Community Affairs
Legislation Committee

Examination of Budget Estimates 2005-2006

Additional Information Received

VOLUME 6

HEALTH AND AGEING PORTFOLIO

Outcomes: whole of portfolio,
Outcomes 1, 2, 3, 4, 6

FEBRUARY 2006

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 2005-2006

Included in this volume are answers to written questions on notice and tabled papers relating to the budget estimates supplementary hearing on 2 November 2005

HEALTH AND AGEING PORTFOLIO

Australian Government

Department of Health and Ageing

Senator Gary Humphries
Chair
Senate Community Affairs Committee
Parliament House
CANBERRA ACT 2600

Dear Senator Humphries

Portfolio Additional Estimates Statements (PAES)

The Department of Finance and Administration advised departments on 22 September 2005 that portfolios are required to notify their Parliamentary Committee of any agencies within their portfolio that would not be providing data within the Additional Estimates process and the reasoning for this.

The Health and Ageing Portfolio would like to advise that the following small agencies within the portfolios have no variations to budget estimates, and therefore will not be updating their estimates in the 2005-06 Health and Ageing Portfolio Additional Estimates Statements:

Professional Services Review
Aged Care Standards and Accreditation Agency
General Practice Education and Training Limited
Private Health Insurance Administration Council
Australian Institute of Health and Welfare
National Institute of Clinical Studies

Yours sincerely

Jamie Clout
Assistant Secretary
Budget Branch
Portfolio Strategies Division

27 October 2005

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the capability map >>>>

APS 1

1. Aligns with organisational objectives	2. Achieves results	3. Supports productive working relationships	4. Shows personal drive and integrity	5. Communicates clearly and effectively	6. Applies and builds appropriate knowledge, skills and experience
1.1 Understands the work and maintains an awareness of Departmental goals	2.1 Takes responsibility for achieving results	3.1 Develops and maintains relationships with internal and external clients	4.1 Behaves professionally and ethically	5.1 Communicates clearly and concisely	6.1 Takes active steps to grow and develop own skills, knowledge and experience
	2.2 Ensures quality standards are maintained	3.2 Values individual differences and diversity	4.2 Shows resilience		
1.2 Applies judgement, intelligence and common sense	2.3 Plans and organises work effectively	3.3 Works collaboratively and supports others	4.3 Ensures ongoing improvement and learning in self and others	5.2 Listens, understands and adapts to audience	
	2.4 Adapts to change		4.4 Commits to action		

APS 2

1. Aligns with organisational objectives	2. Achieves results	3. Supports productive working relationships	4. Shows personal drive and integrity	5. Communicates clearly and effectively	6. Applies and builds appropriate knowledge, skills and experience
1.1 Understands the work and maintains an awareness of Departmental goals	2.1 Takes responsibility for achieving results	3.1 Develops and maintains relationships with internal and external clients	4.1 Behaves professionally and ethically	5.1 Communicates clearly and concisely	6.1 Takes active steps to grow and develop own skills, knowledge and experience
	2.2 Ensures quality standards are maintained	3.2 Values individual differences and diversity	4.2 Shows resilience		
1.2 Applies judgement, intelligence and common sense	2.3 Plans and organises work effectively	3.3 Works collaboratively and supports others	4.3 Ensures ongoing improvement and learning in self and others	5.2 Listens, understands and adapts to audience	
	2.4 Adapts to change		4.4 Commits to action		

APS 3

1. Aligns with organisational objectives	2. Achieves results	3. Supports productive working relationships	4. Shows personal drive and integrity	5. Communicates clearly and effectively	6. Applies and builds appropriate knowledge, skills and experience
1.1 Understands the work and maintains an awareness of the Departmental goals	2.1 Takes responsibility for achieving results	3.1 Develops and maintains relationships with internal and external stakeholders	4.1 Behaves professionally and ethically and accepts responsibility for own action	5.1 Communicates clearly and concisely	6.1 Builds, applies and maintains appropriate experience, skills and knowledge. Where relevant to the position, maintains and demonstrates professional / technical qualifications or specialist expertise.
	2.2 Ensures quality standards are maintained	3.2 Values individual differences and diversity	4.2 Shows resilience	5.2 Listens, understands and adapts to audience	
1.2 Applies judgement, intelligence and commonsense	2.3 Uses resources wisely by planning and organising effectively	3.3 Works collaboratively and supports others	4.3 Ensures ongoing improvement and learning in self and others	5.3 Presents as confident and professional to others	
	2.4 Adapts to change		4.4 Commits to action		

APS 4

1. Aligns with organisational objectives	2. Achieves results	3. Supports productive working relationships	4. Shows personal drive and integrity	5. Communicates clearly and effectively	6. Applies and builds appropriate knowledge, skills and experience
1.1 Understands the work and maintains an awareness of Departmental goals	2.1 Takes responsibility for achieving results	3.1 Develops and maintains relationships with internal and external stakeholders	4.1 Behaves professionally and ethically and accepts responsibility for own actions	5.1 Communicates clearly and concisely	6.1 Builds, applies and maintains appropriate experience, skills and knowledge. Where relevant to the position, maintains and demonstrates professional / technical qualifications or specialist expertise.
	2.2 Ensures quality standards are maintained	3.2 Values individual differences and diversity	4.2 Shows resilience	5.2 Listens, understands and adapts to audience	
1.2 Applies judgement, intelligence and commonsense	2.3 Uses resources wisely by planning and organising effectively	3.3 Works collaboratively and supports others	4.3 Ensures ongoing improvement and learning in self and others	5.3 Presents as confident and professional to others	
	2.4 Adapts to change		4.4 Commits to action		

the capability map

APS 5

1. Contributes to strategic thinking	2. Achieves results	3. Supports productive working relationships	4. Shows personal drive and integrity	5. Communicates with influence	6. Applies and builds appropriate knowledge, skills and experience
1.1 Supports shared purpose and direction	2.1 Takes responsibility for managing performance to achieve results	3.1 Develops and maintains internal and external relationships, partnerships and networks	4.1 Behaves professionally and ethically, and accepts responsibility for own action	5.1 Communicates clearly and concisely	6.1 Builds, applies and maintains appropriate experience, skills and knowledge. Where relevant to the position, maintains and demonstrates professional / technical qualifications or specialist expertise.
1.2 Applies judgment, intelligence and common sense	2.2 Identifies and uses team and individual resources wisely	3.2 Values individual differences and diversity	4.2 Shows resilience	5.2 Listens, understands and adapts to audience	
1.3 Thinks strategically and maximises work linkages, opportunities and solutions		3.3 Listens to, understands and recognises others	4.3 Seeks and applies ongoing improvement and learning and a balanced approach to work		
1.4 Contributes to planning and decision making	2.3 Adapts to, supports and manages change	3.4 Promotes and shares learning and supports and guides others	4.4 Commits to action	5.3 Negotiates persuasively	

APS 6

1. Contributes to strategic thinking	2. Achieves results	3. Supports productive working relationships	4. Shows personal drive and integrity	5. Communicates with influence	6. Applies and builds appropriate knowledge, skills and experience
1.1 Supports shared purpose and direction	2.1 Takes responsibility for managing performance to achieve results	3.1 Develops and maintains internal and external relationships, partnerships and networks	4.1 Behaves professionally and ethically, and accepts responsibility for own action	5.1 Communicates clearly and concisely	6.1 Builds, applies and maintains appropriate experience, skills and knowledge. Where relevant to the position, maintains and demonstrates professional / technical qualifications or specialist expertise.
1.2 Applies judgment, intelligence and common sense	2.2 Identifies and uses team and individual resources wisely	3.2 Values individual differences and diversity	4.2 Shows resilience	5.2 Listens, understands and adapts to audience	
1.3 Thinks strategically and maximises work linkages, opportunities and solutions		3.3 Listens to, understands and recognises others	4.3 Seeks and applies ongoing improvement and learning and a balanced approach to work		
1.4 Contributes to planning and decision making	2.3 Adapts to, supports and manages change	3.4 Promotes and shares learning and supports and guides others	4.4 Engages with risk and shows personal courage	5.3 Negotiates persuasively	
			4.5 Commits to action		

EL1

1. Shapes strategic thinking	2. Achieves results	3. Cultivates productive working relationships	4. Exemplifies personal drive and integrity	5. Communicates with influence	6. Applies and builds appropriate knowledge, skills and experience
1.1 Encourages a shared sense of purpose and direction	2.1 Ensures closure and delivers on intended results	3.1 Nurtures internal and external relationships	4.1 Demonstrates public service professionalism and probity	5.1 Communicates clearly and concisely	6.1 Builds, applies and maintains appropriate experience, skills and knowledge. Where relevant to the position, maintains and demonstrates professional / technical qualifications or specialist expertise.
1.2 Shows judgement, intelligence and commonsense	2.2 Builds Departmental capability and responsiveness	3.2 Values individual differences and diversity	4.2 Displays resilience	5.2 Listens, understands and adapts to audience	
1.3 Focuses strategically	2.3 Steers and implements change and deals with uncertainty	3.3 Facilitates cooperation and partnerships	4.3 Demonstrates self awareness and a commitment to personal development		
1.4 Harnesses information and opportunities	2.4 Marshals professional capability	3.4 Guides, mentors and develops people	4.4 Engages with risk and shows personal courage	5.3 Negotiates persuasively	
			4.5 Commits to action		

EL2

1. Shapes strategic thinking	2. Achieves results	3. Cultivates productive working relationships	4. Exemplifies personal drive and integrity	5. Communicates with influence	6. Applies and builds appropriate knowledge, skills and experience
1.1 Encourages a shared sense of purpose and direction	2.1 Ensures closure and delivers on intended results	3.1 Nurtures internal and external relationships	4.1 Demonstrates public service professionalism and probity	5.1 Communicates clearly and concisely	6.1 Builds, applies and maintains appropriate experience, skills and knowledge. Where relevant to the position, maintains and demonstrates professional / technical qualifications or specialist expertise.
1.2 Shows judgement, intelligence and commonsense	2.2 Builds Departmental capability and responsiveness	3.2 Values individual differences and diversity	4.2 Displays resilience	5.2 Listens, understands and adapts to audience	
1.3 Focuses strategically	2.3 Steers and implements change and deals with uncertainty	3.3 Facilitates cooperation and partnerships	4.3 Demonstrates self awareness and a commitment to personal development		
1.4 Harnesses information and opportunities	2.4 Marshals professional capability	3.4 Guides, mentors and develops people	4.4 Engages with risk and shows personal courage	5.3 Negotiates persuasively	
			4.5 Commits to action		

Australian Government

Department of Health and Ageing

Staff Survey

Wednesday 16 November 2005

Hinds Workforce Research

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

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-014

OUTCOME: Whole of Portfolio

TOPIC: INFORMATION AND COMMUNICATIONS TECHNOLOGY (ICT)

Written Question on Notice

Senator Conroy asked:

For the department and each portfolio agency:

a) Please provide details of total departmental/organisational spending on Information and Communications Technology products and services during the last 12 months?
b) Please break down this spending by ICT function (eg communications, security, private network, websites).
c) Was this spending in line with budget forecasts for this 12 month period? If not, please provide details of:
   (i) The extent that ICT spending exceeded budget forecasts for this 12 month period;
   (ii) Details of specific ICT contracts which resulted in department/organisation spending in excess of budget forecasts for this 12 month period;
   (iii) The reasons ICT spending exceeded budget forecasts for this 12 month period.

Answer:

(a) and (b): The answers to these parts of the question are at Attachment 1.

(c) In the majority of cases spending was in line with budget forecasts. However there were three items in which budgets were exceeded. The first two relate to the Department's Corporate Budget. In both these cases budgets were exceeded due to an unplanned increase in the use of services. The third item relates to the upgrade of a computer network for General Practice Education and Training Limited. Details of the three items are as follows:

Details of Contract	Extent of Overspend
Corporate Budget: increase in use of specialist information lines and mobile phones.	17.5%
Corporate Budget: increase in use of internet.	1.8%
Network LAN upgrade: cost more than initially planned to incorporate better redundancy solutions.	6.1%

Attachment 1

E05000014 – answers to parts (a) and (b)

Agency	Expenditure on Communications for the period 1/11/04 to 31/10/05	Expenditure on Security for the period 1/11/04 to 31/10/05	Expenditure on Private Network for the period 1/11/04 to 31/10/05	Expenditure on Websites for the period 1/11/04 to 31/10/05	Total Expenditure of Information and Communications Technology products and services for the period 1/11/04 to 31/10/05
Department of Health and Ageing	$4,213,008 [1]	See footnote [2]	$1,406,466 [3]	$567,185 [4]	$56,049,896 [5] This includes the amount referred to in footnote [2]
Aged Care Standards and Accreditation Agency Limited (ACSAA)	$155,158	$4,610	$35,931	$36,554	$232,253
Australian Institute of Health and Welfare (AIHW)	$161,782	$462,830	$130,124	$307,420	$1,062,156
Australian Radiation protection and Nuclear Safety Agency (ARPANSA)	Phones including mobile and faxes - $44,327 Communication Network - $188,948	Firewall and software - $25,850	nil	Internet Usage - $38,871	$297,996
Food Standards Australia New Zealand (FSANZ)	$193,925	$15,792	nil	$1,502	$211,219
General Practice Education and Training Limited (GPET)	Not separately accounted for.				$315,642
National Blood Authority	$119,260	nil	$8,368	nil	$127,628

(NBA)					
National Institute of Clinical Studies Ltd (NICS)	NICS captures information on IT spent in a different way to the breakdown requested in the Senate Estimate question. Due to limited resources and given the amount needed to be spent it would not be feasible for NICS to breakdown its reply accordingly.				$220,603
Private Health Insurance Administration Council (PHIAC)	$103,271	$1,367	nil	nil	$104,638
Private Health Insurance Ombudsman (PHIO)	$20,298	$5,752	nil	$1,092	$27,142
Professional Services Review (PSR)	$153,736	$22,500	$1,786	$35,260	$213,282

[1] This is the cost for all telephones and a range of information lines.

[2] The Department of Health and Ageing is unable to capture these costs separately as they are provided by the Department's IT service provider, IBM Global Services Australia (IBMGSA). The total amount paid to IBMGSA and other software and internet suppliers, during the period 1 November 2004 to 31 October 2005 was $33,172,979.

[3] This is the amount expended on the department private wide area data network during the reportable period.

[4] This represents expenditure on external suppliers in developing departmental websites.

[5] This total figure represents departmental expenditures on internal and external service providers. It may exclude some minor expenditures on ITC consultancies undertaken outside DHA's Technology Group

Attachment 2

E05000014 – answer to part (c)

Agency	Was expenditure for the period 1/11/04 to 31/10/05 in line with budget forecasts?	If not, to what extent were budget forecasts exceeded?	What are the reasons for exceeding budget forecasts?	Name of ICT project that ran over budget during the period 1/11/04 to 31/10/05	Extent that budget was exceeded – percentage.	Reasons why budget was exceeded.
Department of Health and Ageing	No	$835,743	Overspends in communications due to increased usage in specialist information lines and mobile phones.	Corporate budget	17.5%	Increased usage
		$23,417	Overspends in Internet due to increased usage.	Corporate budget	1.8%	Increased usage
General Practice Education and Training Limited (GPET)	no	$18,245	Upgrade of computer network cost more than initially planned to incorporate better redundancy solutions.	Network LAN upgrade	6.1%	Additional servers purchased

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-015

OUTCOME: Whole of Portfolio

Topic: INFORMATION AND COMMUNICATIONS TECHNOLOGY (ICT)

Written Question on Notice

Senator Conroy asked:

For the department and each portfolio agency:

Please provide details of any ICT projects that have been commissioned by the department/organisation during the past 12 months that have failed to meet designated project timeframes (ie have failed to satisfy agreed milestones by agreed dates). For such projects that were not completed on schedule, please provide details of:

(i) the extent of any delay;
(ii) the reasons these projects were not completed on time;
(iii) any contractual remedies sought by the department/organisation as a result of these delays (eg penalty payments).

Answer:

Three projects fall into this category.

1. Analysis and design services for the Biosecurity Surveillance Project (Contract commenced in March 2005).
   (i) Thus far, two of nine contracted milestones have been accepted. A further five deliverables are expected to be completed before the Christmas break and have been delayed between six weeks and 16 weeks. Overall, a four week delay in the revised date of contract completion is expected.
   (ii) Delays have been caused by a number of factors, including: a lack of appropriately skilled staff able to be supplied to the project by the contractor; and underestimation by the contractor of the complexity of the work.
   (iii) This work was contracted on a fixed price basis. No contractual remedies have yet been sought, although the Department has intervened to ensure replacement of specified personnel where a skills deficit was apparent.

2. Identity Management and Directory Services Project (Contract commenced in November 2004).
   (i) Implementation has been delayed eight months.
   (ii) Delays are as a result of technical integration issues related to the design.
   (iii) This work was contracted on a fixed price basis. The vendor, at no cost to the department, agreed to resolve the design issues.

3. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) - Record Management Business Classification List development.
   (i) Two months.
   (ii) The project was undertaken by an external consultant who resigned from his company shortly after completion of phase one.
   (iii) A replacement was provided but the absence of knowledge gained through phase one impacted on project progress but not on finance.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-016

OUTCOME: Whole of Portfolio

Topic: INFORMATION AND COMMUNICATIONS TECHNOLOGY (ICT)

Written Question on Notice

Senator Conroy asked:

For the department and each portfolio agency:

Please provide details of any ICT projects delivered in the past 12 months that have materially failed to satisfy project specifications.

Answer:

There were no projects delivered in the past 12 months that materially failed to satisfy project specifications.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-017

OUTCOME: Whole of Portfolio

Topic: INFORMATION AND COMMUNICATIONS TECHNOLOGY (ICT)

Written Question on Notice

Senator Conroy asked:

For the department and each portfolio agency:

Please provide details of any ICT projects that were abandoned by the department / organisation within the last 12 months before the delivery of all project specifications outlined at the time the project was commissioned. For such abandoned projects, please provide details of:

(i) any contractual remedies sought by the department as a result of the abandonment of such projects; and

(ii) any costs of re-tendering the ICT project.

Answer:

There were no ICT projects that were abandoned by the department or by any portfolio agency during the past 12 months.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-146

OUTCOME: Whole of Portfolio

Topic: SENATE ORDER FOR DEPARTMENTAL AND AGENCY (*CONTRACTS*)

Written Question on Notice

Senator Murray asked:

For department and agencies

What guidance is provided to staff with responsibilities for contract negotiations specifically about the requirements of the Senate Order? If relevant guidance is not provided, please explain why this is the case.

Answer:

The Department of Health and Ageing

The department has developed an intranet based procurement toolkit which provides, among other things, guidance to staff on the Senate Order. For example, the Request for Tender template contains guidance to staff on the confidentiality provisions and also provides a link to the Department of Finance and Administration website, where detailed instructions are available.

Apart from the intranet based guidance material mentioned above, the department runs awareness sessions, training and helpdesk services. The combination of these services constitutes the department's Senate Order guidance and decision making framework.

Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)

The ARPANSA's Chief Executive Instruction's require staff to consult the legal advisor over the form and content of all Commonwealth Contracts over $5,000. The requirements of the Senate Order are covered through appropriate legal scrutiny.

Professional Services Review (PSR)

PSR is a very small agency (15 staff), with only one or two contracts per year that reach the Senate Order threshold of $100,000. PSR's Corporate Manager is fully aware of Senate Order requirements and is involved in all contract negotiations for the agency. The Department of Finance undertook an agency specific training/awareness session for all PSR staff involved in contract negotiations on 8 March 2005.

National Blood Authority (NBA)

The National Blood Authority applies approved business processes to its procurement activities and contract negotiations. These processes are made clear to appropriate staff who are expected to adhere to the procedures specified. The approved business processes include sections related to the Senate Order reporting requirements. Additionally, NBA staff are made aware of Senate Order requirements through in-house training and transfer of knowledge between staff.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-147

OUTCOME: Whole of Portfolio

Topic: SENATE ORDER FOR DEPARTMENTAL AND AGENCY (*CONTRACTS*)

Written Question on Notice

Senator Murray asked:

For department and agencies

What training and awareness sessions are provided, either in-house or through other training providers (eg. DOFA, APS Commission or private firms) in respect of the Order? Please provide a list of the dates, the identity of the training providers and the content of the training that staff attended in 2005. If training and awareness sessions are not provided, please explain why this is the case.

