Community Affairs Committee

Examination of Budget Estimates 2006-2007

Additional Information Received
CONSOLIDATED VOLUME 4

HEALTH AND AGEING PORTFOLIO

Outcomes: Whole of Portfolio and Outcomes 1 to 3

FEBRUARY 2007

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

ADDITIONAL INFORMATION RELATING TO THE EXAMINATION OF BUDGET EXPENDITURE FOR 2006-2007

Included in this volume are answers to written and oral questions taken on notice and tabled papers relating to the supplementary budget estimates hearing on 1 November 2006

*** Please note that the tabling date of 8 February 2007 is the proposed tabling date for answers where this date is indicated**

HEALTH AND AGEING PORTFOLIO

Senator	Quest. No.	Whole of portfolio	Vol. 4 Page No.	Date tabled in the Senate*
Ludwig	14	2005-06 annual report	1	08.02.07
Ludwig	17-19	Legal services expenditure	2-4	08.02.07
Nettle	180	Interactions with CSL across the portfolio	5	08.02.07
McLucas	111	Parliamentary library	6	08.02.07
Ludwig	16	Possible Parliamentary questions	7-8	08.02.07
Moore	233	Top 10 underspending programs	9	08.02.07
		Outcome 1: Population Health		
Evans	90	Hepatitis	10	08.02.07
Crossin	5	Joint environmental assessment and siting licence process	11-12	08.02.07
Crossin	6	ARPANSA – timeline and public input	13	08.02.07
Crossin	7	ARPANSA – site investigations	14	08.02.07
Crossin	8	ARPANSA – draft regulatory guidance for radioactive waste facilities	15	08.02.07
Crossin	9	Depleted uranium waste	16	08.02.07
Crossin	10	ARPANSA – ANSTO Act	17	08.02.07
Crossin	11	ARPANSA – community consultation	18	08.02.07
Webber	12	Strattera black box warning	19-20	08.02.07
Fielding	94	Number of doctors licensed to import RU486	21	08.02.07
Fielding	96	Application to import RU486	22	08.02.07
McLucas	117	Consultancy – Deloitte Touche Tohmatsu	23	08.02.07
Nettle	170	Menstrual caps	24	08.02.07
Stott Despoja	3	Pregnancy counselling – pregnancy counselling hotline	25	08.02.07
Stott Despoja	4, 13	Pregnancy counselling	26-27	08.02.07
Moore	221	Meningococcal C immunisation	28-29	08.02.07
Webber	222	Pregnancy support	30	08.02.07
Fielding	95	Number of doses of RU486 imported into Australia	31	08.02.07
Evans	85-88	Hepatitis	32-41	08.02.07
McLucas	116	Funding for sexually transmissible infections (STIS)	42-45	08.02.07
McLucas	119-120	Immunisation	46-48	08.02.07
Barnett	169	RU486 – Cairns Base Hospital Ethics Committee report to the TGA	49	08.02.07
Moore	219	HIV/AIDS and sexually transmissible infections (STIS)	50-53	08.02.07
McLucas	112-114	Blood plasma review	54-82	08.02.07
Moore	216-217	National Bowel Cancer Screening Program	83-85	08.02.07
Moore	218	Cervical screening	86-87	08.02.07
Evans	89	Hepatitis	88	08.02.07
McLucas	118	Immunisation	89-0	08.02.07

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-014

OUTCOME: Whole of Portfolio

Topic: 2005-06 ANNUAL REPORT

Written Question on Notice

Senator Ludwig asked:

1. What date the agency's 2005-06 Annual Report was tabled before parliament?
2. If the annual report was not tabled by 31 October 2006, could the department indicate:
a. When the report was tabled, or if it remains untabled what date the report is expected to be tabled by.
b. Whether the agency's own legislation provides an alternative timeframe for its annual report. If so, could the department provide:
i. A description and reference to the relevant provision and legislation.
ii. An explanation of why the agency cannot meet the general timeframe set out in the Department of Prime Minister and Cabinet's Requirements for Annual Reports, and so requires an alternative timeframe?
iii. The date that the Minister tabled in Parliament a statement explaining why an extension was granted.
iv. A copy of the Minister's statement.
d. Where the agency's legislation doesn't provide for an alternative timeframe (as per question b) nor was the agency granted an extension (as per question c) could the department provide:
i. Explanation for why the Annual Report was tabled outside the timeframe set by DPM&C despite there being no provision alternative timeframe set out in the agency's legislation nor there being any formal extension granted.
ii. Details of any other arrangements in place for the tabling the agency's Annual Report.

Answer:

The *2005-06 Department of Health and Ageing Annual Report* was tabled before Parliament on Thursday, 26 October 2006.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-017

OUTCOME: Whole of Portfolio

Topic: LEGAL SERVICES EXPENDITURE

Written Question on Notice

Senator Ludwig asked:

What sum did the department spend during 2005-2006 on external
(a) barristers and
(b) solicitors (including private firms, the Australian Government Solicitor and any others).

Answer:

(a) The Department of Health and Ageing spent $231,338 (GST inclusive) on barristers during 2005-2006. This figure is inclusive of the Therapeutic Goods Administration (TGA), the Office of the Gene Technology Regulator (OGTR) and the Office of Chemical Safety (including the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)).
(b) The Department of Health and Ageing spent $4,740,774 (GST inclusive) on solicitors during 2005-2006. This figure is inclusive of TGA, OGTR and the Office of Chemical Safety (including NICNAS).

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-018

OUTCOME: Whole of Portfolio

Topic: LEGAL SERVICES EXPENDITURE

Written Question on Notice

Senator Ludwig asked:

What sum did the department spend on internal legal services?

Answer:

The Department of Health and Ageing spent $4,652,582 on internal legal services during 2005-2006. This figure is inclusive of TGA, OGTR and the Office of Chemical Safety (including NICNAS).

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-019

OUTCOME: Whole of Portfolio

Topic: LEGAL SERVICES EXPENDITURE

Written Question on Notice

Senator Ludwig asked:

What is the department's projected expenditure on legal services for 2006-2007?

Answer:

The Departments projected legal expenditure on legal services for 2006-2007 is $10,223,390. This figure is inclusive of TGA, OGTR and the Office of Chemical Safety (including NICNAS).

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-180

OUTCOME: Whole of Portfolio

Topic: INTERACTIONS WITH CSL ACROSS THE PORTFOLIO

Hansard Page: CA 130

Senator Nettle asked:

What interactions do you have with CSL on other areas apart from blood?

Answer:

The Health and Ageing portfolio has interactions with CSL, apart from the manufacture and supply of blood and blood products, in the following areas:

- contracts for the manufacture, storage and distribution of vaccines, medicines, anti-toxins and anti-venom;
- regulation of medicines, vaccines and genetically modified organisms;
- listing and pricing of medicines subsidised under the Pharmaceutical Benefits Scheme;
- World Health Organization influenza collaboration; and
- recipients of National Health and Medical Research Council grants may collaborate with CSL scientists.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-111

OUTCOME: Whole of Portfolio

Topic: PARLIAMENTARY LIBRARY

Written Question on Notice

Senator McLucas asked:

a) Can you provide an update as to how the arrangements with the Parliamentary Library are working?
b) How many departmental people are involved in this vetting process?
c) How many requests does the Secretary personally see, or do you get a report regarding the number and type of requests from the library?
d) How timely is the department's response to these requests? What is the normal turn around time?
e) Can you advise the number of requests, per month, since the arrangement came into effect?

Answer:

a) On 19 April 2006, the Department of Health and Ageing and the Parliamentary Library entered into arrangements to better coordinate requests from the Parliamentary Library, with each request to come to a single point of contact in the department.

Feedback from both parties has indicated the arrangement is working well, with requests more easily allocated and tracked.

b) Requests are not vetted. Each request is passed on to the relevant subject area in the department for appropriate action.

c) The Secretary does not normally see the requests.

d) The median number of days taken to answer a request is four, calculated since the arrangement came into effect until 21 November 2006. This figure is calculated from date of request received until date of final response.

e) There are an average of 4.75 requests per month, calculated since the arrangement came into effect until 21 November 2006.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-016

OUTCOME: Whole of Portfolio

Topic: POSSIBLE PARLIAMENTARY QUESTIONS

Written Question on Notice

Senator Ludwig asked:

With regard to the preparation of Possible Parliament Questions briefs or other such documents intended to brief Ministers on an issue specifically for Question Time, could the department/agency provide:

a) The number of such briefs prepared in each of the last three financial years (2003-04, 2004-05, 2005-06).
b) The number of staff who are responsible for coordinating such briefs and the salary level they are engaged at.
c) The name of internal unit/team that those staff belong to and a description of its other responsibilities.
d) The total budget associated with the unit/team referred to in response to part 3.

Answer:

a)

	2003-04	**2004-05**	**2005-06**
Total Questions Time Briefs	3166	2264	3032

b) Central coordination of Question Time Briefs is undertaken in the department by:

Level	**Salary ***
APS 6 x 1	$59,912 - $67,590
APS 5 x .5	$54,310 – 57,322
APS 4 x .5	$49,933 - $52,759

* salary range as currently applicable under the Department of Health and Ageing's 2004-2007 Certified Agreement

c) Cabinet, Parliamentary Support and CSSS Section: This Unit undertakes a range of functions including provision of support for the Ministers in the area of Parliamentary accountability, including Question Time, Parliamentary Questions on Notice, Senate Estimates and Cabinet. The Section also administers a community organisation funding program.

d) Budgets in the Department are prepared and monitored at Branch and not Section level. The Cabinet, Parliamentary Support and CSSS Section sits within the Ministerial and Parliamentary Support Branch, which currently has an annual budget of $3.1 million.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-233

OUTCOME: Whole of Portfolio

Topic: TOP 10 UNDERSPENDING PROGRAMS

Hansard p.CA68

Senator Moore asked:

I put on notice a question for the Department to update the underspend information it provided at the last estimates hearing which was 'In particular can you please provide updated year to date figures of the top 10 underspending programs that you have provided to the Committee at the last estimates?

Answer:

Accurate information on program expenditure compared to program estimates is not available until July – August 2007. While year to date expenditure figures can be determined, there is no meaningful year to date budget figures that can be used for calculating under or over spending.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-090

OUTCOME 1: Population Health

Topic: HEPATITIS

Written Question on Notice

Senator Evans asked:

Has the Department commissioned any research on Indigenous people with Hepatitis C? In particular on effective preventative strategies?

Answer:

The Australian Government provides funding for Hepatitis C research through four national research centres, which are funded at a total of $8 million per annum to conduct research on HIV, Hepatitis C and sexually transmissible infections.

The Australian Research Centre in Sex, Health and Society (ARCSHS) has been funded to conduct the following research projects on Hepatitis C in Indigenous people:

- Learning to inject inside: Resilience and risk factors in Indigenous men's introduction to injecting while incarcerated 2002-2005
- Indigenous Futures: Sex, drugs and medications 2006-2007
- Recognising and responding to Hepatitis C in Indigenous communities in Victoria 2006-2007

The first two of these research projects focus on the prevention of Hepatitis C while the third project considers barriers to access for Hepatitis C treatment for the Koori community.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-005

OUTCOME 1: Population Health

Topic: JOINT ENVIRONMENTAL ASSESSMENT AND SITING LICENCE PROCESS FOR DUMP

Written Question on Notice

Senator Crossin asked:

From the DEST Radioactive Waste Management site: What's New 26 May 2006

Joint regulatory process for Commonwealth Radioactive Waste Management Facility (CRWMF):

- The Department of the Environment and Heritage and ARPANSA have agreed to a joint environmental assessment and siting licence process. This is expected to reduce the time required for these processes by around six months. However, there will be no overall shortening of the project time frame because of delays in commencement of site studies from late 2005 to early 2006.

a) Have DEH and ARPANSA ever done a joint/simultaneous assessment before?
b) Did DEST facilitate the joint agreement for the Department of the Environment and Heritage (DEH) and ARPANSA to work together?
c) How did the proposal for joint assessments evolve - where did the idea come from and what was the process for obtaining cross agency agreement?
d) What is the detail of the joint process?
e) Will a new contractor do the work for the joint environmental assessment and siting licence process?
f) Did ARPANSA make any announcement of this agreement?
g) How will it work two teams sharing the same space or one team serving two different interests?

Answer:

a) No.

b) No.

c) The CEO of ARPANSA, Dr John Loy, initiated discussions with DEH proposing that, where possible, certain parts of the decision making process for each agency could be conducted jointly. The parties agreed that they would conduct a joint public submission process thereby alleviating the need for two lengthy processes to be conducted separately. The parties will then proceed to review the submissions against their respective legislative requirements.

d) The applicant for a licence to site the CRWMF can apply for approval under the *Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act)* at the same time as applying for a licence under the *Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act)* for authorisation to prepare a site for the CRWMF, and lodge one set of documentation to satisfy the requirements of each of the *EPBC Act* and the *ARPANS Act*. ARPANSA has prepared regulatory guidance on application requirements and DEH has provided their comments. DEH may choose to adopt this guidance or part of it for their own purposes.

e) This information is not known to ARPANSA and is a matter for the applicant.

f) No.

g) The detailed arrangements have not been settled.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-006

OUTCOME 1: Population Health

Topic: ARPANSA - TIMELINE AND PUBLIC INPUT

Written Question on Notice

Senator Crossin asked:

The latest revised timeline on the DEST RWM website shows ARPANSA doing the siting research at the preferred site from mid 2007, with the CEO of ARPANSA making a decision on the siting licence in late 2008/ early 2009. Is that likely?

Answer:

The time required to assess an application will principally depend on the completeness of the information provided by the applicant.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-007

OUTCOME 1: Population Health

Topic: ARPANSA - SITE INVESTIGATIONS

Written Question on Notice

Senator Crossin asked:

From the DEST RWM website

Site investigations
Before deciding on which of the three potential sites will host the Commonwealth Radioactive Waste Management Facility, detailed studies of the sites' physical, biological and socioeconomic environments will be undertaken. The Department of Education, Science and Training has engaged Parsons Brinkkerhoff to undertake these studies. During the site characterisation studies, the following aspects of the sites will be investigated:
geology, hydrogeology, surface hydrology and geomorphology; meteorology, seismic risk, mineral potential, current and potential future land uses, potential population growth in the area, incidence of threatened or endangered flora and fauna.

Given the range of the investigations Parsons Brinkerhoff are undertaking for DEST could the ARPANSA siting investigations be basically done on the desktop using Parsons Brinkerhoff's data?

Answer:

ARPANSA will assess the siting information provided by the applicant. If further information is required for an assessment, ARPANSA will ask the applicant to provide the necessary information.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-008

OUTCOME 1: Population Health

Topic: ARPANSA - DRAFT REG GUIDANCE FOR RADIOACTIVE WASTE FACILITIES

Written Question on Notice

Senator Crossin asked:

Public comment has closed on the Draft Regulatory Guidance for Radioactive Waste Management Facilities: Near Surface Disposal Facilities; and Storage Facilities.

a) What stage are you up to now?

b) When do you expect to release the final document?

Answer:

a) The response to the comments received is being finalised.

b) December 2006.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-009

OUTCOME 1: Population Health

Topic: DEPLETED URANIUM WASTE

Written Question on Notice

Senator Crossin asked:

According to an answer provided by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) in answer to Senate estimates questions ARPANSA says Australia currently exports roughly 11,000 tons of uranium and that if it were all enriched it would produce 1000 tons of exportable enriched uranium and 90% or 10,000 tons would be depleted uranium waste.

It further states "The shallow ground burial facilities currently proposed in Australia are intended for the disposal of smaller quantities than this. Disposal of waste from a uranium enrichment facility would require a disposal facility of a different type than those that have been proposed to date. (ARPANSA Senate estimates answer E06-259)

a) Why wouldn't the proposed dump be suitable and what sort of facility might be needed?

b) Would depleted uranium come under ARPANSA's legal responsibility?

Answer:

a) Depleted uranium is slightly above the activity concentration limits specified in the *Code of practice for the near-surface disposal of radioactive waste in Australia (1992)*. The form of the material is also likely to make it not suitable for disposal in near surface repository. Should it be decided to treat the material as waste, it may need a disposal facility at a depth of between a few tens and a few hundreds of meters.

b) Only depleted uranium within the control of Commonwealth entities is a licensable material under the *Australian Radiation Protection and Nuclear Safety Act 1998.*

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-010

OUTCOME 1: Population Health

Topic: ARPANSA - ANSTO ACT

Written Question on Notice

Senator Crossin asked:

What advice has ARPANSA received in relation to the implications/extended powers of the *ANSTO Amendment Act (2006)* on the operations of any future Commonwealth radioactive waste facility in the NT?

Answer:

None.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-011

OUTCOME 1: Population Health

Topic: ARPANSA - COMMUNITY CONSULTATION

Written Question on Notice

Senator Crossin asked:

How do you reconcile ARPANSA's legislative requirement to adopt best practice' in licensing with the overriding of NT resident's concerns and rights in the *Commonwealth Radioactive Waste Management Act (2005)* given that international best practice includes proper community consultation and informed consent such as the final recommendations of the UK Committee on Radioactive Waste Management at http://www.corwm.org.uk/content-0

DEST would suggest that this does not apply to Australia as the UK only has high level waste. Clearly from this report that is not the case and would request a comment about the level of demonstrated consultation with communities in the siting of a facility before licensing can be granted?

Answer:

The CEO of ARPANSA must, under section 32 of the *Australian Radiation Protection and Nuclear Safety Act 1998*, take into account international best practice in radiation protection and nuclear safety and other matters set out in the ARPANS Regulations when making a decision whether or not to issue a licence to site, construct and operate a nuclear installation (which includes the Commonwealth Radioactive Waste Management Facility). The CEO of ARPANSA must invite public submissions in relation to any application for licence for nuclear installations and must take those submissions into account.

In other words the licensing process itself will involve substantial public involvement by way of a public submission process.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-012

OUTCOME 1: Population Health

Topic: STRATTERA BLACK BOX WARNING

Written Question on Notice

Senator Webber asked:

In December 2004 information on the potential for severe liver damage was added to the Product Information document for ADHD non-stimulant drug Strattera.

On 14 March 2006 a Black Box warning for "suicidal ideation" was added to the Product Information (this is only provided to prescribers) for Strattera. The TGA's black box warning lagged the US FDA black box suicide warning issued in September 2005.

a) What actions (if any) were taken to ensure all medications sold after 14 March carried the black box warning?

b) Given that thousands of Australian children take Strattera why did the TGA fail to issue a press release or take any action to ensure that parents were made aware that this medication might make their child want to commit suicide?

Answer:

a) The boxed warning in the Australian product information (PI) document relating to the association between Strattera (atomoxetine) and suicidal thoughts and behaviours was included in the approved PI by the TGA on 14 March 2006. All product information documents supplied by the sponsor after that date were required to include the boxed warning. The Australian sponsor issued a Dear Health Care Professional letter dated 16 March 2006 informing all health care professionals of the boxed warning and provided copies of the amended PI and Consumer Medicine Information (CMI) documents.

b) Prior to the addition of the boxed warning the Australian PI included precautionary statements on the association between Strattera (atomoxetine) and suicidal ideation and behaviours. On 27 September 2005, the Precautions and Adverse Reactions sections of the Australian PI had been amended to include similar information to that appearing in the subsequent boxed warning. On 29 September 2005, the Australian sponsor issued a Dear Health Professional Letter informing professionals of the association between suicidal ideation and behaviour and Strattera (atomoxetine).

Strattera is a prescription only medicine and available only via prescription from a treating medical practitioner. General information about a medicine and possible adverse effects can be found in the CMI document and is intended to be provided to patients from their dispensing pharmacist. The information in this document is not intended to replace the professional advice from a medical practitioner or dispensing pharmacist. The Pharmaceutical Society of Australia guidelines require pharmacists to provide copies of CMI's to patients whenever there are changes such as updated warnings.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-094

OUTCOME 1: Population Health

Topic: NUMBER OF DOCTORS LICENSED TO IMPORT RU486

Written Question on Notice

Senator Fielding asked:

How many doctors have a license to import RU 486 under the Authorised Prescriber program?

Answer:

Two.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-096

OUTCOME 1: Population Health

Topic: APPLICATIONS TO IMPORT RU486

Written Question on Notice

Senator Fielding asked:

Has the TGA received any application from a pharmaceutical company to import RU486? If so, how many companies have applied and what are their names? What stage is/are the application/s up to?

Answer:

No.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-117

OUTCOME 1: Population Health

Topic: CONSULTANCY – DELOITTE TOUCHE TOHMATSU

Written Question on Notice

Senator McLucas asked:

Reference is the 2005-06 Annual Report p309 Outcome 1.

$484,175 to Deloitte Touche Tohmatsu for "Development of a performance management framework, risk management policy, framework and accountability/ responsibility framework." [sic]

What is this money for? Which part of the Department does it apply to?

Answer:

The Australian National Audit Office (ANAO) conducted a performance audit of the Therapeutic Goods Administration (TGA) over the period September 2003 to October 2004 and tabled its report in December 2004. The report detailed 26 recommendations which addressed a range of administrative and management issues within the broad categories of risk management, documentation and record keeping and establishment of clear procedures for various administrative actions.

In April 2005 the Department engaged Deloitte to:

- assist the TGA in implementing the ANAO recommendations;
- undertake a review of recent key enforcement actions by the TGA to draw lessons for the future – this was in line with recommendation 13 of the ANAO report; and
- take an overarching view of the TGA's governance frameworks.

A copy of the Terms of Reference was provided as part of the Department's response to Additional Estimates 2004-05, 17 February 2005, Question on Notice E05-100. The Deloitte report, received by the Department in June 2005 proposed some major initiatives that in their view, if implemented, would enable improvements and enhancements across the whole of the TGA.

The TGA subsequently engaged Deloitte (in October 2005) to assist in the development of a more contemporary performance management framework (including indicators), a risk management policy and framework and an updated governance and accountability framework. A final report was submitted to the TGA in February 2006 and, at $379,069 (GST inclusive), the cost of the project was less than the original estimate of $484,175.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-170

OUTCOME 1: Population Health

Topic: MENSTRUAL CUPS

Hansard Page: CA 129, CA 130

Senator Nettle asked:

Can the TGA provide the names of menstrual cup products that are approved by the TGA and on the Australian Register of Therapeutic Goods?

Answer:

The menstrual cup products currently listed on the Australian Register of Therapeutic Goods are 'The Keeper Menstrual Blood Collector' (sponsored by The Natural Company Pty Ltd) and 'The Instead Menstrual Blood Collector' (sponsored by Inka Kyto Pty Ltd).

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-003

OUTCOME 1: Population Health

Topic: PREGNANCY COUNSELLING - PREGNANCY COUNSELLING HOTLINE

Written Question on Notice

Senator Stott Despoja asked:

a) Can the Department please detail why there are delays on the impending pregnancy helpline?
b) When does the Department expect the helpline to be in operation?

Answer:

a) & b)
The tender process for the implementation of the National Pregnancy Support Telephone Helpline (the Helpline) is progressing according to the timeline outlined in the Request for Tender. It is anticipated that the Helpline will be operational in early 2007.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-004

OUTCOME 1: Population Health

Topic: PREGNANCY COUNSELLING

Written Question on Notice

Senator Stott Despoja asked:

In response to Estimates question on notice E06-042, the Department stated that the "regulation of helplines (including pregnancy helplines) does not fall within the Health Portfolio.

In light of the statement outlined above, could the Department highlight who will monitor the regulation of the pregnancy counselling helpline, and how this will be achieved?

Answer:

As part of the Request for Tender for the Implementation of the National Pregnancy Support Telephone Helpline (the Helpline), all tenderers were required to provide details on how they will ensure quality assurance and monitoring of the service.

The department will monitor the performance of the operation of the Helpline through the regular quantitative and qualitative reporting requirements of the Department's Contract for Services with the successful tenderer.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-013

OUTCOME 1: Population Health

Topic: PREGNANCY COUNSELLING

Written Question on Notice

Senator Webber asked:

Following our discussion about the provision of counselling services by the proposed Pregnancy Helpline, if counselling is non-referral why is there reference given to specific adoption agencies?

Answer:

Paragraph 5.8 of the Statement of Requirement for the Pregnancy Counselling Helpline states:

'The service provider is not expected to provide referrals to specific service provider agencies but is expected to provide generic information about where clients can find such information.'

It is anticipated that the service provider will provide general information about the pathways available to access details of services eg, direct contact using the Yellow Pages directory; contacting a local family planning clinic; consultation with a GP or seeking a referral to a specialist.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-221

OUTCOME 1: Population Health

Topic: MENINGOCOCCAL C IMMUNISATION

Hansard Page: CA 116

Senator Moore asked:

a) Can we have what data are available from the immunisation register relating to Meningococcal C immunisation, what figures are extracted from that, what was the target for the catch-up program for Meningococcal C immunisation.
b) Whether the catch-up program was extended beyond June 2006 and, if so, why, and the cost?
c) We would like the same kinds of costs as we had before—the costs around the catch-up program, advertising, vaccine, information to doctors, consultancies.
d) If the program was extended beyond June 2006, the additional costs of extending the program beyond that period.

