcode overlaps electoral boundaries, then service usage for the postcode will be allocated to more than one electorate in proportion to population. This can distort the resultant statistics.

Medicare statistics for some patient postcodes cannot be allocated to electorates where the postcodes are not listed on the concordance file. In calendar year 2003, approximately 566,000 non-referred (general practitioner) attendances, involving benefits expenditure of $17.1 million, could not be allocated to electorates because the patients concerned were enrolled in Medicare at post office box type addresses.

The combination of these factors is likely to result in a degree of error in electorate bulk billing data, particularly when this is produced for a short time period. The level of the error has not been measured.

(b) The total cost (ASL and computing resources) of responding to the numerous ad hoc and regular requests for electorate based and similar data from members and Senators, including the cost of the quarterly publication of Medicare statistics by the Department, has been approximately $122,500 per year ($245,000 over 2 years). The workload has been highly variable over the period and has not been allocated to quarters.

(c) The volume of work required to meet these requests and the costs of providing it have been discussed on a number of occasions with the Department by the former and current Ministers and their offices. The figure is based on Departmental estimates and is not a figure that ‘Mr Abbott made up’.

(d) The Department of Health and Ageing publishes statistics on bulk billing and patient copayments, by broad type of service group and by State/Territory of patient. Since the groupings cover specialist attendances, obstetrics, anaesthetics, pathology, diagnostic imaging, operations, assistance at operations, optometry, radiation therapy and other services, they are a proxy for specialist activity.

There are approximately 80 groupings of specialists which are recognised for Medicare purposes. Some of these groupings contain only a few doctors. As a consequence, even at the national level, there can be confidentiality problems associated with statistics compiled by specialty of doctor.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-135

OUTCOME 2 : Access to Medicare

Topic: GP AFTER HOURS SERVICES

Written Question on Notice

Senator McLucas asked:

In response to a question asked at November Senate Estimates (E03-117), the Department Supplied some figures about lack of compliance with the PIP after hours program.

(a) Is the Department aware of situations where the majority of GPs in some areas are not in compliance with the PIP after hours requirements?

(b) Has the Department received any correspondence alerting them to compliance problems in certain areas?

(c) Has the Department acted on this information?

(d) Has the Department taken action to alert some Divisions of General Practice to such practices?

Answer:

(a) No. The Department is not aware of any areas where the majority of GPs are non-compliant with the PIP after-hours requirements.

(b) Yes.

(c) Yes.

(d) No, this is not appropriate.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-136

OUTCOME 2: Access to Medicare

Topic: RETINOPATHY CHECK FOR PEOPLE WITH DIABETES

Written Question on Notice

Senator McLucas asked:

Recent figures show that 20% of Australians with diabetes have not had a recommended biennial retinopathy check. One in six has never had a retinal examination.

(a) What incentives are provided through the Practice Incentive Program for retinopathy checks?

(b) Is retinothapy check an MBS rebatable item:?

Answer:

(a) The Practice Incentives Program (PIP), as part of the National Integrated Diabetes Program, provides a Service Incentive Payment (SIP) of $40 to GPs that complete an annual cycle of care for a patient with diabetes. The annual cycle of care includes ensuring that a comprehensive eye examination is carried out at least once every two years. In addition, the PIP provides an outcome payment for practices that provide an annual cycle of care to at least 20% of their patients with diagnosed diabetes.

(b) Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-137

OUTCOME 2 : Access to Medicare

Topic: MEDICAREPLUS - $5 REBATE

Written Question on Notice

Senator McLucas asked:

(a) How many single consultation events have claims for more than one MBS item?

(b) Generally what types of services are provided in this way?

(c) What advice has been provided to GPs about how they should deal with these events?

Answer:

(a) In the June quarter 2003, there were 23,697,090 non-referred attendances by GPs. Of these, 730,080 (3.1%) services were associated with claims for other items in the MBS (based on same date of service, same patient and same servicing provider).

(b) The main types of additional services provided by GPs where there is more than one MBS item claimed are operations and pathology services.

(c) GPs have been advised that the $5 additional payment may be claimed in conjunction with each MBS item of service that meets the conditions of the new items 10990, 64990 and 74990. These conditions are that the service is provided to a Commonwealth concession card holder or child aged under 16; the service is unreferred; the service is not provided in a hospital or day-hospital facility; and the service is bulk billed.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question:E04 - 138

OUTCOME 2: ACCESS TO MEDICARE

Topic: DOCTOR/PRESCRIPTION SHOPPING PROJECT

Written Question on Notice

Senator McLucas asked:

(a) What was the total cost of the Doctor Shopping project?