Answer:

The Department of Health and Ageing:

Whilst the department does not conduct formal training specifically targeted at the requirements of the Senate Order, these requirements form part of general procurement training and are also included in training on the use of SAP (the department's financial management system). Additionally, the department's policy guidance material contains a link to the Department of Finance and Administration (DoFA) publication- *Confidentiality of Contractors' Commercial Information*.

Information on the dates, training providers and course content is provided in the table below.

Name of Course	Date of Training Course 2005	Training Provider	Training Content Includes:
Procurement Overview	22 February 14 March 8 July 19 August 4 October 4 November	Major Training Services	Overview of the requirements of the Senate Order Opportunity for discussion on Senate Order requirements
Procurement Workshops	11 March 4 April 15 April 15 July 21 October 21 November	Major Training Services	Explains the department's obligations regarding the Senate Order Opportunity for discussion on practical aspects of Senate Order requirements

In addition, general awareness sessions are held prior to the commencement of the data collection process for each Senate Order return. These sessions are conducted by staff who are experienced in the requirements of the Senate Order and provide an opportunity for discussion and information provision. These sessions are supplemented by a helpdesk service which continues for the duration of the Senate Order reporting compilation period.

Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)

All staff with financial delegations have been made aware of the Commonwealth Procurement Guidelines through staff notices issued in December 2004. The officer responsible for preparing the Senate Order information has a good knowledge of the applicable DOFA financial management guide (FMG No. 8). ARPANSA's Chief Executive Instruction's require staff to consult the legal advisor over the form and content of all Commonwealth Contracts over $5,000.

Professional Services Review (PSR)

The Department of Finance undertook an agency specific training/awareness session for all PSR staff involved in procurement and contract management on 8 March 2005. No new staff have been recruited to PSR since this training was undertaken. The Corporate Manager is involved in all contract negotiations for the agency, is fully aware of Senate Order requirements, and is kept up to date by correspondence from the Department of Finance and Administration and the ANAO on this matter.

National Blood Authority (NBA)

The NBA last completed a training session for Contract Administration on 22 June 2005. The content related to the way in which NBA staff are expected to procure blood products and services (specifically) and other goods and services (generally) under the Commonwealth Procurement Guidelines. This training also contained a session related directly to the Senate Order requirements and the reporting thereof. The training was provided by in-house staff.

The NBA has also developed a checklist and template for approvals that includes the Senate Order requirements. Also, relevant staff have been specifically trained in-house on all Senate Order requirements, internal procedures have been documented, and staff have attended update sessions run by our lead portfolio agency, the Department of Health and Ageing.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Estimates 2005-2006, 2 November 2005

Question: E05-148

OUTCOME: Whole of Portfolio

Topic: SENATE ORDER FOR DEPARTMENTAL AND AGENCY (*CONTRACTS*)

Written Question on Notice

Senator Murray asked:

For department and agencies

Has the Department/Agency revised its procurement guidelines to incorporate the new Commonwealth Procurement Guidelines (CPGs) that took effect from 1 January 2005, particularly with respect to the confidentiality elements contained in those guidelines ? If so, when did this occur and can a copy be provided? If not, what is the cause of the delay and when will the revision occur ?

Answer:

The Department of Health and Ageing

The Department revised its internal procurement guidelines to comply with the January 2005 changes to the CPGs in December 2004. This revision resulted in amendments to the Department's procurement manual, procedural rules and various templates, which departmental officers access in an electronic format (as these documents are updated on a regular basis, they are not provided in hardcopy). Copies of these documents can be provided on request.

With respect to the confidentiality elements, there is a direct link from the Department's procedural rules to the Department of Finance and Administration's Guidance on Confidentiality of Contractors Commercial Information document located at http://www.dofa.gov.au/ ctc/confidentiality_of_contractors.html.

Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)

ARPANSA has revised its Chief Executive Instructions (CEI's) to incorporate the new Commonwealth Procurement Guidelines that took effect from 1 January 2005. The CEI's were updated in December 2004 and a relevant extract can be provided. However, the revised guidelines do not specifically address the confidentiality elements associated with a supplier's request for material to be treated confidentially. The matter is dealt with through legal scrutiny.

Professional Services Review (PSR)

PSR has engaged Ascent Audit Consulting to rewrite its CEIs, incorporating the updated procurement guidelines that took effect on 1 January 2005. These CEI's are expected to be finalised in December 2005. Notwithstanding this the Corporate Manager is involved in all contract negotiations for the agency, is fully aware of Senate Order requirements and is kept up to date by correspondence from the Department of Finance and Administration and ANAO on this matter.

National Blood Authority (NBA)

The NBA's procurement procedures were finalised in June 2005 and the contract management procedure was finalised in August 2005. Both documents include changes made to the Commonwealth Procurement Guidelines that took effect from 1 January 2005. Copies of both documents are available on request.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-149

OUTCOME: Whole of Portfolio

Topic: SENATE ORDER FOR DEPARTMENTAL AND AGENCY (*CONTRACTS*)

Written Question on Notice

Senator Murray asked:

For department and agencies

ANAO audits for the last three years have revealed a consistently low level of compliance across most agencies with DoFA confidentiality criteria (February 2003) for determining whether commercial information should be protected as confidential. The ANAO's latest report on the Order (No. 11 2005, September 2005) states that departments and agencies need to give higher priority with this important requirement of the Senate Order.

a) What specific measures have been or will be taken to address this problem, give it higher priority and raise compliance levels?
b) What guidance and training are provided to staff about the confidentiality criteria and the four tests employed to determine whether information should be protected?
c) What internal auditing or checking is performed to test compliance in this area? If none is performed, why not and is the agency considering the adoption of internal controls and checks?

Answers:

<u>The Department of Health and Ageing</u>

(a)
The level of guidance provided is considered appropriate given the low number of claims of confidentiality. For example, in the 2004 calendar year return, there were two claims of confidentiality out of 4,684 contracts reported. Similarly, in the 2004-05 financial year return only three confidentiality claims were made with 4,592 contracts reported.

(b)
The department's policy guidance material contains a link to the Department of Finance and Administration publication - *Confidentiality of Contractors' Commercial Information*. This publication contains information about the confidentiality criteria. Whilst the department does not provide formal training on the confidentiality aspects of the Senate Order, opportunities for staff to clarify these aspects are available at awareness sessions (held prior to each Senate Order compilation) and by a helpdesk staffed by experienced officers.

(c)
The department subjects its Senate Order return to comprehensive quality assurance checks. These checks include confirmation of the validity of claims for exemption on the basis of confidentiality.

Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)

(a)
ARPANSA's internal procedures require that all contracts over $5,000 are reviewed by the legal advisor, who is aware of what commercial information should be protected as confidential.

(b)
Contract management training covering the Commonwealth Procurement Guidelines and all related reporting requirements has been provided to staff. The most recent training was in October 2005. In light of the small number of contracts that exceed the reporting threshold and the fact that all large contracts are subject to legal scrutiny, no specific training has been conducted on the confidentiality criteria of the Senate Order reporting.

(c)
Compliance audit on contract management is part of ARPANSA's internal audit program but has not been used specifically to determining whether commercial information should be protected as confidential. In terms of internal checking, ARPANSA's legal advisor reviews the form and content of all Commonwealth contracts over $5,000.

Professional Services Review (PSR)

(a)
PSR has not had any contracts to date where information has been deemed to be protected by confidentiality provisions. The Corporate Manager is fully aware of the requirements of incorporating these confidentiality issues when negotiating new contracts.

(b)
Due to PSR's small size the Corporate Manager is involved in all contract negotiations and is fully aware of the Department of Finance and Administration's criteria.

(c)
PSR's updated Chief Executive Instructions will be completed in December 2005 and will set the framework for compliance. PSR's internal auditors review for compliance all contracts that are in excess of $80,000.

National Blood Authority (NBA)

(a)
Awareness training was provided by NBA's legal counsel to all NBA staff in 2004 and 2005. The NBA has a suite of contracts for all non-blood-related contracts. These have been developed in-house by NBA's legal counsel. NBA's legal counsel and key negotiating staff are aware of the confidentiality requirements. All blood-related contracts are vetted by NBA's legal counsel prior to signature by the NBA.

(b)
The NBA only uses standard contracts for non-blood related contracts and the blood-related contracts are developed by NBA's legal counsel. Guidance and training has only been provided to key negotiating staff by the legal area.

(c)
There has been no internal audit checking performed in this area to date. A full internal audit plan is being developed now for the next three years and NBA will include a test for confidentiality criteria in this plan, scheduled for the second half of 2005-06. Due to the answers in a) and b), this was considered a low risk and as such, no internal audit action has been required in early 2005-06.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-150

OUTCOME: Whole of Portfolio

TOPIC: SENATE ORDER FOR DEPARTMENTAL AND AGENCY (*CONTRACTS*)

Written Question on Notice

Senator Murray asked:

For department and agencies

What problems, if any, has the agency and/or relevant staff experienced in complying with the Senate Order? What is the nature and cause of any problems? What measures have been, or could be, adopted to address these concerns?

Answer:

<u>The Department of Health and Ageing</u>

The compilation of the Health Ageing Portfolio Senate Order return requires a significant coordination, data collation and quality assurance exercise. This is a resource intensive process. The department believes that consideration could be given to making the compilation of the return an annual requirement rather than twice a year as required under the current arrangements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-277

OUTCOME: Whole of Portfolio

Topic: STAFFING NUMBERS

Hansard Page: CA 10

Senator Carol Brown asked:

Can the Department provide a breakdown of the basis on which the staff in the Department's Hobart Office are employed?

Answer:

The table below provides the breakdown of the basis on which the staff in the Department's Hobart Office are employed as at 30 June 2005.

	Ongoing	Non-Ongoing	Casual	Total Staff
Hobart Office	41	13	1	55

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-278

OUTCOME: Whole of Portfolio

Topic: STAFF SURVEY

Hansard Page: CA 8

Senator Moore asked:

What is the reasoning behind the question in the survey: "Does your mind wander and do you doodle at work?"

Answer:

Senator Moore is referring to the following 2004 and 2005 Staff Survey questionnaire items:

- 'There are times at work when I just wander off into another world'; and
- 'I often 'doodle' and draw things when I am at work'.

These two items are testing for two key symptoms of the presence or absence of employee motivation at work, ie day dreaming and random drawing. Scores on these two items are not used in isolation but, when combined with scores on another 13 items, form part of an aggregate score indicating the level of employee motivation. This 'spectrum of symptoms' approach has proven to be robust and accurately measures employee motivation and performance in both academic and commercial settings.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-279

OUTCOME: Whole of Portfolio

Topic: STAFFING – AUSTRALIAN WORKPLACE AGREEMENTS (AWAS)

Hansard Page: CA 6

Senator Moore asked:

(a) How many staff are covered by AWAs in your Agency/Department?
(b) Can you provide a break down of AWA's by gender and by classification?
(c) Can you tell me how many of the staff on AWA's are paid more than the band for their classification under the certified agreement?
(d) Why were these staff not simply promoted to a higher classification?

Answer:

(a) to (c) The responses to these questions are provided in the table overleaf.

(d) AWAs contain salaries higher than the top of the applicable band under the certified agreement whenever the department or agency seeks flexibility to attract or retain a suitably qualified person and where the work value of the position does not warrant an upgrade to a higher level.

Response to questions (a) to (c)

Agency	(a) How many staff are covered by AWAs in your Agency/Department?	(b) Can you provide a break down of AWAs by gender and by classification?	(c) Can you tell me how many of the staff on AWAs are paid more than the band for their classification under the certified agreement?
Department of Health and Ageing	488	Female – 244 Male – 244 SES Bands 1 to 3 – 72 Senior Medical Officers – 20 Executive Level 2 – 379 Executive Level 1 – 13 APS Level 1 to 6 – 4	46
Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)	12	Female – 3 Male – 9 SES Band 1 – 3 Executive Level 2 – 5 Executive Level 1 – 2 APS Level 6 – 2	9
National Institute of Clinical Studies (NICS)	Staff at the NICS have individual contracts, not AWAs.	n/a	n/a
Australian Institute of Health and Welfare (AIHW)	4	Female – 2 Male – 2 SES Band 1 – 4	n/a
Aged Care Standards and Accreditation Agency Ltd (ACSAA)	None	n/a	n/a
Private Health Insurance Administration Council (PHIAC)	PHIAC staff are not covered by AWAs. Instead they are employed under a 3-year renewable contract which ascribes to the APS Values and Code of Conduct. Salary levels are equal to those set out in the Department of Health and Ageing Certified Agreement.	n/a	n/a
Private Health Insurance Ombudsman (PHIO)	None	n/a	n/a
General Practice Education and Training Ltd (GPET)	None	n/a	n/a

Response to questions (a) to (c) (continued)

Agency	(a) How many staff are covered by AWAs in your Agency/Department?	(b) Can you provide a break down of AWAs by gender and by classification?	(c) Can you tell me how many of the staff on AWAs are paid more than the band for their classification under the certified agreement?
National Blood Authority (NBA)	8	Female – 4 Male – 4 SES Band 1 – 3 Executive Level 2 – 3 Executive Level 1 – 1 APS Level 1 to 6 - 1	3
Professional Services Review (PSR)	10	Female – 6 Male – 4 SES Band 1 – 1 Executive Level 2 – 3 Executive Level 1 – 3 APS Level 5 – 1 APS Level 4 - 2	7
Food Standards Australia New Zealand Ltd (FSANZ)	26	Female – 12 Male – 14 SES Band 2 – 1 SES Band 1 – 3 Executive Level 2 – 18 Executive Level 1 – 1 APS Level 1 to 6 - 3	2

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Estimates 2005-2006, 2 November 2005

Question: E05-276

OUTCOME: Whole of Portfolio

Topic: DEPARTMENT'S FINANCIAL STATEMENTS

Hansard Page: CA 48

Senator McLucas asked:

a) What might be the legal consequences of the contravention of the Constitution in relation to the inappropriate appropriation to the department of $458 million?

b) What might be the legal consequences of the breach of the FMA Act in relation to the inappropriate appropriation to the department of $458 million?

Answer:

a) and b):

Where an agency has breached Section 83 of the Constitution and the FMA Act as a result of spending money without an appropriation authority it is not possible to take action that will correct this breach.

The Department entered into a new Section 31 on 28 June 2005. This agreement does not validate past breaches of Section 83 of the Constitution but does ensure future reporting requirements are met.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Revised Question: E05-276

OUTCOME: Whole of Portfolio

Topic: Department's Financial Statements

Hansard Page: CA 48

Senator McLucas asked:

a) What might be the legal consequences of the contravention of the Constitution in relation to the inappropriate appropriation to the department of $458 million?

b) What might be the legal consequences of the breach of the FMA Act in relation to the inappropriate appropriation to the department of $458 million?

Answer:

a) and b)

Where an agency has breached Section 83 of the Constitution, as a result of spending money without an appropriation authority, it is not possible to take action that will correct this breach. However, this breach has been disclosed in the Department's 2004-05 financial statements.

The legal consequence of breaching Section 48 of the FMA Act is that the Auditor-General, under Section 57 of the FMA Act, is required to state the particulars of the contravention of Section 48 in the Auditor's report. This occurred in the Department's 2004-05 financial statements.

The Department entered into a new Section 31 Agreement on 28 June 2005. This agreement does not validate past breaches of Section 83 of the Constitution but does ensure that the Department will have the authority to spend its receipts in the future and that future reporting requirements are met.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-275

OUTCOME: Whole of Portfolio

Topic: Consultancy agency ACIL Tasman

Hansard Pages: CA 49-50

Senator McLucas asked:

a) Are ACIL Tasman currently competing for any contracts with the department for which Access Economics is also competing?
b) Can the department confirm how many times ACIL Tasman and Access Economics competed for (the same) tenders in the portfolio in the year 2003-04 and in 2004-05?
c) How many times did ACIL Tasman win those bids when they were competing with each other?
d) What was the total worth of the work won by ACIL in 2003-04 and in 2004-05?
e) Can the department confirm whether, with any of the bids won by ACIL Tasman, they (ACIL Tasman) had access to information from Access Economics?
f) What steps has the department taken to assure itself that no improper use of information was used (by ACIL Tasman) to secure work from the department?

Answer:

a) The Department's computerised contracts system does not contain information on tender processes which would enable identification of competing tenderers. However enquiries with those areas of the department who have used the services of ACIL Tasman in the past indicate there are no current tenders where ACIL Tasman is competing with Access Economics.

b) The Department's computerised contracts system does not contain information to determine if ACIL Tasman and Access Economics competed for the same tenders in 2003-04 and 2004-05. However a search of file records for those tenders where ACIL Tasman was successful shows that in all cases for the same periods Access Economics was not a tenderer.

c) See answer b) above. When ACIL Tasman has been awarded a tender, Access Economics has not been competing for the same tender.

d) In 2003-04 ACIL Tasman was awarded contracts valued at $542,723. In 2004-05 contracts valued at $271,683 were awarded to ACIL Tasman.
e) The Department cannot confirm or deny whether ACIL Tasman used information from Access Economics in any of the bids won by ACIL Tasman over the years 2003-04 and 2004-05. However over this same period Access Economics was not a

tenderer in those bids won by ACIL Tasman.

f) The Department has undertaken an investigation into ACIL Tasman. The investigations entailed:
    - interviews of key Departmental officers responsible for managing ACIL Tasman contracts;
    - meeting with representatives of ACIL Tasman; and
    - writing to ACIL Tasman seeking further clarification on some matters.

The investigation did not reveal evidence that suggested that ACIL Tasman secured work from the Department through the use of improperly obtained information.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-212

OUTCOME: Whole of Portfolio

Topic: RESPONSES TO QUESTIONS ON NOTICE

Hansard Page: CA 5

Senator McLucas asked:

For the 24 that arrived last night, could you provide the committee with the date that they were provided to the Minister's office?

Answer:

As previously discussed with the Committee, the preparation and clearance of responses to Senate Estimates questions is an iterative process which sometimes involves some 'to-ing and fro-ing' to ensure that the final information provided to the Committee is accurate and up to date.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-001

OUTCOME: Whole of Portfolio

Topic: AIRFARES

Written Question on Notice

Senator Fielding asked:

a) How much money has the portfolio spent on domestic airfares for each of the last three financial years?
b) How much money has the portfolio spent on overseas airfares for each of the last three financial years?
c) How much money has the portfolio spent on economy class domestic airfares for each of the last three financial years?
d) How much money has the portfolio spent on business class domestic airfares for each of the last three financial years?
e) How much has the portfolio spent on first class domestic airfares for each of the last three financial years?
f) What would be the estimated financial year dollar saving if all public servants in the portfolio travelled economy class for flights of less than one and a half hours duration?

Answer:

(a) and (b)
Portfolio airfare spend for domestic and overseas travel for financial years 2002-03, 2003-04 and 2004-05.

PORTFOLIO AIR TRAVEL	***2002-03*** **$**	***2003-04*** **$**	***2004-05*** **$**
(a) Domestic	10,118,629	12,075,701	12,348,098
(b) Overseas	1,600,948	2,337,686	2,635,857

Notes to the above table

- Figures are not available for Aged Care Standards and Accreditation Agency (ACSAA) in 2002-03
- General Practice Education and Training Ltd (GPET) was unable to provide a breakdown between domestic and overseas travel in 2002-03. For the purposes of this question, GPET's total travel figure for 2002-03 was incorporated into the figure for (a).

(c), (d) and (e)
Portfolio domestic airfare spend by economy class, business class and first class for financial years 2002-03, 2003-04 and 2004-05.

Portfolio Domestic Travel Expenditure	**2002-03 $**	**2003-04 $**	**2004-05 $**
(c) Economy class airfares	7,702,059	9,035,513	9,408,074
(d) Business class airfares	2,214,629	2,871,858	2,848,287
(e) First class airfares	-	-	-

Notes to the above table

- Figures are not available for Aged Care Standards and Accreditation Agency (ACSAA) in 2002-03
- General Practice Education and Training Ltd (GPET) was unable to breakdown its total figure into these categories in 2002-03, 2003-04 and 2004-05.

(f)
To accurately estimate the financial year dollar saving if all public servants in the portfolio travelled economy class for flights of less than one and a half hours duration would take significant resource effort and the Portfolio is not currently in a position to undertake this work.