Answer:

a)
The Australian Childhood Immunisation Register (ACIR) collects the following data about the Meningococcal C Vaccination Program for children up to the age of seven years:

- Details about the immunisation provider;
- Details about the child receiving the vaccine (eg age, address);
- Date of vaccination; and
- Vaccine administered.

From this data information about the number and percentage of valid Meningococcal C vaccinations is generated as well as information about Meningococcal C vaccination coverage at a state, territory and national level.

Data about Meningococcal C vaccination through the school age catch-up program is collected by state and territory governments.

The on-going target group is children aged 12 months.

The target for the catch-up program was children aged 1 to 19 years.

As at 30 September 2006, ACIR reports that meningococcal C vaccination coverage is:

- 92.4% in the cohort of children aged 24 to <27 months;
- 85.3% for children born since 1 January 2002 (that is, children aged < 5 years);
- 73.3% for children aged 6 years (ie born between 1 January 2001 and 30 December 2001); and
- 68.2% for children aged 7 years of age (that is, born between 1 January 2000 and 30 December 2000).

b)
Following a request from Tasmania, South Australia, Queensland, New South Wales and the Australian Capital Territory the catch-up component of the Program was extended to 30 June 2007 in these jurisdictions. The purpose of the extension was to further increase the Program's coverage. These jurisdictions used their unexpended Program funds that had already been provided by the Australian Government to support the implementation of the catch-up Program, that is no additional funds were provided.

c)
For the period 2002-03 to 2004-05, the cost for the purchase of vaccine under the catch-up component of the Program was $187 million.

Funds of $2 million were expended on a communication program, including advertising ($335,000) and materials ($1.1 million). It is not possible to disaggregate the proportion of funds used to support the ongoing and the catch-up programs.

d) As indicated in (b) above, no additional funds were required.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-222

OUTCOME 1: Population Health

Topic: PREGNANCY SUPPORT

Written Question on Notice

Senator Webber asked:

Is there anyone on that Tender expert advisory committee with experience in service provision in rural, regional and remote?

Answer:

Members of the Committee were selected on the basis of their specialist expertise in relevant technical areas such as reproductive health, non-directive counselling, primary health care and telecounselling.

The Expert Advisory Committee recognise that access to pregnancy counselling services can be difficult for those in rural and remote areas. For this reason, it has been careful to take these issues into consideration in their deliberations.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-095

OUTCOME 1: Population Health

Topic: NUMBER OF DOSES OF RU486 IMPORTED INTO AUSTRALIA

Written Question on Notice

Senator Fielding asked:

How many doses of RU 486 have been imported into Australia for abortion?

Answer:

The TGA has granted approval for the importation of 40 x 200mg tablets.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-085

OUTCOME 1: Population Health

Topic: HEPATITIS

Written Question on Notice

Senator Evans asked:

Does the Commonwealth Government have any specific programs in place to address the high rates of Hepatitis C in the Indigenous population?

Answer:

Aboriginal and Torres Strait Islander people are recognised as a priority population at increased risk of Hepatitis C infection in the *National Hepatitis C Strategy 2005-2008* and the *National Aboriginal and Torres Strait Islander Sexual Health and Blood Borne Virus Strategy 2005-2008*.

The Australian Government provides funding for Hepatitis C research through four national research centres, which are funded at a total of $8 million per annum to conduct research on HIV, Hepatitis C and sexually transmissible infections.

The Australian Research Centre in Sex, Health and Society (ARCSHS) has been funded to conduct the following research projects on the prevention of Hepatitis C in Indigenous people:

- Learning to inject inside: Resilience and risk factors in Indigenous men's introduction to injecting while incarcerated 2002-2005
- Indigenous Futures: Sex, drugs and medications 2006-2007
- Recognising and responding to Hepatitis C in Indigenous communities in Victoria 2006-2007

The Indigenous projects described in the table below are funded by the Department of Health and Ageing and pay specific attention to reducing transmission and improving care and support for this group.

Name of project	Amount of funding provided	Program funding provided from	Organisation funding provided to	Period of funding	Details of evaluations on effectiveness
1. Hepatitis C prevention and education activities for young Aboriginal people at greatest risk of hepatitis C	$52,850	Hepatitis C Education and Prevention Initiative	Aboriginal Health and Medical Research Council (NSW) via NSW Health.	July 2005 to June 2007	This project will be evaluated upon completion, in accordance with contractual requirements
2. Hepatitis C awareness raising for Aboriginal and Torres Strait Islander communities in the Darwin Urban region	$100,000	Hepatitis C Education and Prevention Initiative	NT Health.	1 February 2006 to 30 June 2007.	This project will be evaluated upon completion, in accordance with contractual requirements
3. Hepatitis C health promotion program in Tropical North Queensland which targets key risk groups, including Aboriginal and Torres Strait Islander people	$156,000	Hepatitis C Education and Prevention Initiative	Queensland Health.	July 2005 to June 2007.	This project will be evaluated upon completion, in accordance with contractual requirements

4. Continuation of Pre-Existing Hepatitis C Council Rural and Remote Education Project'	$180,900	Hepatitis C Education and Prevention Initiative	Hepatitis C Council of South Australia via the Department of Health South Australia.	July 2005 to June 2007.	This project will be evaluated upon completion, in accordance with contractual requirements
5. Development of Workshop Kit and National Aboriginal Hepatitis C and Injecting Drug User (IDU) Workshop'	$40,000	Hepatitis C Education and Prevention Initiative	Australian Injecting and Illicit Drug Users League (AIVL)	July 2005 to June 2007.	This project will be evaluated upon completion, in accordance with contractual requirements
6. Indigenous Hepatitis C Education and Prevention Project	$133,000	Funds are allocated from OATSIH's one-line appropriation – Aboriginal and Torres Strait Islander Health: Appropriation Bill 1	Australian Hepatitis Council.	March 2006 to February 2007.	This project will be evaluated upon completion, in accordance with contractual requirements

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-086

OUTCOME 1: Population Health

Topic: HEPATITIS

Written Question on Notice

Senator Evans asked:

Have any grants been provided by OATSIH/DoHA in the last 12 months to Indigenous specific Hepatitis C projects? If so, please provide details, including:

a. amounts of funding provided
b. program/s funding provided from
c. organisation/s funding provided to
d. project/s funding provided for
e. period of time funding provided for
f. details of any evaluations on effectiveness of programs funded.

Answer:

Yes – refer to the attached table for details.

Name of project	Amount of funding provided	Program funding provided from	Organisation funding provided to	Period of funding	Details of evaluations on effectiveness
1. Hepatitis C prevention and education activities for young Aboriginal people at greatest risk of hepatitis C	$52,850	Hepatitis C Education and Prevention Initiative	Aboriginal Health and Medical Research Council (NSW) via NSW Health	July 2005 to June 2007	This project will be evaluated upon completion, in accordance with contractual requirements.
2. Hepatitis C awareness raising for Aboriginal and Torres Strait Islander communities in the Darwin Urban region	$100,000	Hepatitis C Education and Prevention Initiative	NT Health	1 February 2006 to 30 June 2007	This project will be evaluated upon completion, in accordance with contractual requirements.
3. Hepatitis C health promotion program in Tropical North Queensland' which targets key risk groups, including Aboriginal and Torres Strait Islander people	$156,000	Hepatitis C Education and Prevention Initiative	Queensland Health	July 2005 to June 2007	This project will be evaluated upon completion, in accordance with contractual requirements.

4. Continuation of Pre-Existing Hepatitis C Council Rural and Remote Education Project	$180,900	Hepatitis C Education and Prevention Initiative	Hepatitis C Council of South Australia via the Department of Health South Australia	July 2005 to June 2007	This project will be evaluated upon completion, in accordance with contractual requirements.
5. Development of Workshop Kit and National Aboriginal Hepatitis C and Injecting Drug User (IDU) Workshop	$40,000	Hepatitis C Education and Prevention Initiative	Australian Injecting and Illicit Drug Users League (AIVL)	July 2005 to June 2007	This project will be evaluated upon completion, in accordance with contractual requirements.
6. Indigenous Hepatitis C Education and Prevention Project	$133,000	Funds are allocated from OATSIH's one-line appropriation – Aboriginal and Torres Strait Islander Health: Appropriation Bill 1	Australian Hepatitis Council	March 2006-February 2007	This project will be evaluated upon completion, in accordance with contractual requirements.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-087

OUTCOME 1: Population Health

Topic: HEPATITIS C

Written Question on Notice

Senator Evans asked:

Has any funding been provided for Hepatitis C specific projects ?

Answer:

The Australian Government provides funding for Hepatitis C research through four national research centres, which are funded at a total of $8 million per annum to conduct research on HIV, Hepatitis C and sexually transmissible infections.

The Australian Research Centre in Sex, Health and Society (ARCSHS) has been funded in 2005-2007 to conduct the following research projects on Hepatitis C in Indigenous people:

- Learning to inject inside: Resilience and risk factors in Indigenous men's introduction to injecting while incarcerated 2002-2005
- Indigenous Futures: Sex, drugs and medications 2006-2007
- Recognising and responding to Hepatitis C in Indigenous communities in Victoria 2006-2007.

Funding has also been provided in 2005-2007 to the states and territories for the Indigenous projects described in the table below.

Name of project	Amount of funding provided	Program funding provided from	Organisation funding provided to	Period of funding	Details of evaluations on effectiveness
1. Hepatitis C prevention and education activities for young Aboriginal people at greatest risk of Hepatitis C	$52,850	Hepatitis C Education and Prevention Initiative	Aboriginal Health and Medical Research Council (NSW) via NSW Health.	July 2005 to June 2007	This project will be evaluated upon completion, in accordance with contractual requirements
2. Hepatitis C awareness raising for Aboriginal and Torres Strait Islander communities in the Darwin Urban region	$100,000.	Hepatitis C Education and Prevention Initiative	NT Health.	1 February 2006 to 30 June 2007.	This project will be evaluated upon completion, in accordance with contractual requirements
3. Hepatitis C health promotion program in Tropical North Queensland' which targets key risk groups, including Aboriginal and Torres Strait Islander people	$156,000.	Hepatitis C Education and Prevention Initiative	Queensland Health.	July 2005 to June 2007.	This project will be evaluated upon completion, in accordance with contractual requirements

4. Continuation of Pre-Existing Hepatitis C Council Rural and Remote Education Project'	$180,900.	Hepatitis C Education and Prevention Initiative	Hepatitis C Council of South Australia via the Department of Health South Australia.	July 2005 to June 2007.	This project will be evaluated upon completion, in accordance with contractual requirements
5. Development of Workshop Kit and National Aboriginal Hepatitis C and Injecting Drug User (IDU) Workshop'	$40,000.	Hepatitis C Education and Prevention Initiative	Australian Injecting and Illicit Drug Users League (AIVL)	July 2005 to June 2007.	This project will be evaluated upon completion, in accordance with contractual requirements
6. Indigenous Hepatitis C Education and Prevention Project	$133,000.	Funds are allocated from OATSIH's one-line appropriation – Aboriginal and Torres Strait Islander Health: Appropriation Bill 1	Australian Hepatitis Council.	March 2006-February 2007.	This project will be evaluated upon completion, in accordance with contractual requirements

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-088

OUTCOME 1: Population Health

Topic: HEPATITIS

Written Question on Notice

Senator Evans asked:

Why don't we know more about the exact number of Indigenous Australians with hepatitis C?

Answer:

The state and territory governments are responsible for providing notifications for infectious diseases such as Hepatitis C to the Australian Government's National Notifiable Diseases Surveillance Scheme (NNDSS).

Systems for reporting infectious diseases vary in each jurisdiction.

There is evidence that some Indigenous Australians do not seek medical help for Hepatitis C until the later stages of disease. This indicates under-reporting at any given time.

For reasons of cultural sensitivity, some Indigenous Australians are unwilling to advise their indigenous status to the health and medical professionals diagnosing or treating them.

The *Hepatitis C Virus Projections Working Group: Estimates and Projections of the Hepatitis C Virus Epidemic in Australia 2006* provides further detail on the issues associated with gathering precise information on the number of Indigenous Australians with Hepatitis C.

A copy has been provided to Senator Evans. This publication can also be found at: http://web.med.unsw.edu.au/nchecr/Downloads/HCVPWG_Report_3_8_Aug06.pdf

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-116

OUTCOME 1: Population Health

Topic: FUNDING FOR SEXUALLY TRANSMISSIBLE INFECTIONS (STIS)

Hansard Page: CA 114-115

Senator McLucas asked:

Please supply the requested information for the following sexually transmitted diseases and other diseases:

- HIV/AIDS
- Gonorrhoea
- Syphilis
- Chlamydia
- Hepatitis C

Information required for the years 1996-97 to 2005-06:

a) Number of reported infections
b) Infection rate
c) Infection rate in the Indigenous community
d) Federal funding (excluding PBS funds)
e) PBS funds

Answer:

The number of reported infections, the infection rate and infection rate in the Indigenous community for HIV/AIDS, gonorrhoea, syphilis, chlamydia and Hepatitis C are at Attachment A.

Federal funding on HIV/AIDS, sexually transmissible infections and Hepatitis C is only available from 1999-2000 and is shown below:

Financial Year	**Expenditure ($ million)**[1]
1999-2000	29.8
2000-2001	35.1
2001-2002	35.1
2002-2003	34.7
2003-2004	34.3
2004-2005	34.3
2005-2006	35.9

1. Includes funding for national prevention programs coordinated by Population Health Division and the Office of Aboriginal and Torres Strait Islander Health, research and surveillance, funding to the states and territories for hepatitis C initiatives, and COAG funding for needle and syringe programs. Funding does not include expenditure on research from the National Health and Medical Research Council, funding provided to the states and territories under the Public Health Outcome Funding Agreements, or expenditure under the Medicare Benefits Schedule, Pharmaceutical Benefits Scheme and Health Care Agreements.

Funding from the Pharmaceutical Benefits Scheme (PBS) on HIV/AIDS, sexually transmissible infections and Hepatitis C is shown below:

Financial Year	**Expenditure ($ million)** [1]
1996-1997	21.3
1997-1998	87.0
1998-1999	103.2
1999-2000	120.2
2000-2001	120.9
2001-2002	139.4
2002-2003	153.0
2003-2004	167.7
2004-2005	190.5
2005-2006	210.8

1. Includes available PBS data for HIV/AIDS, sexually transmissible infections and hepatitis C treatment. Includes HIV/AIDS treatments from 1997-98 and hepatitis C treatments from 1999-2000.

Estimated number of cases of newly diagnosed HIV infection*

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Number of new HIV diagnoses (1)	899	721	645	685	656	690	825	812	849	928
Number of new HIV diagnoses in Indigenous people (2)	19	15	28	9	16	14	25	23	21	17
HIV diagnosis rate** - Non-Indigenous	6.3	5.9	4.0	3.9	4.1	4.2	4.6	4.7	4.9	5.2
HIV diagnosis rate** - Indigenous	5.2	4.5	7.4	2.1	4.5	4.0	7.1	6.4	5.5	4.5

1. Numbers given are the estimated number of HIV diagnoses in each year not reported in previous years.

2. Not adjusted for multiple reporting. Information on Indigenous status was not available from ACT by 31 March 2006. Information on Indigenous status was available in VIC from 1 June 1998.

*Adjusted for multiple reporting.
** Age standardised rate per 100 000 population.

Number of AIDS diagnoses*

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Number of new AIDS diagnoses	671	395	328	212	262	209	237	247	216	257
Number of new AIDS diagnoses in Indigenous people (1)	10	4	9	5	5	5	8	11	11	8
AIDS diagnosis rate** - Non-Indigenous	3.7	2.2	1.6	1.1	1.4	1.1	1.2	1.2	0.9	1.0
AIDS diagnosis rate**- Indigenous	2.9	1.2	2.6	1.2	1.5	2.2	2.3	3.1	3.9	2.3

1. Not adjusted for reporting delay. Information on Indigenous status was not available from ACT by 31 March 2006. Information on Indigenous status was available from VIC from 1 June 1998.

*Adjusted for reporting delay.
**Age standardised rate per 100,000 population.

Number and rate of diagnoses of gonorrhoea

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Number of reported gonorrhoea diagnoses	4141	4640	5469	5587	5897	6291	6279	6792	7187	8015
Gonorrhoea diagnosis rate (1)	22.6	25.0	29.0	30.0	31.4	33.5	33.1	35.7	37.6	41.5
Number of diagnoses of gonorrhoea - Indigenous (2)	1612	1834	1905	1765	2011	2042	2321	265	3122	3524
Gonorrhoea diagnosis rate Indigenous (3)	1291	1192	1240	1184	1134	946	854	898	1013	1155

1. Age standardised rate per 100,000 population.

2. Number of diagnoses of gonorrhoea in state/territory health jurisdictions in which Indigenous status was reported for more than 50% of diagnoses in each year.

3. Interpretation of trends in diagnoses of gonorrhoea in Indigenous people is limited by incomplete information on Indigenous status.

Source: National Centre for HIV Epidemiology and Clinical Research 2006.

Number and rate of diagnosis of syphilis infection

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Number of reported syphilis diagnoses	1512	1254	1678	1824	1855	1851	1958	2007	2332	2203
Syphilis diagnosis rate (1)	8.3	6.7	8.9	9.6	9.6	9.5	9.9	10.0	11.6	10.7
Number of diagnoses of syphilis - Indigenous (2)	325	309	383	357	317	757	749	634	593	539
Syphilis diagnosis rate - Indigenous (3)	260	221	308	305	214	216	206	182	188	171

1. Age standardised rate per 100,000 population.

2. Number of diagnoses of syphilis in state/territory health jurisdictions in which Indigenous status was reported for more than 50% of diagnoses in each year.

3. Interpretation of trends in diagnoses of syphilis in Indigenous people is limited by incomplete information on Indigenous status.

Number and rate of diagnosis of chlamydia infection

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Total Number of reported chlamydia diagnoses	8351	9176	10928	14046	17023	20330	24043	30439	36227	41311
Chlamydia diagnosis rate (1)	45.6	50.1	87.1	74.7	89.9	109.5	129.0	162.7	192.5	217.2
Number of diagnoses of chlamydia - Indigenous (2)	997	994	1240	1765	1537	1686	1736	2241	2406	2392
Chlamydia diagnosis rate - Indigenous (3)	798	636	761	1184	861	921	944	1225	1319	1280

1. Age standardised rate per 100,000 population.

2. Number of diagnoses of chlamydia in state/territory health jurisdictions in which Indigenous status was reported for more than 50% of diagnoses in each year.

3. Interpretation of trends in diagnoses of chlamydia in Indigenous people is limited by incomplete information on Indigenous status.

Number and rate of diagnosis of hepatitis C infection

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Number of reported hepatitis C diagnoses	19261	17261	17783	19168	20188	20031	14857	14210	13403	12594
Hepatitis C diagnosis rate (1)	105.2	92.8	94.6	102.3	107.2	105.6	76.9	73.1	68.1	63.4
Number of diagnoses of hepatitis C - Indigenous (2,3)	N/A	121	193	227	304	432	562	483	613	535

1. Age standardised rate per 100,000 population.

2. Number of diagnoses of hepatitis C infection in state/territory health jurisdictions in which Indigenous status was reported for more than 50% of diagnoses in each year.

3. Interpretation of trends in diagnoses of hepatitis C in Indigenous people is limited by incomplete information on Indigenous status.

N/A – data not available

Source: National Centre for HIV Epidemiology and Clinical Research 2006.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-119

OUTCOME 1: Population Health

Topic: IMMUNISATION

Written Question on Notice

Senator McLucas asked:

Information provided in E06-260 shows that the vaccine program was over budget by $32.65 million in 2005-06. It was stated that "increased expenditure is due to greater than anticipated uptake in both the newborn time-limited catch-up cohorts under the Childhood Pneumococcal Vaccination Program.

a) What does it mean that uptake was greater than anticipated?
b) What was the anticipated uptake for newborns and for catch up?
c) How does this fit with news reports in December that only 75% of eligible toddlers had received the vaccine?

Answer:

a) Funding for the Childhood Pneumococcal Vaccination Program (the Program) was based on the assumption that 90% of children aged 1-6 months, 70% of children aged 7-17 months and 60% of children aged 18-24 months would access the vaccine provided under the Program. However, the up-take was greater than anticipated. The Australian Childhood Immunisation Register (ACIR) shows that 85% of all 1-24 month old children eligible under the catch-up program have been vaccinated.

b) The anticipated up-take rate for children aged 1-6 months was 90%, 70% for children aged 7-17 months; and 60% for children aged 18-24 months.

c) According to the ACIR, 85% of children eligible for catch-up have been vaccinated.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-120

OUTCOME 1: Population Health

Topic: IMMUNISATION

Written Question on Notice

Senator McLucas asked:

a) What data is available about the effectiveness of the catch-up program for meningococcal C immunisation?
b) What percentage of the eligible population is now vaccinated?
c) What was the target?
d) Why was the catch up program extended beyond June 2006?
e) What were the costs associated with the catch up program – advertising, information to doctors, vaccine used, consultancies etc?
f) What were the additional costs of extending the catch up program beyond June 2006?

Answer:

a) Meningococcal C cases have fallen from 173 cases in 2000 to 23 cases in 2006.

In 2006, only 8 cases have been reported in children and young adults aged under 19 years.

b) As at 30 September 2006, the Australian Childhood Immunisation Register (ACIR) reports that meningococcal C vaccination coverage is:

- 92.4% in the cohort of children aged 24 to less than 27 months;
- 85.3% for children born since 1 January 2002 (that is, children aged less than 5 years);
- 73.3% for children born between 1 January 2001 and 30 December 2001 (that is, children aged 6 years);
- 68.2% for children born between 1 January 2000 and 30 December 2000 (that is, children aged 7 years).

There are no data available for children and adolescents over 7 years of age because the ACIR does not record vaccinations given to those over 7 years of age.

c) The target for children and adolescents to be immunised in the catch up program was 50% for each year cohort.

d) Following a request from Tasmania, South Australia, Queensland and New South Wales and the Australian Capital Territory the catch up component of the Program was extended to 30 June 2007 in these jurisdictions. The purpose of the extension was to further increase the Program's coverage.

e) For the period 2002-03 to 2004-05 the cost for the purchase of vaccine under the catch up component of the Program was $187 million.

Funds of $2 million were expended on a communication program, including advertising ($335,000) and materials ($1.1 million). It is not possible to disaggregate the proportion of funds used to support the ongoing and catch up programs.

f) The jurisdictions used their unexpended Program funds, that had already been provided by the Australian Government, for the catch-up Program. No additional funds were provided.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-169

OUTCOME 1: Population Health

Topic: RU486 - CAIRNS BASE HOSPITAL ETHICS COMMITTEE REPORT TO THE TGA

Hansard Page: CA 122, CA 123

Senator Barnett asked:

Can the report from the Cairns Base Hospital Ethics Committee to the TGA on RU486 be made available to the Committee?

Answer:

The Ethics Committee report is considered confidential and cannot be released. The report from the Ethics Committee, required as part of the approval, has been received by the TGA and fulfils the requirements of the approval.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-219

OUTCOME 1: Population Health

Topic: HIV/AIDS AND SEXUALLY TRANSMISSIBLE INFECTIONS (STIS)

Hansard Page: CA 114-115

Senator Moore asked:

(b) [In relation to] HIV/AIDS, gonorrhoea, syphilis, chlamydia and hepatitis C, I want the number of reported infections, the infection rate, the particular infection rate in the Indigenous community, Federal funding excluding PBS funds, and PBS funds in their own right from 1996-97 financial year until now.
(c) [In relation to] the range of HIV drugs [antiretrovirals] provide the PBS funding.

Answer:

(a) The number of reported infections, the infection rate and infection rate in the Indigenous community for HIV/AIDS, gonorrhoea, syphilis, chlamydia and Hepatitis C are at Attachment A.

Federal funding on HIV/AIDS, sexually transmissible infections and Hepatitis C is only available from 1999-2000 and is shown below:

Financial Year	**Expenditure ($ million)**[1]
1999-2000	29.8
2000-2001	35.1
2001-2002	35.1
2002-2003	34.7
2003-2004	34.3
2004-2005	34.3
2005-2006	35.9

1. Includes funding for national prevention programs coordinated by Population Health Division and the Office of Aboriginal and Torres Strait Islander Health, research and surveillance, funding to the states and territories for hepatitis C initiatives, and COAG funding for needle and syringe programs. Funding does not include expenditure on research from the National Health and Medical Research Council, funding provided to the states and territories under the Public Health Outcome Funding Agreements, or expenditure under the Medicare Benefits Schedule, Pharmaceutical Benefits Scheme and Health Care Agreements.