(b) How many people/doctors were successfully targeted?

(c) How much money was saved from the PBS budget?

(d) How much money will support the Prescription Shopping program?

(e) How much money will be saved from the PBS budget?

Answer:

(a) The Health Insurance Commission (HIC) was given $5.25 million in the 1996-97 Federal Budget for the Doctor Shopping project. HIC utilised this funding to operate the project until 30 June 2002.

(b) In the first year of the Doctor Shopping project, 13,240 patients were identified as meeting the definition of doctor shopping behaviour. By the end of 2000-01 this had fallen to 8,179 patients. Both the number of medical practitioners attended and prescription medicines dispensed had reduced by 47 per cent and 41 per cent respectively.

(c) A HIC evaluation measured savings of $15.6 million in Medicare and Pharmaceutical Benefits Scheme (PBS) costs for five years, to the end of June 2001. Savings for the final year of the program were not measured.

(d) The HIC was given $4.189 million in the 2002-03 Federal Budget for the Prescription Shopping project to the end of June 2006.

(e) It is expected that the Prescription Shopping project will achieve savings of $19,889 million to the PBS to June 2006.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-188

OUTCOME 2: Access to Medicare

Topic: PHARMACEUTICAL BENEFITS SCHEME / FREE TRADE AGREEMENT

Hansard Page: CA 28

Senator Allison asked:

(a) Is it possible to get data on what percentage of resubmissions might be successful?

(b) Commentary has suggested that this will tie up all sorts of generic manufacturing prospects in the courts for lengthy periods. Is that not your reading of how this would work? Can just explain how they are overcome at present?

Answer:

(a) The Pharmaceutical Benefits Advisory Committee (PBAC) received a total of 76 submissions in 2002 for a new listing or a change to listing for a drug on the PBS. Of the 76 submissions received, 47 were recommended for listing by the PBAC, 25 were not recommended, 2 were deferred for a future consideration and 2 were withdrawn by the sponsors. The total number of re-submissions received in 2002 was 29, where 8 were recommended, 18 were not recommended, 2 were deferred and 1 withdrawn. (Note – these re-submissions may have been submissions in 2002 or previous years).

The PBAC received a total of 61 submissions in 2003 for a new listing or a change to listing for a drug on the PBS. Of the 61 submissions received, 37 were recommended by the PBAC, 21 were not recommended, 2 were deferred and 1 was withdrawn by the sponsor. The total number of re-submissions for 2003 was 27, where 9 were recommended, 14 were not recommended and 4 were deferred for future consideration. (Note – these re-submissions may have been submissions in 2002 or previous years).

(b) Provisions in the Patents Act affecting generic manufacturers will not change as a result of the Australia United States Free Trade Agreement. Currently, enforcement of patent rights is the responsibility of the patent owner. If a patent owner believes that a generic manufacturer is marketing a product that is protected by their patent, and are unable to reach an agreement with them, they can sue the generic manufacturer for infringement of that patent in the courts. The patent owner can also ask the court for an injunction preventing the generic manufacturer from continuing to market the product. Whether an injunction is granted is a matter for the court to decide and will depend upon the facts of the particular case.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-189

OUTCOME 2: Access to Medicare

Topic: PET NUMBERS

Hansard Page: CA 32

Senator Denman asked:

(a) In regards to the numbers provided in response to the QoN from November 2003 – why don't the numbers reconcile?

(b) Can the Department provide numbers up to the end of December 2003?

Answer:

(a) There are prescribed clinical conditions which patients receiving PET scans must satisfy to be eligible for a Medicare rebate. Not all Tasmanian PET patients funded under the Patient Travel Assistance Scheme (PTAS) would comply with these conditions. The number of PET scans performed on Tasmanian patients receiving PTAS assistance is therefore always likely to be greater than the number of Medicare-eligible scans performed on Tasmanian patients.

(b) From July to December 2003, 130 Tasmanian patients received assistance through the Patient Travel Assistance Scheme to travel interstate to receive PET scans. The number of Medicare-eligible PET scans performed on Tasmanian patients in this period was 92. All of these 92 scans were performed in Victoria with the exception of four performed in New South Wales.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2003

Question: E04-190

OUTCOME 2: Access to Medicare

Topic: MANAGEMENT OF UNWANTED, OBSOLETE AND OUT OF DATE MEDICINES

Hansard Page: CA37

Senator Allison asked:

(a) Is data available on the amount of medicines returned to pharmacies through a Commonwealth funded program for return of unwanted medicines?