COUNTRY OF ORIGIN

Comparison of existing standard and revised standard

	Current Transitional Standard	Revised Standard
Packaged Food	Label must identify the country in which the food was made, manufactured or packed for retail sale or If ingredients are from a different country, label must state that the food is made from imported ingredients or Requirements are met if the name and address of the manufacturer are on the label and this includes the country in which the food was made or produced	Strengthening of requirement - There must be a specific declaration of the country of origin of the food product. - No longer adequate to note that ingredients are 'imported'. This declaration can be an unqualified claim such as 'Made in country X' or 'Product of country X' or a qualified claim such as 'Made in country X from local and imported ingredients'.
Unpackaged fresh whole or cut fruit and vegetables	Label must state the country or origin or that the fruit and vegetables are imported	Strengthening of requirement There must be a label on or in connection with the display of the food identifying country or countries of origin
Unpackaged fish including processed fish, cut fish, filleted fish and fish mixed with one or more foods	No mandatory CoOL for fish coated with, or mixed with, other foods and cooked fish other than cooked prawns	Extension of requirements - Processed fish must meet the same requirements as other unpackaged fish, fruit, vegetables
Processed unpackaged whole or cut fruit and vegetables e.g. preserved, pickled cooked, frozen, dehydrated) other than where mixed with another food	No requirements for CoOL	Extension of requirements - Unpackaged processed fruit and vegetables must meet the same requirements as unpackaged unprocessed fruit and vegetables
Unpackaged fresh or preserved pork	No requirements for CoOL	Extension of requirements Unpackaged fresh or processed pork must meet the same requirements as unpackaged fruit and vegetables
Other information	In the Code the definition of fruit and vegetables includes nuts (Standard 2.3.1) Prohibition on false or misleading representations concerning the place of origin of goods TPA sets out requirements re use of the terms 'product of' and 'made in''(including 'manufactured in' and 'Australian made'). Labelling must comply with Standard 1.2.9 re legibility.	

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-119

OUTCOME 1: Population Health

Topic: DECISION MAKING BY THE THERAPEUTIC GOODS ADMINISTRATION (TGA)

Written Question on Notice

Senator Forshaw asked:

a) Has the TGA ever made decisions about whether to approve a new medicine, or a change to an existing medicine, that was different from the equivalent decision by another major agency? If so, why was the TGA's decision different?
b) Why would Australia's agency, the TGA, reach a different conclusion from other countries?
c) Does the TGA ever revisit its original decisions?
d) Does the TGA ever overturn its original decision?
e) Is this based on new evidence?
f) Is it ever the case that the TGA overturns its original decision based on the same evidence?
g) Is it true that in some cases the TGA has overturned its own decision without any new evidence?
h) What is the justification for the TGA overturning its own decisions without any new evidence?
i) If that occurs, are the companies involved informed about that and the reasons for that decision?
j) How is the process monitored? Can the companies monitor this process?

Answer:

a) Yes. The TGA decisions are based on the TGA Delegate's scientific assessment of the quality, safety and efficacy of the medicine for marketing in the Australian health environment. Decisions made by other regulatory agencies may be based on data different to that submitted in Australia, different legislative requirements for granting marketing approval, specific country population needs or different health system requirements. The TGA does not record how often a decision made about a new medicine in Australia is different from a decision made in an overseas country.
b) See a)
c) Yes.
d) Yes.
e) Not always.

f) Yes. The sponsors may appeal the Delegate's original decision and if the appeal from the sponsor were successful, the original decision would be overturned by the body determining the appeal. This decision may be based on a different interpretation of the same data set.
g) Yes.
h) The sponsor company may appeal the decision. The Delegate of the Minister may substitute a new decision as part of the determination of an appeal. Decisions may also be replaced by a decision of the Administrative Appeals Tribunal.
i) Yes.
j) The appeal process is monitored by both the TGA and the sponsor company.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-122

OUTCOME 1: Population Health

Topic: DECISION MAKING BY THE THERAPEUTIC GOODS ADMINISTRATION (TGA)

Written Question on Notice

Senator Forshaw asked:

k) What are the respective roles of Australian Drug Evaluation Committee (ADEC), the Delegate and the Clinical Evaluator? Can one over-rule the other?
l) Have there been instances where one has disagreed with the other?
m) How are disputes between them resolved?
n) Do companies have any knowledge of this process, and how involved are they allowed to be?
o) Do they get a say in whether a decision about their product is overturned?

Answer:

a) For new medicines, the Clinical Evaluator evaluates the clinical data submitted as part of the submission from the sponsor company and prepares the clinical evaluation report. The evaluation reports are forwarded to the sponsor company for comment as soon as they have been accepted by the Drug Safety and Evaluation Branch. Detailed reports are also usually prepared on quality and manufacturing and on pharmacology and toxicology. These are also sent to the sponsor company for comment.

The Delegate considers the evaluation report and prepares a summary and review. This is also sent to the sponsor company who has an opportunity to respond in writing direct to the ADEC.

The ADEC receives all the evaluations, the Delegate's summary overview and the sponsor company's response and makes a recommendation in the form of a resolution. The Delegate will consider all available information, including the ADEC resolution, before making a decision to approve or reject an application.

The ADEC is appointed by the Minister for Health and Ageing and provides advice to the Minister and the Secretary of the Department of Health and Ageing through the Therapeutic Goods Administration (TGA), on:

- the quality, risk-benefit, effectiveness and access within a reasonable time of any drug referred to it for evaluation;
- medical and scientific evaluations of applications for registration of prescription drugs (eg new chemical entities, new forms of previously registered drugs and therapeutic variations to registered drugs).

b) Yes.

c) The Secretary or his/her Delegate is the final decision maker. The ADEC provides advice only.

d) Sponsor companies have knowledge of the process and are kept up to date on the progress of their submission, including access to an electronic tracking system if required. Evaluation reports are provided to the sponsor who is invited to respond to the findings. When a 'Summary for ADEC advice' is prepared by the TGA Delegate, the sponsor company is given an opportunity to respond directly to ADEC. Once the decision is finalised, the sponsor company may also elect to appeal the decision of the Delegate.

e) There are a number of review mechanisms available to the sponsor company if it does not agree with the TGA Delegate's decision. Decisions on approvals or rejections of new medicines by the Secretary, or a delegate of the Secretary, may be appealed under Section 60 of the Act. Appeals are made to the Minister and are usually dealt with by a Delegate of the Minister. Appeals may also be made to the Administrative Appeals Tribunal (AAT) if the sponsor company is unhappy with the outcome of Section 60 review by the Minister's delegate. Whereas the AAT provides a merit review process, affected parties may take action in the Federal Court, on matters of law.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-123

OUTCOME 1: Population Health

Topic: DECISION MAKING BY THE THERAPEUTIC GOODS ADMINISTRATION (TGA)

Written Question on Notice

Senator Forshaw asked:

p) Is the process that TGA follows in evaluating new registrable (prescription) medicines the same as other major agencies?
q) How are the TGA's processes different from other overseas countries?
r) Is there anything that could be learnt from these other agencies to make the Australian process more efficient without lowering our standards for quality safety and efficacy?

Answer:

f) Yes, all major agencies review data on quality, safety and efficacy. However, business and administrative processes for receipt and management of submissions vary internationally.

g) There are a number of differences in the processes used in comparable overseas countries. The US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA) for example have completely different administrative processes but both, like the TGA, assess quality, safety and efficacy. In the process of reviewing existing administrative requirements, the TGA has reviewed international differences in these. Examples of differences are set out in the Discussion Paper 'Workflow practices within the Drug Safety and Evaluation Branch of TGA'. The document is available on the TGA website www.tga.gov.au

h) Yes, a number of changes are being proposed to the current administration process in the TGA using the processes used by overseas countries as a guide. See (b). While the TGA is keen to identify means by which to improve its business practices (including through appropriate streamlining) it is equally important to ensure that this in no way impacts on the rigor of the TGA's evaluation of medicines. In relation to specific regulatory standards the TGA adopts international regulatory requirements wherever possible.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-128

OUTCOME 1: Population Health

Topic: VIOXX RECALL

Written Question on Notice

Senator Forshaw asked:

Following the Vioxx withdrawal in October 2004, the Senate Estimates Committee was advised by TGA that it was conducting a review of the Cox-2 class of medicines.

a) Leaving aside the specifics of the Vioxx case and the therapeutic area, has the TGA changed the way it handles and reacts to reports of potential problems with medicines or devices?
b) Has this occurred both in relation to adverse reaction reports it receives from Australian doctors, pharmacists and consumers, and also advice from a variety of sources including other agencies (such as the FDA, European Agency for the Evaluation of Medical Products) and the media?

Answer:

a) The Therapeutic Goods Administration (TGA) has an ongoing process of examining international best practice in the field of post-marketing evaluation of medicines and devices.

   In regard to adverse events related to medicines, this has recently produced changes in the system of searching adverse event database entries to enable analysis of event severity. A change to the search functions of the Adverse Drug Reactions Advisory Committee (ADRAC) database was made in March 2005. These changes allowed automatic searching for cases that were fatal, life-threatening, involved hospitalisation or prolongation of hospitalisation, or that resulted in recovery with sequelae.

   The investigation of medical device incident reports from all sources (including the medical profession, allied health professionals, consumers, and overseas regulatory agencies) is undertaken using risk assessment procedures governed by TGA Laboratory's externally accredited Quality Management System. This management system is subject to a regular internal audit of the procedures.

   The processes for reacting to reports of potential problems with medicines or devices have been designed to enable rapid assessment and management of adverse reactions to minimise harm to the Australian public.

b) Procedures for obtaining advice from sources external to the TGA have not changed. The TGA continues to require that sponsor companies keep it informed of serious adverse events reported in Australia, provide regular reports of the international adverse event profile and to keep it informed of regulatory action taken anywhere in the world. The TGA also exchanges information with its overseas counterparts (including New Zealand, the USA, Canada and Singapore) on both pre- and post- market regulation of products.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-129

OUTCOME 1: Population Health

Topic: VIOXX RECALL

Written Question on Notice

Senator Forshaw asked:

Has the Therapeutic Goods Administration (TGA) put in place any changes/procedures to avoid something similar to the Vioxx event from occurring? What safeguards do we have in place here, considering our research and clinical trials are meant to be of a high standard here?

Answer:

In some cases, adverse events will not become apparent until market place experience is gained with a medicine, even with the most carefully designed clinical trial. Patient groups, comorbidities, comedications, etc, can differ.

The TGA requires sponsor companies to inform the TGA of serious adverse events reported in Australia, provide regular reports of the international adverse event profile and to keep it informed of regulatory action taken anywhere in the world. The TGA also exchanges information with its overseas counterparts (including New Zealand, the USA, Canada and Singapore) on both pre- and post- market regulation of products.

There have been recent changes in the system of searching adverse event database entries to enable analysis of event severity. Changes to the search functions of the Adverse Drug Reactions Advisory Committee database were made in March 2005. These changes allowed automatic searching for cases that were fatal, life-threatening, involved hospitalisation or prolongation of hospitalisation, or that resulted in recovery with sequelae.

The processes for reacting to reports of potential problems with medicines or devices have been designed to enable rapid assessment and management of adverse reactions to minimise harm to the Australian public.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-130

OUTCOME 1: Population Health

Topic: VIOXX RECALL

Written Question on Notice

Senator Forshaw asked:

Has anything changed in the TGA's procedures since Vioxx? If so, what?

Answer:

The Therapeutic Goods Administration (TGA) has an ongoing process of examining international best practice in the field of post-marketing evaluation of medicines and devices.

There have been recent changes in the system of searching adverse event database entries to enable analysis of event severity. A change to the search functions of the Adverse Drug Reactions Advisory Committee (ADRAC) database was made in March 2005. These changes allowed automatic searching for cases that were fatal, life-threatening, involved hospitalisation or prolongation of hospitalisation, or that resulted in recovery with sequelae.

The investigation of medical device incident reports from all sources (including the medical profession, allied health professionals, consumers, and overseas regulatory agencies) is undertaken using risk assessment procedures governed by an internal quality management system. The internal management system is subject to a regular internal audit of the procedures.

The processes for reacting to reports of potential problems with medicines or devices have been designed to enable rapid assessment and management of adverse reactions to minimise harm to the Australian public.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-134

OUTCOME 1: Population Health

Topic: ANAO AUDIT OF THE REGULATION OF NON-PRESCRIPTION MEDICINES

Written Question on Notice

Senator Forshaw asked:

What is the Therapeutic Goods Administration (TGA) doing about the findings and recommendations of the Australian National Audit Office (ANAO) Audit Report on the Regulation of Non- Prescription Medicines?

Answer:

The ANAO made 26 recommendations designed to improve the transparency, quality and reliability of regulatory decisions taken by the TGA and improve its accountability mechanisms by enhancing its management information systems.

The TGA has fully implemented 17 recommendations, six are in progress and implementation of the remaining three is contingent upon full operation of the new Manufacturer Information System (anticipated completion May 2006).

Relevant standard operating procedures have been reviewed and improved; additional staff training and education has been implemented including in relation to records management; and information management systems have been improved. In addition, structural changes have been made to improve the overall management and governance framework.

The TGA has established an ANAO Report Implementation Review Committee to monitor and review progress reports addressing the outstanding areas of action arising from the ANAO report.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-135

OUTCOME 1: Population Health

Topic: ANAO AUDIT OF THE REGULATION OF NON-PRESCRIPTION MEDICINES

Written Question on Notice

Senator Forshaw asked:

What measures has the TGA instituted to respond to the problems identified in the ANAO Audit Report?

Answer:

Relevant standard operating procedures (SOP) have been reviewed and improved; additional staff training and education has been implemented including in relation to records management; information management systems have been improved and a number of structural changes have been made to improve the overall management and governance framework.

In addition, the Therapeutic Goods Administration (TGA) has engaged Deloitte to assist in a review of its business management, risk management and accountability frameworks.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-136

OUTCOME 1: Population Health

Topic: ANAO AUDIT OF THE REGULATION OF NON-PRESCRIPTION MEDICINES

Written Question on Notice

Senator Forshaw asked:

a) I understand that the TGA contracted a consultant (Deloittes) to conduct a review and assist the TGA to respond to the ANAO recommendations. When will this review be completed?
b) What is the TGA's objectives behind this review - what does the TGA hope to achieve from the review?
c) What does the TGA plan to do once the review has been completed?
d) How much will the review cost?
e) Who will pay for this review?
f) Will it be made publicly available? If not, why not?

Answer:

a) The Department of Health and Ageing previously engaged Deloitte to review the progress of the Therapeutic Goods Administration (TGA) in implementing the Australia National Audit Office (ANAO) recommendations. Subsequent to that review the TGA has used Deloitte to assist in refining business management, risk management and accountability frameworks. This work will be completed by 31 December 2005.
b) This work aims to ensure that the revised frameworks are integrated, systematic and structured.
c) The work is being incorporated into the TGA business cycle. As part of the TGA's commitment to continuous performance and quality improvement, implementation of the initiatives referred to in (b) above will be monitored and evaluated to identify areas for possible further improvement.
d) Up to $385,000 (inclusive of GST) for the work being done for TGA.
e) The cost will be met by the TGA.
f) The TGA's revised performance, risk management and accountability frameworks will be incorporated into the TGA's Strategic and Business Plans for 2006/07. These will be published on the TGA's internet site.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-137

OUTCOME 1: Population Health

Topic: ANAO AUDIT – THERAPEUTIC GOODS ADMINISTRATION (TGA) REVIEW

Written Question on Notice

Senator Forshaw asked:

Has anything come out of the review yet - that is, has the consultant provided any assistance/feedback so far? If so, what were the findings and/or recommendations?

Answer:

The consultant (Deloitte) was engaged to assist in the review of the TGA's business management, risk management and accountability frameworks. The work will be completed by 31 December 2005.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-138

OUTCOME 1: Population Health

Topic: ANAO AUDIT OF THE REGULATION OF NON-PRESCRIPTION MEDICINES

Written Question on Notice

Senator Forshaw asked:

Does TGA overall have an internal quality management system, and if so, what does that entail?

Answer:

The Therapeutic Goods Administration (TGA) Laboratories are accredited to ISO 17025.

Manufacturer Assessment Branch's (MAB) internal quality management system is ISO 9002:1994; MAB is currently upgrading its quality management system to include all aspects of ISO Guide 62.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-139

OUTCOME 1: Population Health

Topic: ANAO AUDIT OF THE REGULATION OF NON-PRESCRIPTION MEDICINES

Written Question on Notice

Senator Forshaw asked:

Is the TGA's quality management equivalent to that required of the companies that TGA audits?

Answer:

Yes. The TGA's Manufacturer Assessment Branch maintains and operates a quality management system that is equivalent to that required of companies it audits for Good Manufacturing Practice (GMP) compliance.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-140

OUTCOME 1: Population Health

Topic: THERAPEUTIC GOODS AMENDMENT BILL 2005

Written Question on Notice

Senator Forshaw asked:

What is the purpose/objective of the Bill?

Answer:

The Bill will provide new alternative enforcement options to enable the Therapeutic Goods Administration (TGA) to deal more effectively and efficiently with suppliers and manufacturers who place public health and safety at risk by failing to fully comply with regulatory requirements including product and manufacturing standards. The Bill will also enable the regulator to better calibrate its response to behaviour that breaches the *Therapeutic Goods Act 1989* (the Act), depending on the severity of the breach.

The Bill represents the Government's intention to address the problems associated with the limited options currently available to the TGA in exercising their enforcement role. TGA's enforcement role is important to address and deter continuing serious breaches of regulatory requirements that can potentially expose the public to unacceptable risk or harm. The new enforcement measures are intended to complement the changes made to the Act as a consequence of the Pan Pharmaceuticals incident in 2003. These new measures are also necessary to address serious on-going non-compliance with important regulatory requirements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-141

OUTCOME 1: Population Health

Topic: THERAPEUTIC GOODS AMENDMENT BILL 2005

Written Question on Notice

Senator Forshaw asked:

a) Did the TGA consult key industry groups when drafting this legislation? If so, who were they?
b) How many times were meetings/briefings held with these groups?
c) Were recommendations/suggestions made by these groups?
d) If so, what were they? Did the TGA consider or act upon these recommendations?
e) Was a discussion paper released? Did any of these groups make written submissions? If so, are they publicly available?

Answer:

a) A draft of the proposed amendments to the Act was released to industry for comments in March 2005, along with an explanatory document outlining the rationale for the provisions of the Bill.

   A number of organisations received verbal briefings to further explain the rationale and provision of the intended legislation. The groups included Medicines Australia; Complementary Healthcare Council of Australia (CHC); Australian Self Medication Industry (ASMI); Generic Manufacturers Industry Association of Australia; the Medical Industry Association of Australia and ACCORD. These meetings enabled Departmental officials to fully understand any issues raised by industry.

b) Attachment A to this answer provides a schedule of the consultation meetings that have been held with industry groups in relation to the Bill.

c), d) and e)

A range of matters were raised particularly focussing on how the legislation would be applied. Several guidelines were developed in consultation with the industry to deal with these matters.

The Bill was referred to the Senate's Community Affairs Committee for review and consideration. A total of seven submissions, including the Department's submission, were received by that Committee before its public hearing on 13 October 2005. A further two submissions were received after the public hearing on 13 October 2005, and one further submission was received after the Committee reported its findings. The Committee reported on 4 November 2005, and did not recommend any changes to the Bill.

ATTACHMENT A

Consultation Summary

Industry Meetings – re Therapeutic Goods Amendment Bill 2005

15 March 2005 - Industry Briefing on Therapeutic Goods Amendment Bill - Complementary Healthcare Council of Australia (CHC)
Verbal and detailed briefing at the TGA, included provision of the exposure draft of the Bill and briefing materials.

15 March 2005 Industry Briefing on Therapeutic Goods Amendment Bill - Medicines Australia
Verbal and detailed briefing at the TGA, included provision of the exposure draft of the Bill and briefing materials.

16 March 2005 - Industry Briefing on Therapeutic Goods Amendment Bill - Australian Self-Medication Industry (ASMI)
Verbal and detailed briefing at the TGA, included provision of the exposure draft of the Bill and briefing materials.

17 March 2005 Industry Briefing on Therapeutic Goods Amendment Bill – Medical Devices Industry of Australia (MIAA)
Verbal and detailed briefing at MIAA headquarters in Sydney, included provision of the exposure draft of the Bill and briefing materials.

23 March 2005 - Therapeutic/Industry Consultative Committee (TICC) Bi-lateral Meeting, Morning session with CHC &ASMI
CHC raised the issue of the need for civil penalties regime.

1 April 2005 - Industry Briefing on Therapeutic Goods Amendment Bill - Generic Medicines Industry Association (GMIA)
Verbal and detailed briefing.

7 April 2005 - ASMI meeting with TGA
Juliet raised issues that ASMI had with the Bill and tabled some ASMI legal advice.

22 April 2005 - Direct Selling Association and CHC
Meeting was predominately re advertising issues but issue of why the Civil penalties in the Bill were required was raised by the CHC and a wide ranging discussion followed on the rationale for the Bill and issues of concern raised by the CHC.