Funding from the Pharmaceutical Benefits Scheme (PBS) on HIV/AIDS, sexually transmissible infections and Hepatitis C is shown below:

Financial Year	Expenditure ($ million) [1]
1996-1997	21.3
1997-1998	87.0
1998-1999	103.2
1999-2000	120.2
2000-2001	120.9
2001-2002	139.4
2002-2003	153.0
2003-2004	167.7
2004-2005	190.5
2005-2006	210.8

1. Includes available PBS data for HIV/AIDS, sexually transmissible infections and Hepatitis C treatment. Includes HIV/AIDS treatments from 1997-98 and hepatitis C treatments from 1999-2000.

(b) Funding for HIV antiretroviral agents is as follows:

Financial Year	Expenditure ($ million) [1]
1997-1998	61.8
1998-1999	67.0
1999-2000	69.8
2000-2001	67.2
2001-2002	67.1
2002-2003	76.1
2003-2004	81.6
2004-2005	92.2
2005-2006	103.8

1. Includes all available PBS data.

Estimated number of cases of newly diagnosed HIV infection*

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Number of new HIV diagnoses (1)	899	721	645	685	656	690	825	812	849	928
Number of new HIV diagnoses in Indigenous people (2)	19	15	28	9	16	14	25	23	21	17
HIV diagnosis rate** - Non-Indigenous	6.3	5.9	4.0	3.9	4.1	4.2	4.6	4.7	4.9	5.2
HIV diagnosis rate** - Indigenous	5.2	4.5	7.4	2.1	4.5	4.0	7.1	6.4	5.5	4.5

1. Numbers given are the estimated number of HIV diagnoses in each year not reported in previous years.

2. Not adjusted for multiple reporting. Information on Indigenous status was not available from ACT by 31 March 2006. Information on Indigenous status was available in VIC from 1 June 1998.

*Adjusted for multiple reporting.
** Age standardised rate per 100 000 population.

Number of AIDS diagnoses*

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Number of new AIDS diagnoses	671	395	328	212	262	209	237	247	216	257
Number of new AIDS diagnoses in Indigenous people (1)	10	4	9	5	5	5	8	11	11	8
AIDS diagnosis rate** - Non-Indigenous	3.7	2.2	1.6	1.1	1.4	1.1	1.2	1.2	0.9	1.0
AIDS diagnosis rate**- Indigenous	2.9	1.2	2.6	1.2	1.5	2.2	2.3	3.1	3.9	2.3

1. Not adjusted for reporting delay. Information on Indigenous status was not available from ACT by 31 March 2006. Information on Indigenous status was available from VIC from 1 June 1998.

*Adjusted for reporting delay.
**Age standardised rate per 100,000 population.

Number and rate of diagnoses of gonorrhoea

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Number of reported gonorrhoea diagnoses	4141	4640	5469	5587	5897	6291	6279	6792	7187	8015
Gonorrhoea diagnosis rate (1)	22.6	25.0	29.0	30.0	31.4	33.5	33.1	35.7	37.6	41.5
Number of diagnoses of gonorrhoea - Indigenous (2)	1612	1834	1905	1765	2011	2042	2321	265	3122	3524
Gonorrhoea diagnosis rate Indigenous (3)	1291	1192	1240	1184	1134	946	854	898	1013	1155

1. Age standardised rate per 100,000 population.

2. Number of diagnoses of gonorrhoea in state/territory health jurisdictions in which Indigenous status was reported for more than 50% of diagnoses in each year.

3. Interpretation of trends in diagnoses of gonorrhoea in Indigenous people is limited by incomplete information on Indigenous status.

Source: National Centre for HIV Epidemiology and Clinical Research 2006.

Number and rate of diagnosis of syphilis infection

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Number of reported syphilis diagnoses	1512	1254	1678	1824	1855	1851	1958	2007	2332	2203
Syphilis diagnosis rate (1)	8.3	6.7	8.9	9.6	9.6	9.5	9.9	10.0	11.6	10.7
Number of diagnoses of syphilis - Indigenous (2)	325	309	383	357	317	757	749	634	593	539
Syphilis diagnosis rate - Indigenous (3)	260	221	308	305	214	216	206	182	188	171

1. Age standardised rate per 100,000 population.

2. Number of diagnoses of syphilis in state/territory health jurisdictions in which Indigenous status was reported for more than 50% of diagnoses in each year.

3. Interpretation of trends in diagnoses of syphilis in Indigenous people is limited by incomplete information on Indigenous status.

Number and rate of diagnosis of chlamydia infection

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Total Number of reported chlamydia diagnoses	8351	9176	10928	14046	17023	20330	24043	30439	36227	41311
Chlamydia diagnosis rate (1)	45.6	50.1	87.1	74.7	89.9	109.5	129.0	162.7	192.5	217.2
Number of diagnoses of chlamydia - Indigenous (2)	997	994	1240	1765	1537	1686	1736	2241	2406	2392
Chlamydia diagnosis rate - Indigenous (3)	798	636	761	1184	861	921	944	1225	1319	1280

1. Age standardised rate per 100,000 population.

2. Number of diagnoses of chlamydia in state/territory health jurisdictions in which Indigenous status was reported for more than 50% of diagnoses in each year.

3. Interpretation of trends in diagnoses of chlamydia in Indigenous people is limited by incomplete information on Indigenous status.

Number and rate of diagnosis of hepatitis C infection

	1996	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
Number of reported hepatitis C diagnoses	19261	17261	17783	19168	20188	20031	14857	14210	13403	12594
Hepatitis C diagnosis rate (1)	105.2	92.8	94.6	102.3	107.2	105.6	76.9	73.1	68.1	63.4
Number of diagnoses of hepatitis C - Indigenous (2,3)	N/A	121	193	227	304	432	562	483	613	535

1. Age standardised rate per 100,000 population.

2. Number of diagnoses of hepatitis C infection in state/territory health jurisdictions in which Indigenous status was reported for more than 50% of diagnoses in each year.

3. Interpretation of trends in diagnoses of hepatitis C in Indigenous people is limited by incomplete information on Indigenous status.

N/A – data not available

Source: National Centre for HIV Epidemiology and Clinical Research 2006.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-07, 1 November 2006

Question: E06-112

OUTCOMES: 1 - Population Health (TGA) and 13 - Acute Care (NBA)

Topic: BLOOD PLASMA REVIEW

Written Question on Notice

Senator McLucas asked:

Please provide a list of all meetings that the TGA and the NBA have held with State and Territory officials since January 2006 on issues to do with blood and blood products. Please include date, location, attendees and topics discussed.

Answer:

Therapeutics Goods Administration (TGA)
The TGA is an observer on the Jurisdictional Blood Committee, a subcommittee of Australian Health Ministers' Advisory Council (AHMAC). TGA is represented by the TGA National Manager and on occasion he may delegate to the Director of Office of Devices Blood and Tissues and the Head of the Blood and Tissues Unit, Office of Devices Blood and Tissues.

National Blood Authority (NBA)
The NBA was established to manage the national blood supply on behalf of all governments who have agreed to jointly fund the national blood supply and to implement a nationally agreed framework for the management of safety and quality issues within the Australian blood sector. In that role it is the NBA's responsibility to meet on a regular basis with representatives of all governments to discuss blood and blood products.

The NBA provides secretariat services (and has observer/expert status) for the Jurisdictional Blood Committee (JBC), the main Commonwealth/state/territory body that oversights blood and blood matters for Health Ministers. Most formal interaction has occurred through this Committee. Meetings have been held in Canberra or via teleconference on:

- 24 January 2006;
- 2 March 2006 (teleconference);
- 21 April 2006;
- 13 June 2006 (teleconference);
- 22 June 2006;
- 1 September 2006; and
- 16 November 2006.

Topics have included:

- Australian Red Cross Blood Society (ARCBS) Deed matters
- ARCBS Funding claims for prior financial years
- Funding policy for blood services provided by the Australian Red Cross Society
- JBC Strategic Framework
- Bacterial Contamination of ARCBS Products
- 2006-07 and 2007-08 National Supply Plans and Budgets
- Product Supply and Funding Policy issues
- Plasma Derived factor VIII and IX Supply issues including plasma for next generation Intragam P
- NBA operational matters
- TGA issues including Trans Tasman Regulatory Authority and Blood Products Regulatory Authority and National Blood Management System status report
- ARCBS infrastructure and capital issues
- ARCBS Interim National Emergency Blood Management Plan
- Plasma Fractionation Review processes
- Administration matters including AHMAC/ Australian Health Ministers' Conference (AHMC) papers and incoming correspondence
- ARCBS business study
- Transfusion safety data
- Overseas supply policy
- IVIg criteria for use
- Schedule 4 procedures
- Inventory Management priorities including QLD Pacific Commerce Ordering and Receipting system pilot
- Review of the National Blood Arrangements
- 2006 JBC Annual Report

Attendees have been JBC members (see list). The NBA has attended all these meetings.

In addition to these formal meetings, staff from the NBA are in regular contact with various JBC members and other representatives within the states and territories to gather the views of the jurisdictions on a range of issues covering the work of the NBA as determined by JBC. We do not keep records of all these occurrences. These discussions would typically cover issues such as:

- Supply plan performance, adjustment and requirements
- Invoicing and acquittal procedures
- Risk mitigation procedures and practices
- JBC procedures such as finalisation of minutes and action items
- Inventory management issues
- Supplier contract performance
- Product specific status and issues such as intensive product management around products in short supply
- Options and strategies to improve practices relating to the use and management of blood and blood products.

Name	Title	Organisation
Ms Kerry Flanagan	First Assistant Secretary Acute Care Division	Commonwealth Department of Health and Ageing
Mr Bill Heiler	Director, Clinical Policy	NSW Department of Health
Dr Chris Brook	Director, Rural and Regional Health and Aged Care Services	Victorian Department of Human Services
Dr Peter Lewis-Hughes	Executive Director, Clinical and Statewide Services	Queensland Health
Ms Joan Bedford	Senior Portfolio Officer Statewide Contracting Health System Support	Health Department of WA
Ms Susan Ireland	Manager Blood, Organ and Tissue Programs	SA Department of Health
Dr Paul McCann	Senior Medical Consultant Acute Health Services	Tasmanian Department of Health and Human Services
Dr Paul Dugdale	Chief Health Officer	ACT Health
Ms Meri Fletcher	Director Policy & Services Development Acute Care	NT Department of Health & Community Services

Secretariat		
Ms Stephanie Gunn	Deputy General Manager, Corporate Management	National Blood Authority
Ms Judith Shackley	Manager, Secretariat	National Blood Authority
Ms Nada Martinovic	Secretariat Officer	National Blood Authority

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-07, 1 November 2006

Question E06-113

OUTCOMES: 1 - Population Health (TGA) and 13 - Acute Care (NBA)

Topic BLOOD PLASMA REVIEW

Written Question on Notice:

Senator McLucas asked:

Please provide a list of all meetings that the TGA and the NBA have held with CSL since January 2006 on issues to do with blood and blood products. Please include date, location, attendees and topics discussed.

Answer:

Therapeutics Goods Administration (TGA)
CSL is a manufacturer and product sponsor of registered medicines, including blood products and reagent red blood cell in vitro diagnostics. The TGA as the regulator of these products holds regular meetings with CSL on a whole range of regulatory issues which may include issues on manufacturer audits, product applications, product safety issues, adverse reaction reports, recalls and batch testing.

Date	Location	Attendees	Topics Discussed
24 March 2006	Therapeutic Goods Administration, Narrabundah Lane, Symonston ACT 2609	TGA • Head of Blood and Tissues • Clinical Unit Head, Drug Safety and Evaluation Branch • Medical Officer, Drugs Safety and Evaluation Branch • Medical Officer, Drugs Safety and Evaluation Branch CSL • Medical and	• Product Registration Issues

		Research Director • Head of Regulatory Affairs • Consultant • Consultant	
20 – 23 March 2006	CSL Bioplasma 189 Camp Road Broadmeadows VIC	TGA • 2 x TGA specialist auditors	• Routine GMP Audit of the facility
3 April 2006	CSL Bioplasma 189 Camp Road	TGA 2 x TGA specialist auditors	• Routine GMP Audit of the facility
8-9 May 2006	CSL Bioplasma 189 Camp Road	TGA • Evaluator, Blood and Tissues Unit, Office of Devices Blood and Tissues CSL • Principal Regulatory Affairs Associate • General Manager	• Educational visit regarding the physical and functional aspects of the facility.
2 June 2006	CSL Bioplasma 189 Camp Road	TGA • National Manager • Director, Office of Devices Blood and Tissues • Head of Blood and Tissues Unit, Office of Devices Blood and Tissues CSL • President, CSL Bioplasma • General Manager • Medical and Research Director • Head of Regulatory Affairs • Quality Director • Manufacturing Director	• Regulatory Issues
5 July 2006	CSL Bioplasma 189 Camp Road	TGA • Assistant Secretary, Manufacturers	• Meeting to discuss audit findings

		Assessment Branch • TGA Specialist Auditor <u>CSL</u> • Quality Director • General Manager • Quality Assurance Manager	
23 Aug 2006	CSL Bioplasma, 189 Camp Road	<u>TGA</u> • Director, Office of Devices Blood and Tissues • Head of Blood and Tissues Unit, Office of Devices Blood and Tissues <u>CSL</u> • Medical and Research Director • General Manager • Quality Director • Principal Regulatory Affairs Associate • Regulatory Affairs Manager (International) • Acting Head, Regulatory Affairs • Principal Regulatory Affairs Associate • Regulatory Affairs Manager (Compliance)	• Consultation on proposed Australia New Zealand Therapeutic Products Authority (ANZTPA) Blood Rule.
30 Aug 2006	Therapeutic Goods Administration, Narrabundah Lane, Symonston ACT 2609	<u>TGA</u> • Head of Blood and Tissues Unit, Office of Devices Blood and Tissues • Section Head, Blood Products, Blood and Tissues Unit, Office of	• Product safety issues.

		Devices Blood and Tissues • Clinical Unit Head, Drug Safety and Evaluation Branch • Team Leader, Immunology, TGA Laboratories Branch <u>CSL</u> • Senior Regulatory Affairs Associate • Medical and Research Director • Research and Development Manager • Head of Virology • Project Manager • Senior Scientist	
6 Sept 2006	Teleconference	<u>TGA</u> • Team Leader, Viral Safety, TGA Laboratories Branch • Evaluator, Viral Safety, TGA Laboratories Branch <u>CSL</u> • Head of Virology • Senior Scientist	• Product safety issues
28 Nov 2006	Therapeutic Goods Administration, Symonston, Canberra	<u>TGA</u> • Clinical Unit Head, Drug Safety and Evaluation Branch • Clinical Advisor, Blood and Tissues Unit, Office of Devices Blood and Tissues • Head of Blood	• Product clinical issues

		and Tissues Unit, Office of Devices Blood and Tissues <u>CSL</u> • Senior Regulatory Affairs Associate • Medical and Research Director • Acting Head of Regulatory Affairs • Clinical Programme Manager <u>New Zealand</u> • Stewart Jessamine (via teleconference)	

National Blood Authority (NBA)

The NBA was established to manage the national blood supply on behalf of all governments who have agreed to jointly fund the national blood supply and to implement a nationally agreed framework for the management of safety and quality issues within the Australian Blood sector.

In that role it is the NBA's responsibility to meet on a regular basis with CSL to discuss issues relating to the supply of product provided for under the various contractual obligations established between the parties.

These meetings can be either formal face to face meetings such as for annual stock take purposes and formal contract review meetings or phone based discussions in relation to specific product or contract related issues. We do not keep records of all these occurrences.

Issues that may be covered in these formal and informal meetings include:

- Management and operation of the Plasma Products Agreement (PPA)
- Management of product in short supply
- Supply planning requirements
- Data clarification
- Supply trends, production yields and status of batch processes

Some of the more significant meetings that the NBA has held with CSL include:

Date	Location	Attendees	Topics Discussed
18 January 2006	Teleconference	Shannon Gibson Jeff Davies Vito Micucci Peter DeGraaff and others	Monthly Operational Report (MOR) Meeting
22 February 2006	Teleconference	Shannon Gibson Jeff Davies Vito Micucci Di Black Liz Campbell Peter DeGraaff and others	MOR Meeting
16 March 2006	CSL	Shannon Gibson John Lontos Ravi Hattarki Cheryll McLeod Barry Melgaard and others	NBA Tour of CSL Operations
17 March 2006	Teleconference	Shannon Gibson Cheryll McLeod Peter DeGraaff Barry Melgaard Rob Clifford	Review March NBA Plan and Issues with Over Supply
21 March 2006	Teleconference	Shannon Gibson Jeff Davies	MOR Meeting

		Angelo Chiodo Liz Campbell Cheryll McLeod Di Black Vito Micucci Peter DeGraaff Barry Melgaard Rob Clifford Niv Sivapalan	
21 March 2006	Teleconference	Shannon Gibson Cheryll McLeod Peter DeGraaff Barry Melgaard Niv Sivapalan	NBA Confirmed Quarterly Requirements (CQR) Quarter 2
24 March 2006	Teleconference	Shannon Gibson Cheryll McLeod Peter DeGraaff Barry Melgaard and others	NBA CQR Quarter 2 Follow Up
29 March 2006	National Blood Authority	Jeff Davies Shannon Gibson Peter DeGraaff Barry Melgaard Rob Clifford David Knight	Proposal for Distribution of Hyperimmune Products
19 April 2006	Teleconference	Shannon Gibson Jeff Davies Angelo Chiodo Liz Campbell Cheryll McLeod Di Black Vito Micucci Peter DeGraaff Barry Melgaard	MOR Meeting
22 May 2006	CSL	Jeff Davies Vito Micucci Liz Campbell Shannon Gibson Di Black Peter DeGraaff Barry Melgaard	MOR Meeting
26 May 2006	Teleconference	Shannon Gibson Cheryll McLeod Peter DeGraaff Barry Melgaard	Review NBA Revised Annual Supply Estimates (ASE's)
21 June 2006	Teleconference	Barry Melgaard Peter Hade Rob Clifford Niv Sivapalan Shane Marshall Jeff Davies Shannon Gibson	MOR and CQR Review

		Vito Micucci Di Black Liz Campbell	
23 June 2006	National Blood Authority	Barry Melgaard Niv Sivapalan Shane Marshall Peter Hade Rob Clifford Jeff Davies and others	CQR Planning
26 June 2006	National Blood Authority	Sandra Cochrane Helen Fowler Niv Sivapalan Shane Marshall Tony Glen Susan James Peter Hade Rob Clifford Barry Melgaard Peter DeGraaff Shannon Gibson Jeff Davies	Supply Planning Meeting for 2007-08
26 June 2006	National Blood Authority	Barry Melgaard Andrew Bartlett Rob Clifford Shannon Gibson	ARs, Reconciliation Report, FXI, FXIII and e-portal training
27 June 2006	National Blood Authority	Peter DeGraaff Peter Hade and others	Tender Debrief,
28 June 2006	Parkville and Broadmeadows, Melbourne	NBA and CSL teams	Stocktake
4 July 2006	Teleconference	Sam Houcher Shannon Gibson Peter DeGraaff Barry Melgaard Rob Clifford	PPA Report Review
6 July 2006	National Blood Authority	Peter DeGraaff Shane Marshall Barry Melgaard Rob Clifford Tony Glen Peter Hade CSL	OPM Meeting with CSL and ARCBS
20 July 2006	National Blood Authority	Rob Clifford Peter Hade Niv Sivapalan Shane Marshall Peter DeGraaff Shannon Gibson Jeff Davies Vito Micucci	MOR Meeting

		Di Black Liz Campbell	
3 August 2006	Teleconference	Jeff Davies Peter DeGraaff	Tele with Peter and Jeff
21 August 2006	Teleconference	Jeff Davies Peter DeGraaff	IG Next Gen
23 August 2006	Teleconference	Shannon Gibson Cheryll McLeod Peter DeGraaff Barry Melgaard Rob Clifford	NBA S&OP Plan
24 August 2006	Teleconference	Shannon Gibson Jeff Davies Vito Micucci Di Black Liz Campbell Peter DeGraaff Barry Melgaard Rob Clifford	MOR Meeting
5 September 2006	CSL	Peter DeGraaff Rob Clifford Shannon Gibson Sam Haouchar Alan Olsen	Goods Receipt Verification
20 September 2006	Teleconference	Peter DeGraaff Rob Clifford Shannon Gibson Jeff Davies Vito Micucci Di Black Liz Campbell	MOR Meeting
5 October 2006	National Blood Authority	Peter DeGraaff Peter Hade Jeff Davies Tom Giarla Shannon Gibson	Range of Operational Issues
12 October 2006	National Blood Authority	Shane Marshall Tian Erho Sandra Cochrane Helen Fowler Peter Hade Rob Clifford John Cullen Debbie Hurlbut Sherrie Choikee CSL	CSL IPM Meeting
26 October 2006	Teleconference	Michael Stone Rob Clifford Peter Hade Shannon Gibson Jeff Davies Vito Micucci	MOR Meeting

		Di Black Liz Campbell	
2 November 2006	National Blood Authority	Michael Stone Peter Hade Jeff Davies Shannon Gibson	Contingency Planning Meeting
13 November 2006	CSL	Jeff Davies Darryl Maher Liz Campbell Shannon Gibson Vito Micucci Michael Stone Peter Hade Leigh McJames	Meeting with NBA and CSL
14 November 2006	CSL	Michael Stone Peter Hade Jeff Davies Darryl Maher Liz Campbell Shannon Gibson Vito Micucci	Range of Operational Issues
23 November 2006	Teleconference	Leigh McJames Michael Stone Peter Hade Shannon Gibson Jeff Davies Vito Micucci Di Black Liz Campbell	MOR Meeting
29 November 2006	National Blood Authority	Julie Bland Rob Clifford William Hogan CSL	CSL National Blood Supply Change Program (NBSCP)
8 December 2006	CSL	Debbie Hurlbut Shannon Gibson Mark Disco	Plant Tour for Debbie Hurlbut
8 December 2006	CSL	Debbie Hurlbut Sam Haouchar Rey Sumaru Shannon Gibson	Exploring Options of Data Communications with NBA

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-07, 1 November 2006

Question: E06-114

OUTCOMES: 1 - Population Health (TGA) and 13 - Acute Care (NBA)

Topic: BLOOD PLASMA REVIEW

Written Question on Notice

Senator McLucas asked:

Please provide a list of all meetings that the TGA and the NBA have held with ARCBS since January 2006 on issues to do with blood and blood products. Please include date, location, attendees and topics discussed.

Answer:

Therapeutics Goods Administration (TGA)
The Australian Red Cross Blood Service (ARCBS) is the manufacturer of labile blood components and the supplier of plasma to CSL for the manufacture of plasma derived blood products. CSL is the sponsor of the plasma derived products which are distributed within Australia by the ARCBS.

The TGA as the regulator of these products holds regular meetings with ARCBS on a whole range of regulatory issues which may include issues on manufacturer audits, product standards, product safety issues, adverse reaction reports, recalls and QC testing.