(b) Could the Department provide details of when and where a reference to the study of the results of home medicines reviews was made?

Answer:

(a) The 2001-02 Federal Budget allocated $5 million over four years to continue and expand the National Medicines Disposal Program, which was introduced in the 1998-1999 Federal Budget. This program uses the national community pharmacy network to collect expired and unwanted medicines from consumers. These are then destroyed in an environmentally friendly manner using high-temperature incineration. This means of disposal avoids the significant environmental health hazard posed by inappropriate disposal through the sewerage system and landfill.

To support this program, the Australian Government provides funding to National Return and Disposal of Unwanted Medicines Ltd. This not-for-profit company collects and destroys unwanted and out-of-date medicines. During the period July 2002 – June 2003 an average of 30 tonnes per month of returned medicines was collected Australia-wide. This represents a 27% increase compared to the previous financial year.

(b) *Australian Pharmacist* (Volume 23, Number 2, February 2004) contained an article in its News section which provided a brief summary of research carried out by the Victorian College of Pharmacy and presented at the Australasian Pharmaceutical Sciences Association conference in Sydney in December 2003. The stated aim of the study was to describe and quantify unnecessary medications removed during a domiciliary visit from the homes of patients returning to independent care but identified as being at risk of medication misadventure. The researchers were Vuong T, Siderov J, Kong DCM and Marriott J. The Department understands that the research will be published in the *Medical Journal of Australia* sometime in the near future.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-221

OUTCOME 2 : Access to Medicare

Topic: EPC HEALTH ASSESSMENTS

Hansard Page: CA 21

Senator McLucas asked:

How much was the EPC item in surgery?

Answer:

The rebate for an EPC health assessment in consulting rooms (items 700 or 704) is $133.90.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-149

OUTCOME 2: ACCESS TO MEDICARE

Topic: PIP PROGRAM

Hansard Page: CA 15

Senator McLucas asked:

Of the 181 noncompliant practices, are there any regional inconsistencies?

Answer:

Regional classifications for PIP practices are defined by the *Rural, Remote, and Metropolitan Areas* (RRMA) category of the main practice location. The total number of PIP practices by RRMA classification are:

RRMA	**Total PIP practices in RRMA category (percentage of total as at Nov 2003)**	**Locality example**
1 - Metropolitan	2,921 (63.2%)	Brisbane, Canberra
2 - Other Metropolitan	355 (7.7%)	Townsville, Newcastle, Geelong
3 - Large Rural	301 (6.5%)	Cairns, Mackay, Launceston
4 - Small Rural	287 (6.2%)	Gympie, Maryborough, Port Pirie
5 - Other Rural	615 (13.3%)	Ingham, Atherton, Margaret River, Byron Bay
6 - Remote Centre	53 (1.1%)	Mt Isa, Roma, Alice Springs, Kalgoorlie
7 - Other Remote	89 (1.9%)	Normanton, Weipa, Yulara
All RRMAs	4,621 (100.0%)	n/a

For the 181 noncompliant practices, the RRMA code distribution is shown in the table below. These results were obtained from separate audits conducted over a three-year period. The sample size and basis of sample selection varied between audits. Because of this, the results are not comparable between RRMAs.

RRMA	**non-compliant practices** Number (percentage of total)
1 - Metropolitan	73 (40.3%)
2 - Other Metropolitan	40 (22.1%)
3 - Large Rural	13 (7.2%)
4 - Small Rural	22 (12.1%)
5 - Other Rural	18 (10.0%)
6 - Remote Centre	9 (5.0%)
7 - Other Remote	6 (3.3%)
Total	**181 (100.0%)**

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 18 February 2004

Question: E04-150

OUTCOME 2: ACCESS TO MEDICARE

Topic: OVERSEAS DRUG DIVERSION OF PBS MEDICINES

Hansard Page: CA 32

Senator McLucas asked:

(a) How much was the research component associated with the campaign?

(b) How many events have occurred where people have been identified as illegally exporting PBS supported medicines?

Answer:

(a) Expenditure on the research associated with the campaign will total $177,100. $86,550 of this was spent in the 2002-03 financial year. The remainder will be spent in the 2003-04 financial year.

(b) During 2002-03, there were 41 detentions reported by the Australian Customs Service to the Health Insurance Commission in respect of suspected illegal diversion of medicines subsidised by the Pharmaceutical Benefits Scheme.