4 May 2005 - Industry Briefing on Therapeutic Goods Amendment Bill Advocate for the Consumer, Cosmetic, Hygiene and Speciality Products Industry (ACCORD)
Verbal and detailed briefing at briefing at the TGA, included provision of the exposure draft of the Bill and briefing materials. Accord raised the issue of Regulatory Impact Statement (RIS), were advised that this was discussed in detail with ORR who advised that RIS was not required.

5 May 2005 - Therapeutic Industry Consultative Committee meeting (TICC) Meeting of industry representatives at TGA
MIAA, ASMI, CHC, Consumers Health Forum, Dental Industry Association, Australia Biotech, Medicines Australia, GMIA.
CHC raised concerns about the Bill.

5 May 2005 - ASMI meeting at TGA
Discussion and clarification of issues ASMI raised in relation to the Bill.

12 May 2005 - ASMI (topic of meeting ASMI issues in relation to data exclusivity and market protection)

Meeting not specifically about Bill but ASMI raised the 2 issues

1. The Bill should have been accompanied by simpler explanatory notes.
2. Consultation should have started with drafting instructions, TGA explained that this was not possible and that we had to get PM approval to release exposure draft of the Bill.

Consultation on Draft Guidelines

2 September 2005 ASMI meeting at TGA to discuss draft Guidelines for the Bill
9 September 2005 GMIA meeting at TGA to discuss draft Guidelines for the Bill
16 September 2005 Medicines Australia meeting at TGA to discuss draft Guidelines for the Bill
16 September 2005 CHC meeting at TGA to discuss draft Guidelines for the Bill
22 September 2005 MIAA, AusBiotech & ADIA meeting at TGA to discuss draft Guidelines for the Bill

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-143

OUTCOME 1: Population Health

Topic: THERAPEUTIC GOODS AMENDMENT BILL 2005

Written Question on Notice

Senator Forshaw asked:

Will the operation of the Act have different effects on the different health care sectors - ie: prescription medicines (usually assessed as high risk), and over the counter and complementary medicines (usually assessed as low risk)? If so, how?

Answer:

The new enforcement measures proposed in the Bill are intended to apply to all therapeutic goods, including prescription, over-the-counter and complementary medicines, and medical devices and blood. The risk to the community of non-compliance with regulatory requirements is not limited to certain industry sectors.

The risk of the product itself is not always the issue. Low risk products poorly manufactured without the necessary quality assurance applying can give rise to unsafe products having the potential to cause harm and injury. A prescription medicine or a herbal ointment can both cause harm if, for example, the levels of microbial or other contaminants render it dangerous.

The Bill is designed to give the Therapeutic Goods Administration (the TGA) the ability to better calibrate its response to breaches of existing regulatory requirements under the *Therapeutic Goods Act 1989*. To this end, applicable sanctions have been refined to take into account the severity of a particular breach of regulatory requirements and the consequences of that breach.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-144

OUTCOME 1: Population Health

Topic: THERAPEUTIC GOODS AMENDMENT BILL 2005

Written Question on Notice

Senator Forshaw asked:

a) Can the TGA guarantee the penalty provisions will be imposed in a consistent and fair manner? How does the TGA plan to justify its decisions?
b) Has the TGA drafted guidelines for industry on how the Bill will operate?
c) Has the TGA received any feedback on these guidelines? If so, what was the feedback?
d) Was there any criticism of the guidelines? If so, what were they based on?
e) Any recommendations? If so, what were they and will the TGA be considering them? If so, what does the TGA plan to do?
f) Will the TGA be amending the guidelines?

Answer:

a) Penalty provisions are determined and administered only by courts and not by the Therapeutic Goods Administration (TGA). When the TGA wishes to bring criminal proceedings for a relevant breach of regulatory requirements, it can only lodge a brief of evidence with the Director of Public Prosecutions (DPP). The ultimate decision as to whether or not to pursue criminal proceedings rests with the DPP. If the DPP decides to prosecute, it is up to the court to determine whether or not an offence has been committed, and if so, what appropriate sanctions should apply.

   Similarly, if the TGA wishes to commence civil proceedings for a breach of regulatory requirements, it would be required under the Legal Services Directions to first obtain independent legal advice indicating that it had grounds for doing so before initiating such action. The Legal Services Directions are issued by the Attorney-General under the *Judiciary Act 1903*. These Directions set out the framework and requirements for the performance of Commonwealth legal services and, in particular, the conduct of litigation by Commonwealth agencies.

   Any decision regarding whether a breach of a regulatory requirement has occurred so as to warrant judicial action is a question solely for a court to decide, as is also the issue of what penalty should apply in relation to that breach. The TGA cannot determine these issues, it can only seek to bring a matter to the court.

b) Yes. Guidelines were prepared by the TGA on the following aspects of the Bill:
   - civil proceedings vs criminal prosecutions;
   - general principles for issuing infringement notices; and
   - enforceable undertakings.

c), d), e) and f)

The TGA received feedback in relation to the guidelines from the Complementary Healthcare Council of Australia (CHC) and the Australian Self-Medication Industry (ASMI). Both those industry groups believe that the Guidelines could be more detailed and clearer. To this end, CHC recommended that a working group be established to discuss the Guidelines, and the TGA has agreed to this.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-151

OUTCOME 1: Population Health

Topic: AUSTRALIAN FEDERATION OF PREGNANCY SUPPORT SERVICES (AFPSS)

Written Question on Notice

Senator Nettle asked:

In answer to Question on Notice No. 365 (9/8/05) asked by Senator Allison you replied "The AFPSS must gain and maintain accreditation as an Australian National Training Authority recognised Registered Training Organisation for training health educators, health professionals and other workers, and accrediting trained counsellors in affiliated agencies." In response to my question in the Supplementary Budget Estimates Community Affairs Legislation Committee (2/11/05) you stated that AFPSS counsellors "complete a counselling skills development course for pregnancy workers. That is recognised as a professional development short course by the Australian Counselling Association and can be credited towards ongoing professional development requirements for counsellors".

a) Did AFPSS not receive accreditation as an Australian National Training Authority recognised Registered Training Organisation for training health educators, or is there an application pending?

b) If there is an application pending what is the status of that application?

c) Or did AFPSS decide not to pursue registration as a RTO?

Answer:

a,b,c) AFPSS is currently developing its application for accreditation as a Recognised Training Organisation (RTO) in accordance with the Australian Quality Training Framework (AQTF). The AQTF is the set of nationally agreed quality assurance arrangements for training organisations, which was endorsed by the then Australian National Training Authority. The AFPSS application process is expected to be completed prior to 30 June 2007.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-152

OUTCOME 1: Population Health

Topic: AUSTRALIAN FEDERATION OF PREGNANCY SUPPORT SERVICES (AFPSS)

Written Question on Notice

Senator Nettle asked:

a) If the AFPSS is in the process of applying for accreditation as an Australian National Training Authority recognised Registered Training Organisation, what is the name of the Registered Training Organisation (RTO)?

b) How much federal funding would the RTO associated with AFPSS receive if their application is approved?

Answer:

a) AFPSS is expected to apply for accreditation as an RTO under its own name.

b) Under the current funding agreement, the AFPSS receives funding to deliver a number of key outputs. These include the development and implementation of appropriate training for counsellors, and working towards accreditation of the AFPSS as an RTO. Funding for the development of the RTO application is not separately specified.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-153

OUTCOME 1: Population Health

Topic: AUSTRALIAN FEDERATION OF PREGNANCY SUPPORT SERVICES (AFPSS)

Written Quest

Senator Nettle asked:

a) What states and territories is AFPSS seeking to run training in through their Registered Training Organisation (RTO)?

b) How many students does any RTO course run by AFPSS intend to have?

c) What are any anticipated average student contact hours per course run by a AFPSS RTO?

Answer:

a, b, c) The AFPSS is currently developing its application for accreditation as an RTO. The department is unable to provide details of intended courses until the application process is completed.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-154

OUTCOME 1: Population Health

Topic: AUSTRALIAN FEDERATION OF PREGNANCY SUPPORT WORKERS (AFPSS)

Written Question on Notice

Senator Nettle asked:

Are there any requirements for the qualifications of teachers in such a Registered Training Organisation (RTO)? If so what are they? What are the qualifications of those who are being proposed as teaching any AFPSS associated RTO?

Answer:

The Australian Quality Training Framework (AQTF) standards for RTOs include requirements for the competence of staff involved in training, assessment or client service. RTOs must ensure that training is delivered by a person who:

1. holds the Certificate IV in Training and Assessment from the Training and Assessment Training Package or is able to demonstrate equivalent competencies, or
2. is under the direct supervision of a person who has the above competencies, and
3. is able to demonstrate vocational competencies, at least to the level of those being delivered.

The AFPSS is currently developing its application for accreditation as an RTO. The department is unable to provide details of the staff who will be delivering training until this process is complete.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-155

OUTCOME 1: Population Health

Topic: AUSTRALIAN FEDERATION OF PREGNANCY SUPPORT SERVICES (AFPSS)

Written Question on Notice

Senator Nettle asked:

What are the names and qualifications of the individuals who have developed the course curriculum for any RTO application from AFPSS?

Answer:

The AFPSS currently employs a Counselling Skills and Development Officer who is developing the AFPSS application to be a Registered Training Organisation (RTO). This employee of the AFPSS holds the following qualifications: Master of Education; Bachelor of Nursing; Bachelor of Education; and Certificate of Humanistic Psychology & Counselling, and has also commenced a PhD in Education on the subject of development, evaluation and education of counsellors. In the interests of privacy, the department is not prepared to disclose the name of this individual employee.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-156

OUTCOME 1: Population Health

Topic: AUSTRALIAN FEDERATION OF PREGNANCY SUPPORT SERVICES (AFPSS)

Written Question on Notice

Senator Nettle asked:

Please provide any other information available on any AFPSS Registered Training Organisation (RTO) such as RTO delivery or assessment status, registration conditions or registration restrictions.

Answer:

There are currently no RTOs associated with AFPSS. AFPSS is developing its application for accreditation as an RTO.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-157

OUTCOME 1: Population Health

Topic: AUSTRALIAN FEDERATION OF PREGNANCY SUPPORT SERVICES (AFPSS)

Written Question on Notice

Senator Nettle asked:

Please provide a copy of the proposed curriculum for any RTO run by AFPSS.

Answer:

AFPSS is currently developing its application for accreditation as an RTO. The Department is unable to provide the proposed curriculum at this stage as it is still being developed. AFPSS has advised that they will provide a copy of the proposed curriculum when available.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-158

OUTCOME 1: Population Health

Topic: AUSTRALIAN FEDERATION OF PREGNANCY SUPPORT SERVICES (AFPSS)

Written Question on Notice

Senator Nettle asked:

a) For the AFPSS counselling skills development course for pregnancy workers that is recognised as a professional development short course by the Australian Counselling Association, how much federal funding does the course receive?

b) What is the name of the organisation that provides this course?

c) What states and territories is the course available in?

d) How many AFPSS students have participated in the course?

e) What are the average student contact hours?

f) Are their any requirements for the qualifications of teachers? If so what are they? What are the qualifications of those currently running/teaching the course?

g) Please provide the course outline, list of reading material and curriculum for the course and any other information available on the AFPSS course.

Answer:

a) Under the current funding agreement, the AFPSS receives funding to deliver a number of key outputs. These include the development, implementation and monitoring of appropriate training for counsellors. Amounts of funding have not been separately specified for training.

b) Australian Federation of Pregnancy Support Services (AFPSS).

c) The AFPSS Counselling Skills Development Course for Pregnancy Workers is available to all AFPSS affiliated agencies. There are affiliated agencies in all states and territories with the exception of the Northern Territory.

d) Since the Counselling Skills Development Course for Pregnancy Workers was accredited in 2002 with the Australian Counselling Association, 283 students have participated in the course. This figure includes some counsellors who did the full training course a second time for re-skilling or in-service purposes, or in preparation for the role of support person within the agency.

e) The course involves approximately six full days of training, the completion of a number of exercises in the counsellors' own time, and ongoing skills development.

f) There are no qualification requirements for trainers delivering the AFPSS Counselling Skills Development Course for Pregnancy Workers. However, the course is currently delivered by the Counselling Skills and Development Officer, who holds the following qualifications: Master of Education; Bachelor of Nursing; Bachelor of Education; and Certificate of Humanistic Psychology & Counselling, and has also commenced a PhD in Education on the subject of development, evaluation and education of counsellors.

g) The course has recently been reviewed by the AFPSS and a new training manual is in the final stages of preparation. AFPSS has advised that they will provide a copy of the new training manual, which accurately reflects the current course, and all other course resources when available.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-159

OUTCOME 1: Population Health

Topic: PREGNANCY COUNSELLING AND *TRADE PRACTICES ACT 1974*

Written Question on Notice

Senator Nettle asked:

I refer you to two different answers to questions on notice asked by Senator Allison.

In reply to question No. 365 (9/8/05) in reference to pregnancy counselling services, it was stated that "Consumers are protected by the provisions of the *Trade Practices Act 1974* which deals with misleading or deceptive conduct by a corporation."

But then from Question No. 1091 (6/10/05) it was stated that "Section 75AT of the *Trade Practices Act 1974*, which contains provisions against price exploitation, does not apply to pregnancy support and counselling services that are provided at no cost."

Given this confirmation that the *Trade Practices Act* does not actually apply; can you now explain what mechanisms the Federal Government has put in place to ensure that consumers are protected from misleading and deceptive conduct by pregnancy counselling service providers?

Answer:

The Department of Health and Ageing ensures the quality of services provided by organisations funded to deliver family planning and sexual and reproductive health through the overall quality framework, based on funding agreements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-165

OUTCOME 1: Population Health

Topic: PREPARATIONS FOR THE 2006 WINTER FLU SEASON

Written Question on Notice

Senator McLucas asked:

(a) Will the flu vaccination campaign for winter 2006 differ in any way to that of previous years?

(b) Will there be efforts to ensure that more people (especially those at highest risk) are vaccinated?

(c) What do we know about vaccination rates of high risk groups (eg elderly) from previous years?

Answer:

(a) In previous years, the Minister for Health and Ageing has launched the National Influenza Vaccine Program for Older Australians at the start of each influenza season. Along with the publicity generated by a Ministerial launch, the Department of Health and Ageing has previously provided information on the Program and posters for general practitioners, and a fact sheet and multi-lingual fact sheet for consumers. States and Territories have taken on responsibility for distribution of promotional material for the Program.

It is proposed that the vaccination campaign for the 2006 season also include promotional material on the Program such as posters and fact sheets. The Influenza Specialist Group also conducts an awareness campaign for influenza vaccination for the general population.

The Department's Immunise Australia website and the 1800 Immunisation Infoline will continue to provide support to the general public and immunisation providers regarding the National Influenza Vaccine Program for Older Australians and the National Indigenous Pneumococcal and Influenza Immunisation Program.

(b) Australian Government and State and Territory vaccination campaigns will focus on those at highest risk, including those aged 65 years and over and the Indigenous population.

(c) Since the introduction in 1999 of the National Influenza Vaccine Program for Older Australians, vaccination rates for those aged 65 years and over have risen from 69% in 1999 to 79.1% in 2004.

It is estimated that, of about 2.6 million Australians in the target age group, 2.1 million were vaccinated against influenza in 2004.

The Department has no data on the vaccination coverage rate of influenza vaccine in other high-risk populations.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, November 2005

Question: E05-166

OUTCOME 1: Population Health

Topic: PANDEMIC VACCINE PRODUCTION

Written Question on Notice

Senator Jan McLucas asked:

What work is being done to test the safety of this vaccine for:

(i) infants;

(ii) the elderly;

(iii) the immuno-compromised; and,

(iv) people with egg allergies?

Answer:

Testing of a vaccine for pandemic influenza is currently underway. The first phase of testing is with healthy people and is designed to test safety and effectiveness. Once safety in healthy people has been assessed, testing is planned to be undertaken for people in various risk categories.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-167

OUTCOME 1: Population Health

Topic: PANDEMIC VACCINE PRODUCTION

Written Question on Notice

Senator McLucas asked:

Given that a potential scenario is a partially effective vaccine, what will be the vaccination and treatment protocols in this case?

Answer:

As vaccine testing is currently underway, it is too soon to say what protocols will be used.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 Nov 2005

Question: E05-168

OUTCOME 1: Population Health

Topic: VACCINE PRODUCTION FOR A FLU PANDEMIC

Written Question on Notice

Senator McLucas asked:

In the event of a pandemic, how will Australia ensure that it gets the vaccines it has agreed to purchase from Sanofi Pasteur? Can CSL meet all our requirements?

Answer:

Under the terms of Australia's Deed of Agreement for Supply of Influenza Vaccine, Sanofi Pasteur Pty Ltd (Sanofi) is only required to supply pandemic influenza vaccine if and when Australia places a purchase order with Sanofi. Sanofi's contractual obligation to Australia is regardless of any other agreements Sanofi may have entered into.

Under the terms of Australia's Deed of Agreement for Supply of Influenza Vaccine with CSL Ltd (CSL), Australia has first priority ahead of any other country in the provision of pandemic vaccine in the event of an influenza pandemic. CSL has the potential capacity to produce sufficient vaccine for all Australians.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-169

OUTCOME 1: Population Health

Topic: PANDEMIC VACCINE PRODUCTION

Written Question on Notice

Senator Jan McLucas asked:

If an avian flu pandemic emerges elsewhere (eg in Indonesia) will Australia send vaccine there for use?

Answer:

The Prime Minister recently announced that Australia will provide $100 million over four years for initiatives to combat the threat of pandemics and other emerging infectious diseases within the region. Of this package, $90 million will be spent on bilateral assistance to enhance preparedness in regional economies and to support the work of multilateral institutions, such as the World Health Organization and the Food and Agriculture Organization. A further $10 million will be used for specific Asia-Pacific Economic Cooperation (APEC) activities on avian influenza.

Whether Australia provides vaccine to other countries will be a decision for Government in light of the circumstances at that time.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-171

OUTCOME 1: Population Health

Topic: AUSTRALIAN SENTINEL PRACTICE RESEARCH NETWORK (ASPREN)

Written Question on Notice

Senator McLucas asked:

a) How many GPs (or GP practices) are currently part of this network?

b) Where are these GPs located?

Answer:

a) There are currently 51 GPs participating in the ASPREN surveillance network.

b) In 2004, there were 15 GPs in New South Wales, 15 in South Australia, 9 in Victoria, 5 in Queensland, 4 in Tasmania, 2 in Western Australia and 1 in the ACT.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-172

OUTCOME 1: Population Health

Topic: AUSTRALIAN SENTINEL PRACTICE RESEARCH NETWORK (ASPREN)

Written Question on Notice

Senator McLucas asked:

What diseases does ASPREN monitor?

Answer:

ASPREN was established as a national network of general practitioners who report presentations of defined medical conditions each week. The list of medical conditions reported on is reviewed annually. The aim of ASPREN is to provide an indicator of the burden of disease in the primary health care setting and to detect trends in consultation rates. In 2005, ASPREN monitored eight 'conditions' including influenza-like illness (with two case definitions), gastroenteritis, chickenpox, shingles, antibiotics for acute exacerbation of chronic obstructive pulmonary disease (COPD), use of spirometry for COPD and use of ambulatory blood pressure monitor.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-173

OUTCOME 1: Population Health

Topic: AUSTRALIAN SENTINEL PRACTICE RESEARCH NETWORK (ASPREN)

Written Question on Notice

Senator McLucas asked:

a) To which body/official does ASPREN report?
b) How often are reports made?
c) How are reports made?
d) What happens to these reports? What is the follow-up procedure?

Answer:

a) ASPREN is owned and operated by the Royal Australian College of General Practitioners (RACGP) and managed by the South Australian and Northern Territory Faculty of RACGP. The Director of ASPREN is based within the Department of General Practice at the University of Adelaide. Reports are made to the Australian Government Department of Health and Ageing, the South Australian Department of Health, the Department of General Practice and Rural Health at the University of Adelaide, the 'Medical Observer', CSL and the WHO Collaborating Centre for Reference and Research in Influenza.

b) Participating GPs make reports to the RACGP weekly. Summary data are sent from the RACGP to the stakeholder groups weekly.

c) Each patient presenting to an ASPREN GP with a 'condition' which is being monitored is recorded on a paper report form. This form records only the sex and age group of the patient and the condition. GPs also record the total number of consultations they have had in each week. The form is mailed back to the ASPREN coordinator at the end of each week and the report forms are scanned into a computer. Reports are generated in terms of the number of reportable conditions per 1,000 consultations. Reports are stratified by state/territory and age group and sex.