Date	Location	Attendees	Topics Discussed
10 Jan 2006	ARCBS, Springwood QLD	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager ARCBS • Quality Department Representative	• Routine Good Manufacturing Practice (GMP) Audit
17 Jan 2006	ARCBS, Sale VIC	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine GMP Audit

23 – 24 Jan 2006	ARCBS, Hobart TAS	TGA • 3 x GMP Specialist Auditors ARCBS • Quality Department Representatives x 2	• Routine GMP Audit
24 Jan 2006	ARCBS, Sydney NSW	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager • Section Head, Therapeutic Goods Administration Laboratories Branch	• Regulatory GMP Audit
25 Jan 2006	Manufacturers Assessment Branch, Therapeutic Goods Administration, Melbourne Office, Level 8, Casselden Place, Melbourne	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager • GMP Specialist Auditor ARCBS • Quality Manager ARCBS Queensland • Project Manager – Brisbane Operations Centre	• New Brisbane Manufacturing facility
25 Jan 06	Manufacturers Assessment Branch, Therapeutic Goods Administration, Melbourne Office, Level 8, Casselden Place, Melbourne – participation via teleconference	TGA • Director, Office of Devices Blood and Tissues • Blood, Tissue & Cellular Therapies Audit Team Manager • Section Head, Therapeutic Goods Administration Laboratories Branch • Clinical Adviser, Blood and Tissues Unit, Office of Blood Devices and Tissues ARCBS • Transfusion Medicine	• Transfusion associated bacterial contamination

		Specialist • Transfusion Medicine Specialist • National Quality Manager • National Regulatory Affairs Manager • NSW Health Representatives	
30 Jan 2006	ARCBS, Nepean NSW	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
31 Jan 2006	ARCBS, Dubbo NSW	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
1 Feb 2006	ARCBS, Bourke Street VIC	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
1 Feb 2006	ARCBS, Orange NSW	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
2 Feb 2006	ARCBS, Shepparton VIC	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit

13 Feb 2006	ARCBS, Mildura VIC	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
14 Feb 2006	ARCBS, Horsham VIC	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
14 Feb 2006	Via teleconference	TGA • Head of Blood and Tissues Unit, Office of Devices Blood and Tissues • Clinical Advisor, Blood and Tissues Unit, Office of Devices Blood and Tissues • Blood, Tissue & Cellular Therapies Audit Team Manager • Chief Microbiologist, TGA Laboratories ARCBS • National Operations Manager • Chief Medical Officer • National Donor Medical Services Manager • National Govt & International Relations Manager • National Change, Learning & Development Manager • National Quality Manager	• Microbial contamination rates
16 Feb 2006	Via teleconference	TGA • Clinical Advisor, Blood and Tissues	• Microbial contamination rates

		Unit, Office of Devices Blood and Tissues ARCBS • National Operations Manager • Transfusion Medicine Specialist NSW • National Change, Learning & Development Manager • National Quality Manager • National Regulatory Affairs Manager	
16 Feb 2006	ARCBS, Traralgon VIC	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
24 Feb 2006	Therapeutic Goods Administration, Narrabundah Lane, Symonston ACT 2609	TGA • Director, Office of Devices Blood and Tissues • Head of Blood and Tissues Unit, Office of Devices Blood and Tissues • Clinical Advisor, Blood and Tissues Unit, Office of Devices Blood and Tissues • Manufacturers Assessment Branch Auditor • Head Medical Devices Assessment Section, Office of Devices Blood and Tissues • Manager, IVD Assessment, Medical Device Assessment Section, Office of Devices Blood and Tissues • Head Policy and Regulatory Liaison	• Sector bilateral update against Business Plan, updates and trends

		Section, Office of Devices Blood and Tissues ARCBS • Chief Executive Officer • National Operations Manager • National Quality & Systems Manager • National Quality Manager • National Donor & Product Safety Specialist • National Regulatory Affairs Manager	
27 Feb 2006	ARCBS, Currie Street SA	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
28 Feb 2006	ARCBS, Midland WA	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
1 Mar 2006	ARCBS, Townsville QLD	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
1 Mar 2006	ARCBS, Rockingham WA	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
2 Mar 2006	ARCBS, Fremantle WA	TGA • GMP Specialist	• Routine Audit

		Auditor ARCBS • Quality Department Representative	
27 Mar 06		TGA • National Manager ARCBS • ARCBS Board	• ARCBS Board regulatory discussion
29 Mar 2006	ARCBS, Broome WA	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager	• Routine Audit
31 Mar 2006	ARCBS, Cannington WA	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager ARCBS • Quality Department Representative	• Routine Audit
6 Apr 2006	ARCBS, Wollongong NSW	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
10 Apr 2006	ARCBS, Gosford NSW	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
12 – 13 Apr 2006	ARCBS, ACT	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit

2 May 2006	ARCBS, Swan Hill VIC	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
24 May 06	ARCBS, Taree NSW	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
30 May – 1 Jun 2006	ARCBS, Southbank VIC	TGA • 3x GMP Specialist Auditor ARCBS • Quality Department and OU Representatives x 6	• Routine Audit
12 Jun 2006	Manufacturers Assessment Branch, Therapeutic Goods Administration, Geoscience Building Cnr Hindmarsh & Jerrabomberra Drives Symonston ACT 2609	TGA • Audit Team Manager, Manufacturers Assessment Branch, Therapeutic Goods Administration ARCBS • National Quality & Systems Manager • National Blood Management Systems Manager	• National Blood Management System
20 Jun 2006	Manufacturers Assessment Branch, Therapeutic Goods Administration, Melbourne Office, Level 8, Casselden Place, Melbourne	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager ARCBS • National Regulatory Affairs Manager • Regulatory Affairs Associate	• GMP matters, TMF changes, notification of licence changes, Manufacturers Assessment Branch (MAB) structure
28 – 29	ARCBS, Darwin NT	TGA	• Routine Audit

Jun 2006		• GMP Specialist Auditor ARCBS • Quality Department Representative	
29 Jun 2006	ARCBS, Southport QLD	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager ARCBS • Quality Department Representative	• Routine Audit
5 July 2006	Therapeutic Goods Administration, Narrabundah Lane, Symonston ACT 2609	TGA • Head of Blood and Tissues Unit, Office of Devices Blood and Tissues • Section Head, Blood Products, Blood and Tissues Unit, Office of Devices Blood and Tissues • Clinical Advisor, Blood and Tissues Unit, Office of Devices Blood and Tissues ARCBS • National Donor & Product Safety Specialist • National Regulatory Affairs Manager	• Sector bilateral update against Business Plan, updates and trends.
17 – 20 Jul 2006	ARCBS, Sydney	TGA • 2 x GMP Specialist Auditor ARCBS • Quality Department Representatives x 4	• Routine Audit
21 Jul 2006	ARCBS, Tamworth NSW	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit

27 Jul 2006	ARCBS, Parramatta NSW	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager ARCBS • Quality Department Representative	• Routine Audit
23 Aug 2006	ARCBS South Melbourne	TGA • Director, Office of Devices Blood and Tissues • Head of Blood and Tissues Unit, Office of Devices Blood and Tissues ARCBS • National Donor & Product Safety Specialist • National Regulatory Affairs Manager	• Consultation on proposed Australia New Zealand Therapeutic Products Authority (ANZTPA) Blood Rule
30 Aug 2006	Sydney	TGA • Clinical Advisor, Blood and Tissues Unit, Office of Devices Blood and Tissues. • Evaluator, Blood Products ARCBS • Various	• ARCBS Strategic Risk Management Forum
6 Sept 2006	ARCBS Level 6, 464 St Kilda Road VIC	TGA • Assistant Secretary, Manufacturers Assessment Branch, Therapeutic Goods Administration • Blood, Tissue & Cellular Therapies Audit Team Manager ARCBS • National Quality & Systems Manager • National Blood Management Systems Manager • National Operations	• National Blood Management System • Brief overview of GMP regulation • Overview of the Blood, Tissues and Cellular Therapies Technical Expert Reference Group

		Manager • National Regulatory Affairs Manager	
13 Sept 2006	ARCBS, Ballarat VIC	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
14 Sept 2006	ARCBS, Wangaratta VIC	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
15 Sept 2006	Manufacturers Assessment Branch, Therapeutic Goods Administration, Geoscience Building Cnr Hindmarsh & Jerrabomberra Drives Symonston ACT 2609	TGA • Audit Team Manager, Manufacturers Assessment Branch, Therapeutic Goods Administration ARCBS • National Blood Management Systems Manager	• National Blood Management System
4 Oct 2006	ARCBS, Mackay QLD	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
4 Oct 2006	ARCBS, Clarence Street Sydney	TGA • Audit Team Manager, Manufacturers Assessment Branch, Therapeutic Goods Administration ARCBS • National Quality Manager • NBMS Config & Validation Team	• National Blood Management System

		Member (by teleconference)	
5 – 6 Oct 2006	ARCBS, Cairns and Mareeba QLD	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
23 Oct 2006	ARCBS, SA	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
1 Nov 2006	ARCBS, Launceston TAS	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager ARCBS • Quality Department Representative	• Routine Audit
2 Nov 2006	ARCBS, Burnie TAS	TGA • Blood, Tissue & Cellular Therapies Audit Team Manager ARCBS • Quality Department Representative	• Routine Audit
2 Nov 2006	ARCBS, Springwood QLD	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit
3 Nov 2006	ARCBS, Lismore NSW	TGA • GMP Specialist Auditor ARCBS • Quality Department Representative	• Routine Audit

15 Nov 2006	Sydney	TGA • Section Head, Recalls, Office of Devices Blood and Tissues • Deputy Recall Coordinator, Office of Devices Blood and Tissues • Administrative Officer, Recalls Unit, Office of Devices, Blood and Tissues • Clinical Advisor, Blood and Tissues Unit, Office of Devices Blood and Tissues (via teleconference) ARCBS • National Quality Manager • National Quality Database Co-ordinator	• Review the implementation of the Monthly Reporting of Donor Initiated Recalls
17 Nov 2006	Via Teleconference	TGA • Blood, Tissue and Cellular Therapies Audit Manager, Manufacturers Assessment Branch • Clinical Advisor, Blood and Tissues Unit, Office of Devices Blood and Tissues ARCBS ▪ National Regulatory Affairs Manager	• MABTERG, Manufacturing Processes and Protocols

National Blood Authority (NBA)

The NBA was established to manage the national blood supply on behalf of all governments who have agreed to jointly fund the national blood supply and to implement a nationally agreed framework for the management of safety and quality issues within the Australian Blood sector.

In that role it is the NBA's responsibility to meet on a regular basis with ARCBS to discuss issues relating to the supply of product provided for under the various contractual obligations established between the parties. These meetings are either formal face to face meetings such as for contract review meetings or phone based discussions relating to specific product or contract related issues. We do not keep records of all these occurrences.

Issues that may be covered in these discussions include:

- Performance against agreed supply plan targets

- Funding and resource requests to governments
- Negotiations to sign the Deed
- Progress with implementation of the Deed, in particular scoping projects for the improvement in the management of blood inventory
- Risk management and contingency preparedness
- Priorities for the transfusion medicine services arm of ARCBS
- Effective management of product in short supply
- Ordering, Receipting invoicing and acquittal procedures
- Scope and process for the implementation of the Business Study agreed as a side letter to the Deed
- Capital planning
- Supply planning
- Development of protocols for the management of the Deed

Some of the more significant meetings that the NBA has held with ARCBS include:

Date	Locations	Attendees	Topics Discussed
4 April 2006	ARCBS Brisbane	ARCBS Risk Management NBA Fresh Blood Products	Establishment of National Managed Fund
26 May 2006	NBA Canberra	ARCBS Government and International Relations NBA Fresh Blood Products	Deed Implementation Meeting
26 June 2006	NBA Canberra	ARCBS Government and International Relations Transfusion Medicine NBA Fresh Blood Products and Supply Planning	Supply Planning Meeting
28 June 2006	ARCBS Melbourne	ARCBS Government and International Relations Transfusion Medicine NBA Fresh Blood Products	Deed Implementation Meeting
29 June 2006	ARCBS Melbourne	ARCBS Government and International	CFO Meeting 2006-07 Budget and Annual Capital Plan and Strategic

		Relations Capital Planning NBA Fresh Blood Products	Capital Investment Plan
5 September 2006	NBA Canberra	ARCBS Government and International Relations NBA Fresh Blood Products and Supply Planning	Deed Implementation Meeting and Supply Planning Issues
21 September 2006	NBA Canberra	ARCBS Government and International Relations NBA Fresh Blood Products	Deed of Agreement Protocols
3 October 2006	ARCBS Melbourne	ARCBS Government and International Relations NBA Fresh Blood Products	Financial and Deed Implementation Meeting
3 November 2006	NBA Canberra	ARCBS Risk Management NBA Fresh Blood Products	National Managed Fund
23 November 2006	NBA Canberra	ARCBS Government and International Relations NBA Fresh Blood Products	Deed Implementation Meeting
30 November 2006	ARCBS Brisbane	ARCBS Risk Management NBA Fresh Blood Products	National Managed Fund
1 December 2006	Teleconference	ARCBS Government and International Relations	Supply Planning and Mid-Year

		NBA Fresh Blood Products and Supply Planning	
6 December 2006	NBA Canberra	ARCBS Executive NBA Executive	Quarterly CEO Meeting #1 FY 2005-06 in Review, and review of Quarter 1 2006-07 -Annual Business Planning -Capital Planning -ARCBS Funding -Key Performance Indicators -Third Party Reviews -ARCBS Risk Management -Deed Implementation Progress -ARCBS Service Level Agreements with Approved Health Providers and other joint initiatives -ARCBS Business Study -2007-08 Supply Plan and Budget

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-216

OUTCOME 1: Population Health

Topic: NATIONAL BOWEL CANCER SCREENING PROGRAM

Hansard Page: CA 111

Senator Moore asked:

Can we find out where Faecal Occult Blood Test kits went to, not to whom but by state [and territory] breakdown?

How many went to people who were involved in the pilot program?

Answer:

As outlined in the table below, a total of 52,556 invitations were sent out during the period August to 31 October 2006. Of these, 1,651 have been sent out in Queensland, 49,414 in New South Wales and 1,491 have been sent out in the ACT. A total of 1,588 invitations have been sent to people who were involved in the Bowel Cancer Screening Pilot Program (noted as Pilot Participant Invitations in the table below).

NATIONAL BOWEL CANCER SCREENING PROGRAM - AUG 06 - OCT 06

	Aug-06	Sep-06	Oct-06	YTD
QLD				
National Program Invitations	41	40	30	111
Pilot Participant Invitations	560	560	420	1540
NSW				
National Program Invitations	12300	16517	20549	49366
Pilot Participant Invitations	12	16	20	48
ACT				
National Program Invitations	0	486	1005	1491
Pilot Participant Invitations	0	0	0	0
National				
National Program Invitations	12341	17043	21584	50968
Pilot Participant Invitations	572	576	440	1588
Total number of invitations sent	**12913**	**17619**	**22024**	**52556**

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-217

OUTCOME 1: Population Health

Topic: NATIONAL BOWEL CANCER SCREENING PROGRAM

Hansard Page: CA 110

Senator Moore asked:

Can you give us a breakdown of how the $43 million committed to the [bowel cancer screening] program is currently being spent?

Have you got an expenditure to date; for example, in terms of publicity, pathology, data collection and that kind of thing?

When you do that breakdown, can you advise as to the funds being provided to each state and territory and what you know those funds are being used for?

Answer:

Over the life of the Program, $26.5 million is forecast to be expended on:
(a) Faecal Occult Blood Test kits and pathology services
(b) Data collection services:
    i. Establishing and maintaining the national register and information hotline and state/territory information managers;
    ii. Mailhouse functions, including postage costs for sending invitations and program letters;
    iii. Information payments to health professionals.

The remaining funds will be spent on program evaluation and publicity, including printed materials, consumer awareness campaigns and educational activities for health professionals and program administration.

The $43.4 million committed to the National Bowel Cancer Screening Program has been spent to date as follows:

*Total Expenditure**	**2005-06**	**2006-07**
Administration and Evaluation	$731,815	$373,702
Register/Data Collection	$2,567,357	$1,494,828
Information/Awareness raising	$4,198	$547,391
FOBT Kits & pathology		$784,850
	$3,349,950	**$3,200,771**

*Includes both Departmental and Administered expenditure.
Expenditure is linked to commencement dates for sending out Program invitations to the eligible population.

No funding has been provided directly to state or territory governments for the rollout of this Program.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-218

OUTCOME 1: Population Health

Topic: CERVICAL SCREENING

Hansard Page: CA 112

Senator Moore asked:

a) Can we get a breakdown of Commonwealth funding spent [estimated amount] on cervical cancer screening programs together with the uptake [participation] rate as it has been reported each financial year from 1996-97?
b) Can you make a statement [about accuracy] when you give us the [expenditure] figures?

Answer:

a) The breakdown of Commonwealth Government funding spent on the National Cervical Screening Program (NCSP) is as follows:

Financial Year	**Australian Government Funding including Medicare[1] ($ million)**
1996-97	44.2[2]
1998-99	61.0[3]
1999-00	57.9[3]
2000-01	61.8[3]
2001-02	66.9[3]
2002-03	62.8[3]
2003-04	65.6[3]

[1]The National Cervical Screening Program is funded by the Commonwealth and state and territory governments. The Commonwealth funding includes Medicare payments and allocations to the states and territories. State and territory expenditure is not included in the table above.

[2]This figure represents the sum of the Commonwealth Specific Purpose Payments (1996-97) ($10 million) and Pathology paid for cervical cancer screening related MBS items 02081, 02338, 73053, 73055, 73057 and 73901 (1996-97) and does not include Medicare benefits paid for GP visits as there are no computerised attendance costs available for 1996-97.

[3] AIHW National Public Health Expenditure Reports 1998-99, 1999-00, 2000-01, 2001-02 to 2003-04. This figure does not include funds provided to the states and territories through the Public Health Outcome Funding Agreements to support cervical screening.

The breakdown of the proportion of women participating in the NCSP in Australians aged 20-69 years is as follows:

Years	Number of women participating in the Program	Participation rate[4]
1996 and 1997	2,630,235	62.4
1997 and 1998	2,721,650	62.6
1999 and 2000	3,314,787	61.3
2001 and 2002	3,365,111	61.0
2003 and 2004	3,412,852	60.7

Source: AIHW Cervical Screening in Australia 2003-04.

[4]The participation rate is age-standardised and represents the proportion of women in the target age range who have had a Pap smear in the two year interval.

b) The NCSP is a cost-shared program of the Australian and state and territory governments. In 1996-97, the Commonwealth Government provided funding to the states and territories through Specific Purpose Payments of $10 million to support the operation of the NCSP.

In 1997-98, Commonwealth Government funding for cervical screening was broadbanded into the Public Health Outcome Funding Agreements (PHOFAs). It is not possible, therefore, to disaggregate Commonwealth Government funding to states and territories from 1997-98. These Agreements provide funds for a range of public health programs and activities. State and territory governments decide how to allocate funds across the programs and activities. Current PHOFA funding for 2004-05 to 2008-09 is $812 million.

The estimates in the table have been sourced from the annual Australian Institute of Health and Welfare (AIHW) Public Health Expenditure reports which include both estimates of PHOFA contributions and Medicare Benefits Schedule (MBS) payments associated with NCSP.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-089

OUTCOME 1: Population Health

Topic: HEPATITIS

Written Question on Notice

Senator Evans asked:

Is anything being done to improve surveillance?

Answer:

New Australian Government funding of $1.8 million, over four years, was announced with the launch of the new National Hepatitis C Strategy on 1 July 2005. These funds are currently being allocated to state and territory governments for projects to support improvements to national Hepatitis C surveillance.

The Communicable Diseases Network Australia is considering recommendations from a discussion paper *Improving Indigenous Identification in communicable disease reporting systems* prepared for the Australian Government Department of Health and Ageing. Improvements in this area will result in better surveillance of many communicable diseases, including Hepatitis C.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-118

OUTCOME 1: Population Health

Topic: IMMUNISATION

Written Question on Notice

Senator McLucas asked:

a) What data is available about the effectiveness of the catch up program for pneucococcal immunisation?
b) What percentage of the eligible population is now vaccinated?
c) What was the target?
d) Was the catch up program extended beyond December 2005?
e) What were the costs associated with the catch up program – advertising, information to doctors, vaccine used, consultancies, etc?

Answer:

a)
The National Childhood Pneumococcal Vaccination Program commenced on 1 January 2005 as an ongoing program. It included a time-limited catch-up component with all children born from 1 January 2003 to 31 December 2004 eligible for free pneumococcal vaccine during 2005.

In 2004 there were 701 cases of invasive pneumococcal disease among children aged less than five years. During 2005, when the National Childhood Pneumococcal Vaccination Program was introduced, there were 305 cases of pneumococcal disease in children aged less than five years. This is a decrease of 56% in cases of pneumococcal disease in children under five years of age after just one year of the Program.

In 2004, 16 children under five years of age died from pneumococcal disease. In 2005, this had dropped to nine deaths. This is a decrease of 44% in deaths from pneumococcal disease in children under five years of age. To date in 2006 there have been 173 cases and 3 deaths in children less than five years.

b)
As of 30 June 2006, reports from the Australian Childhood Immunisation Register indicate that 89% of infants received the full schedule of three doses of pneumococcal vaccine when assessed at 12 months of age. Uptake of the time-limited catch-up program was also high with 85% of eligible children up to date for age.

c)
The target coverage rate for children aged 0-6 months was 90%; for children aged 7-17 months was 70%; and for children aged 18-24 months was 60% (age as of 1 January 2005).

d)
No.

e)
In 2005, $62.4 million was spent on the purchase of vaccine for the catch-up program. In addition, $6.4 million was allocated to meet the administrative support costs for the catch-up program (for example, staffing and redevelopment of the Australian Childhood Immunisation Register system). Of this, $5.6 million was spent on publicity and promotional activities.

There were no consultancies entered into in relation to this program.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-220

OUTCOME 1: Population Health

Topic: PNEUMOCOCCAL IMMUNISATION

Hansard Page: CA 115

Senator Moore asked:

g) What data is available about the effectiveness of the catch-up program for pneumococcal immunisation?
h) What percentage of the eligible population is now vaccinated?
i) Do you know the target that you aimed for?
j) Can you tell us what the costs associated with the catch-up program were? The kinds of things we expect they would be are: the advertising; doctors' information; the actual vaccines used; and consultancies. We are wanting to know the break-up. It is both the use and the administrative funds.
k) What was the anticipated uptake for newborns and for catch-up? So there would be the two: newborn children, which would be determined by how many children are born, and the catch-up period to get the people who missed out.

Answer:

a)
The National Childhood Pneumococcal Vaccination Program commenced on 1 January 2005 as an ongoing program. It included a time-limited catch-up component with all children born from 1 January 2003 to 31 December 2004 eligible for free pneumococcal vaccine during 2005.

In 2004 there were 701 cases of invasive pneumococcal disease among children aged less than five years. During 2005, when the National Childhood Pneumococcal Vaccination Program was introduced, there were 305 cases of pneumococcal disease in children aged less than five years. This is a decrease of 56% in cases of pneumococcal disease in children under five years of age after just one year of the Program.

In 2004, 16 children under five years of age died from pneumococcal disease. In 2005, this had dropped to nine deaths. This is a decrease of 44% in deaths from pneumococcal disease in children under five years of age. To date in 2006 there have been 173 cases and 3 deaths in children less than five years.

b)
As of 30 June 2006, reports from the Australian Childhood Immunisation Register indicate that 89% of infants received the full schedule of three doses of pneumococcal vaccine when assessed at 12 months of age. Uptake of the time-limited catch-up program was also high with 85% of eligible children up to date for age.

c) The target coverage rate for children aged 0-6 months was 90%; for children aged 7-17 months was 70%; and for children aged 18-24 months was 60% (age as of 1 January 2005).

d)
In 2005, $62.4 million was spent on the purchase of vaccine for the catch-up program. In addition, $6.4 million was allocated to meet the administrative support costs for the catch-up program (for example, staffing and redevelopment of the Australian Childhood Immunisation Register system). Of this, $5.6 million was spent on publicity and promotional activities.

There were no consultancies entered into in relation to this program.

e) Refer to answer in c).

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-020

OUTCOME 1: Population Health

Topic: AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AUTHORITY (ANZTPA)

Written Question on Notice

Senator Nettle asked:

a) During negotiations for the proposed Australia New Zealand Therapeutic Products Authority, is the Government prepared to allow New Zealand to carve out responsibilities relating to potential ever-greening obligations imposed on Australia's TGA under 17.10.4 of the AUSFTA?

b) Is the Government prepared to allow New Zealand to carve out obligations that relate to "fast-track discussions" with the US food and drug administration under annex 2C.4 of the AUSFTA?

c) If the above obligations are intended to be imposed on New Zealand what trade gains - if any - is NZ being offered for accepting these obligations?

Answer:

a) Australia has proposed that the current patent certification provisions of the *Therapeutic Goods Act 1989* will apply to the same range of applicants and products under the joint agency arrangements. This would mean that applicants in Australia and New Zealand seeking marketing approval of the class of products in which patent certification is required would have to certify that they:
   i. do not intend to market the product in a way that would infringe an Australian patent; or
   ii. if they do intend to enter the Australian market prior to the expiration of an Australian patent covering the product, that they have notified the patent holder of their intention to do so.

   This proposal has been put forward to ensure that Australia's obligations under AUSFTA Article 17.10.4 will continue to apply to products marketed in Australia under the new arrangements.

b) Regulatory cooperation under Annex 2-C is about advancing the existing dialogue between regulatory agencies. Dialogue currently occurs between the Therapeutic Goods Administration and the United States Food and Drug Administration. It is envisaged under the joint agency arrangements that dialogue will continue between the respective regulatory agencies.

c) Australian proposals in relation to Questions a) and b) above do not impose additional obligations on New Zealand.

Outcome 2

Pharmaceutical Benefits Pricing Authority Annual report 2005-2006

http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/D54934A7E75638F6CA2572170082946F/$File/pbpa%20annual%20report%202006.pdf

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-122

OUTCOME 2: Access to Pharmaceutical Services

Topic: REVIEW OF 12.5% GENERICS POLICY

Written Question on Notice

Senator McLucas asked:

a) Is this policy under review?
b) Is the review being conducted in-house or by a consultant?
c) If a consultant, who is this, and what is the cost of the consultancy?
d) When is the report on the impact of the policy due?
e) What information does the Department currently have on the discounts which are offered to pharmacists on PBS listed medicines? (is this collected in a systematic way?)