   ASPREN reporting mechanisms will be improved through the implementation of web-based electronic reporting though the Department's Biosecurity Surveillance System (BSS) project which was funded by the Government in the 2004-05 Budget.

d) ASPREN data on influenza-like illness are reported in the National Influenza Surveillance Scheme as a fortnightly report on the Department of Health and Ageing website during the annual influenza season (May to October). Data on all ASPREN conditions are also published in the Department's quarterly bulletin *Communicable Diseases Intelligence (CDI)*. An ASPREN annual report is produced and circulated to stakeholders.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-174

OUTCOME 1: Population Health

Topic: AUSTRALIAN SENTINEL PRACTICE RESEARCH NETWORK (ASPREN)

Written Question on Notice

Senator McLucas asked:

a) How many GPs should be part of this network for it to be effective?

b) Are GPs provided with financial compensation for their services?

c) What is this compensation?

Answer:

a) An evaluation of the ASPREN system commissioned by the Department of Health and Ageing in early 2005 recommended the expansion of the network to improve the representativeness of the ASPREN data. The focus of recruitment should be to make the sample of consultations report more representative of the general Australian population rather than simply increasing the total number of GPs reporting in each State. The department is funding ASPREN in the current financial year to undertake a recruitment project to strategically increase the number of reporting GPs (see answer to E05-175).

b) and c) GPs currently participating in the ASPREN scheme do not receive any financial compensation. An incentive is provided by way of Continuing Professional Development (CPD) points. In the 2002-2004 triennium participants earned 20 RACGP QA-CPD (clinical audit) points.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-175

OUTCOME 1: Population Health

Topic: AUSTRALIAN SENTINEL PRACTICE RESEARCH NETWORK (ASPREN)

Written Question on Notice

Senator McLucas asked:

a) There is a report that ASPREN sought $200,000 from the Department three months ago but it is still waiting for this money. Is this report correct?

b) What were the funds requested for?

c) Why has there been a delay in providing this funding?

Answer:

a) ASPREN were invited to apply for funding for expanding their network in June 2005 as part of the Australian Government's pandemic preparedness.

b) Funds were requested to develop a recruitment strategy, to engage more GPs and to hold workshops with GPs to improve the quality and completeness of reporting.

c) The funding application from ASPREN was approved on 27 October 2005.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-198

OUTCOME 1: Population Health

Topic: FUNDING – NATIONAL IMMUNISATION PROGRAM

Written Question on Notice

Senator McLucas asked:

Are the funding arrangements for the National Immunisation Program (NIP) altered as a result of the PBAC assessment of vaccination programs for funding under the NIP? That is, are funds for the NIP still available through the Special Appropriation for Vaccines or will they be bundled into the broader PBS funding arrangements?

Answer:

Funding arrangements for the National Immunisation Program will remain as they currently are. Currently funded vaccines and any new vaccines recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) and approved by the Minister will be funded through the Special Appropriation for Vaccines.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-211

OUTCOME 1: Population Health

Topic: NATIONAL STORE ADVISORY COMMITTEE

Hansard Page: CA 113

Senator Crossin asked:

Do you know when the National Store Advisory Committee met last?

Answer:

According to Australian Radiation Protection and Nuclear Safety Agency's (ARPANSA) records, the National Store Advisory Committee last met on 24 February 2003.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-230

OUTCOME 1: Population Health

Topic: FAMILY PLANNING ORGANISATIONS

Written Question on Notice

Senator Nettle asked:

Can I put on notice the starting date for each of those four (the four directly funded by the Department)?

Answer:

Department of Health and Ageing funding has been provided since 1974 to the Australian Catholic Social Welfare Commission. This funding was transferred to the Australian Episcopal Conference of the Roman Catholic Church in 1990.

Department of Health and Ageing funding for the Australian Federation of Pregnancy Support Services commenced in 1999-2000.

The Commonwealth Government began funding Family Planning Organisations in 1974. It is understood that funding for the peak body, formerly Family Planning Australia and now Sexual Health and Family Planning Australia, also started in 1974.

Working Women's Health has advised that Department of Health and Ageing funding has been provided to them since the mid to late 1980s. However, the Department no longer holds the relevant files to identify the exact starting date.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-231

OUTCOME 1: Population Health

Topic: INFLUENZA VACCINE FOR THE 2006 INFLUENZA SEASON

Hansard Page: CA 103

Senator McLucas asked:

In relation to the preparations for the 2006 winter influenza season, how many doses of the regular preventative winter flu vaccine have we ordered or will order?

Answer:

Preparations are in progress for the supply of influenza vaccine for the 2006 season.

A total indicative forecast of 2,454,056 doses has been sent to the two vaccine suppliers contracted to supply influenza vaccine for the Government programs for the 2006 season. The national demand forecast was based on the 2005 season figures provided to the Australian Government by states and territories with adjustments made based on actual usage for the 2005 season.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-170

OUTCOME 1: Population Health

Topic: AVIAN INFLUENZA

Senator McLucas asked:

a) What will the Government do to ensure that there is no price gouging on the private prescriptions for Tamiflu and Relenza?

b) What will the Government do to ensure the availability of these medicines for the 2006 winter flu season and for people with Chronic Obstructive Pulmonary Disease who need to take this medicine to prevent pneumonia, particularly given the current shortage due to personal stockpiling?

c) Is the Government aware of any evidence that the manufacturer of Tamiflu is currently directing supplies to Europe and the US rather than to Australia?

Answer:

a) There is no evidence of recent price increases for Relenza or Tamiflu. The Australian Government does not control the prices of medicines dispensed as private prescription

b) While there is currently a global shortage of antivirals, both of the manufacturers of influenza antiviral medication have expanded their capacity to meet the shortfall and have also recently announced their willingness to work with other manufacturers to sublicense production.

c) We are aware of no evidence to suggest that supplies of Tamiflu are currently being directed to Europe and the United States rather than Australia.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-099

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

The Joint Agency with New Zealand is scheduled to commence operation on 1 July 2006. Are the Department and TGA still on track to meet this time frame?

Answer:

Following a meeting of the Therapeutic Products Interim Ministerial Council meeting on 7 December 2005, it was announced that the Rules of the new scheme will be ready for consultation in early 2006, with consultation on the legislation to commence mid-year.

After this time it is proposed that the legislation will be introduced to the New Zealand parliamentary system and released as an exposure draft for industry consultation in Australia. In both countries this will signal the beginning of formal consultations with interested parties on the legislation.

This will mean that the start up date for the new Authority, scheduled for 1 July 2006, will need to be deferred.

This will provide for an extensive consultation program to enable industry, in particular, to review and comment on the legislation and rules for the new Authority.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-100

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

a) In November last year, the TGA said that they were on track for a 1 July 2005 commencement. In mid February 2005 the timeline was delayed by twelve months by the Parliamentary Secretary, Mr Pyne. What were the underlying reasons for that decision?
b) Can you now guarantee that 1 July 2006 will be the start date?

Answer:

(a) and (b)
Please refer to answer to Question: E05-099.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-101

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

When will the legislation relating to the new agency be tabled in Parliament?

Answer:

No date has been set for when the legislation will be tabled in Parliament. The legislation will be introduced following a thorough consultation process. The Rules of the new scheme will be ready for consultation in early 2006, with consultation on the legislation to commence mid-year.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-102

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

a) Are there any draft legislation/rules as this point of time?
b) If so, have they been or will they be, made available to industry or other organisations? Please provide a list.
c) Have they been invited to comment?

Answer:

a) The Bill and the Rules to implement the trans-Tasman therapeutic products regulatory scheme are currently being drafted.
b) The draft Bill and Rules have not yet been made available to any organisations. Once drafting is completed an exposure draft of the Bill and key Rules will be released so that consultation can occur.
c) Please refer to answer to Question: E05-106.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-103

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

a) What is the exact situation in relation to the Trans Tasman agency - where is the TGA up to in all of this?
b) What is the current process?

Answer:

a) and b)

Implementing Bills for the Treaty are being drafted in both countries through a cooperative work program at officials' level. The joint regulatory scheme will be set out in a single set of 'Ministerial Council Rules' which will apply in both countries. Drafting of these Rules has been underway for some time.

Exposure drafts of both the Australian implementing Bill and the Rules will be made available for stakeholder consultation prior to their introduction to Parliament. The Therapeutic Products Interim Ministerial Council will need to approve the release of both the Bills and the Rules for consultation.

Due to the need to coordinate consultation and Parliamentary consideration in both Australia and New Zealand, the Therapeutic Products Interim Ministerial Council will be oversighting this process very carefully.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-104

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

How much time will industry be given to plan for the new regime to commence on 1 July 2006?

Answer:

Please refer to answer to Question: E05-099.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-105

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

a) What consultation with industry has already occurred?
b) What consultation with industry is planned between now and 1 July?

Answer:

a) Industry organisations were provided with a detailed description of the regulatory system on 16 December 2004 to assist industry to understand the scheme and the Rules. Discussion documents and other reports and documents designed to keep stakeholders informed on development of the regulatory detail are regularly published on the Agency project website (http://www.tgamedsafe.org).

Industry stakeholders in Australia have been provided with regular updates on progress towards the implementation of the new joint regulatory scheme with New Zealand for therapeutic products. Consultation with all major industry sectors on specific aspects of the new scheme such as transition arrangements and advertising has also occurred and is ongoing.

b) Consultation through regular meetings involving stakeholders, bilateral meetings, industry conferences and fora is being planned for each industry sector affected by the proposed arrangements and will focus on both providing information and education on the operation of the proposed arrangements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-106

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

The Therapeutic Goods Administration has previously advised the Committee that there will be consultation with industry concerning the legislation that will establish the Joint Agency and the regulatory regime. However, it is now November and the legislation (the Bill or Rules) has not been tabled in the Parliament or, as I understand, provided to industry to review. When do you anticipate undertaking that consultation?

Answer:

Please refer to answer to Question: E05-099.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-107

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

a) There will evidently be significant work required to put in place the new Trans-Tasman agency. Do you have a work plan, program or timeline which describes all the steps that need to occur for the Agency to be operational?
b) Is this work plan available to industry and other stakeholders?
c) How does consultation with other stakeholders, such as industry feature in the timetable?

Answer:

a) Australia has agreed with New Zealand on the steps to be taken for the Agency to become operational. The timeline should be clearer now that the New Zealand election process has concluded.
b) The Government will be discussing with New Zealand the release of the steps required to complete the project to stakeholders, including industry.
c) The Government is committed to ensuring that industry is appropriately consulted on the draft legislation, once it is completed. A thorough consultation process will be conducted prior to finalising the draft legislation for introduction into Parliament.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-108

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

Notwithstanding the lack of availability of the Bill and draft Rules, what consultation has there been with industry about the detailed regulatory scheme that will come into operation on 1 July 2006?

Answer:

Please refer to answer to Question: E05-105.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-109

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

What guarantees can you give the Committee that, unlike last time, the agency will be up and running on 1 July 2006?

Answer:

Please refer to answer to Question: E05-099.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-110

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

Is there any guarantee that the harmonisation efforts will not be further delayed, or is there a risk of Australia being in the same predicament as the EU in their harmonisation attempts (they first announced a 3 year period to harmonise regulations, and this has been extended to 5 years now)?

Answer:

Please refer to answer to Question: E05-099.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-111

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

What guarantees can you give the Committee that, unlike the debacle we've seen with the implementation of the new Customs Services' new software, industry will be consulted all through the process and will be adequately prepared for the 1 July start date.

Answer:

The Government is committed to ensuring that industry is appropriately consulted on the draft legislation, once it is completed. A thorough consultation process will be conducted prior to finalising the draft legislation for introduction into Parliament.

Industry has been given a commitment of six weeks consultation on the exposure draft of the implementing Bill, and at least two months on the draft Ministerial Council Rules. Further consultation with industry is also planned on specific elements of the new scheme, such as the Orders that will contain matters of regulatory detail. Information and education are planned with material in the form of "questions and answers" published on the website.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-112

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

With respect to the establishment of different committees for the purpose of defining standards that will apply under the new Agency is industry (as opposed to industry expertise included) on those Committees?

Answer:

An expert advisory committee was appointed by the Therapeutic Products Interim Ministerial Council to oversee the establishment of standards for therapeutic products under the new Agency. As an expert committee, membership of the Joint Interim Advisory Committee on Standards includes experts in chemistry, pharmaceutical sciences, biomedical engineering, blood, tissues and cellular therapies, microbiology and virology, and good manufacturing practices, quality systems and consumer issues. There are no representative members on any of the Committees which have been established to provide expert advice.

Peak industry bodies in both Australian and New Zealand were consulted about the proposed membership of this expert committee.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-113

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

Does the industry appear to be satisfied that the decisions that will be made by these Committees will not impose unreasonable new requirements on the industry and therefore add to the burden from the new Agency?

Answer:

Generally key stakeholders have welcomed the opportunity for a review of the standards currently applied by the Therapeutic Goods Administration. The expert advisory committees are to make recommendations on standards to the Therapeutic Products Interim Ministerial Council, following careful consideration of the opinions reflected in submissions received as part of the public consultation process.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-114

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

a) How will this whole Trans-Tasman process be funded? What is the cost of establishing the Joint Agency?
b) Who will pay for it? How will this cost be met - through revenue generated from fees and charges supplied by industry or from an appropriation from the Government?
c) Or cost-shared?
d) What is the breakdown of costs?
e)Will the costs be shared equally between both Australia and New Zealand?

Answer:

(a) (b) (c) (d) and (e)
The trans-Tasman process to establish the Australia New Zealand Therapeutic Products Authority has been funded by the Australian and New Zealand Governments. The full cost of implementing the new Authority will not be known until commencement, but Australia's share of the implementation funding for infrastructure development is AUD2.9 million which is matched equally by New Zealand. Each country is responsible for the costs of its own project team.

Australia has to date committed AUD12.5 million to this project, of which
AUD7 million will be repaid by the Authority over its first five years of operation.

Once the Authority commences, it will operate on a fully cost-recovered basis. Fees will be levied on industry in Australia and New Zealand, with these fees being calibrated to cover the cost of the required regulatory activity.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-115

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

a)How many people are currently employed by the TGA, and/or the Government to work on the establishment of the Trans-Tasman agency, and subsequent legislation?
b)Will extra people be employed for this purpose? If so, how many?

Answer:

(a) The Average Staffing Level funded by the Australian Government to work directly on the establishment of the Agency is 12.

(b) No, it is not envisaged that extra people will be required in addition to (a).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-116

OUTCOME 1: Population Health

Topic: JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Forshaw asked:

Have the TGA and Medsafe (the NZ agency) determined what the level of fees and charges that will apply under the new Agency?
If so, have they communicated these to the industry?
If not, when will the fees and charges be finalised and available for consultation with industry?

Answer:

The Therapeutic Goods Administration and Medsafe have not determined what level of fees and charges will apply to regulatory activity under the joint scheme.

In the regulation of therapeutic products, fees and charges will be set so as to fully cost recover the operations of the Agency.

The subject of fees and charges is being actively considered by the Australian and New Zealand Governments, ahead of release for stakeholder consultation in the context of the exposure draft of the Bill and Rules.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-117

OUTCOME 1: Population Health

Topic: DECISION MAKING BY THE THERAPEUTIC GOODS ADMINISTRATION (TGA)

Written Question on Notice

Senator Forshaw asked:

It is an object in the Therapeutic Goods Act that therapeutic goods supplied in Australia are of appropriate quality, safety and efficacy, and also that they are made available to the public manner [sic] in a timely way. How does TGA's performance in reviewing and approving new medicines (specifically new prescribed medicines) compare with other comparable agencies such as the US FDA (Food and Drug Administration) and the European agency? Is it, on average, faster, slower or about the same?

Answer:

TGA compares favourably with other agencies in cases where the information can be compared.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-118

OUTCOME 1: Population Health

Topic: DECISION MAKING BY THE THERAPEUTIC GOODS ADMINISTRATION (TGA)

Written Question on Notice

Senator Forshaw asked:

Does the TGA often make a decision about a new medicine that differs from a decision made by other regulatory agencies and, if so, how often does this occur?

Answer:

The TGA makes decisions based on its own evaluation of the data submitted by the sponsor. The TGA does not record how often a decision made about a new medicine in Australia is different from a decision made in an overseas country.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-120

OUTCOME 1: Population Health

Topic: DECISION MAKING BY THE THERAPEUTIC GOODS ADMINISTRATION (TGA)

Written Question on Notice

Senator Forshaw asked:

How is the TGA made accountable for its decision making?

Answer:

The TGA is a Division of the Department of Health and Ageing, and is accountable to the Secretary of the Department. Activity undertaken by the TGA is delegated by the Secretary under the *Therapeutic Goods Act 1989*.

The decisions made by the TGA are subject to the appeal provisions as spelt out in Section 60 of the *Therapeutic Goods Act 1989*.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-121

OUTCOME 1: Population Health

Topic: DECISION MAKING BY THE TGA

Written Question on Notice

Senator Forshaw asked:

Who makes the recommendations and decisions in the TGA?

Answer:

This would depend on the nature of the decision being made as there are many possible legislative outcomes for action by the TGA. Decisions on the approval or rejection of an application for the registration of a prescription medicine are made by the delegate of the Secretary, usually on the advice of the independent expert advisory committee the Australian Drug Evaluation Committee.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-124

OUTCOME 1: Population Health

Topic: DECISION MAKING BY THE THERAPEUTIC GOODS ADMINISTRATION (TGA)

Written Question on Notice

Senator Forshaw asked:

Is there any process of benchmarking the TGA against other agencies overseas? If so, are there any results publicly available of those benchmarking exercises? If not, why not?

Answer:

The TGA produces quarterly reports on work processes for the information of industry and other stakeholders.

In relation to prescription medicines, the TGA recently participated in research run by the Centre for Medicines Research International (CMR International).

For several years CMR International and, more recently, the Institute for Regulatory Science have collected data on timelines and procedures for applications submitted to the Center for Drug Evaluation and Research (Food and Drug Administration (FDA)), the European Medicines Agency (EMEA), Switzerland, Health Canada and Australia and tracked their progress through each authority until review completion.

CMR International instigated a benchmarking study in April 1998 to evaluate the review process of five authorities: FDA, EMEA, TGA (Australia), Health Canada and Swissmedic (formerly IKS). In the first study, data was collected on applications submitted to the authorities between 1997 and 1998 with outcomes tracked through to July 2000 utilising common milestones to mark the progress of each application. This was completed in February 2002.

A second study has been undertaken to collect data for applications submitted in 1999 to 2002 and tracked through to July 2003. A report on the study will be published early in 2006. The results of research by CMR International, if available, may be obtained from the Centre for Medicines Research website available at: www.cmr.org

The TGA is preparing further data for future CMR International studies.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-125

OUTCOME 1: Population Health

Topic: REVIEW OF DRUG EVALUATION PROCESS

Written Question on Notice

Senator Forshaw asked:

There was a major review of Australia's drug evaluation processes in 1991 by Professor (and former Senator) Peter Baume. This review recommended wide ranging changes to the Australian drug evaluation process which, when implemented, brought about significant improvements in the timeliness of drug evaluations and made Australia's system more closely aligned with that of Europe and the US. Has the Department or TGA considered holding another review of the medicines evaluation process to assure itself and its stakeholders that its processes are best practice with respect to efficiency and effectiveness? If so, when will the review occur, who will be conducting the review and will it be an open review inviting submissions from all stakeholders?

Answer:

A number of reviews have been completed since the Baume review. In mid-1996, the Parliamentary Secretary with responsibility for the Therapeutic Goods Administration (TGA), directed the Commonwealth Department of Health and Family Services to commission a review by KPMG of Australia's approach to the regulation of medicinal products.

In October 1996, the Auditor-General presented Audit Report no.8 of 1996-1997. The audit's objective was to assess the efficiency, effectiveness and accountability of TGA's evaluation and approval of prescription drugs for public use. ANAO reported that the TGA's drug evaluation process was efficient, but there was scope (with the assistance of the pharmaceutical companies) for the evaluation time to be reduced, particularly the time to obtain and assess additional data. The report found that TGA could increase the effectiveness of its drug evaluation processes by:

- improving its information technology
- developing an adequate system to assess the cost of TGA's services to the pharmaceutical industry; and
- giving more attention to monitoring adverse drug reactions.

A follow-up audit was conducted from late September 1999 and published as Audit Report No.2 of 2000-2001. The follow-up review found that generally the TGA's implementation has been consistent with the thrust of that 1996-97 Report.

In 2002, the TGA convened a working party consisting of representatives of industry and consumer organisations to work with it to review administrative and business rules around prescription medicine evaluation processing. Regular meetings of the working party were held over the next two years. In 2005, the work from this group was referred to a consultant to develop a discussion paper and manage a broader consultation process.

The Discussion Paper:

- provides background information about the current workflow practices within the Drug Safety and Evaluation Branch;
- provides summary information about similar processes in some comparable countries;
- identifies some opportunities for streamlining current pre-market workflow processes to provide greater planning capacity for the TGA and better meet the needs of industry; and
- explores opportunities to improve the transparency of decisions made by the TGA.

It is anticipated that the TGA will implement any improvements that can be made to their current business processes as a result of this review. The consultation paper has therefore been drafted to reference current Australian practice when describing the status quo and commenting on alternative approaches.

Because the feedback from this consulation will also flow through into the development of business practices for the joint agency, feedback is also being sought from both New Zealand and Australia stakeholders.

Details of the consultation process are available on the TGA website www.tga.gov.au

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-126

OUTCOME 1: Population Health

Topic: REVIEW OF DRUG EVALUATION PROCESS

Written Question on Notice

Senator Forshaw asked:

Is the Therapeutic Goods Administration (TGA) taking a more precautionary approach to its regulatory responsibilities?

Answer:

The approach of the TGA to its regulatory responsibilities has not changed.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-127

OUTCOME 1: Population Health

Topic: REVIEW OF DRUG EVALUATION PROCESS

Written Question on Notice

Senator Forshaw asked:

Does the Therapeutic Goods Administration (TGA) consult with the company that supplies a medicine before it makes any public statement about the medicine? In every instance?

Answer:

The TGA will usually endeavour to consult with the company that supplies a medicine before it makes a public statement about the medicine.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-131

OUTCOME 1: Population Health

Topic: VIOXX RECALL

Written Question on Notice

Senator Forshaw asked:

a) Is the Therapeutic Goods Administration (TGA) involved in any way in the class action against the manufacturer? If so, how?
b) How many people have joined the class action against the manufacturer?

Answer:

a) No.
b) The TGA is not involved in the class action against the manufacturer of Vioxx and is unable to provide the number of people who may have joined the action.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-132

OUTCOME 1: Population Health

Topic: VIOXX RECALL

Written Question on Notice

Senator Forshaw asked:

c) What complaints has the Therapeutic Goods Administration (TGA) received in relation to Vioxx? Please provide details of these complaints - who were they against, a breakdown, and specifically what were they for?
d) How has the TGA dealt with this?

Answer:

c) The TGA has not received any complaints in relation to Vioxx.

d) Not applicable.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-133

OUTCOME 1: Population Health

Topic: VIOXX RECALL

Written Question on Notice

Senator Forshaw asked:

f) What dispute resolution procedures does TGA have?
g) What is the complaints process?
h) Is there a review of complaints, and the process? If so, who does it and how?

Answer:

(a) The Therapeutic Goods Administration (TGA) encourages persons to inform the TGA of their complaints if they believe that the TGA failed to meet its service commitments.

The TGA, and in particular the Drug Safety and Evaluation Branch (DSEB), which processes the registration of prescription medicines, encourages the informal resolution of any disputes relating to decisions on prescription medicines under the *Therapeutic Goods Act 1989* (the Act).

In addition, DSEB has in place informal appeal mechanisms allowing an applicant for the variation of information in relation to therapeutic goods, or an application for the registration of prescription medicines, to request a review by the Standing Arbitration Committee. Where the dispute relates to the delegate of the Secretary determining that the application needs to be supported by clinical, non-clinical or bioequivalence data, the applicant can request a review by the Pharmaceutical Subcommittee of the Australian Drug Evaluation Committee.

A number of decisions in relation to therapeutic goods are reviewable through formal appeal mechanisms. A person who is adversely affected by a decision by the Secretary or the delegate of the Secretary can by notice in writing request the Minister for Health and Ageing to reconsider that decision under section 60 of the Act. The reviewable decisions are listed under subsection 60(1) of the Act. If that person is dissatisfied with the decision by the Minister upon reconsideration, he or she can make an application to the Administrative Appeals Tribunal for review of that decision. Administrative decisions under the Act are reviewable under the *Administrative Decision (Judicial Review) Act 1977*.

(b) and (c) Complaints relating to the TGA's failure to meet its service commitment

The person who has a complaint is encouraged to first try to resolve the problem with the TGA officer he or she is dealing with. If the person is still not satisfied, he or she is encouraged to talk to the TGA officer's supervisor. If the above approaches are not satisfactory, the person should contact the National Manager or the Customer Feedback/Complaints Service. The complaint will be responded to within ten days of receipt.

If the person is still not satisfied with the National Manager's response, he or she can raise the concerns with the Commonwealth Ombudsman.

Review of decisions by the Minister for Health and Ageing under section 60 of the Act:

A person whose interests are affected by a decision of the Secretary or the delegate of the Secretary (the initial decision) may by notice in writing given to the Minister, request the Minister to reconsider the decision. These reviewable decisions are listed in subsection 60(1) of the Act. The notice must be given to the Minister within 90 days of the gazettal of the particulars of the initial decision, or within 90 days after the initial decision first comes to the person's notice. The Minister is required to reconsider the decision within 60 days of the request. As a result of the reconsideration, the Minister may confirm the initial decision, revoke the initial decision or revoke that initial decision and make a decision in substitution of the initial decision.

Review by the Administrative Appeals Tribunal:

A person who is dissatisfied with the decision by the Minister for Health and Ageing upon reconsideration of the initial decision can apply to the Administrative Appeals Tribunal for review of that decision within 28 days of the decision being notified to the applicant.

Review under the *Administrative Decisions (Judicial Review) Act 1977*:

Persons aggrieved by an administrative decision under the Act can apply to the Federal Court of the Federal Magistrates Court for review of that decision within 28 days of receiving a statement of reasons, or within 28 days of being notified that no reasons will be furnished. In other cases, within a reasonable time after the decision was made.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-142

OUTCOME 1: Population Health

Topic: THERAPEUTIC GOODS AMENDMENT BILL 2005

Written Question on Notice

Senator Forshaw asked:

i) How will the TGA make its decisions on what penalties to impose? What does it base its decisions on?
j) Can these decisions be reviewed? If so, by whom and how?
k) If it is found that the TGA has made an error in the initial decision it has made, is there any course for redress?

Answer:

c) In relation to a contravention of a civil penalty provision or the commission of an offence under the *Therapeutic Goods Act 1989* (the Act), the TGA has no power to impose penalties. It is up to the relevant court to determine firstly, whether a breach has occurred, and if so, the appropriate penalty. The TGA decides only whether to commence civil proceedings following independent legal advice that there are grounds for doing so, or provide a brief of evidence for consideration by the Director of Public Prosecutions as to whether prosecution should proceed. As an alternative to civil action, the TGA may also choose to issue infringement notices. The recipient of any infringement notice is under no legal obligation to pay and may elect to ignore the notice and instead proceed to litigation to enable a court to determine the issues. If the recipient elects to pay the infringement notice the TGA would be precluded from taking the matter any further. Payment of infringement notices may be likened to a settlement out of court agreed between the two parties involved.

d) Decisions to take a matter to court, such as applying to the Federal Court for a civil penalty order, should not be reviewable, as generally the issue of whether or not the Commonwealth has grounds to pursue a matter is one that will be dealt with in the course of proceedings brought before a court (just as a decision to prosecute someone is not reviewable). The person affected by a decision to take judicial action can contest the matter during the court proceedings.

The Administrative Appeals Tribunal (AAT) in *Toll and Australian Securities Commission* (the ASC) held that it lacks jurisdiction to review a decision to prosecute breaches of the Corporations Law. The AAT held that the administrative steps to:

(i) the formation of the regulator's view that a person may have committed an offence;
(ii)the causing of a prosecution; or
(iii) the way in which the prosecution is to be conducted

can not be regarded as a reviewable decision because none of these is an ultimate or operative determination. The courts have also generally excluded judicial review of decisions to prosecute.

e) As with all matters brought before a court, it is up to the court to determine the outcome of the matter. If a party to the proceedings disagrees with a court's finding, that party may consider appealing to a higher court.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-145

OUTCOME 1: Population Health

Topic: THERAPEUTIC GOODS AMENDMENT BILL 2005

Written Question on Notice

Senator Forshaw asked:

g) What will happen to the Bill once the Trans-Tasman agency comes into effect?
h) Will the enforcement provisions of the Bill be transferred to the new legislation applicable to the Trans-Tasman agency, or will a new regulatory regime be drafted and implemented?

Answer:

c) The Therapeutic Goods Amendment Bill 2005 (the TG Bill) was passed by the House of Representatives on 9 November 2005 and is scheduled for introduction in the Senate during the current sittings. In contrast, the Bill proposing to implement the Australia New Zealand Therapeutic Products Authority has not yet been introduced in Parliament. The measures proposed in the TG Bill will be implemented in Australia prior to the Trans-Tasman agency coming into effect. Officers from the Department of Health and Ageing and New Zealand Ministry of Health are currently considering the sanctions regime that is proposed to apply in the regulation of therapeutic goods in both countries.

d) The measures in the Bill are intended to more effectively address problems that could compromise public health and safety.

It is intended that the joint scheme for the regulation of therapeutic products in Australia and New Zealand will be based on existing legislation, including the measures proposed by the TG Bill. Transferring the enforcement measures contained in the Bill, in full or in part, to the legislation creating the new joint agency will depend on the agreement by the New Zealand Government. Both countries are at this stage still negotiating the details of the enforcement measures that will apply to both countries.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-356

OUTCOME 1: Population Health

Topic: STRAINS OF HEMAGGLUTININ AND NEURAMINIDASE IN THE 2006 FLU VACCINE

Hansard Page: CA 102

Senator Nettle asked:

Has the decision been made for what strains of hemagglutinin and neuraminidase will be in the 2006 flu vaccine?

Answer:

The Australian Influenza Vaccine Committee met on 6 October 2005 and agreed to adopt the World Health Organization's recommendations for the components of the 2006 influenza vaccine.

The Committee decided that the influenza vaccine components for the year 2006 Season should contain the following:

- **A (H1N1):** an A/New Caledonia/20/99 (H1N1) - like strain, 15 µg HA per dose
- **A (H3N2):** an A/California/7/2004 (H3N2) - like strain, 15 µg HA per dose
- **B:** a B/Malaysia/2506/2004 - like strain, 15 µg HA per dose

The following viruses are recommended as suitable vaccine strains:

- A/New Caledonia/20/99 (IVR-116)
- A/New York/55/2004 (NYMC X-157)
- B/ Malaysia/2506/2004

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-357

OUTCOME 1: Population Health

Topic: RU486 – ADVICE ON MEDICAL CONSEQUENCES OF RU486 PREPARED FOR LEGISLATION IN 1996

Hansard Page: CA 123

Senator Nettle asked:

Do you know whether, in 1996 when the legislation went through, there was any material produced by the Department on the medical consequences of RU486?

Answer:

The Therapeutic Goods Administration provided some information to Senator Woods on statements by Senator Harradine. The information was sourced primarily from the French product information document for RU486.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-255

OUTCOME 1: Population Health

Topic: US PRODUCT INFORMATION FOR RU486

Hansard Page: CA 123

Senator Nettle asked:

(a) Can you provide a copy of the US Product Information for RU486?

(b) Who did the studies for the clinical trials in the US? Do they include the study by the American College of Obstetricians and Gynaecologists?

Answer:

(a) The document known in Australia as the Product Information document is known in the US as the Product Label. A copy of the US Product Label for RU486 (mifepristone; Mifeprex) is available from:

the US Food and Drug Administration website available at:
http://www.fda.gov
and the sponsor's website available at:
http://www.earlyoptionpill.com

(b) The Therapeutic Goods Administration is not able to determine if the study mentioned was definitely submitted by the sponsor as part of its application to have the medicine registered in the US.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2005-2006, 1 & 2 June 2005

Question: E05-213

OUTCOME 2: Medicines and Medical Services

Topic: IMPACT ON SCRIPT VOLUMES FROM PATIENT CO-PAYMENT INCREASE

Hansard Page: CA 77 – 1 June

Senator Allison asked:

What decrease in script volumes has been assumed in estimates of the impact of the PBS patient co-payment increase measure?

Answer:

The reductions in prescription volumes estimated to flow from the co-payment increase were as follows:

2004-05	1,626,000 prescriptions
2005-06	4,542,000 prescriptions
2006-07	4,360,000 prescriptions
2007-08	4,487,000 prescriptions

Scripts for PBS January - March Quarter

	2004			
	Jan	**Feb**	**Mar**	**Total**
Concession*	12,099,240	10,305,295	11,160,139	33,564,674
General*	2,868,802	2,001,564	2,129,858	7,000,224
Total	14,968,042	12,306,859	13,289,997	40,564,898

2005			
Jan	**Feb**	**Mar**	**Total**
12,508,366	9,865,935	11,021,036	33,395,337
3,033,079	1,735,678	1,882,909	6,651,666
15,541,445	11,601,613	12,903,945	40,047,003

* Excludes Doctors Bag

		2005-06 $m	2006-07 $m	2007-08 $m	2008-09 $m
Pharmaceutical Benefits Scheme - price reduction for new brand listings					
Department of Health and Ageing	Departmental	0.174	0.398	0.109	0.110
	Departmental capital	0.150	-	-	-
	Administered	- 129.226	- 251.970	- 276.903	- 302.254
	Subtotal	- 128.902	- 251.572	- 276.794	- 302.144
Department of Veterans' Affairs	Administered	- 10.300	- 20.200	- 22.200	- 24.200
	Total	- 139.202	- 271.772	- 298.994	- 326.344
Pharmaceutical Benefits Scheme - reinforcing safety net arrangements					
Department of Health and Ageing	Departmental	0.326	0.034	0.035	0.035
	Administered	- 4.059	- 20.102	- 20.585	- 21.095
	Subtotal	- 3.733	- 20.068	- 20.550	- 21.060
Health Insurance Commission	Departmental	0.853	0.151	0.072	0.072
	Capital	0.098	-	-	-
	Subtotal	0.951	0.151	0.072	0.072
Department of Veterans' Affairs	Administered	- 0.216	- 1.934	- 1.878	- 1.924
	Total	- 2.998	- 21.851	- 22.356	- 22.912
Quality Use of Medicines Program					
Department of Health and Ageing	Departmental	0.393	0.306	0.479	0.469
	Administered	- 5.407	- 4.759	- 4.135	- 3.695
	Subtotal	- 5.014	- 4.453	- 3.656	- 3.226
Department of Veterans' Affairs	Administered	- 1.410	- 1.452	- 1.159	- 1.102
	Total	- 6.424	- 5.905	- 4.815	- 4.328
Strengthening Cancer Care - Sydney Children's Hospital Magnetic Resonance Imaging unit - Medicare Benefits Schedule eligibility					
	Departmental	-	-	-	-
	Administered	1.065	1.198	1.347	1.447
	Total	1.065	1.198	1.347	1.447
Treatment of Breast Cancer - continued funding for Herceptin					
	Departmental	-	-	-	-
	Administered	-	-	-	-
	Total	-	-	-	-

DoHA (4)

CALCIUM TABLETS- Deletion from PBS – 2005-06 Budget Decision - Advice to the Minister - July 2005 PBAC meeting

(250 mg (as citrate), Citrocal®, Key Pharmaceuticals Pty Ltd;
500 mg (as carbonate), Cal-Sup®, 3M Pharmaceuticals Australia Pty Ltd;
600 mg (as carbonate), Caltrate®, Wyeth Consumer Healthcare).

The PBAC noted the policy context of the Budget decision and Government's view that the Pharmaceutical Benefits Scheme (PBS) does not need to subsidise inexpensive over-the-counter medicines that are required in low doses to obtain health outcomes or where dietary modification could suffice to meet clinical needs. It also noted that the current restricted benefit listing allows for prescribing for hyperphosphataemia in chronic renal failure, hypocalcaemia, osteoporosis, or proven calcium malabsorption.

The PBAC recalled that at the June 2005 Special Meeting it had identified the following patient groups where calcium supplementation is clinically necessary - patients with hyperphosphataemia in chronic renal failure; patients with established osteoporosis and taking bisphosphonates; patients with bone metastases associated with certain malignancies and taking bisphosphonates; and patients with multiple myeloma and taking bisphosphonates.

With respect to use in chronic renal failure, the PBAC again acknowledged that particularly large doses of calcium were required in the treatment of this condition and therefore these patients would be particularly disadvantaged by the de-listing of calcium tablets.

The PBAC recalled that the PBS listings for the anti-resorptive agents (including alendronate, risedronate, raloxifene and recently recommended strontium) for established osteoporosis with prior fracture, had been made on the basis that the combination was clinically appropriate, and, when used in combination with calcium, the cost-effectiveness ratio was acceptable. Similarly, the cost-effectiveness of the bisphosphonates in the treatment of bone metastases and multiple myeloma was acceptable on the basis of co-administration with calcium. The PBAC was concerned that these patient groups would not be optimally treated if they ceased taking calcium tablets should they become less affordable by de-listing.

The PBAC considered an authority required listing for calcium for the patient groups identified above would ensure that calcium would not be subsidised for dietary supplementation.

Australian National Audit Office

29 July 2005

Ms Jane Halton PSM
Secretary
Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601

Dear Ms Halton

Performance Audit: Pharmaceutical Benefits Scheme

The Auditor-General has approved the conduct of a performance audit of an aspect of the Department of Health and Ageing's management of the Pharmaceutical Benefits Scheme (PBS), pursuant to Part 4, Division 2 of the *Auditor-General Act*. As required by sub-section 15.2, a report on the audit will be tabled in Parliament and provided to the Minister as soon as practicable after completion of the audit.

The objective of the audit is:

> In the light of Pharmaceutical Benefits Advisory Committee recommendations, to examine how effectively the Department of Health and Ageing manages the risk of Pharmaceutical Benefits Scheme medicines not be used according to Pharmaceutical Benefits Scheme subsidy conditions.

It is proposed that the audit will look at two areas of the Department's management of the program:

- during listing, how Health identifies and implements measures to decrease the risks of PBS medicines being used outside subsidy conditions; and
- following listing, how Health confirms that usage and expenditure of PBS medicines is consistent with estimates.

The audit team will consist of Dr Paul Nicoll, Executive Director, Ms Deborah Jackson, Senior Director, and Ms Andrea Donaldson, Performance Analyst.

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Centenary House 19 National Circuit
BARTON ACT
Phone (02) 6203 7300 Fax (02) 6203 7777

In order to discuss the audit issues, scope and approach, and to officially commence the audit fieldwork, we propose an opening interview with relevant officers from the Department of Health and Ageing. We will contact you shortly to arrange a convenient time for this interview. It is anticipated that fieldwork will be conducted from August to October 2005, and the report will be tabled in June 2006. The ANAO has also written to Ms Catherine Argall, Managing Director of the Health Insurance Commission, and Professor Lloyd Sansom, Chair of the Pharmaceutical Benefits Advisory Committee, to inform them of this audit.

Please contact Dr Nicoll on telephone number 6203 7759 or myself on 6203 7360 if you would like to discuss any aspect of this performance audit.

Yours sincerely

J Meert
Group Executive Director
Performance Audit Services Group

cc: Mr Phillip Jones
Audit and Fraud Control Branch
Department of Health and Ageing

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-160

OUTCOME 2: Medicines and Medical Services

Topic: INDEPENDENT REVIEW OF ASSISTED REPRODUCTIVE TECHNOLOGIES

Written Question on Notice

Senator Stott Despoja asked:

The media release issued by the Government announcing the Independent Review of Assisted Reproductive Technologies stated "The review will report to the Minister by the end of February 2006." (4/5/05) Is the Review on schedule to report back by this date?

Answer:

Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-161

OUTCOME 2: Medicines and Medical Services

Topic: INDEPENDENT REVIEW OF ASSISTED REPRODUCTIVE TECHNOLOGIES

Written Question on Notice

Senator Stott Despoja asked:

Can you explain how the review will be conducted? Will the review include hearings? If so, will these be public hearings and when and where will they take place? Which stakeholders' will be heard?

Answer:

The Review of Assisted Reproductive Technologies (ART) will consider and advise the Government on the clinical and cost-effectiveness of ART for the purposes of public funding under the Medicare Benefits Schedule, in light of the most recent evidence from Australia and overseas.