Answer

a) The policy has been considered as part of the development of proposals for PBS reform.

b) A separate formal review has not been conducted as this was overtaken by PBS reform.

c) Not applicable, see b) above.

d) Not applicable, see b) above.

e) Historically, the department has not had access to information on the discounts provided to pharmacists. However, during the PBS reform consultations, the department was provided with limited information on these discounts. When the new pricing arrangements for PBS listed medicines are implemented, the department will regularly have access to more detailed information on the prices at which medicines are actually sold.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-124

OUTCOME 2: Access to Pharmaceutical Services

Topic: INFORMATION CAMPAIGN TO IMPROVE COMMUNITY UNDERSTANDING OF GENERIC MEDICINES 2005-06 BUDGET

Written Question on Notice

Senator McLucas asked:

a) What has been done to implement this budget commitment?
b) What funds were provided to the NPS for this work?
c) Where did these funds come from within the Department?
d) What has been spent to date on this commitment?
e) Please provide details of spending.
f) What additional spending is planned?

Answer:

a) The National Prescribing Service (NPS) is funded by the Commonwealth Government to improve appropriate and cost effective prescribing of medicines. The current four-year funding agreement (expiring on 30 June 2009) includes provision for NPS to develop and deliver programs for health professionals and consumers to improve awareness, understanding and use of generic medicines.

Activity to date has included:
- NPS News 44 (February 2006) focused on generic medicines. NPS News is an information newsletter circulated to more than 50,000 health professionals.
- An article published in *Australian Pharmacist,* April 2006 edition. *Australian Pharmacist* is circulated to 8,200 pharmacists, who are members of the Pharmaceutical Society of Australia.
- An article published in *Australian Prescriber* outlining the equivalence between originator and generic medicines. *Australian Prescriber* is circulated to more than 50,000 health professionals.
- NPS, in partnership with Consumers' Health Forum of Australia, held a generic medicines consumer consultation forum in February 2006. This forum was attended by over 20 consumers with presentations by pharmacists, generic medicines industry representatives and Government representatives.
- Development of a generic medicines training module for peer educators and for senior consumers attending Quality Use of Medicines community education sessions. The module is currently being pilot tested through Council on the Ageing (COTA) organisations.
- An article included in Medicines Talk – a community group newsletter circulated to consumer groups.

b) It is not possible to separately identify funding to NPS for this specific measure. Rather, NPS is provided with core funding to support a number of objectives within its funding agreement.

Total funding for the four-year period to 30 June 2009 for NPS programs is as follows:

- Core Program, $68.9 million – comprising information materials and health programs for health professionals;
- Production of the *Australian Prescriber* journal, $5.9 million – published 6 times per year and distributed to more than 50,000 health professionals;
- Consumer Education $20.2 million – comprising activities to promote the appropriate use of medicines in the community.

c) The NPS programs described in answer to (b) above are funded through an administered appropriation as components of the 2005-06 Budget '*Quality Use of Medicines Programme'* measure.

d) As much of the activity described is part of general NPS activity it is not possible to separately identify NPS initiatives related to this measure.

e) Specific NPS activity supporting generic medicines awareness is at (a) above.

f) The following activities are planned:

- Generic medicine messages as part of a *Get to know your medicines* national awareness campaign in the second half of 2007, incorporating generic medicines messages.
- Update of Medimate (a consumer resource) to include a section on brand substitution.
- Insertion of materials into a community multicultural program to explain that generics offer the consumer choice.
- Provision of consumer materials through GPs and pharmacists, as research by NPS suggests that for serious conditions the GP's approval of the use of a generic medicine is important.
- Further articles have been commissioned for *Australian Prescriber*.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-202

OUTCOME 2: Access to Pharmaceutical Services

Topic: PBS GROWTH MODEL

Hansard Page: CA 23

Senator McLucas asked:

I understand it is a very complex model, but there must be a set of inputs that go into that point. You know – someone realises: 'Oh my goodness! There are so many more people with diabetes; we have got to factor that into the model.'

Ms Huxtable *– I think that previously, on notice, we have answered questions that go to how the model works, in general terms, and we can certainly refresh that and provide it again.*

Answer:

The Government's Accrual Information Management System (AIMS) contains three PBS components – 'general', 'concessional' and 'PB other'.

- In essence, the 'general' and 'concessional' components cover scripts issued in community pharmacies (drugs listed under Section 85 of the National Health Act). This amounts to around 90% of all PBS expenditure.

- 'PB other' covers a range of programs such as drugs listed under Section 100 of the National Health Act including highly specialised drugs and drugs included in doctor's bags.

The PBS Model is designed to produce forecasts of Government expenditure and script volumes for the general and concessional components spanning the forward estimates period (four years).

- The model does not attempt to deal with scripts that fail to attract any Government benefit (i.e. those below the general patient co-payment which is currently $29.50).

- The model's key output comprises tables of forecast monthly and annual Government expenditure and script volumes, broken down by concessional eligibility category and drug classification.

The model is routinely updated annually. This process commences at the end of each financial year with preparation of the following data:

- monthly Medicare Australia expenditure and script volume data to the end of the last financial year;
- latest population data from the Australian Bureau of Statistics; and
- latest concession card coverage data.

These data provide an indication of how trends in the utilisation of drugs have changed in the previous 12 months, which is an indirect measure of how diseases are being managed in the community setting via the use of medication. In addition, the data provide an indication of how population characteristics are changing (birth rates, death rates, age distribution) and the extent of concessional card coverage.

These factors are used to update the historical trend data in the model to produce estimates of future expenditure.

The final component of the model update is to adjust these figures for any known and anticipated effects, such as Budget measures, recent and expected major new listings.

Completion of the model update is aimed at the point at which the Government's Additional Estimates process is finalised for the year.

At any point the Government can vary the forward estimates to reflect new policy (especially in the May Budget) and to allow for apparent new trends. The model is subsequently updated to incorporate these changes where appropriate.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-203

OUTCOME 2: Access to Pharmaceutical Services

Topic: COST OF LISTINGS

Hansard Page: CA 24

Senator McLucas asked:

Can we have a breakdown of that drop in PBS due to lower demand and also costs of new listings? Can you disaggregate that answer – that $7.7 million?

Answer:

A deviation from forecast of $7.7 million in a PBS budget in excess of $6 billion is a 0.1% error and is well within acceptable margins of error for such a program. It is not possible to provide further information on the factors that contribute to a discrepancy of this order.

The following table summarises the impact on PBS Forward Estimates from major new listings and extensions listed in 2005-06:

New Listing/Extension	**Indication**	**Total Estimated Cost 2005-06 to 2008-09**
Eloxatin (Oxaliplatin)	Colon Cancer	$95.0m
Eloxatin – Additional Filgrastim Costs	Colon Cancer	$34.3m
Arimidex (Anastrozole)	Breast Cancer	$44.5m
Inspra (Eplerenone)	Hypertension	$16.0m
Vytorin (Ezetimibe with Simvastatin)	High Blood Cholesterol	$96.2m
Raptiva (Efalizumab)	Psoriasis	$169.0m

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-204

OUTCOME 2: Access to Pharmaceutical Services

Topic: PBS EXPENDITURE

Hansard Page: CA 24

Senator McLucas asked:

Is it possible to disaggregate according to those three categories of drugs?
Ms Huxtable *– What we certainly can do is show what the actuals have been year on year in respect of those drugs and you can see from that some of the patterns and the changed patterns in utilisation.*

Answer:

The table below shows PBS prescription numbers and Government benefit for the requested drug groups for the last 5 years.

	2001-02	2002-03	2003-04	2004-05	2005-06
Lipid modifying agents					
Scripts ('000)	12,301	13,320	14,709	16,215	17,365
Government benefit ($ m)	647.3	731.5	835.5	918.7	940.7
Antiinflammatory and antirheumatic products					
Scripts ('000)	8,653	9,095	9,143	7,696	5,874
Government benefit ($ m)	201.7	209.3	213.0	159.6	100.7
Psychoanaleptics (includes antidepressant drugs)					
Scripts ('000)	10,396	11,104	12,001	12,595	12,181
Government benefit ($ m)	293.3	317.3	350.5	360.1	329.6
Sex hormones and modulators of the genital system (includes HRT drugs)					
Scripts ('000)	5,738	4,371	3,791	3,563	3,246
Government benefit ($ m)	107.2	91.3	77.3	77.0	72.5

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-206

OUTCOME 2: Access to Pharmaceutical Services

Topic: PBS SCHEDULE

Hansard Page: CA 26

Senator McLucas asked:

Can we get a list of them and can we get the specific?
Ms Corbett *– They are listed on the PBS schedule. With each update of the PBS schedule there is a green lift-out, but we can certainly table the lift out from the last update.*

Answer:

The lift-out from the December Schedule of Pharmaceutical Benefits is attached, listing all brands of drugs which have a brand price premium as of 1 December 2006.

Weblink to above:
http://www.pbs.gov.au/html/healthpro/browseby/price-premiums#therapeutic_group_premium

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-208

OUTCOME 2: Access to Pharmaceutical Services

Topic: THERAPEUTIC GROUP PREMIUMS

Hansard Page: CA 27

Senator Moore/McLucas asked:

a) Could we get an indication of the number of authority approvals for scripts where doctors have requested that the premium payment not be applied? Is that possible?

Ms Corbett *– It is possible for us to identify the exemptions in the categories where they are available, yes. The data is collected by Medicare Australia. I do not have the details of it with me, but we could do that.*

Answer:

In the 2005-06 there were 4,064,382 prescriptions dispensed with a Therapeutic Group Premium. There were an additional 717,940 prescriptions dispensed where the prescribing doctor obtained an authority approval from Medicare Australia for waiving of the premium on the basis that the patient could not take an alternative medication.

In the 2005-06 there were 481,220 prescriptions dispensed with a Special Patient Contribution (SPC). There were an additional 293,805 prescriptions dispensed where the SPC was waived.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-210

OUTCOME 2: Access to Pharmaceutical Services

Topic: SPECIAL PATIENT CONTRIBUTIONS

Hansard Page: CA 30

Senator Moore asked:

a) We started out asking about special patient contributions and I will ask on notice for each medicine?
b) The amount of the special patient contribution? and,
c) When it was added?

Answer:

Drug	Use	Current SPC	SPC Start date
Bleomycin	Some cancers	$445.90	1 April 1986
Levetiracetam	Epilepsy	$7.13 - $19.84	1 August 2005
Topiramate	Epilepsy	$2.32 – $2.62	1 August 2005
Escitalopram	Depression	$3.20 – $4.33	1 August 2005
Pemetrexed	Non-small cell lung cancer	$398.72	1 August 2005
Lansoprazole (oral solution)	Proton pump inhibitor	$3.63	1 August 2006
Amoxycillin (paediatric drops)	Antibiotic for use in children	$0.58	1 October 2006

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-211

OUTCOME 2: Access to Pharmaceutical Services

Topic: SPC FINANCIAL YEAR CONTRIBUTIONS

Hansard Page: CA 30

Senator Moore asked:
I know that Senator Allison has asked and we have asked questions before about how much was paid in special patient contributions, but I want to clarify that for financial year 2005-06. Is that in someone's report? 1 August 2005 to 30 June 2006? I just want the financial year. *(Update of E06-202)*

Answer:

In the financial year 2005-06, it is estimated that $2.45 million was paid by patients in special patient contributions in respect of 481,220 prescriptions.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-212

OUTCOME 2: Access to Pharmaceutical Services

Topic: ALIMTA

Hansard Page: CA 31

Senator Moore asked:

The one that is not covered in that question is Alimta, for lung cancer. We have been following up on that. How many dispensed scripts attracted an SPC particularly in that area?

Answer:

In the financial year 2005-06, a total of 1,478 PBS scripts were dispensed for Alimta. Of these, 410 prescriptions were subject to a Special Patient Contribution.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-213

OUTCOME 2: Access to Pharmaceutical Services

Topic: WEIGHTED AVERAGE MONTHLY TREATMENT COSTS (WAMTC)

Hansard Page: CA 31

Senator Moore asked:

a) What is expected to happen to the brand premiums when these 1 December price changes happen?
b) Has any work been done on out-of-pocket costs to patients for these medicines?
c) How many PBS prescriptions were dispensed for SSRIs in 2004-05 and 2005-06?

Answer:

a) **SSRIs Drugs**
There has been no change to the brand premiums for Cipramil® (citalopram), Luvox® (fluvoxamine), and Zoloft® (sertraline).

The brand premium on Prozac® (fluoxetine) increased from $3.97 to $5.25 for both the 20 mg tablet and capsule. The brand premium on Aropax® (paroxetine) increased from $1.06 to $1.10 for the 20 mg tablet.

The introduction of a new brand of escitalopram on 1 December 2006 resulted in the conversion of special patient contributions to brand premiums for Lexapro® (escitalopram). The SPC of $3.20 for the 10 mg tablet became a brand premium. The SPC of $5.35 for the 20 mg tablet also became a brand premium.

SSRIs – plus drugs
There has been no change to the brand premiums for Avanza® (mirtazapine), Remeron® (mirtazapine), and Aurorix® (moclobemide).

b) No. However, the Department does not expect the impact on out-of-pocket costs to patients to be large. Every product with a brand premium has a product without a brand premium which is substitutable at the individual patient level.

c)

SSRIs Drugs		
	1 July 2004 – 30 June 2005	**1 July 2005 – 30 June 2006**
Total Scripts	8,177,507	8,494,663

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-214

OUTCOME 2: Access to Pharmaceutical Services

Topic: FOSAMAX

Hansard Page: CA 32

Senator Moore asked:

Minister, can you give us any information about the process of FOSAMAX going to Cabinet for approval?

Answer:

The Government expects to consider a possible extension to the listing of alendronate (Fosamax) in the near future.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-215

OUTCOME 2: Access to Pharmaceutical Services

Topic: PBPA CHAIR

Hansard Page: CA 33

Senator Moore asked:

Minister, would you be able to get an update for us on the expectation of permanently filling the position of PBPA chair?

Answer:

The Government is considering a possible permanent appointment to chair the Pharmaceutical Benefits Pricing Authority (PBPA). The Assistant Secretary, Pharmaceutical Evaluation Branch, is acting PBPA Chair and will chair the December 2006 PBPA meeting.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-121

OUTCOME 2: Access to Pharmaceutical Services

Topic: PATIENTS' OUT OF POCKET COSTS FOR MEDICINES WHERE THE COST IS LESS THAN THE (GENERAL) CO-PAYMENT

Written Question on Notice

Senator McLucas asked:

The Government allows pharmacists to charge patients an additional fee when the price of the drug falls below the (general) co-payment which is currently $29.50. This discretionary fee is up to $3.45, as agreed to between the Government and the Pharmacy Guild, although there is no ability to regulate this and we know that some pharmacists charge more.

a) In what percentage of eligible prescriptions (or in how many prescriptions) each year) does the pharmacist charge the additional fee?
b) In what percentage (or in how many prescriptions) is the fee more than $3.45?
c) What about the specific case of Coversyl: Coversyl 5 mg costs $23.12, and it seems that many pharmacists are charging the full $29.50. This means they are pocketing $6.38.
d) Is the Department aware of this? What is the Department's attitude to this?
e) If the prices of PBS medicines decline over time and the amount of the PBS co-payment increases over time, then aren't patients paying more and more out of pocket?
f) How can the Department measure the impact of changes to the PBS on patients and health outcomes if they are not assessing data on 23% of PBS medicines?
g) What is this fee compensating pharmacists for?

Answer:

a) The Department of Health and Ageing does not collect this data.

b) The Department of Health and Ageing does not collect this data.

c) and d)
The dispensed price is calculated according to a formula agreed as part of the Fourth Community Pharmacy Agreement, Part 2, Clause 21. For items priced below the maximum general co-payment, the Fourth Community Pharmacy Agreement enables pharmacists to charge the sum of:

(1) the Commonwealth price;
(2) an additional patient charge which, when combined with the Commonwealth price, will equal the list or agreed price as referred to in subsection 84C(7) of the *National Health Act 1953* (currently up to $0.99); and

(3) a further additional patient charge amounting to 10% of the maximum general patient contribution, plus 50 cents (currently up to $3.45, optional charge) up

to a maximum of the general co-payment ($29.50), but excluding brand premiums.

The non-concessional dispensed price for Coversyl 5mg 30 tablets calculated according to the formula agreed in the Fourth Community Pharmacy Agreement enables pharmacists to charge up to $27.57 when supplied under PBS arrangements. The maximum recordable amount to the PBS Safety Net is $23.12.

e) It has been the policy of several Governments since 1990 that patients are required to pay a co-payment prescription charge toward the cost of all subsidised PBS medicines. Patient co-payments are increased on 1 January each year, in line with Consumer Price Index. This measure is designed to keep the PBS affordable for taxpayers. Patients with high out-of-pocket costs are protected by the PBS Safety Net.

f) The department analyses survey based data on under co-payment prescriptions. A major pharmacy computer software supplier (Amfac) is commissioned to administer the collection of the survey data. Whereas this cannot be as accurate as the collection of the actual dispensing records, it gives a good basis for monitoring the use of all PBS listed drugs.

g) Additional fees for medicines priced under the general co-payment were negotiated with the Pharmacy Guild of Australia as part of the First Community Pharmacy Agreement in 1990, and have been continued as a negotiated package of measures in subsequent Community Pharmacy Agreements.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-123

OUTCOME 2: Access to Pharmaceutical Services

Topic: COST-EFFECTIVENESS ASSESSMENT BY THE PBAC AND THE USE OF A 5% DISCOUNT RATE FOR VACCINES

Written Question on Notice

Senator McLucas asked:

a) Does the PBAC routinely apply a 5% discount rate to vaccines?
b) Has this discount rate always been used for vaccines? Was it used when vaccine approval was the responsibility of ATAGI?
c) Are there grounds for applying a different discount rate to vaccines than applies to other PBS medicines?

Answers:

a) Yes.

b) This discount rate has always been used for vaccines considered by the PBAC.

In formulating its recommendations to Government, ATAGI used a 5% discount rate whenever it commissioned a cost-effectiveness analysis.

c) It has been argued that an inter-generational benefit with vaccines justifies a lower discount rate. However, issues such as these were taken into consideration when the PBAC decided to routinely apply a 5% discount rate to vaccines. The PBAC decided that there were more compelling grounds to retain the same discount rate for vaccines and other PBS medicines, for example, to promote consistency of decision making.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-201

OUTCOME 2: Access to Pharmaceutical Services

Topic: PBS GROWTH

Hansard Page: CA 23

Senator McLucas asked:

a) Could you provide us with almost a chronology from 2003 until now of when the modelling predicted a growth rate and when those were changed?
b) Also could you give us an indication of what were the factors that meant there was a change, such as a new listing, new information about demographics or something like that?

Answer:

a) The following table displays the changing forecast annual growth numbers, at key points in the budget cycle, across all years since 2003-04. Actual growth numbers are also shown. 'AE's' refers to Additional Estimates and 'PEFO' refers to Pre-Election Fiscal and Economic Outlook.

Year of Forecast Growth	Forecast Growth at Budget	Revised Forecast Growth at AEs /PEFO	Revised Forecast Growth at Next Budget	Actual Annual Growth
2003-04	1.5%	14.3%	14.0%	10.9%
2004-05	8.1%	8.9%	7.7%	7.0%
2005-06	7.8%	5.6%	2.8%	2.7%
2006-07	7.3%	N/A	N/A	N/A

b) Factors that have impacted forecast growth rates since 2003 include the following:

- 26 high cost drugs were listed or had extensions to listings between July 2003 and December 2006;

- increases in patient contributions in January 2005, from $3.80 to $4.60 for concessional patients and from $23.70 to $28.60 for general patients reduced the government subsidy per prescription and resulted in a number of prescriptions falling below the general co-payment;

- the delisting of Vioxx® in late-2004 and an associated reduction in the use of other

related drugs;

- changing prescribing patterns, with doctors writing fewer prescriptions overall, and particularly in the treatment of high blood cholesterol and depression; and

- 12.5% price reduction measure.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-205

OUTCOME 2: Access to Pharmaceutical Services

Topic: PBS UNDERSPEND

Hansard Page: CA 25

Senator Moore asked:

Ms Huxtable, I refer to the answer to the questions which covered two successive financial years – and the same answer was given in 2004-05 and 2005-06 – and the under-spend. I think that is one of the reasons we are following up on the question. That under-spend was significant in 2004-05. Whilst not as great in 2005-06, it was the same. It was a downward pattern, as explained by Professor Horvath, and exactly the same reason was given in the response. That is why we wanted to follow up and see what the rationale was, given the same thing was happening significantly over two successive years.

Answer:

In both 2004-05 and 2005-06, demand was lower than expected in some drug groups, particularly those for the treatment of high blood cholesterol and depression. In particular, the withdrawal from the PBS of Vioxx® in September 2004 had a significant impact on expenditure in 2004-05. In 2003-04, $88 million was spent on this drug on the PBS and its withdrawal from the PBS was associated with reductions in expenditure on similar drugs due to safety concerns.

These effects were factored into the projections for 2005-06 and expenditure forecasts were adjusted accordingly. Whilst these adjustments addressed most of the effects, they were not great enough as expenditure in these areas continued to be below expected levels in 2005-06. As such, while the level of under-spend in 2005-06 was lower than that for 2004-05, the factors contributing to the under-spend were the same.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-207/209

OUTCOME 2: Access to Pharmaceutical Services

Topic: BRAND PREMIUMS

Hansard Page: CA 26

Senator Moore asked:

a) Does that data show the numbers that have come on to the brand premium process since the introduction of the change – newly listed ones?

b) Ms Corbett – *The one thing that we may need to do for you on notice is to specifically look at brand premiums that came on in relation to 12.5% price reductions, but there are not very many of those, so that one is simple to do on notice.*

Topic: THERAPEUTIC GROUP PREMIUM

Hansard Page: CA 27

Senator Moore/McLucas asked:

a) Since the time that the new policy, the 12.5% generic policy, came in, can we find out how many drugs have got a new therapeutic premium listing?

b) And the same information, what they are, what the premium is?

c) And the dose form?

Answer:

a) Companies are free to apply or adjust brand premiums or therapeutic group premiums, in accordance with the Government's premium policies, provided at Attachment A.

Patients, if they choose, can avoid paying these premiums because there are alternative brands or products available at the benchmark price, or because they are eligible for an exemption to paying the premium. See Attachment A.

The five rounds of implementation of the 12.5% policy from 1 August 2005 to 1 December 2006 have, resulted in:

- 9 brands with new brand premiums,
- 14 brands with increases in brand premiums,
- 3 brands with new therapeutic group premiums,
- 2 brands with increases in therapeutic group premiums, and
- 6 brands with new special patient contributions.

b) & c)

A list of these premiums is at Attachment B.

Brand premium policy

The principle is that there should always be available at least one therapeutically equivalent brand without a brand premium. Unless the prescribing doctor has specifically indicated otherwise on the prescription, a pharmacist can dispense another brand of the same medicine at the patient's request. In this way, patients can avoid paying a brand premium.

Therapeutic group premium policy

The policy applies within specifically defined groups of drugs which have similar safety and health outcomes. Within these groups, the drugs can be interchanged at the patient level. The Government subsidises all drugs within a group to the level of the lowest priced drug. The difference in price between the lowest priced drug and higher priced drugs within the group is called a therapeutic group premium (TGP). The TGP is paid by the patient and goes to the supplier, not to the Government.

The principle is that there is always at least one drug within each group of drugs available without a TGP. In addition, when a patient, for a medical reason, is only able to take a drug with a premium, the prescribing doctor can request an exemption from the premium from Medicare Australia.

Special Patient Contributions (other than Brand Premiums or Therapeutic Group Premiums)

The Government has ensured that patients will not be financially disadvantaged with the recent introduction of the new special patient contributions. The treating doctor can seek an authority from Medicare Australia to waive this type of special patient contribution where there is no clinically suitable alternative listed on the PBS at the benchmark price. Doctors are encouraged to seek a waiver whenever appropriate so that patients are not financially disadvantaged.

Attachment B

New brand listings for 1 August 2005 resulting from 12.5% price reduction policy

Price reductions, flow-on effects and price premium outcomes

Name of drug where new brand triggers 12.5% reduction	Number of new brands listing on 1 August 2005	Other drugs in same reference pricing group with flow-on reductions	Number of brands affected across all drugs in group	New or increased price premium outcomes (including brand premiums, therapeutic group premiums & other special patient contributions)
Lamotrigine (epilepsy)	3	Gabapentin Tiagabine Topiramate Vigabatrin Levetiracetam Oxcabazepine	17	**1 new brand premium** Lamictal® (lamotrigine) 5mg tablet ($1.00) GSK **2 with special patient contributions** Keppra® (levetiracetam) 250mg ($7.35), 500mg ($12.31) & 1g ($20.50) tablets UCB Pharma; Topmax® (topiramate) 25mg ($2.40), 50mg ($2.40),100mg ($2.70) and 200mg ($2.69) tablets and 15mg, 25mg and 50mg capsules (all $2.40) Janssen Cilag
Calcitriol (bone diseases)	1	Disodium Etidronate and Calcium Carbonate	6	**Nil**
Fluvoxamine and citalopram (depression)	1 of each	Escitalopram Oxalate Fluoxetine Hydrochloride Mirtazapine Moclobemide Paroxetine Hydrochloride Reboxetine Mesilate Sertraline Hydrochloride	42	**2 increases in existing brand premiums** Luvox® (fluvoxamine maleate) 50mg & 100mg tablets (from $1.60 - $3.90) Solvay Pharmaceuticals; Remeron® (mirtazapine) 30mg tablet (from $22.76 - $26.69) Organon **1 with a special patient contribution** Lexapro® (escitalopram oxalate) 10mg ($3.31) & 20mg ($5.53) tablets & 10mg ($4.46) oral solution Lundbeck
Paclitaxel (cancers)	1	Docetaxel Pemetrexed Sodium Gemcitabine Hydrochloride Vinorelbine Tartrate	6	**1 with a special patient contribution** Alimta® (pemetrexed sodium) 500 mg powder for IV infusion Eli Lilly ($460.75)
Simvastatin (blood cholesterol)	6	Atorvastatin Pravastatin Fluvastatin	8	**2 new brand premiums** Lipex® (simvastatin) 5mg tablets ($0.71) Amrad; Zocor® (simvastatin) 5mg tablets ($0.71) Merck Sharpe and Dohme **1 increase in existing brand premium** Zocor® (simvastatin) 5mg,10mg (from $0.70 - $0.71), 20mg, 40mg & 80mg tablets Merck Sharp & Dohme **1 decrease in existing brand premium** Zocor® (simvastatin) 80mg tablets (from$0.71 - $0.70) Merck Sharp & Dohme **1 new therapeutic group premium** Lipitor® (atorvastatin) 10mg ($4.66), 20mg ($6.87), 40mg ($9.66) & 80mg ($13.83) tablets Pfizer
Doxorubicin (cancers)	1	Not referenced priced	2	**Nil**
Ipratropium (asthma)	1	Not referenced priced	8	**Nil**
Codeine with paracetamol (pain)	1	Not referenced priced	5	**1 increase in an existing brand premium** Panadeine Forte® 20 (from $1.58 - $1.89) & 60 (from $4.74 - $5.67) pack sizes of 30mg – 500mg Dakota Pharmaceuticals

Name of drug where new brand triggers 12.5% reduction	Number of new brands listing on 1 August 2005	Other drugs in same reference pricing group with flow-on reductions	Number of brands affected across all drugs in group	New or increased price premium outcomes (including brand premiums, therapeutic group premiums & other special patient contributions)
Tramadol (pain)	1	Not referenced priced	2	**1 increase in an existing brand premium** Tramal® 100mg (from$0.79 - $1.04), 150mg (from $0.81 - $1.04) & 200mg (from $0.79 - $1.05) tablets CSL
TOTAL	**17**	**21**	**96**	**11 drugs (comprising 13 brands) experienced new or increased price premiums:** **3 new brand premiums** (3 forms and strengths) **5 increases in existing brand premiums** (13 different forms, strengths and pack sizes) **1 new therapeutic group premiums** (4 different forms and strengths) **4 new special pharmaceutical benefits** (14 different forms and strengths)

As a result of the new listings for 1 August, the flow on reductions will apply to drugs in 6 of the 104 reference pricing groups (group numbers 26, 46, 57, 61, 62, 71).

Summary of new brand listings for 1 December 2005 resulting from 12.5% price reduction policy

Price reductions, flow-on effects and price premium outcomes

Name of drug where new brand triggers 12.5% reduction	Number of new brands listing on 1 December 2005	Other drugs in same reference pricing group with flow-on reductions	Number of brands across all drugs in group	New or increased price premium outcomes (including brand premiums, therapeutic group premiums & other special patient contributions)
Biscodyl (laxatives)	1	*Not referenced*	1	Nil
Clarithromycin (antibacterials)	1	Erythromycin Erythromycin Ethyl Succinate Roxithromycin	19	**1 increase in existing brand premium** Eryc® (Erythromycin) 250 mg capsule (from $1.20 - $1.77) Mayne Pharma
Electrolyte replacement (oral) (oral rehydration)	2	*Not referenced*	2	Nil
Etoposide (cancer)	1	Etoposide Phosphate	3	Nil
Frusemide (diuretics)	1	*Not referenced*	1	Nil
Metformin Hydrochloride (blood glucose lowering)	1 (across 3 strengths)	*Not referenced*	21	**1 new brand premiums** Diabex 1000® (Metformin Hydrochloride) 1 g tablet ($1.81) Alphapharm Medical
Methotrexate (Antineoplastics)	1	*Not referenced*	6	Nil
Methylphenidate Hydrochloride (ADHD)	1	Dexamphetamine Sulfate	2	**1 new brand premiums** Ritalin 10 (Methylphenidate Hydrochloride) 10 mg tablet ($1.28) Novartis
Paracetamol (analgesics)	2	*Not referenced*	18	Nil
Terbinafine (antifungal)	4	*Not referenced*	2	Nil
TOTAL **10**	**15**	**5**	**75**	**3 brands experienced new or increased price premiums:** **2 new brand premiums** **1 increases in existing brand premiums**

As a result of the new listings for 1 December, the flow on reductions will apply to drugs in 3 of the 105 reference pricing groups (group numbers 45, 48, and 75).

No new special patient contributions

Rejection of request for retrospective special patient contributions

Summary of new brand listings for 1 April 2006 resulting from 12.5% price reduction policy

Price reductions, flow-on effects and price premium outcomes

Name of drug where new brand triggers 12.5% reduction	Number of new brands listing on 1 April 2006	Other drugs in same reference pricing group with flow-on reductions	Number of branded products affected across all drugs in group	New or increased price premium outcomes (including brand premiums, therapeutic group premiums & other special patient contributions)
Bupropion Hydrochloride	2	*Not referenced*	2	**1 new brand premium** Zyban® (Bupropion Hydrochloride) Tablet 150 mg (sustained release) ($0.90) GlaxoSmithKline
Calcium folinate	1 (across 2 strengths)	*Not referenced*	3	Nil
Ciprofloxacin	1 (across 2 strengths)	*Not referenced*	19	Nil
Glimepiride	1 (across 4 strengths)	Gliclazide	16	**1 increase in existing brand premium** Diamicron® (Gliclazide) Tablet 80 mg (from $1.35 - $2.48) Servier **1 request for SPC** Diamicron® (Gliclazide) Tablet 30 mg modified release Servier - No SPC applied
Mitozantrone Hydrchloride	1	*Not referenced*	7	Nil
Ondansetron	2 (across 2 strengths of tablet, wafer and IV Injection)	Granisetron Tropisetron Dolasetron	21	**1 new brand premium** Zofran® (Ondansetron) 4 g tablet ($0.71) Zofran® (Ondansetron) 8 g tablet ($0.70) Zofran® (Ondansetron) I.V. injection 4 mg in 2 mL ($0.70) Zofran® (Ondansetron) I.V. injection 8 mg in 4 mL ($0.71) Zofran Zydis® (Ondansetron) 4 g Wafer ($0.71) Zofran Zydis® (Ondansetron) 8 g Wafer ($0.70) GlaxoSmithKline
Tramadol Hydrochloride	1	Pethidine Hydrochloride	3	**1 item withdrawn from the PBS** MX® (Pethidine Hydrochloride) Injection 50 mg in 1 mL Mayne Pharma
Omeprazole	1	Esomeprazole Magnesium Trihydrate, Rabeprazole Sodium, Pantoprazole Sodium Sesquihydrate and Lansoprazole	22	**2 requests for SPCs** Zoton® (Lansoprazole) Sachet containing granules for oral suspension, 30 mg per sachet ($3.75) Wyeth Pariet® (Raberprazole Sodium) 10 mg tablet Pariet® (Raberprazole Sodium) 20 mg tablet Janssen-Cilag – No SPC
TOTAL **8**	**10**	**8**	**93**	**3 brands experienced new or increased price premiums:** **2 new brand premiums** **1 increase in existing brand premium** **3 requests for SPCs; 1 granted.** **1 item withdrawn from the PBS**

As a result of the new listings for 1 April, the flow on reductions will apply to drugs in 4 of the 105 reference pricing groups (group numbers 3, 5, 15 and

Summary of new brand listings for 1 August 2006 resulting from 12.5% price reduction policy

Price reductions, flow-on effects and price premium outcomes

Name of drug where new brand triggers 12.5% reduction	Number of new brands listing on 1 August 2006	Other drugs in same reference pricing group with flow-on reductions	Number of branded products affected across all drugs in group	New or increased price premium outcomes (including brand premiums, therapeutic group premiums & other special patient contributions)
Aciclovir	1	Famciclovir; Valaciclovir Hydrochloride.	29	
Cefaclor	1	Amoxycillin with Clavulanic Acid; Cefuroxime Axetil	44	**1 increase in Brand Premium** Ceclor CD® (cefaclor) 375mg Tablet (sustained release) (from$1.54 - $2.91) Ceclor® (cefaclor) 125mg Powder for oral suspension (from $1.53 - $2.54) Ceclor® (cefaclor) 250mg Powder for oral suspension (from $1.55 - $2.62)
Cephalexin	1 (across 2 strengths)	Amoxycillin.	74	**1 new SPC** Amoxil® (amoxycillin) powder for paediatric drops (effective 1 Oct 06) **2 increases in Brand Premium** Amoxil® (amoxycillin) 125mg Powder for syrup (from $1.00 - $1.22) Keflex® (cephalexin) 250mg Capsule (from $1.76 - $2.39) Keflex® (cephalexin) 500mg Capsule (from $1.87 - $2.84) Keflex® (cephalexin) 125mg Granules for syrup (from $1.78 - $2.47) Keflex® (cephalexin) 250mg Granules for syrup (from $1.87 - $2.82)
Imipramine Hydrochloride	1 (across 2 strengths)	Amitriptyline Hydrochloride.	5	**1 new Brand Premium** Tofranil® (imipramine) 10mg Tablet ($0.89) Tofranil® (imipramine) 25mg Tablet ($0.89)
Fluorouracil	1	*Not referenced*	1	
Cisplatin	1	*Not referenced*	4	
Quinapril Hydrochloride	1 (across 3 strengths)	Captopril; Enalapril Maleate; Fosinopril Sodium; Lisinopril; Perindopril Erbumine; Ramipril; Trandolapril;	118	**2 new Therapeutic Group Premiums** Ramace® (ramipril) 1.25mg tablet ($1.00) Ramace® (ramipril) 2.5mg tablet (1.46) Ramace® (ramipril) 5mg tablet ($1.83) Ramace® (ramipril) 10mg capsule ($3.23) Ramace® (ramipril) titration pack ($2.84) Tritace® (ramipril) 1.25mg tablet ($1.00) Tritace® (ramipril) 2.5mg tablet ($1.46) Tritace® (ramipril) 5mg tablet ($1.83) **1 increase in Therapeutic Group Premium** Tritace® (ramipril) 10mg capsule (from $1.35 - $3.23) **1 new Brand Premiums** Accupril® (quinapril) 5mg Tablet (base) ($0.49) Accupril® (quinapril) 10mg Tablet (base) ($0.66) Accupril® (quinapril) 20mg Tablet (base) ($0.98) **3 increases in Brand Premiums** Amprace® (elanapril) 5mg Tablet (from $2.45 -$3.14) Amprace® (elanapril) 10mg Tablet (from $2.45 - $3.14) Amprace® (elanapril) 20mg Tablet (from $2.45 - $3.14) Odrik® (trandolapril) 500 mcg capsules (from $1.00 -$1.50) Odrik® (trandolapril) 1mg capsules (from $1.01 - $1.50) Odrik® (trandolapril) 2mg capsules (from$0.99 - $1.50) Zestril® (lisinopril) 5mg Tablet (from $2.15 - $2.65) Zestril® (lisinopril) 10mg Tablet (from $2.15 - $2.65) Zestril® (lisinopril) 20mg Tablet(from $2.15 - $2.65)

Name of drug where new brand triggers 12.5% reduction	Number of new brands listing on 1 August 2006	Other drugs in same reference pricing group with flow-on reductions	Number of branded products affected across all drugs in group	New or increased price premium outcomes (including brand premiums, therapeutic group premiums & other special patient contributions)
Ranitidine Hydrochloride	1 (across 2 strengths)	Cimetidine; Famotidine; Nizatidine.	49	**1 increase in Therapeutic Group Premiums** Zantac® (ranitidine) 150mg Effervescent tablet (base) (effective 1 Oct 06) (from $2.10 - $4.18) **1 increase in Brand Premium** Tazac® (nazitidine) 150mg Capsule (from $2.80 - $5.28) Tazac® (nizatidine) 300mg Capsule (from $2.80 - $5.28)
Sodium Cromoglycate	1	*Not referenced*	1	
TOTAL **9**	**9**	**16**	**325**	**1 new SPC** **2 New Therapeutic Group Premiums** **2 Increases in Therapeutic Group Premium** **2 New Brand Premiums** **7 Increases in Brand Premiums**

Note: octreotide and flow-ons due to its listing are not included. A new brand of octreotide was listed on 1 Aug but was not supplied. Any associated flow-on price reductions been reversed.

As a result of the new listings for 1 August, the flow on reductions will apply to drugs in 6 of the 108 reference pricing groups (group numbers: A02(2), C09(1), J01(2), J01(3), J05(1), and N06(1))

Summary of new brand listings for 1 December 2006 resulting from 12.5% price reduction policy

Price reductions, flow-on effects and price premium outcomes

Name of drug where new brand triggers 12.5% reduction	Number of new brands listing on 1 August 2006	Other drugs in same reference pricing group with flow-on reductions	Number of branded products affected across all drugs in group	New or increased price premium outcomes (including brand premiums, therapeutic group premiums & other special patient contributions)
Carboplatin	1	*Not referenced*	6	Nil
Fluconazole	4	Did not flow on to itraconazole	3	Nil
Ceftriaxone	1	Cefotaxime	13	Nil
Oxaliplatin	2	Irinotecan hydrochloride trihydrate	6	Nil
TOTAL **4**	**8**	**2**	**28**	Nil

As a result of the new listings for 1 December, the flow on reductions will apply to drugs in 2 of the 110 reference pricing groups (group numbers J01(4) and L01(3))

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-125

OUTCOME 2: Access to Pharmaceutical Services

Topic: MANDATING PRICE LISTS IN PHARMACIES

Written Question on Notice

Senator McLucas asked:

a) What has been done to implement this budget commitment?
b) What funds were provided for this work?
c) Where did these funds come from within the Department?
d) What has been spent to date on this commitment?
e) Please provide details of spending.
f) What additional spending is planned?
g) Are these lists required to provide information about Special Patient Contributions, therapeutic and brand premiums, and allowable costs added on by the pharmacist?

Answer:

a) The 2005/06 Budget measure to improve Pharmaceutical Benefits Scheme (PBS) price information for consumers has been implemented via inclusion of prices in the new on-line publication system for the PBS Schedule. Price information for all PBS items and patient payment categories has been incorporated into that system and search functionality has been improved for consumers and health professionals. The on-line publication system was released on 1 December 2006. The address for the web site is: www.pbs.gov.au

b) Nil. No funding was provided for provision of improved price information for consumers. Implementation of improved listing and publication processes for PBS medicines (the 'PharmBiz' project) is funded under a separate 2005-06 Budget measure.

c) Not applicable.

d) Not applicable.

e) Not applicable.

f) Nil.

g) Price information is presented as the price to consumer. These prices include any special patient contributions, therapeutic and brand premiums payable by the consumer, plus allowable additional pharmacy fees where relevant. There is also a consolidated list of all the brand premiums, therapeutic group premiums, and other special patient contributions available on http://pbs.gov.au/html/healthpro/browseby/price-premiums

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-126

OUTCOME 2: Access to Pharmaceutical Services

Topic: PATHOLOGY COSTS ASSOCIATED WITH CERTAIN CANCER DRUGS

Written Question on Notice

Senator McLucas asked:

a) When a pathology test is required before a PBS drug is prescribed (as for Iressa and Herceptin) who pays for this test?
b) How many cancer drugs require such pathology tests before they can be prescribed?
c) How many patients does this involve each year?
d) What was the cost of such tests last year to Medicare?
e) What is the estimated cost of such tests in 2006-07?
f) Is it correct that the gene test required before Iressa is prescribed for lung cancer costs over $1000 and is not widely available?
g) Since Iressa was listed in late 2004, what further assessment has been done by the PBAC of:
- The cost and availability of the gene test
- The accuracy of this test
- The relationship between the test and the effectiveness of the drug
h) Is it correct that the decision to require this test was based on a US study of 25 people?
i) What additional studies are now available to support this limiting criterion?

Answer:

a) If a pathology test is listed on the Medical Benefits Schedule (MBS), then the cost of the test is met (in whole or in part) through Medicare. If a pathology test is not listed on the MBS, then the cost of the test may be met from a number of sources such as the patient, private health insurance, the sponsoring company or a providing hospital.

b) Currently three cancer drugs gefitinib (Iressa®), trastuzumab (Herceptin®) and imatinib (Glivec®) require a copy of the specific pathology testing to be submitted to Medicare Australia before they can be prescribed on the PBS.

c) In 2005-06 there were 53 people accessing the PBS program for gefitinib (Iressa®) and 1,396 people for imatinib (Glivec®). Herceptin was listed on the PBS for the treatment of early stage breast cancer as of 1 October 2006. In the month of October 2006, the most recent month for which data are available, 28 services were subsidised for the use of Herceptin in early breast cancer under the PBS.

d) The only PBS listed cancer drug that requires an MBS listed pathology test before it can be prescribed is imatinib. Data on the numbers of tests specifically associated with the prescribing of imatinib are not separately collected.

e) See (d) above.

f) No information has been presented to the Department on the cost of this test. In regard to availability, Medicare Australia has advised that there are two testing laboratories in Victoria, one in South Australia and two in Western Australia. Biopsy samples may be sent from anywhere in Australia to these testing facilities.

g) There has been no further assessment by the Pharmaceutical Benefits Advisory Committee (PBAC) of the accuracy or cost of the gene test nor would further assessment by the PBAC be expected. An application to list a pathology test on the MBS would normally be considered by the Medical Services Advisory Committee. No such application has been received.

In considering the application in respect of gefitinib, the PBAC considered that identification of the activating mutation of the EGFR gene would support targeting to the population of patients who are most likely to achieve at least partial response. The PBAC has been following reports of the effectiveness of the drug, and the relationship between the test and the effectiveness of the drug from various agencies including the Therapeutic Goods Administration (TGA) and the US Food and Drug Administration (FDA).

h) No. The 25 patients were the number of patients from a much larger trial who showed a clinically significant response to treatment with Iressa. The study from *The New England Journal of Medicine* supported the view that screening for such mutations in lung cancers might identify patients who would have a response to Iressa. The PBAC considered the results were supported by other data published in *Science*.

i) Additional reports from the FDA indicate that Iressa does not demonstrate a significant survival benefit in the overall study population nor in patients who had high levels of a surface marker called “EGFR” and as a consequence the FDA has limited the use of Iressa in patients who, in the opinion of their treating physician, are currently benefiting, or have previously benefited, from Iressa treatment. The PBAC will continue to monitor overseas developments.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-128

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

Written Question on Notice

Senator McLucas asked:

a) Please provide the funding for the operation of MSAC for each financial year since its inception.
b) How many FTE staff does MSAC currently have?
c) What financial reimbursements do the members of MSAC receive?
d) Who appoints the Members?
e) When were the current members appointed?
f) How often does MSAC meet?

Answer:

a) Information covering the years 2004-05 and 2005-06 is attached. To gather the requested information for the years prior to 2004-05 would require a significant diversion of resources. The Department does not currently have the resources to answer this question.
(b) The MSAC does not have any full-time equivalent (FTE) staff.
(c) Members of the MSAC are paid sitting fees in accordance with the rate set for 'Professional Committees - Health Portfolio', as set by the Remuneration Tribunal. In addition members are given a travel allowance and reimbursed for any out-of-pocket costs relating to their attendance at face-to-face meetings.
(d) Members of the Committee are appointed by the Minister.
(e) Fourteen members were appointed in 2005. Eight members were appointed in 2004.
(f) The MSAC meets four times a year.

MSAC FUNDING

Financial Year	04/05	05/06
Committee Related Expenses	404,381.83	427,318.12
Consultant Related Expenses	2,765,099.57	1,796,462.73
TOTAL	**3,169,481.40**	**2,223,780.85**
TOTAL FUNDING FROM 04/05 to 05/06		**5,393,262.25**

Note 1: Committee Related Expenses includes all expenses related to travel and sitting fees for committee members

Note 2: Consultant Related Expenses covers fees paid to consultants for systematic reviews of MSAC applications. Figures for 04/05 are higher as there were more evaluators contracted than in 05/06.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-129

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

Written Question on Notice

Senator McLucas asked:

g) Who decides which submissions will be assessed?
h) What is the average time for the completion of such an assessment?
i) What is the longest time such an assessment has taken?
j) How is a decision made that a submission is ineligible?

Answer:

a) The Senior Medical Adviser in the Medical Benefits Division decides whether an individual application is eligible for assessment.
b) The average time taken to assess a submission is 18.6 months.
c) The longest time taken to assess a submission was 36.5 months.
d) A submission is ineligible for assessment if the proposed new treatment or technology does not constitute a clinically relevant medical service, as only clinically relevant services are eligible for a rebate under the Medicare Benefits Scheme.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-130

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

Written Question on Notice

Senator McLucas asked:

k) For each financial year since the inception of MSAC, please provide a list of submissions received, submissions accepted and assessments of submissions published. Please include assessments currently underway.
l) Who decides what is referred for assessment?
m) What is the average time for the completion of such an assessment?
n) What is the longest such an assessment has taken?

Answer:

a) See attached spreadsheet.
b) The Senior Medical Advisor, Medical Benefits Division, decides which applications for assessment are referred to the MSAC, following confirmation of eligibility for assessment.
c) The average time for completion of an assessment is 18.6 months.
d) The longest time taken to complete an assessment is 36.5 months.

Senate Questions – Senator McLucas – 1St November 2006

For each financial year since the inception of MSAC, please provide a list of submissions received, submissions accepted and assessments of submissions published. Please include assessments currently underway.