A Review Committee, chaired by Professor Ian Fraser, Professor of Reproductive Medicine, University of Sydney, has been formed to conduct the Review. The Committee comprises Dr Andrew Pesce, Professor Peter Illingworth and Dr Terese McGee, clinicians with experience in fertility treatments, Ms Bettina Arndt, a consumer representative, and the Commonwealth Medical Officer, Professor John Horvath. The Committee is reviewing recent literature on ART, and current clinical practice in Australia and overseas, and is expected to report by the end of February 2006. Its Terms of Reference are attached.

While the Review is not conducting public hearings, it is consulting with key stakeholders. To date discussions have been held with *ACCESS* - Australia's National Infertility Network, the Fertility Society of Australia and the IVF Directors Group.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-163

OUTCOME 2: Medicines and Medical Services

Topic: INDEPENDENT REVIEW OF ASSISTED REPRODUCTIVE TECHNOLOGIES

Written Question on Notice

Senator Stott Despoja asked:

The media release also says "the AMA had not been advised of the inclusion of 'clinical appropriateness' in talks with the Government and had no expectation or anticipation that the review would extend into the clinical area." (AMA media release 5/7/05) Given that the Government consulted with the AMA about the Review, why was the AMA not told in that this would be one of the Review's terms of reference?

Answer:

Following discussion with the Australian Medical Association (AMA) the Government framed and announced the Terms of Reference for the review of Assisted Reproductive Technology (ART) on 4 July 2005. The Terms of Reference include "the clinical appropriateness of ART interventions for the management of infertility, including societal impacts".

Consideration of clinical issues, including the clinical appropriateness of ART, is an essential aspect of the review. It was the Government's prerogative to determine the Terms of Reference, informed by the views of stakeholders.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-164

OUTCOME 2: Medicines and Medical Services

Topic: INDEPENDENT REVIEW OF ASSISTED REPRODUCTIVE TECHNOLOGIES

Written Question on Notice

Senator Stott Despoja asked:

AMA President, Dr Mukesh Haikerwal has said "A major concern is the Government's apparent invasion of the consulting room to question clinical practice." (AMA media release 5/7/05) Is it the role of the Government to intervene in clinical practice?

Answer:

The Government does not intervene in clinical practice. Clinical treatment remains a decision of the individual doctor and his/her patient.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-199

OUTCOME 2: Medicines and Medical Services

Topic: IMPACT OF 100% MEDICARE ON DOCTORS' INCOME

Written Question on Notice

Senator McLucas asked:

(a) Does the Department know how doctors use the additional rebate received under the 100% Medicare package?
(b) How much of this goes to the GPs?
(c) What is the average increase in income as a result of this provision?
(d) How much of this is handed on in reduced out-of-pocket costs to patients?

Answer:

(a), (b) and (d)
From 1 January 2005, the Medicare rebate for GP attendances increased from 85% to 100% of the Medicare schedule fee. For a standard consultation by a vocationally recognised GP, the Medicare rebate increased by $4.60 from $26.25 to $30.85. 100% Medicare applies to both bulk billed and non-bulk billed services.

Where services are bulk billed (approximately three-quarters of all GP attendances), all of the Medicare rebate, including the additional $4.60, is paid to the GP. Where services are not bulk billed, it is not possible to quantify what proportion of the additional $4.60 is paid to the GP or passed onto the patient in the form of lower out-of-pocket expenses due to the influence of other factors on co-payments.

(c)
It is not possible to calculate the average increase in GP income from the 100% Medicare rebate in isolation from other measures.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-258

OUTCOME 2: Medicines and Medical Services

Topic: AMENDMENT TO SECTION 19A OF THE HEALTH INSURANCE ACT

Hansard Page: CA 40

Senator McLucas asked:

What are the eight examples of situations where new technologies have been claimed under an item without having received MSAC approval?

Answer:

During 2003 and 2004 there were eight instances where it appeared that items were being used inappropriately for new technologies, as follows:

1. Vertebroplasty: A procedure involving the injection of artificial bone cement and an opacifier into the marrow space of fractured vertebra. This procedure was being claimed under Medicare Benefits Schedule (MBS) item 47684 (spine, treatment of fracture, dislocation or fracture or dislocation, with spinal cord involvement, with immobilisation by calipers) but did not use calipers for immobilisation.
2. Collagen meniscus implants (CMI): These implants are used to replace torn or damaged cartilages of the knee. This procedure was being claimed under items 49560 or 49561 (both items for variations of arthroscopic knee surgery) even though this procedure does not include meniscectomy. There are no items in the MBS which cover CMI.
3. Peripheral nerve stimulator implants: These implants are used to stimulate nerves with cutaneous placement outside of the spinal cord for the management of chronic pain. MBS item 39130 (epidural lead, percutaneous placement) was being claimed inappropriately for this procedure as it does not involve percutaneous placement.
4. Uterine artery embolisation: A procedure used for blocking the blood flow to treat fibroids. This is a new procedure which was being claimed under MBS item 35321 (peripheral arterial or venous catheterisation). When this item was introduced, it was not envisaged to cover uterine artery embolisms.
5. Carotid stenting: A procedure where a tube, usually metallic, is inserted into the carotid artery to widen narrowed arteries and maintain blood flow to the brain. Either MBS item 33500 (endarterectomy of artery or arteries of the neck) or MBS item 35309 (transluminal stent insertion – 1 limb) were being claimed. Neither item was intended for carotid stenting.

6. Intracytoplasmic sperm injection: This is a procedure used to retrieve sperm for invitrofertilisation. This procedure was being claimed under either MBS item 30074 or 30075 (diagnostic biopsy of lymph gland muscle or other deep tissue or organ). However the purpose of the procedure in this case was not diagnostic testing but sperm extraction for invitrofertilisation procedures and the testis is not considered to be a deep tissue or organ.
7. Amplatz devices: A device inserted to treat atrial septal defects. This procedure was being claimed under MBS item 38742 (Atrial septal defect, closure by open exposure direct suture or patch, for congential heart disease). Amplatz devices are inserted under a closed operative procedure. There are no MBS items that describe the techniques using the Amplatz device for the treatment of atrial septal defects.
8. Spinal disc replacement surgery: A procedure where spinal discs are replaced with prostheses. This procedure was being claimed under MBS item numbers 48660 (spinal fusion) and 48684 (spine internal segment fixation) for spinal disc replacement surgery. Neither item describes spinal disc replacement surgery.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-352

OUTCOME 2: Medicines and Medical Services

Topic: ONLINE BILLING

Written Question on Notice

Senator McLucas asked:

What is the Department doing to address the concerns that GPs have about how this system currently operates, viz: that the transactions are in real time?

Answer:

The Department is aware of the perceived limitations by GPs with the current system of Medicare online claiming and is working with the Department of Human Services to explore a range of options to improve claiming arrangements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-257

OUTCOME 2: Medicines and Medical Services

Topic: HIV TESTING FOR PREGNANT WOMEN

Hansard Page: CA 43

Senator McLucas asked:

Senator McLUCAS—The public education in the Torres Strait, especially the top western islands, is very high. When you see the great big box of condoms that comes in on the ferry every month, you realise that it is working. So that is good. How would the Medicare item work? I am interested to know why you need a separate item for pregnant women. Can't I just roll up and get an HIV test? Do I have to have some indication that I might need it?

Ms Halton—My understanding is that we have not actually subsidised HIV testing broadly for anyone and everyone.

Senator McLUCAS—There is no item for HIV testing at the moment.

Ms Halton—Let us come back to you on notice in respect of the specific provisions. But most of the HIV testing, I think you would be aware, has been conducted by the states and in respect of things like life insurance et cetera. This was a new thing to have done.

Senator McLUCAS—So if an Indigenous woman presents to her GP and says, 'I'm pregnant,' she will get an HIV test as part of the care process. Is that how it would work?

Ms Halton—Again, that is my understanding. But I am happy, by the time we get onto 'Indigenous health' this afternoon, for us to get someone to confirm the precise arrangements and we will revisit the issue, if you are happy to do that.

Answer:

In launching the Fifth National HIV/AIDS Strategy the Minister announced the Government's decision, in principle, to make diagnostic testing for HIV/AIDS available under Medicare. The Minister further confirmed that the Government will ensure that existing testing principles of voluntary testing, confidentiality and pre- and post-test counselling will be maintained.

With effect from 1 November 2005, HIV diagnostic serology testing can be claimed against either the general serology items or as part of the pregnancy-specific serology items in the Medicare Benefits Schedule (MBS) (Items 69384, 69387, 69390, 69393, 69396, 69399, 69402, 69405, 69408, 69411, 69413, 69415).

There are currently no restrictions on the utilisation of these items in addition to those general requirements for Medicare eligibility.

Through the use of these general items patient confidentiality can be maintained while providing MBS funding for the tests. The items further highlight the need for specific counselling of patients by requesting practitioners both prior to testing and following reporting.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-260

OUTCOME 2: Medicines and Medical Services

Topic: SUBMISSIONS TO THE MEDICARE BENEFITS CONSULTATIVE COMMITTEE (MBCC)

Hansard Page: CA 37

Senator Allison asked:

(a) On average, how many submissions are received by the committee every year in relation to changing Medicare items?

(b) Do you have a schedule that shows how many there have been over, say, the last few years?

Answer:

(a) Submissions to the Medicare Benefits Consultative Committee (MBCC) are initially received by the Department or the Australian Medical Association. They are assessed for appropriateness and if acceptable are referred to the MBCC for consideration.

On average, about 14 formal submissions are considered by the MBCC every year. Changes to diagnostic imaging and pathology services are managed under Memoranda of Understanding, and are not considered by the MBCC.

(b) The number of MBCC submissions received since 2003 is outlined below.

Year	**No. of Submissions**
2003	**15**
2004	**10**
2005	**19**
Total	**44**

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Questions: E05-327

OUTCOME 2: Medicines and Medical Services

Topic: MEDICARE REBATES FOR SERVICES PROVIDED BY ABORIGINAL HEALTH WORKERS (AHWs)

Written Question on Notice

Senator Patricia Crossin asked:

a) I understand that AHWs are eligible as allied health care providers for the delivery of chronic care under the Medicare Benefits Schedule (item 10950). In addition, the Practice Nurse Incentive makes it possible for AHWs to be employed, if preferable, instead of nurses under this scheme. I also understand that the Dept has been advised that 'wound care' is a core element of an Aboriginal health workers competency. Why then are AHWs excluded from claiming the MBS item for wound care in the same way that practice nurses can?

b) As a result, Practice Nurses are increasingly becoming a preferred workforce due to financial incentives directed towards their employment and not AHWs. I understand, there has been an agreement to allow AHWs in the Northern Territory to claim these rebates. However, AHWs have competencies for wound care in every other jurisdiction, with competencies established from recognised training providers as listed by the Health Insurance Commission. Therefore, why is the Dept preventing AHWs from every other State in Australia from claiming these MBS items?

c) Registration in the NT does not assure skills- it is merely a tool that recognises an AHW holds a qualification. Registration across other jurisdictions is not a viable option in that jurisdictions are seeking alternative and preferred mechanisms to assure skills (other than statutory). Is the Dept intending to modify the MBS descriptor for wound care and immunisation and Pap smears in order to correct this anomalous funding process that provides for a perverse incentive against the employment of AHWs?

Answer:

a, b and c)
As part of the Strengthening Medicare package, the Government introduced new Medicare items for immunisation and wound management services provided by a practice nurse on behalf of a general practitioner.

The Department is aware that some stakeholders would like to see the immunisation and wound management items extended to AHWs in every State and Territory. However, there are a number of issues that would require further investigation before this could occur, eg the lack of registration requirements in all States/Territories, the lack of standardised training and qualification requirements between States/Territories, and current State/Territory legislative restrictions that preclude AHWs from administering vaccines in the majority of jurisdictions.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-002

OUTCOME 2: Medicines and Medical Services

Topic: MEDICARE SAFETY NET THRESHOLDS

Written Question on Notice

Senator Fielding asked:

(a) Please provide details of how many people, for each threshold, in the first year after implementation, are estimated will miss out on qualifying for the Medicare Safety Net as a result of the Government's decision to increase the thresholds.

(b) What is the average payment made to people who reach the higher (now $1000) threshold for the year 2004-05?

(c) What is the average payment made to people who reach the lower (now $500) threshold for the year 2004-05?

(d) Please provide a table that shows, for each threshold and for each of the last twelve months, the number of people who reach the thresholds of the Medicare Safety Net for each income decile and, for each threshold and for each of the last twelve months, the average total value of the subsidy or payment received by people in each income decile.

Answer:

(a) Prior to the change in the thresholds it was expected that 2.5 million people would qualify for the extended Medicare safety net in 2006. With the thresholds at $500 and $1000 it is expected that 1.5 million people will qualify, comprising single people and all the members of families who are expected to reach the thresholds.

Of the one million people who are no longer expected to reach the thresholds in 2006, approximately 800,000 will no longer reach the lower threshold ($500), and approximately 200,000 will no longer reach the higher threshold ($1,000).

(b) The extended Medicare safety net operates on a calendar year basis. The average payment made to people who reached the higher threshold of $700 for the calendar year 2004 and received a Medicare safety net benefit was $324.69.

(c) The average payment made to people who reached the lower threshold of $300 for the calendar year 2004 and received a Medicare safety net benefit was $119.20.

(d) The Department does not hold data by income decile, however the number of families and singles reaching the thresholds for each month in the last twelve months of the extended Medicare safety net are set out below.

November 2004 to October 2005	Numbers of families and singles reaching the lower threshold	Numbers of families and singles reaching the higher threshold	Total numbers of families and singles reaching the thresholds
November	68,169	25,374	93,543
December	65,654	25,956	91,610
January	2,409	1,104	3,513
February	10,332	4,431	14,763
March	19,934	7,858	27,792
April	27,612	11,181	38,793
May	32,785	12,423	45,208
June	44,886	16,635	61,521
July	45,440	16,239	61,679
August	59,841	18,655	78,496
September	55,410	21,903	77,313
October	55,886	21,639	77,525

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-162

OUTCOME 2: Medicines and Medical Services

Topic: INDEPENDENT REVIEW OF ASSISTED REPRODUCTIVE TECHNOLOGIES

Written Question on Notice

Senator Stott Despoja asked:

The Australian Medical Association (AMA) stated in a media release it was "concerned with the inclusion of clinical appropriateness of assisted reproductive technologies (ART) in the terms of reference for the Government's new IVF Review Committee." (AMA media release 5/7/05) Can you clarify what is meant by "the clinical appropriateness of ART interventions for the management of fertility, including societal impacts"?

Answer:

The Review is assessing the clinical appropriateness of ART interventions for the management of infertility, including societal impacts. For the purpose of this Review, clinical appropriateness refers to the outcome of a process of clinical decision making that maximises net gain within society's available resources, including consideration of clinical evidence, the setting in which the service is provided and expected outcomes. [1]

1 This definition is based on an article by Buetow SA, Sibbald B, Cantrill JA, Halliwell S. Appropriateness in health care: application to prescribing. *Social Science & Medicine* 1997;45(2):261-271.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-177

OUTCOME 2: Medicines and Medical Services

Topic: PBS SAFETY NET CHANGES/20 DAY RULE

Written Question on Notice

Senator McLucas asked:

What type of medicines will be exempt from this ruling?

a) Will asthma medicines be exempt?
b) Will pain relief medicines be exempt?
c) Will medicines used to treat mental illness be exempt?

Answer:

The Minister for Health and Ageing is responsible for determining the medicines which are subject to the Safety Net 20 day rule. The legislation relating to the Safety Net 20 day rule arrangements was passed by Parliament in December 2005. The list of specified medicines is contained in the *National Health (Pharmaceutical Benefits – early supply) Instrument 2005* made under subsection 84AAA(2) of the *National Health Act 1953*.

The list of medicines subject to the Safety Net 20 day rule (if supplied within 20 days of a previous supply) does not include:

(a) metered dose inhalers for asthma (some tablets for asthma are included)
(b) medicines for pain
(c) medicines for the management of schizophrenia, depression, or Alzheimer's disease.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-259

OUTCOME 2: Medicines and Medical Services

Topic: CHANGES TO MEDICARE BENEFITS FEES

Hansard Page: CA 38

Senator Allison asked:

(a) Do you have records of what WCI-5 has been in percentage terms over, say, the last four or five years?

(b) Is it possible to get a list of the rebates which have been altered, whether increased, decreased or not increased at the rate of the indexation that is common to other rebates, for 2005?

(c) Is it possible to get a list of the variations from the norm, not for new procedures but for existing procedures, for 2005?

Answer:

(a) Over the last 4 years, the indexation rates by WCI-5 in percentage terms were:

1 November 2002	**2.5%**
1 November 2003	**2.5%**
1 November 2004	**2.1%**
1 November 2005	**2.0%**

(b) On 1 November 2005, all services in the General Medical Services Table of the Medicare Benefits Schedule were subject to WCI-5 indexation rate of 2.0% with the exception of items in Group A2 (other non-referred attendances), acupuncture attendance item 173, Group A19 items (PIP incentive payments, other non-referred attendances) and Group T10 Relative Value Guide for Anaesthetic (RVG) items.

As services in the Diagnostic Imaging Services Table and the Pathology Services Table are managed under Memoranda of Understanding with the relevant medical professional groups, separate indexation rates apply to those Tables.

(c) In 2005 a number of rebates were altered at a rate different from or in addition to WCI-5 indexation:

In January 2005

- The Schedule fee for the emergency after-hours items (1, 2, 97, 601, 602, 697 and 698) was increased by $10: and additionally, the Medicare benefit applicable to non-referred attendances (ie consultations) provided by GPs increased from 85% to 100% of the Schedule fee, except where the patient has been admitted to hospital which would still be rebatable at 75%. The 100% Medicare rebate also applies to services provided by practice nurses on behalf of GPs.

In November 2005:

- there was no fee increase or indexation for Group A2 (other non-referred attendances), acupuncture attendance item 173 or Group A19 (PIP incentive payments, other non-referred attendances);
- fees for items in intensive care services in Subgroups 9 and 10 were increased as part of a package of changes to reflect changed clinical practice and the increase in complexity over the last ten years;
- as part of a funding package agreed between the Department and the Australian Society of Anaesthetists, the RVG unit fee was increased from $16.85 to $17.15; and
- the fees for paediatric orthopaedic items 50349 and 50351 were increased to $271.70 from $135.85 and $1,355.20 from $847.00 respectively, to acknowledge the relative complexity of these procedures.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-261

OUTCOME 2: Medicines and Medical Services

Topic: REGISTRATION STATISTICS FOR MEDICARE SAFETY NET

Hansard Page: CA 33

Senator McLucas asked:

(a) What is the monthly registration for the Medicare safety net —it is a cumulative figure?

(b) When a family changes its composition, is that counted as a re-registration? What do you do with that?

Answer:

(a) Yes.

(b) Additions or deletions to a registered family are not counted as re-registrations. If a family's composition changes such that a new family is formed (eg as a result of separation or divorce) the new family composition may need to be registered and that is counted as a new registration.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-354

OUTCOME 2: Medicines and Medical Services

Topic: REGISTRATION LEVELS – MEDICARE SAFETY NET

Hansard Page: CA 33

Senator McLucas asked:

What are the registration levels for this year for the Medicare safety net?

Answer:

Calendar Year 2005	Total families registered at the end of calendar month	Net Number of families registering during month*
January	3,705,214	18,471
February	3,751,754	46,540
March	3,792,266	40,512
April	3,825,927	33,661
May	3,870,978	45,051
June	3,898,855	27,877
July	3,933,288	34,433
August	3,984,262	50,974
September	3,997,941	13,679
October	4,023,300	25,359
November	4,044,923	21,623
December	4,062,299	17,376

*The net count of families comprises new registrations and ceased registrations. Figures are extracted from reports provided by Medicare Australia. Some periods may not be an exact calendar month, due to variations in the date on which these reports were produced.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-353

OUTCOME 2: Medicines and Medical Services

Topic: ONLINE BILLING

Written Question on Notice

Senator McLucas asked:

Does the Department plan to re-introduce the HIC Online proposal from Fairer Medicare where patients were required to only pay the gap?

Answer:

It is not current Government policy to enable patients to pay only the gap for Medicare services at the point of service delivery.

Medicare billing arrangements are matters for Government to determine. The Department cannot comment on whether or not the Government will at some time in the future vary policy in this regards.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-176

OUTCOME 2: Medicines and Medical Services

Topic: PBS SAFETY NET CHANGES/20 DAY RULE

Written Question on Notice

Senator McLucas asked:

What modelling has been done on the impact of these changes on the rate of growth of the PBS?