Financial Year	Applications received	Applications accepted	Applications published
2006 – 07	1114 Urinary metabolic profile (pending) 1113 Endo venous laser treatment for varicose veins (EVLT) 1112 BioEnterics intragastric balloon 1111 MIT data analysis (pending) 1110 Staging of rectal carcinoma by means of magnetic resonance imaging (MRI) 1109 Deep brain stimulation for essential tremor (pending) 1108 Endobronchial ultrasound in the staging of lung cancer and the diagnosis of mediastinal masses of unknown origin	1113 Endo venous laser treatment for varicose veins (EVLT) 1112 BioEnterics intragastric balloon 1110 Staging of rectal carcinoma by means of magnetic resonance imaging (MRI) 1108 Endobronchial ultrasound in the staging of lung cancer and the diagnosis of mediastinal masses of unknown origin	
2005 – 06	1107 Acticon artificial bowel sphincter 1106 Endoscopic argon plasma coagulation therapy	1107 Acticon artificial bowel sphincter 1106 Endoscopic argon plasma coagulation therapy	1095 Computed tomography colonography 1092 Deep brain stimulation for Parkinson's disease

	1105 Computed tomography coronary angiography 1104 Endoscopic ultrasound and fine needle aspiration for lung cancer	1105 Computed tomography coronary angiography 1104 Endoscopic ultrasound and fine needle aspiration for lung cancer	1090 Artificial intervertebral disc replacement (AIDR) 1085 Carbon labelled urea breath tests for diagnosis of Helicobacter Pylori infection
Financial Year	**Applications received**	**Applications accepted**	**Applications published**
2005 - 06	1103 Fetal fibronectin test for preterm labour 1102 Double balloon enteroscopy 1101 Repetitive transcranial magnetic stimulation (rTMS) 1100 Intersphinteric injection of silicone biomaterial for severe passive faecal incontinence	1103 Fetal fibronectin test for preterm labour 1102 Double balloon enteroscopy 1101 Repetitive transcranial magnetic stimulation (rTMS) 1100 Intersphinteric injection of silicone biomaterial for severe passive faecal incontinence	1084 UroVysion fluorescence in situ hybridization (FISH) assay 1082 SIR-Spheres for the treatment of non-resectable liver tumours 1081 Uterine artery embolisation 1080 Coronary (Radi) pressure wire 1076 High-energy transurethral microwave thermotherapy for benign prostatic hyperplasia (HE-TUMT) 1042 Cardiac resynchronisation therapy (CRT)
2004 – 05	1099 Lumbar non-fusion posterior stabilisation devices 1098 Breast magnetic resonance imaging (MRI) 1097 Topical negative pressure therapy via the VAC system – ineligible	1099 Lumbar non-fusion posterior stabilisation devices 1098 Breast magnetic resonance imaging (MRI) 1096 Hepatitis B DNA testing	1089 Brachytherapy for prostate cancer 1078 Multifocal multi-channel objective perimetry for the diagnosis of visual field defects 1077 Sacral nerve stimulation for faecal

	1096 Hepatitis B DNA testing 1095 Computed tomography colonography 1094 Rapid opiate detox with sedation – ineligible 1093 Endovascular neurointerventional procedures 1092 Deep brain stimulation for Parkinson's disease	1095 Computed tomography colonography 1093 Endovascular neurointerventional procedures 1092 Deep brain stimulation for Parkinson's disease 1091 Laparoscopic remotely assisted radical prostatectomy	incontinence 1071 The use of INR point-of-care testing in general practice 1068 Prostate specific antigen (PSA) near patient testing for diagnosis and management of prostate cancer 1067 Genotypic resistance testing of antiretrovirals in HIV 1065 Sentinel lymph node biopsy in breast
Financial Year	**Applications received**	**Applications accepted**	**Applications published**
2004 - 05	1091 Laparoscopic remotely assisted radical prostatectomy 1089 Brachytherapy for prostate cancer 1088 Needling of glaucoma bleb – ineligible 1087 (incorporating 1086) B-type natriuretic peptide 1086 (subsumed by 1087) Measurement of B-type natriuretic peptide 1085 Carbon labelled urea breath tests for diagnosis of Helicobacter Pylori infection 1084 UroVysion fluorescence in situ	1089 Brachytherapy for prostate cancer 1087 B-type natriuretic peptide - incorporating Application 1086 1085 Carbon labelled urea breath tests for diagnosis of Helicobacter Pylori infection 1084 UroVysion fluorescence in situ hybridization (FISH) assay 1083 Intac implants	cancer 1062 CEA-SCAN® for imaging recurrence and/or metastases in patients with histologically demonstrated carcinoma of the colon or rectum

	hybridization (FISH) assay 1083 Intac implants		
2003 – 04	1090 Artificial intervertebral disc replacement (AIDR) 1082 SIR-Spheres for the treatment of non-resectable liver tumours 1081 Uterine artery embolisation 1080 Coronary (Radi) pressure wire 1079 Peripheral arterial tonometry with ascending aortic waveform analysis using the SphygmoCor system	1090 Artificial intervertebral disc replacement (AIDR) 1082 SIR-Spheres for the treatment of non-resectable liver tumours 1081 Uterine artery embolisation 1080 Coronary (Radi) pressure wire 1079 Peripheral arterial tonometry with ascending aortic waveform analysis using the SphygmoCor system	1061 Implantable loop recorder for unexplained recurrent syncope 1059 Endo venous laser treatment for varicose veins 1055 Hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implant
Financial Year	**Applications received**	**Applications accepted**	**Applications published**
2003 - 04	1078 Multifocal multi-channel objective perimetry for the diagnosis of visual field defects 1077 Sacral nerve stimulation for faecal incontinence 1076 High-energy transurethral microwave thermotherapy for benign prostatic hyperplasia (HE-TUMT)	1078 Multifocal multi-channel objective perimetry for the diagnosis of visual field defects 1077 Sacral nerve stimulation for faecal incontinence 1076 High-energy transurethral microwave thermotherapy for benign prostatic hyperplasia (HE-TUMT)	

	1075 (subsumed by 1072) Endoscopic ultrasound for the diagnosis and pre-operative staging of hepato-biliary neoplasms 1074 Freelight lambda and freelight kappa 1073 Photodynamic therapy with METVIX 1072 (incorporating 1069 and 1075) Endoscopic ultrasound for staging pancreatic, gastric, oesophageal and hepato-biliary neoplasms 1070 Innovative patent in tobacco smoking – ineligible 1069 (subsumed by 1072) Endoscopic ultrasound for the pre-operative staging of gastric and oesophageal neoplasms 1068 Prostate specific antigen (PSA) near patient testing for diagnosis and management of prostate cancer 1067 Genotypic resistance testing of antiretrovirals in HIV	1074 Freelight lambda and freelight kappa (withdrawn) 1073 Photodynamic therapy with METVIX (withdrawn) 1072 Endoscopic ultrasound for staging pancreatic, gastric, oesophageal and hepato-biliary neoplasms – incorporates 1069 and 1075 1071 The use of INR point-of-care testing in general practice 1068 Prostate specific antigen (PSA) near patient testing for diagnosis and management of prostate cancer 1067 Genotypic resistance testing of antiretrovirals in HIV 1066 Drug eluting stents – absorbed into Ref 21	
Financial Year	**Applications received**	**Applications accepted**	**Applications published**
2003 - 04	1066 Drug eluting stents – absorbed into Ref 21		
2002 – 03	1065 Sentinel lymph node biopsy in breast cancer	1065 Sentinel lymph node biopsy in breast cancer	1056 LeukoScan®: for the use in diagnostic imaging of the long bones and feet in patients with suspected osteomyelitis,

	1064 3D Magnetic electroanatomical radiofrequency ablation for cardiac arrhythmias - ineligible 1063 Photodynamic therapy (Visudyne) Commercial-in-Confidence application 1062 CEA-SCAN® for imaging recurrence and/or metastases in patients with histologically demonstrated carcinoma of the colon or rectum 1061 Implantable loop recorder for unexplained recurrent syncope 1060 Bone mineral densitometry 1059 Endo venous laser treatment for varicose veins 1058 QuantiFERON - TB Gold 1057 M2A® capsule endoscopy for the evaluation of obscure gastrointestinal bleeding in adult patients	1063 Photodynamic therapy (Visudyne) Commercial-in-Confidence application 1062 CEA-SCAN® for imaging recurrence and/or metastases in patients with histologically demonstrated carcinoma of the colon or rectum 1061 Implantable loop recorder for unexplained recurrent syncope 1060 Bone mineral densitometry (subsumed by Ref 19 then withdrawn) 1059 Endo venous laser treatment for varicose veins 1058 QuantiFERON - TB Gold (withdrawn) 1057 M2A® capsule endoscopy for the evaluation of obscure gastrointestinal bleeding in adult patients	including those with diabetic foot ulcers 1054 Hyperbaric oxygen therapy 1053 Placement of artificial bowel sphincters in the management of faecal incontinence 1052 Radiofrequency ablation of liver tumours 1050 Optical biometry using partial coherence interferometry prior to cataract surgery 1049 M-VAX™ : a treatment for patients with advanced stage III melanoma 1048 Intradiscal electrothermal anuloplasty: a treatment for patients with chronic lower back pain due to anular disruption of contained herniated discs 1045 Intra-articular viscosupplementation for treatment of osteoarthritis of the knee 1044 Intra-articular viscosupplementation for treatment of osteoarthritis of the knee 1043 Thyrogen™ (thyrotropin alfa) as a diagnostic agent for well-differentiated
Financial	**Applications received**	**Applications accepted**	**Applications published**

Year			
2002 - 03			thyroid cancer 1041 Intravascular brachytherapy
2001 – 02	1056 LeukoScan®: for the use in diagnostic imaging of the long bones and feet in patients with suspected osteomyelitis, including those with diabetic foot ulcers 1055 Hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implant 1054 Hyperbaric oxygen therapy 1053 Placement of artificial bowel sphincters in the management of faecal incontinence 1052 Radiofrequency ablation of liver tumours 1051 VAC therapy (vacuum assisted closure) – ineligible 1050 Optical biometry using partial coherence interferometry prior to cataract surgery 1049 M-VAX™ : a treatment for patients with advanced stage III melanoma	1056 LeukoScan®: for the use in diagnostic imaging of the long bones and feet in patients with suspected osteomyelitis, including those with diabetic foot ulcers 1055 Hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implant 1054 Hyperbaric oxygen therapy 1053 Placement of artificial bowel sphincters in the management of faecal incontinence 1052 Radiofrequency ablation of liver tumours 1050 Optical biometry using partial coherence interferometry prior to cataract surgery 1049 M-VAX™ : a treatment for patients with advanced stage III melanoma	1039 Photodynamic therapy with verteporfin for macular degeneration 1038 Conformal radiotherapy 1037 Advanced Breast Biopsy Instrumentation (ABBI®) System for non-palpable breast lesions 1036 Percutaneous transluminal coronary rotational atherectomy for lesions of the coronary arteries 1035 Genetic test for Fragile X syndrome 1034 Selective internal radiation therapy for hepatic metastases using SIR-Spheres® 1032 Intravascular ultrasound (IVUS) 1030 Low intensity ultrasound treatment for the acceleration of bone fracture healing - Exogen™ bone growth stimulator 1026 Near patient cholesterol testing using the Cholestech LDX

	1048 Intradiscal electrothermal anuloplasty: a treatment for patients with chronic lower back pain due to anular disruption of contained herniated discs	1048 Intradiscal electrothermal anuloplasty: a treatment for patients with chronic lower back pain due to anular disruption of contained herniated discs	1014 TransUrethral Needle Ablation (TUNA) for benign prostatic hyperplasia
Financial Year	**Applications received**	**Applications accepted**	**Applications published**
2000 – 01	1047 Endoluminal gastroplication for the treatment of gastro-oesophageal reflux disease (GORD) 1046 Implantation of the Interstim® device for sacral nerve stimulation 1045 Intra-articular viscosupplementation for treatment of osteoarthritis of the knee 1044 Ostase immunoassay for the mass measurement of serum bone alkaline phosphatase 1043 Thyrogen™ (thyrotropin alfa) as a diagnostic agent for well-differentiated thyroid cancer 1042 Cardiac resynchronisation therapy (CRT) 1041 Intravascular brachytherapy 1040 Anatomical biomodelling – ineligible 1039 Photodynamic therapy with verteporfin for	1047 Endoluminal gastroplication for the treatment of gastro-oesophageal reflux disease (GORD) 1046 Implantation of the Interstim® device for sacral nerve stimulation 1045 Intra-articular viscosupplementation for treatment of osteoarthritis of the knee 1044 Ostase immunoassay for the mass measurement of serum bone alkaline phosphatase 1043 Thyrogen™ (thyrotropin alfa) as a diagnostic agent for well-differentiated thyroid cancer 1042 Cardiac resynchronisation therapy (CRT) 1041 Intravascular brachytherapy 1039 Photodynamic therapy with verteporfin for macular degeneration	1031 Deep brain stimulation for symptoms of advanced Parkinson's disease 1029 Brachytherapy for the treatment of prostate cancer 1028 Gamma knife radiosurgery 1018 – 1020 Hyperbaric oxygen therapy 1012 Vertebral axial decompression therapy for chronic lower back pain 1011 Lung volume reduction surgery - for advanced emphysema

	macular degeneration 1038 Conformal radiotherapy 1037 Advanced Breast Biopsy Instrumentation (ABBI®) System for non-palpable breast lesions 1036 Percutaneous transluminal coronary rotational atherectomy for lesions of the coronary arteries	1038 Conformal radiotherapy 1037 Advanced Breast Biopsy Instrumentation (ABBI®) System for non-palpable breast lesions 1036 Percutaneous transluminal coronary rotational atherectomy for lesions of the coronary arteries	
Financial Year	**Applications received**	**Applications accepted**	**Applications published**
2000 - 01	1005 Visual electrodiagnosis		
1999 – 00	1035 Genetic test for Fragile X syndrome 1034 Selective internal radiation therapy for hepatic metastases using SIR-Spheres® 1033 Autogenous cartilage transplantation 1032 Intravascular ultrasound (IVUS) 1031 Deep brain stimulation for symptoms of advanced Parkinson's disease 1030 Low intensity ultrasound treatment for the acceleration of bone fracture healing - Exogen™ bone growth stimulator 1029 Brachytherapy for the treatment of prostate	1035 Genetic test for Fragile X syndrome 1034 Selective internal radiation therapy for hepatic metastases using SIR-Spheres® 1033 Autogenous cartilage transplantation (suspended August 2002) 1032 Intravascular ultrasound (IVUS) 1031 Deep brain stimulation for symptoms of advanced Parkinson's disease 1030 Low intensity ultrasound treatment for the acceleration of bone fracture healing - Exogen™ bone growth stimulator	1024 Total ear reconstruction 1023 Placement of artificial bowel sphincters in the management of faecal incontinence 1021 Hepatitis C viral load testing 1016 Samarium^{153}-lexidronam for bone pain due to skeletal metastases 1015 Directional vacuum-assisted breast biopsy 1010 Intravascular extraction of chronically implanted permanent transvenous pacing leads

	cancer 1028 Gamma knife radiosurgery 1013 Treatment for diseased states of the inner ear – ineligible 1012 Vertebral axial decompression therapy for chronic lower back pain 1005 Visual electrodiagnosis	1029 Brachytherapy for the treatment of prostate cancer 1028 Gamma knife radiosurgery 1012 Vertebral axial decompression therapy for chronic lower back pain 1005 Visual electrodiagnosis	1009 Sacral nerve stimulation for urinary incontinence 1005 Visual electrodiagnosis 1004 Transmyocardial laser revascularisation 1003 OctreoScan® scintigraphy for gastro-entero-pancreatic neuroendocrine tumours 1002 Oto-acoustic emission audiometry

Financial Year	Applications received	Applications accepted	Applications published
1998 – 99	1027 (subsumed into Ref 2) Provision of positron emission tomography (PET) services 1026 Near patient cholesterol testing using the Cholestech LDX 1025 (subsumed into ref 2) Provision of positron emission tomography (PET) services 1024 Total ear reconstruction 1023 Placement of artificial bowel sphincters in the management of faecal incontinence 1022 Clotest for H. Pylori – ineligible 1021 Hepatitis C viral load testing 1018-1020 Hyperbaric oxygen therapy 1017 Chelation therapy – ineligible. 1016 Samarium^{153}-lexidronam for bone pain due to skeletal metastases 1015 Directional vacuum-assisted breast biopsy 1014 TransUrethral Needle Ablation (TUNA) for benign prostatic hyperplasia	1027 – incorporated into Ref 2 1026 Near patient cholesterol testing using the Cholestech LDX 1025 – incorporated into Ref 2 1024 Total ear reconstruction 1023 Placement of artificial bowel sphincters in the management of faecal incontinence 1021 Hepatitis C viral load testing 1018-1020 Hyperbaric oxygen therapy 1016 Samarium^{153}-lexidronam for bone pain due to skeletal metastases 1015 Directional vacuum-assisted breast biopsy 1014 TransUrethral Needle Ablation (TUNA) for benign prostatic hyperplasia 1010 Intravascular extraction of chronically implanted permanent transvenous pacing leads	1008 Photodynamic therapy for skin and mucosal cancer 1007 Saline infusion sonohysterography 1006 Endoluminal grafting for abdominal aortic aneurysm 1001 Advanced breast biopsy instrumentation

	1013 Treatment of diseased states of the inner ear – ineligible. 1010 Intravascular extraction of chronically implanted permanent transvenous pacing leads		
Financial Year	**Applications received**	**Applications accepted**	**Applications published**
1997 – 98	1011 Lung volume reduction surgery - for advanced emphysema 1009 Sacral nerve stimulation for urinary incontinence 1008 Photodynamic therapy for skin and mucosal cancer 1007 Saline infusion sonohysterography 1006 Endoluminal grafting for abdominal aortic aneurysm 1004 Transmyocardial laser revascularisation 1002 Oto-acoustic emission audiometry 1001 Advanced breast biopsy instrumentation	1011 Lung volume reduction surgery - for advanced emphysema 1009 Sacral nerve stimulation for urinary incontinence 1008 Photodynamic therapy for skin and mucosal cancer 1007 Saline infusion sonohysterography 1006 Endoluminal grafting for abdominal aortic aneurysm 1004 Transmyocardial laser revascularisation 1002 Oto-acoustic emission audiometry 1001 Advanced breast biopsy instrumentation	
1996 - 97	1003 OctreoScan® scintigraphy for gastro-entero-pancreatic neuroendocrine tumours	1003 OctreoScan® scintigraphy for gastro-entero-pancreatic neuroendocrine tumours	

Current Applications:
1114 Urinary metabolic profile
1113 Endo venous laser treatment for varicose veins (EVLT)
1112 BioEnterics intragastric balloon
1111 MIT data analysis
1110 Staging of rectal carcinoma by means of magnetic resonance imaging (MRI)
1109 Deep brain stimulation for essential tremor (pending)
1108 Endobronchial ultrasound in the staging of lung cancer and the diagnosis of mediastinal masses of unknown origin
1106 Endoscopic argon plasma coagulation therapy
1105 Computed tomography coronary angiography
1104 Endoscopic ultrasound and fine needle aspiration for lung cancer
1103 Fetal fibronectin test for preterm labour
1102 Double balloon enteroscopy
1101 Repetitive transcranial magnetic stimulation (rTMS)
1100 Intersphinteric injection of silicone biomaterial for severe passive faecal incontinence
1099 Lumbar non-fusion posterior stabilisation devices
1098 Breast magnetic resonance imaging (MRI
1096 Hepatitis B DNA testing
1087 (incorporating 1086) B-type natriuretic peptide
1086 (subsumed by 1087) Measurement of B-type natriuretic peptide
1072 (incorporating 1069 and 1075) Endoscopic ultrasound for staging pancreatic, gastric, oesophageal and hepato-biliary neoplasms

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-199

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

Hansard Page: CA 75 and CA 76

Senator Moore asked:

o) Please provide some figures on the funding for the operation of MSAC for each financial year since its inception.
p) How many FTE staff does MSAC currently have?
q) What financial reimbursements do the members of MSAC receive?
r) Who appoints the Members?
s) When were the current Members appointed?
t) How often does MSAC meet?
u) Who decides which submissions will be assessed?
v) What is the average time for the completion of such as assessment?
w) What is the longest time such an assessment has taken?
x) How is a decision made that a submission is ineligible?
y) What is the basis for that?
z) For each financial year since the inception of MSAC can you please provide a list of submissions received, submissions accepted and assessments of submissions published?

Answer:

a) Information covering the years 2004-05 and 2005-06 is attached. To gather the requested information for the years prior to 2004-05 would require a significant diversion of resources. The Department does not currently have the resources to answer this question.
b) The MSAC does not have any full-time equivalent (FTE) staff.
c) Members of the MSAC are paid sitting fees in accordance with the rate set for 'Professional Committees - Health Portfolio', as set by the Remuneration Tribunal. In addition members are given a travel allowance and reimbursed for any out-of-pocket costs relating to their attendance at face-to-face meetings.
d) Members of the Committee are appointed by the Minister.
e) Fourteen members were appointed in 2005. Eight members were appointed in 2004.
f) The MSAC meets four times a year.
g) The Senior Medical Adviser, Medical Benefits Division, decides whether an individual submission is eligible for assessment.
h) The average time taken to assess a submission is 18.6 months.
i) The longest time taken to assess a submission was 36.5 months.

j) A submission is ineligible for assessment if the proposed new treatment or technology does not constitute a clinically relevant medical service, as it would not then be eligible for reimbursement under the Medicare Benefits Scheme.
k) See answer to j) above
l) See attached spreadsheet.

MSAC FUNDING

Financial Year	04/05	05/06
Committee Related Expenses	404,381.83	427,318.12
Consultant Related Expenses	2,765,099.57	1,796,462.73
TOTAL	**3,169,481.40**	**2,223,780.85**
TOTAL FUNDING FROM 04/05 to 05/06		**5,393,262.25**

Note 1: Committee Related Expenses includes all expenses related to travel and sitting fees for committee members

Note 2: Consultant Related Expenses covers fees paid to consultants for systematic reviews of MSAC applications. Figures for 04/05 are higher as there were more evaluators contracted than in 05-06.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-131

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY

Written Question on Notice

Senator McLucas asked:

For each financial year since the inception of MSAC, please provide a list of referrals received, referrals accepted and assessments of referrals published. Please include assessments currently underway.

Answer:

See attached spreadsheet.

For each financial year since the inception of MSAC, please provide a list of references received, references accepted and assessments of references published. Please include assessments currently underway.

Financial Year	References received	References accepted	References published
2006 - 07	39 Human Papilloma virus: triage of Pap smears 38 Methods to detect the HER-2 neu oncogene in breast cancer tissue	39 Human Papilloma virus: triage of Pap smears 38 Methods to detect the HER-2 neu oncogene in breast cancer tissue	
2005 - 06	37 Digital mammography 36 NFCs 35 Positron emission tomography (PET) review: colorectal, melanoma and ovarian cancer	37 Digital mammography 36 NFCs 35 Positron emission tomography (PET) review: colorectal, melanoma and ovarian cancer	32 Implantable cardioconverter defibrillators for the prevention of sudden cardiac death 27 Vertebroplasty
2004 - 05	34 Gamma knife stereotactic radiosurgery 33 Treatment of cerebral aneurysms 32 Implantable cardioconverter defibrillators for the prevention of sudden cardiac death	34 Gamma knife stereotactic radiosurgery 33 Treatment of cerebral aneurysms 32 Implantable cardioconverter defibrillators for the prevention of sudden cardiac death	31 Endometrial ablation techniques for chronic refractory menorrhagia 30 Drug eluting stents 25 Magnetic resonance cholangiopancreatography (MRCP)

Financial Year	References received	References accepted	References published
2003 - 04	31 Endometrial ablation techniques for chronic refractory menorrhagia 30 Drug eluting stents 29 Artificial intervertebral disc replacement (AIDR) 28 Laparoscopic removal of malignancies 27 Vertebroplasty 26 Positron emission tomography (PET) for epilepsy 25 Magnetic resonance cholangiopancreatography (MRCP) 24 Injection of Botulinum toxin for the treatment of focal spasticity in adults 23 Injection of Botulinum toxin for the treatment of spasticity following stroke 22 Treatment of hyperhidrosis of the axillae	31 Endometrial ablation techniques for chronic refractory menorrhagia 30 Drug eluting stents 28 Laparoscopic removal of malignancies (withdrawn) 27 Vertebroplasty 26 Positron emission tomography (PET) for epilepsy 25 Magnetic resonance cholangiopancreatography (MRCP) 24 Injection of Botulinum toxin for the treatment of focal spasticity in adults (withdrawn) 23 Injection of Botulinum toxin for the treatment of spasticity following stroke (withdrawn) 22 Treatment of hyperhidrosis of the axillae (withdrawn)	18 Faecal occult blood test (FOBT) 16 Positron emission tomography (PET) for non-small-cell lung cancer and solitary pulmonary nodules 14 Laparoscopic adjustable gastric banding for morbid obesity 12e The use of human Papillomavirus testing to monitor effectiveness of treatment of high-grade intraepithelial abnormalities of the cervix 9a (iii) Polymerase chain reaction in the diagnosis and monitoring of patients with AML1-ETO and CBF-MYH11 gene rearrangement in acute myeloid leukaemia 9a (iv) Polymerase chain reaction in the diagnosis and monitoring of patients with BCR-ABL gene rearrangement in acute lymphoid leukaemia

Financial Year	References received	References accepted	References published
2002 - 03	21 Drug (Sirolimus) eluting stents 20 Carotid stenting 19 Bone mineral densitometry 18 Faecal occult blood test (FOBT) 17 Neonatal hearing screening 16 Positron emission tomography (PET) for non-small-cell lung cancer and solitary pulmonary nodules	21 (subsumed by Ref 30) Drug (Sirolimus) eluting stents 20 Carotid stenting 19 Bone mineral densitometry 18 Faecal occult blood test (FOBT) 17 Neonatal hearing screening 16 Positron emission tomography (PET) for non-small-cell lung cancer and solitary pulmonary nodules	15 Transanal endoscopic microsurgery 13 Multifocal multi-channel objective perimetry (MMOP) 12a Liquid based cytology for cervical screening 12b Human Papillomavirus testing in women with cytological prediction of low-grade abnormality 12d Human Papillomavirus testing for cervical cancer 9a (i) Polymerase chain reaction in the diagnosis and monitoring of patients with BCR-ABLgene rearrangement in chronic myeloid leukaemia 9a (ii) Polymerase chain reaction in the diagnosis and monitoring of patients with PML-RAR and PLZF-RAR gene rearrangement in acute promyelocytic leukaemia 9b Pathology testing - Thrombophilia testing in pregnancy

Financial Year	References received	References accepted	References published
2001 - 02	15 Transanal endoscopic microsurgery 14 Laparoscopic adjustable gastric banding for morbid obesity 13 Multifocal multi-channel objective perimetry (MMOP	15 Transanal endoscopic microsurgery 14 Laparoscopic adjustable gastric banding for morbid obesity 13 Multifocal multi-channel objective perimetry (MMOP)	11a Off-pump coronary artery bypass (OPCAB) with the aid of tissue stabilisers 11b Minimally invasive direct coronary artery bypass (MIDCAB) with the aid of tissue stabilisers 8 Intra-operative transoesophageal echocardiography 7b Magnetic resonance imaging for staging cervical and endometrial cancer 4 Nuchal translucency measurement in the first trimester of pregnancy for screening of trisomy 21 and other autosomal trisomies

Financial Year	References received	References accepted	References published
2000 - 01	12a Liquid based cytology for cervical screening 12b Human Papillomavirus testing in women with cytological prediction of low-grade abnormality 12c Computer-assisted image analysis for cervical screening 12d Human Papillomavirus testing for cervical cancer 12e The use of human Papillomavirus testing to monitor effectiveness of treatment of high-grade intraepithelial abnormalities of the cervix 11a Off-pump coronary artery bypass (OPCAB) with the aid of tissue stabilisers 11b Minimally invasive direct coronary artery bypass (MIDCAB) with the aid of tissue stabilisers 10 (2 i) Positron emission tomography (PET) - additional indications 10 (2 ii) Positron emission tomography (PET) - additional indications 9a (i) Polymerase chain reaction in the	12a Liquid based cytology for cervical screening 12b Human Papillomavirus testing in women with cytological prediction of low-grade abnormality 12c Computer-assisted image analysis for cervical screening 12d Human Papillomavirus testing for cervical cancer 12e The use of human Papillomavirus testing to monitor effectiveness of treatment of high-grade intraepithelial abnormalities of the cervix 11a Off-pump coronary artery bypass (OPCAB) with the aid of tissue stabilisers 11b Minimally invasive direct coronary artery bypass (MIDCAB) with the aid of tissue stabilisers 10 (2 i) Positron emission tomography (PET) - additional indications 10 (2 ii) Positron emission tomography (PET) - additional indications 9a (i) Polymerase chain reaction in the	10 (2 (i) Positron emission tomography (PET) - additional indications 10 (2 (ii) Positron emission tomography (PET) - additional indications 5 Provision of pulmonary thromboendarectomy (PTE)

	diagnosis and monitoring of patients with BCR-ABLgene rearrangement in chronic myeloid leukaemia	diagnosis and monitoring of patients with BCR-ABLgene rearrangement in chronic myeloid leukaemia	
Financial Year	**References received**	**References accepted**	**References published**
	9a (ii) Pathology testing 9a (iii) Pathology testing 9a (iv) Polymerase chain reaction in the diagnosis and monitoring of patients with BCR-ABL gene rearrangement in acute lymphoid leukaemia 9b Pathology testing - Thrombophilia testing in pregnancy 8 Intra-operative transoesophageal echocardiography 7a - Magnetic resonance cholangiopancreatography (MRCP) 7b Magnetic resonance imaging for staging cervical and endometrial cancer	9a (ii) Polymerase chain reaction in the diagnosis and monitoring of patients with PML-RAR and PLZF-RAR gene rearrangement in acute promyelocytic leukaemia 9a (iii) Polymerase chain reaction in the diagnosis and monitoring of patients with AML1-ETO and CBF-MYH11 gene rearrangement in acute myeloid leukaemia 9a (iv) Polymerase chain reaction in the diagnosis and monitoring of patients with BCR-ABL gene rearrangement in acute lymphoid leukaemia 9b Thrombophilia testing in pregnancy 8 Intra-operative transoesophageal echocardiography 7a (subsumed by Ref 25) Magnetic resonance cholangiopancreatography (MRCP) 7b Magnetic resonance imaging for staging cervical and endometrial cancer	

Financial Year	References received	References accepted	References published
1999 - 00	6 Intracytoplasmic sperm injection 5 Provision of pulmonary thromboendarectomy (PTE) 4 Nuchal translucency measurement in the first trimester of pregnancy for screening of trisomy 21 and other autosomal trisomies 3 Assisted reproductive technology (ART) 2 Positron emission tomography 1 Prostate cancer screening	6 Intracytoplasmic sperm injection 5 Provision of pulmonary thromboendarectomy (PTE) 4 Nuchal translucency measurement in the first trimester of pregnancy for screening of trisomy 21 and other autosomal trisomies 3 Assisted reproductive technology (ART) 2 Positron emission tomography 1 Prostate cancer screening	

Current References:
39 Human Papilloma virus: triage of Pap smears
38 Methods to detect the HER-2 neu oncogene in breast cancer tissue
37 Digital mammography
36 Nationally Funded Centres
35 Positron emission tomography (PET) review: colorectal, melanoma and ovarian cancer
34 Gamma knife stereotactic radiosurgery

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-132

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

Written Question on Notice

Senator McLucas asked:

Why was no report produced for reference 03 on Assisted Reproductive Technology?

Answer:

A report was produced for reference 03, which was prepared by a working party of the Australian Health Technology Advisory Committee (AHTAC), a committee which predated the formation of the Medical Services Advisory Committee (MSAC). The MSAC was established in April 1998, and was asked to auspice the AHTAC report and make a decision about its release.

Although the report was not published, copies of the report were made available to interested parties upon request.

The MSAC website has been updated to reflect this.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-133

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

Written Question on Notice

Senator McLucas asked:

Why was the report for submission 1046 – Implantation of the Interstim® device for sacral nerve stimulation not published?

Answer:

The MSAC report for application 1046 was not published on the request of the applicant, as it contained commercial-in-confidence material.

However, with the agreement of the applicant, the Department published a brief abstract outlining the main findings and the MSAC recommendation, without specific reference to the commercial-in-confidence material. This abstract is available on the MSAC website.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-134

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

Written Question on Notice

Senator McLucas asked:

aa) Why does it say under submission 1060 – Bone mineral densitometry that it is deferred, but under Reference 19 – Bone Densitometry Testing, it says that the reference is withdrawn by the Department?
bb) Why was this reference withdrawn?
cc) When was it withdrawn?
dd) Who asked for its withdrawal?

Answer:

a) Application 1060 was deferred, pending the receipt of a referral from the Department for an assessment of the same tests as those in Application 1060. The application and the referral were combined for the purposes of the assessment.
b) The reference was withdrawn because the draft assessment report was unable to appropriately address the Department's referral.
c) The reference was withdrawn in January 2005.
d) The request to withdraw the reference was made by the Senior Medical Officer, Medical Benefits Division.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-135

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

Written Question on Notice

Senator McLucas asked:

ee) How is the decision made to do a Horizon Scanning Brief?
ff) Why have no Horizon Scanning Briefs been published since March 2003?
gg) What Horizon Scanning Briefs are currently underway?
hh) When are these expected to be completed?

Answer:

a) The Health Policy Advisory Committee on Technology (HealthPACT), a multi-jurisdictional sub-committee of the MSAC, decides which technologies will be the subject of a brief. Briefs may be a short review called a prioritising summary, or in the case of more significant emerging technologies, an in-depth horizon scanning report may be requested.
b) Since March 2003, Horizon Scanning briefs have not been published in hard copy format. Horizon scanning reports continue to be published electronically on the horizon scanning website found at: www.horizonscanning.gov.au
c) There are currently three horizon scanning reports underway: Autologous bone marrow cell transplantation for myocardial infarction; Nanomedicine; and Proton beam therapy for treatment of cancer.
d) All three reports are expected to be completed and published on the horizon scanning website by the end of March 2007.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-136

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

Written Question on Notice

Senator McLucas asked:

Will MSAC look at the issues raised in the recent prostheses study from the Australian Centre for Health Research which showed that some newer prostheses performed no better than older, cheaper models?

Answer:

The MSAC's terms of reference include assessing applications and references relating to new and emerging health treatments and technologies and advising the Minister about whether public funding should be supported, based on the available evidence. Individual studies, like the one mentioned above could be looked at in the context of a future application or referral.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-138

OUTCOME 3: Access to Medical Services

Topic: CANCER SERVICES

Written Question on Notice

Senator McLucas asked:

Was the Medicare item for the provision of multidisciplinary care to cancer patients introduced on November 1? When was this announced?

Answer:

Two items for case conferencing for patients with cancer were included in the Medicare Benefits Schedule (MBS) on 1 November 2006. Item 871 provides for the lead and coordination of a case conference on a patient with cancer to develop a multidisciplinary treatment plan. Item 872 provides for participation in a case conference on a patient with cancer to develop a multidisciplinary treatment plan.

The introduction of MBS items for cancer case conferencing was announced by the Minister for Health and Ageing on 10 February 2006, as part of the Australian Better Health Initiative package agreed by the Council of Australian Governments (COAG).

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-110

OUTCOME 3: Access to Medical Services

Topic: NATIONAL ONLINE REGISTER OF MEDICAL DEVICES

Written Question on Notice

Senator McLucas asked:

a) What role does this Department play in this new register?
b) Was the Department consulted about the establishment of this new register?
c) Doesn't this register subsume some of the activities of the TGA and MSAC?
d) Does the Department have concerns about this register?
e) What checks will be made by the Department and the information provided through the register to ensure that it is accurate?

Answer:

a)
The register will be established under the auspices of an Industry Cooperative Innovation Program grant which will be administered by the Department of Industry, Tourism and Resources. The Department of Health and Ageing has provided high level advice concerning the establishment of the register.

b)
The Department was consulted on the high level concept of the register.

c)
It is not intended that the register will subsume any functions of the Therapeutic Goods Administration (TGA) or the Medical Services Advisory Committee (MSAC). The register is largely an information sharing mechanism for medical device manufacturers. It will not subsume any of the TGA's activity in relation to pre-market evaluation of medical devices; licensing of manufacturers; or post-market surveillance. The register will also not impact on the activities of the MSAC conducting evidence based assessment of new medical technologies to inform public funding decisions.

d)
The Department has no concerns about the register concept at this stage but will be taking an interest in the detail of the register as it develops and putting views to the Department of Industry, Tourism and Resources, as necessary.

e)
The Department will not have a formal role in reviewing the accuracy of information contained within the register.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-162

OUTCOME 3: Access to Medical Services

Topic: ACCESS TO PSYCHOLOGISTS AND PSYCHIATRISTS

Written Question on Notice

Senator McLucas asked:

Please provide the following information with respect to Medicare-funded, out-patient psychiatric services for the years 2000-01 and 2005-06:

ii) Total number of services
jj) Total number of patients treated
kk) Total Medicare benefits paid
ll) % of services bulk billed
mm) Out-of-pocket costs to see a psychiatrist who does not bulk bill
nn) Number of psychiatrists who delivered at least one Medicare service.

Answer:

The requested Medicare statistics for 2000-01 and 2005-06 (year of processing) are as follow:

MEDICARE - NON-INPATIENT PSYCHIATRIC SERVICES 2000-01 & 2005-06 (YEAR OF PROCESSING)		
Measure	**2000-01**	**2005-06**
Number of services	1,923,699	1,760,203
Number of patients	280,208	267,276
Benefits paid	$183,859,301	$202,300,424
% of services bulk billed	49.0%	40.9%
Average patient contribution per service - for psychiatrists who only patient billed	$ 29.75	$ 28.06
Number of providers	1,826	1,877

Notes to the Statistics

These statistics were compiled having regard to the Group A8 (Consultant Psychiatrist attendance to which no other item applies) and to the Consultant Psychiatrist Case Conference items (Item numbers 855 to 866) in the Medicare Benefits Schedule.

The statistics relate to services rendered on a 'fee-for-service' basis for which claims for benefits were processed by Medicare Australia in the respective years.

For all measures other than the 'average patient contribution per service' the statistics relate to non-hospital bulk billed and patient billed services. Statistics on the average patient contribution per service were based on non-hospital patient billed services only.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-200

OUTCOME 3: Access to Medical Services

Topic: BULK-BILLING - PSYCHIATRISTS

Hansard Page: CA 71

Senator Webber asked:

What is the current average out-of-pocket cost, say, for a patient to see a psychiatrist who does not bulk bill?

Answer:

The average patient contribution per service for all non-hospital patient billed psychiatrist services under Medicare in 2005-06 (year of processing), involving psychiatrists who exclusively patient billed was $28.06.

These statistics were compiled having regard to the Group A8 (Consultant Psychiatrist attendance to which no other item applies) and to the Consultant Psychiatrist Case Conference items (Item numbers 855 to 866) in the Medicare Benefits Schedule.

The statistics relate to non-hospital patient billed services that were rendered on a ‘fee-for-service’ basis for which claims for benefits were processed by Medicare Australia in 2005-06.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-194

OUTCOME 3: Access to Medical Services

Topic: INDIGENOUS CHILD HEALTH CHECK

Hansard Page: CA 82

Senator Evans asked:

What were your targets? That is only five months, but what were you expecting in the way of take-up? Does it meet expectations? Are you pleased or is it slower than you thought?

Answer:

While estimates of uptake are prepared for the purpose of estimating likely costs of new Medicare items, actual service volumes for Medicare items are demand driven and are not tied to or tracked against targets. As such, there are no targets for the Indigenous child health check.

Data for the period 1 May 2006 to 30 September 2006 shows that there has been uptake of the Indigenous child health check Medicare item. The total number of child health checks provided for this five month period in Australia was 1,721. The following table disaggregates these figures by the month of processing.

Table 1: Number of Indigenous Child Health Checks, by Month of Processing

2006	**Total**
May	128
June	295
July	256
August	551
September	491
Total	1,721

Take-up of the Indigenous child health check is still increasing, and it is anticipated that take-up will increase in the future with further communications activities targeted at providers and patients to familiarise them to the new MBS item.

At this stage, it is too early to comment on overall progress of the item.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-127

OUTCOME 3: Access to Medical Services

Topic: OUT OF HOSPITAL SURGICAL TREATMENTS

Written Question on Notice

Senator McLucas asked:

We are aware that some cosmetic surgeons are doing work in their (unaccredited) rooms under completely unregulated conditions which enables patients to claim their costs (as high as $5000) on the Medicare safety net.

a) Why do some procedures which should never be done outside a hospital allow for an 85% reimbursement level?
b) Doesn't this encourage out-of-hospital services where this is not necessarily in the patient's best interests?
c) Doesn't this encourage unscrupulous doctors (e.g. cosmetic surgeons) to perform procedures in their rooms and then allow patients to claim on the Medicare safety net?
d) What procedures are in place to ensure that:
    i) The right Medicare item is claimed?
    ii) If a claim is made for an out-of-hospital procedure, then this is appropriate?
    iii) Claims on the Medicare safety net are appropriate?
    iv) Is the Department aware, for example, of the increase in the number of claims on Medicare for item 30171 (lipectomy) since the introduction of the Medicare safety net? Is this a matter for concern?

Answer:

a) Medicare benefits are payable at 75 per cent of the Medicare Schedule fee, where a private patient is admitted as a hospital in-patient or day patient. Insured private patients obtain the difference between 75 per cent and 100 per cent of the Schedule fee, together with additional benefits for hospital accommodation and other hospital charges from their private health fund. For patients undergoing treatment in an out-of-hospital setting, Medicare benefits are payable at 85 per cent of the Schedule fee.

    The decision as to whether a service should be provided as an in-hospital or an out-of-hospital service is made by the treating practitioner having regard to current and appropriate clinical practice, the individual circumstances of the patient, the nature of the service and the facility in which the treatment would be provided. The Government does not generally preclude services being provided out-of-hospital at the 85 per cent rate in recognition of these differing clinical circumstances and changes to clinical practice over time.

b) No. Whether a service is provided as an in-hospital or out-of-hospital service is a matter for the clinical judgement of the treating practitioner.

The Department would expect that patients undergoing procedures on an out-of - hospital basis are being treated in accredited facilities, licensed under state and territory legislation to perform such services. The accreditation/licensing status of particular facilities are matters for state and territory health authorities and appropriate professional medical authorities. It is not a matter for Medicare.

The payment of Medicare benefits is confined to the professional component of a service. Legislation prevents the inclusion of non-Medicare eligible services such as facility fees in the fee for Medicare eligible services.

c) Issues surrounding inappropriate practice under Medicare can be raised with Medicare Australia which administers the Medicare program. If Medicare Australia has sufficient cause to believe a practitioner is engaging in inappropriate practice, it can refer the practitioner to the Professional Services Review (PSR) Scheme. The PSR Scheme provides a process for reviewing and investigating the provision of services by a practitioner to determine whether the practitioner has engaged in inappropriate practice in the rendering or initiating of Medicare services or in prescribing under the Pharmaceutical Benefits Scheme (PBS).

Issues of professional misconduct are a state government responsibility. Dissatisfaction with the conduct of a particular medical practitioner can, in the first instance, be raised with the practitioner, and followed up by reporting the matter to the relevant state health department or health care commissioner.

(d) (i) (ii) and (iii) - As these questions fall within the responsibility of Medicare Australia, they have been referred for response. Medicare Australia will provide its response directly to the Committee.
(iv) No. There is no evidence to suggest that the introduction of the EMSN has resulted in an increase in item 30171 for lipectomy as an out-of-hospital procedure. The incidence of item 30171 for lipectomy wedge increased from 662 in 2003 to 757 in 2004 and to 846 in 2005. The number of services performed out of hospital and therefore eligible for the extended Medicare safety net was 50 in 2003, 37 in 2004 and 39 in 2005.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-137

OUTCOME 3: Access to Medical Services

Topic: RADIATION ONCOLOGY SERVICES

Written Question on Notice

Senator McLucas asked:

For each financial year from 2002-03 to YTD, please provide the budgeted funds and the expended funds for radiation oncology services under Better Treatment for Cancer Patients / Better Access to Radiation Oncology

Answer:

The table below shows the budgeted funds and expended funds for the Better Treatment for Cancer Patients budget measure during the period of its operation from 2002-03 to 2005-06, and the Better Access to Radiation Oncology budget measure from its commencement in 2006-07 to YTD as at 31 October 2006:

Table 1. Better Treatment for Cancer Patients / Better Access to Radiation Oncology

	2002/03	2003/04	2004/05	2005/06		2006/07 YTD
	$'000	$'000	$'000	$'000		$'000
Budget	13,000	18,800	20,400	20,400		2,104
Rephased Budget	-10,880	-10,014	-4,650	15,444		
Total Budgeted Funds	**2,120**	**8,786**	**15,750**	**35,844**		**2,104**
Expended funds	1,144	8,211	14,539	22,963		1,145
Variance	**976**	**575**	**1,211**	**12,881**		**958**

Notes:

1. Of the remaining $12.881m unspent funds in 2005-06, $12.6m is being sought for rephasing to future years for the Better Access to Radiation Oncology measure.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-168

OUTCOME 3: Access to Medical Services

Topic: AUSTRALIAN HEALTH CARE

Written Question on Notice

Senator McLucas asked:

As identified in E06-260, in 2004-05 there was a $22.8 million underspend in the "demand-driven sub-programs included in this program structure."

*Please list these sub-programs
*For each subprogram please provide, for financial years since 2003-04:
oThe expected expenditure
oThe actual expenditure
oWhat happened to the funds that were not expended.

Answer:

The sub-programs relating to the $22.8 million underspend in 2004-05 Access to Public Hospitals Program, are listed in Table 1 attached.

For each of these sub-programs, this table also shows the budgeted expected expenditure, actual expenditure, and what happened to the funds that were not expended for financial years 2003-04, 2004-05 and 2005-06.

Table 1. Sub-programs in the 2004-05 Access to Public Hospitals Program showing budgeted expenditure, actual expenditure and what happened to unspent funds for 2003-04, 2004-05 and 2005-06

Sub-Programs	2003-04				2004-05				2005-06			
	Budgeted Expend. $'000	Actual Expend. $'000	Variance $'000	What happened to the funds not expended?	Budgeted Expend. $'000	Actual Expend. $'000	Variance $'000	What happened to the funds not expended?	Budgeted Expend. $'000	Actual Expend. $'000	Variance $'000	What happened to the funds not expended?
Act of Grace Payments FMA Act	"Sub-Program did not exist"				7,528	3,035	4,493	Lapsed	10	-830	840	N/A as there is no underspend. Negative expenditure resulted from overstatement of 30/6/2005 liability due to the demand driven nature of the program and the difficulty in estimating the outstanding liability.
AHCA's - Pathways Home - Step Down	32,000	17,627	14,373	Residual rephased according to states requests	86,497	86,497	0	n/a	55,074	55,074	0	n/a
Base Health Care Grants	7,376,925	7,379,604	-2,679	Variation for updated ABS population data	7,768,751	7,768,751	0	n/a	8,273,641	8,269,590	4,051	Variation for updated ABS population data
Breast Cancer Patients - Herceptin	18,773	25,369	-6,596	All funds were expended	32,738	33,201	-463	All funds were expended	37,649	41,271	-3,622	All funds were expended
Ex Gratia Payments - Bali	5,900	439	5,461	Lapsed	3,654	306	3,348	Lapsed	315	351	-36	n/a
Fin Assistance for Medical Treatment O/S	1,605	-510	2,115	Lapsed. Note that the negative expenditure resulted from the overstatement of 30/6/2003 liability due to difficulty in anticipating when approved treatment overseas will occur.	2,601	1,543	1,058	Lapsed	1,601	1,423	178	Lapsed
Fin Assistance for Life Saving Drugs	7,891	21,154	-13,263	All funds were expended	31,745	29,045	2,700	Lapsed	35,084	30,817	4,267	Lapsed
Health Services Provision Grants	3,606	3,604	2	Lapsed	3,829	3,827	2	Lapsed	3,911	2,997	914	Lapsed
HPG NT District Medical Officer	618	600	18	Lapsed	650	600	50	Lapsed	684	300	384	Lapsed
PKU - Medical Food Subsidy	2,587	1,438	1,149	Lapsed	2,633	1,780	853	Lapsed	2,697	1,757	940	$585,000 approved to support implementation of PBS Safety Net 20 day rule. Remaining unexpended funds lapsed.
Royal Children's Hosp - Cancer Cntr	"Sub-Program did not exist"				10,000	10,000	0	n/a	"Sub-Program did not exist"			
Scottsdale Hosp - Health Prof Accom	"Sub-Program did not exist"				50	0	50	Rephased to 2005-06	100	50	50	$50k rephase to 2006-07 has been requested
Tsunami Health Care Assistance	"Sub-Program did not exist"				2,292	0	2,292	was paid out of Ex Gratia Payments-Bali	2,174	160	2,014	Lapsed
Visudyne Therapy	19,032	12,638	6,394	Lapsed	24,261	15,831	8,430	Lapsed	24,443	15,418	9,025	Lapsed
TOTALS	**7,468,937**	**7,461,963**	**6,974**		**7,977,229**	**7,954,416**	**22,813**		**8,437,383**	**8,418,378**	**19,005**	

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2006-2007, 1 November 2006

Question: E06-142

OUTCOME 3: Access to Medical Services

Topic: CHRONIC DISEASE MANAGEMENT

Written Question on Notice

Senator McLucas asked:

Can we have an updated list of out-of-pocket costs for the various AHS items as supplied at the last Senate Estimates?

Answer:

See attached table.

Medicare Allied Health and Dental Care Initiative

Uptake for 2005-06 (12 months) - by date of processing

Item	No. of services	Medicare benefits paid	Average out-of-pocket cost per service *
Aboriginal Health Worker 10950	7	$315	$0
Diabetes Educator 10951	7,781	$354,694	$10
Audiologist 10952	319	$15,218	$23
Exercise Physiologist 10953	3,929	$180,250	$10
Dietitian 10954	72,824	$3,322,457	$11
Mental Health Worker 10956	2,730	$134,043	$33
Occupational Therapist 10958	4,928	$237,755	$23
Physiotherapist 10960	202,455	$9,224,902	$5
Chiropodist / Podiatrist 10962	149,507	$6,781,536	$4
Chiropractor 10964	19,524	$859,068	$3
Osteopath 10966	9,855	$451,950	$11
Psychologist 10968	45,531	$2,262,888	$41
Speech Pathologist 10970	11,371	$552,339	$17
ALLIED HEALTH ITEMS	**530,795**	**$24,379,056**	**$11**
Dental Assessment 10975	2,502	$187,184	$26
Dental Treatment 10976	2,989	$411,393	$77
Assessment or Treatment by Dental Specialist 10977	41	$84,995	$692
DENTAL CARE ITEMS	**5,532**	**$683,645**	**$61**

* For services not bulk billed.