Answer:

It is expected that the impact of these changes (Pharmaceutical Benefits Scheme (PBS) safety net thresholds adjustments and 20 day supply rule) will result in a 0.3 percentage point reduction in the rate of growth of the PBS over the period 2004-05 to 2008-09, from a previously forecast four year growth of 9.3% to a current forecast growth of 9.0%.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-178

OUTCOME 2: Medicines and Medical Services

Topic: PBS SAFETY NET CHANGES/20 DAY RULE

Written Question on Notice

Senator McLucas asked:

a) On what basis will the Minister decide which medicines will be exempt from the 20 day rule?

b) Which expert bodies will the Minister consult?

Answer:

a) The legislation does not specify or limit the considerations that the Minister could take into account in determining which medicines will be subject to the Safety Net 20 day rule or which medicines will be excluded.

b) The Minister may seek advice from any source, including experts. Advice from the Pharmaceutical Benefits Advisory Committee (PBAC) will be available to the Minister.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-179

OUTCOME 2: Medicines and Medical Services

Topic: PBS SAFETY NET CHANGES/20 DAY RULE

Written Question on Notice

Senator McLucas asked:

How will doctors know what type of prescription they should write for a patient?

Answer:

The Safety Net 20 day rule does not affect the processes and requirements for writing Pharmaceutical Benefits Scheme (PBS) prescriptions.

The Safety Net 20 day rule comes into play, for some medicines, if an early supply of a repeat prescription is required under the existing rules for 'immediate supply'. The prescriber is not directly involved in the person requesting, or a pharmacist providing, an early repeat supply of a PBS medicine. The circumstances where 'immediate supply' is allowed are unchanged.

Under Regulation 24 a prescriber can order that all repeats of a prescription be supplied at the one time. This provides for people requiring on-going therapy and who are unable to access repeat supplies due to distance from a pharmacy. This operates separately from 'immediate supply' provisions. There is no change to Regulation 24 arrangements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-180

OUTCOME 2: Medicines and Medical Services

Topic: PBS SAFETY NET CHANGES/20 DAY RULE

Written Question on Notice

Senator McLucas asked:

What will happen if a patient loses their medicines and these need to be replaced?

Answer:

Under the existing arrangements for 'immediate supply' (Regulation 25), an early repeat supply can be made as a PBS-subsidised supply only if the medicine has been destroyed, lost or stolen, or having regard to the person's circumstances, is necessary without delay for the treatment of the person. The circumstances in which an early PBS-subsidised repeat supply can be made are unchanged by the new Safety Net 20 day rule.

Loss of a medication is one of the circumstances where an early repeat PBS-subsidised supply is allowed.

The difference with the new Safety Net 20 day rule, is that for some medicines, early repeat supplies would fall outside Safety Net, that is, the patient contribution would not accrue to the Safety Net tally, and the charge would be the person's usual PBS rate, not the Safety Net rate.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-181

OUTCOME 2: Medicines and Medical Services

Topic: PBS SAFETY NET CHANGES/20 DAY RULE

Written Question on Notice

Senator McLucas asked:

a) Was the pharmacy profession consulted about these changes?

b) Were doctors' groups consulted about these changes?

Answer:

a) As these measures were announced in the Budget context, it would not have been appropriate to consult third party organisations prior to an announcement. The pharmacy profession has been consulted on implementation issues.

The Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Australian Association of Consultant Pharmacy, and the Society of Hospital Pharmacists of Australia have been consulted on implementation issues.

b) No.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-182

OUTCOME 2: Medicines and Medical Services

Topic: PBS SAFETY NET CHANGES/20 DAY RULE

Written Question on Notice

Senator McLucas asked:

a) Did the Department consider other possible ways to educate people about hoarding medicines?

b) Why were these not implemented?

Answer:

(a) and (b)

Medicare Australia brochures on the Pharmaceutical Benefits Scheme (PBS) (eg. *How to save money on medicines*) include information which encourages people to access medicines responsibly, not to obtain extra quantities of medicines before they are needed, and not to store large amounts of medicines. The risks of stockpiling are outlined.

The community awareness campaign about PBS medicines which ran during 2003 and 2004 informed consumers of a number of important quality use of medicines messages including filling prescriptions only as required for personal use and not stockpiling.

The Australian Government also funds the National Prescribing Service to provide a range of consumer education initiatives about quality use of medicines.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-183

OUTCOME 2: Medicines and Medical Services

Topic: PBS REFORM

Written Question on Notice

Senator McLucas asked:

(a) Is the Department aware of recent media reports about an interdepartmental working group looking at PBS reform? For example, the Financial Review of 24 September reported an inter-departmental working group looking at PBS reform and generics and co-payment policies.
(b) What departments are involved in this IDC? Is the Department of Health and Ageing involved?
(c) What is the involvement of the Minister for Health and Ageing?
(d) What is the working group examining? What are its terms of reference?

Answer:

(a) Yes. The Department is aware of media reports along these lines.
(b) The Interdepartmental Committee (IDC) comprises representatives from a number of government departments including the Departments of Health and Ageing, Industry, Tourism and Resources, Prime Minister and Cabinet, Finance and Administration, and the Treasury.
(c) The IDC will report to Minsters when it concludes its deliberations.
(d) The IDC is considering a range of strategic issues of relevance to the PBS including ways to ensure value for money for the Australian taxpayer and maintain the affordability of the program into the future.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-184

OUTCOME 2: Medicines and Medical Services

Topic: PBS REFORM

Written Question on Notice

Senator McLucas asked:

Is the Government considering changes to co-payment policies? Are there further co-payment increases planned?

Answer:

The Department cannot provide information on policy that may or may not currently be under consideration by Government.

Co-payments will be increased according to movements in the Consumer Price Index, on 1 January 2006.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-185

OUTCOME 2: Medicines and Medical Services

Topic: PBS REFORM

Written Question on Notice

Senator McLucas asked:

Is the Government considering a system where a lower co-payment applies to generic manufacturers?

Answer:

The Department cannot provide information on policy that may or may not currently be under consideration by Government.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-186

OUTCOME 2: Medicines and Medical Services

Topic: THE PBS 12.5% PRICE REDUCTION MEASURE FOR GENERIC DRUGS

Written Question on Notice

Senator McLucas asked:

a) Given the substantial number of changes to the 12.5% generics policy since it was first put forward, is the Government planning to conduct a review of the 12.5% policy?
b) If so, who will do it, what will it look at and when will it be done? Will it be public and will the results be released?

Answer:

a) Yes.

b) The 12.5% price reduction policy is scheduled for review around April 2006. The Minister for Health and Ageing will determine how the review will be conducted and whether its results will be released. Decisions on these matters have not yet been taken.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-187

OUTCOME 2: Medicines and Medical Services

Topic: PHARMACY AGREEMENT

Written Question on Notice

Senator McLucas asked:

(a) When is it expected that the Fourth Pharmacy Agreement will be in place?
(b) Will this delay affect the Government's Budget forward estimates?
(c) How will the forward estimates be changed?

Answer:

(a) The Fourth Community Pharmacy Agreement was signed by the Australian Government and the Pharmacy Guild of Australia on 16 November 2005. It commenced 1 December 2005.
(b) The delays in finalising the agreement will have no impact on the current forward estimates.
(c) See (b) above.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-188

OUTCOME 2: Medicines and medical services

Topic: PHARMACY AGREEMENT

Written Question on Notice

Senator McLucas asked:

Given the apparent agreement over the Pharmacy Location Rules (as announced last week), why is the legislative provision contained in the Health Legislation Amendment Bill 2005 which would extend the current authority of the Australian Community Pharmacy Authority until 30 June 2006 still needed?

Answer:

The new pharmacy location arrangement provided for in the Fourth Community Pharmacy Agreement commences from 1 July 2006. The Health Legislation Amendment Bill 2005 allows the existing location rules to continue until that time. A Bill that gives effect to the new location arrangements will be introduced in early 2006.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-189

OUTCOME 2: Medicines and Medical Services

Written Question on Notice

Topic: PHARMACY AGREEMENT

Senator McLucas asked:

What assumptions are made in the Pharmacy Agreement about the growth in prescriptions over the life of the Agreement?
What assumptions are made in the Pharmacy Agreement about the rate of growth of the PBS over the life of the Agreement?

Answer:

The Agreement has been negotiated and agreed based on the official Government Forward Estimates for the Pharmaceutical Benefits Scheme (PBS) and the Schedule of Pharmaceutical Benefits medicines dispensed under the Repatriation Pharmaceutical Benefits Scheme (RPBS) arrangements, as at August 2005.

The estimated growth in PBS and RPBS prescription volumes as they relate to payments to pharmacists, are set out in Clause 15 of the Fourth Community Pharmacy Agreement, as follows:

	2005-06	**2006-07**	**2007-08**	**2008-09**	**2009-10**
PBS & RPBS Prescription Volumes*	186.208	199.416	209.282	218.847	228.333

* Includes PBS medicines and medicines listed on the Schedule of Pharmaceutical Benefits provided under the RPBS.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-191

OUTCOME 2: Medicines and Medical Services

Topic: PHARMACY AGREEMENT

Written Question on Notice

Senator McLucas asked:

(a) In the year to September PBS scripts fell by 7.3%. If this fall in PBS scripts continues, will the Pharmacy Agreement be renegotiated?
(b) In the year to September PBS growth was only 4.6%. If this fall in PBS costs continues, will the Pharmacy Agreement be renegotiated?

Answer:

(a) The Fourth Community Pharmacy Agreement includes provision to adjust the dispensing fee, should Pharmaceutical Benefits Scheme (PBS) or Repatriation Pharmaceutical Benefits Scheme (RPBS) prescription volumes vary significantly from those set out in the Agreement (Part 2 of the Agreement refers).

Payments to pharmacists will be adjusted if prescription volumes are less than 95% or greater than 105% of the forecast forward estimates for any particular year.

For every PBS/RPBS prescription above or below these thresholds, the value of payments to pharmacists (retail mark up and dispensing fee) will be shared 50:50 between pharmacy and the Australian Government.

(b) Changes to growth in the average price of PBS medicines will not affect payments to pharmacists. The provisions of the Fourth Community Pharmacy Agreement as described at (a) above, relate to changes in the volume of PBS and RPBS prescriptions, not changes in the average price of these medicines.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-192

OUTCOME 2: Medicines and Medical Services

Topic: PHARMACY AGREEMENT

Written Question on Notice

Senator McLucas asked:

Why are the growth parameters of the Pharmacy Agreement so different from the current figures?

Answer:

The growth parameters for prescription volumes set out in the Fourth Community Pharmacy Agreement are based on official Government Forward Estimates for the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS), as at August 2005.

The Forward Estimates are based on extensive historical data, and the use of forecasting methods to project future growth. In line with standard government processes, the estimates are updated periodically, and therefore change over time.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-193

OUTCOME 2: Medicines and Medical Services

Topic: NEW ARRANGEMENTS FOR PBAC

Written Question on Notice

Senator McLucas asked:

a) What steps have been, or will be introduced, to ensure that PBAC has access to sufficient expertise around population programs and herd immunity benefits when considering vaccine applications?
b) Whether the PBAC will make use of the ATAGI in assessing vaccine applications either as a formal sub-committee or external advisory group?
c) If the new arrangements will be implemented in time for the first batch of vaccine applications to come forward to the PBAC in March 2006?

Answer:

a) The *National Health Amendment (Immunisation Program) Act 2005* was agreed to by both houses of Parliament on 10 November 2005. It provides for two additional members of the Pharmaceutical Benefits Advisory Committee (PBAC). These members are expected to have relevant expertise to review submissions to the PBAC seeking funding of vaccines. It is expected that one of these two members will also be a member of the Australian Technical Advisory Group on Immunisation (ATAGI). Similarly, two additional members with relevant expertise will be appointed to the Economics Sub-Committee of the PBAC.
b) The PBAC will make use of the ATAGI as an external advisory group in assessing vaccine applications as required.
c) The new arrangements are scheduled for implementation in time to consider any vaccine applications lodged in March 2006 for PBAC consideration.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-194

OUTCOME 2: Medicines and Medical Services

Topic: NEW ARRANGEMENTS FOR PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC)

Written Question on Notice

Senator McLucas asked:

More specifically, can the Department outline:
How the PBAC processes have been altered to take into account the:

a) Fundamental difference between assessing a vaccine for inclusion in the National Immunisation on the one hand, and the assessment of an application to list a pharmaceutical on the PBS for individual treatment?
b) How the PBAC cost-effectiveness assessment will take into account the added population benefit of immunisation programs through herd immunity?
c) What consultation has been undertaken in the revision of these procedures and guidelines?

Answer:

a) An appendix to the Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee is being developed. The appendix will provide guidance for potential applicants as to whether funding under the National Immunisation Program or listing on the Pharmaceutical Benefits Scheme (PBS) should be sought for a new vaccine.
b) This appendix will state that an applicant should submit relevant evidence in support of a claim for added population benefit of an immunisation program involving its vaccine through herd immunity. This claim should be supported by mathematical modelling of assumptions where this is necessary.
c) The Economics Sub-Committee of the PBAC is developing the appendix on behalf of the PBAC. Formal consultations to date have involved (i) the Medicines Australia Vaccines Industry Group, which is representing all vaccine companies in Australia whether or not the vaccine company is a member of Medicines Australia; and (ii) Australian Technical Advisory Group on Immunisation (ATAGI) members representing this recently re-constituted committee.

   A draft-for-discussion version of this appendix was provided for consideration by the ATAGI at its first face-to-face meeting in November 2005. Further consultation is being planned through ATAGI with other bodies involved with vaccine supply such as the National Immunisation Committee and Communicable Diseases Network Australia. Following ATAGI consideration, the draft appendix will be placed on the department's website with an invitation for wider public comment.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-195

OUTCOME 2: Medicines and Medical Services

Topic: NEW ARRANGEMENTS FOR PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC)

Written Question on Notice

Senator McLucas asked:

Apart from the inclusion of two members to the PBAC, will the PBAC utilise the expertise available on ATAGI when considering vaccine applications?

Answer:

Yes, as required.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-196

OUTCOME 2: Medicines and Medical Services

Topic: NEW ARRANGEMENTS FOR PBAC

Written Question on Notice

Senator McLucas asked:

The new bill provides for the Minister to direct the PBAC to establish a sub-committee to assist PBAC in its vaccine funding advisory role.

a) Will PBAC be directed to establish such a committee?
b) Has the Department provided such advice to the Minister?
c) Does the Department support the value of formal linkages between the PBAC and ATAGI?
d) When might an announcement on this be made?

Answer:

a & b) The *National Health Amendment (Immunisation Program) Act 2005* does not make such a provision therefore no action to establish such a sub-committee has been taken.

c) Yes.

d) The Department will consult the Minister, the Pharmaceutical Benefits Advisory Committee (PBAC) and the Australian Technical Advisory Group on Immunisation (ATAGI) on the nature and timing of any relevant announcements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-197

OUTCOME 2: Medicines and Medical Services

Topic: NEW ARRANGEMENTS FOR PBAC

Written Question on Notice

Senator McLucas asked:

If no new vaccine subcommittee is established, will the ATAGI be asked to provide advice to existing PBAC subcommittees (such as the economics subcommittee) in relation to the technical and population benefits of immunisation?

Answer:

In general, it is expected that advice from the Australian Technical Advisory Group on Immunisation (ATAGI) will be provided to the Pharmaceutical Benefits Advisory Committee (PBAC) as required. There may be a need, on some issues, for the Economics Sub-Committee (ESC) to also take into account the advice that ATAGI provides.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-262

OUTCOME 2: Medicines and Medical Services

Topic: ALZHEIMER DRUGS

Hansard Page: CA 33

Senator McLucas asked:

Can you tell me the number of people that move from one Alzheimer drug to the next one and then to the next one?

Answer:

In 2004, 1007 patients were dispensed more than one of the PBS listed drugs donepezil (Aricept®), rivastigmine (Exelon®) and galantamine (Reminyl®) for the treatment of Alzheimer Disease.

Of these, 28 patients were dispensed all three drugs.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-263

OUTCOME 2: Medicines and Medical Services

Topic: ALZHEIMER DRUGS

Hansard Page: CA33

Senator McLucas asked:

Is there any problem with taking three different types of Alzheimer drugs in sequence like that?

Answer:

There is no additional risk of toxicity from taking donepezil (Aricept®), rivastigmine (Exelon®) and galantamine (Reminyl®) sequentially. However, they must not be taken concurrently because of the accumulation of adverse effects.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-264

OUTCOME 2: Medicines and Medical Services

Topic: WRITTEN AUTHORITY

Hansard Page: CA 32

Senator McLucas asked:

Provide a list of PBS listed drugs that require written authority.

Answer:

Drug Name:	**Brief Indication(s) for PBS subsidy**
Gefitinib (Iressa®)	• locally advanced or metastatic non-small cell lung cancer
Etanercept (Enbrel®)	• ankylosing spondylitis • rheumatoid arthritis • polyarticular course juvenile chronic arthritis
Infliximab (Remicade®)	• ankylosing spondylitis • rheumatoid arthritis
Anakinra (Kineret®)	• rheumatoid arthritis
Adalimumab (Humira®)	• rheumatoid arthritis
Bosentan (Tracleer®)	• primary pulmonary hypertension
Iloprost (Ventacis®)	• primary pulmonary hypertension
Imatinib (Glivec®)	• gastrointestinal stromal tumour • chronic myeloid leukaemia
Donepezil (Aricept®)	• Alzheimers disease (ongoing treatment)
Galantamine (Reminyl®)	• Alzheimers disease (ongoing treatment)
Rivastigmine (Exelon®)	• Alzheimers disease (ongoing treatment)

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-265

OUTCOME 2: Medicines and Medical Services

Topic: ALZHEIMER DRUGS – RURAL AREAS

Hansard Page: CA 33

Senator McLucas asked:

a) What happens in rural areas, where access to specialists is limited?
b) Is there any opportunity for a shared care arrangement with a GP?

Answer:

a) No special arrangements are made for rural areas.

b) The requirement for eligibility of mild to moderately severe Alzheimer's disease is that 'Confirmation of the diagnosis must be made by a specialist/consultant physician'. It is not a requirement that the patient see the specialist. A general practitioner may make the diagnosis and confirm this diagnosis in discussion with a specialist.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-266

OUTCOME 2: Medicines and Medical Services

Topic: INSULIN GLARGINE

Hansard Page: CA 24

Senator Barnett asked:

1. Total number of Australians that would benefit from the listing of Glargine?
2. If so, how many?

Answer:

If the Pharmaceutical Benefits Advisory Committee were to recommend the listing of insulin glargine on the Pharmaceutical Benefits Scheme (PBS), the number of patients who would be eligible for treatment would depend on the wording of the PBS restriction. It is therefore not possible to estimate the total number of Australians who would benefit.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-267

OUTCOME 2: Medicines and Medical Services

Topic: PRESCRIPTION DRUGS

Hansard Page: CA 23

Senator Barnett asked:

Provide the volume and the cost of the top 10 prescription drugs - last three years.

Answer:

Tables One and Two provide information on the top ten prescription drugs by cost and volume respectively.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-268

OUTCOME 2: Medicines and Medical Services

Topic: PRESCRIPTION DRUGS

Hansard Page: CA 23

Senator Barnett asked:

Top 10 drugs by script volume and the cost in terms of growth? Including the strongest growth by drug category.

Answer:

Tables One and Two provide volume and cost data (respectively) on the top ten prescription drugs by rate of growth. Tables Three and Four provides volume and cost data (respectively) on the top ten drug groups by rate of growth.

Table One - Highest Government cost increase PBS Drugs by Generic name
Year ending June 2003 to Year ending June 2005

		Year Ending Jun 03		Year Ending Jun 04		Year Ending Jun 05	
Rank	Drug	Script volume	Govt Cost $	Script volume	Govt Cost $	Script volume	Govt Cost $
1	ATORVASTATIN	5,848,277	314,430,315	6,629,408	368,554,153	7,629,221	433,526,445
2	ESOMEPRAZOLE	944,849	48,861,880	2,051,597	100,249,623	2,745,394	130,782,301
3	TIOTROPIUM BROMIDE	97,217	7,006,564	578,834	42,315,436	885,784	64,398,798
4	SIMVASTATIN	5,056,541	294,159,174	5,526,791	333,669,341	5,849,104	344,032,752
5	CLOPIDOGREL	1,023,755	81,173,216	1,369,634	108,117,378	1,665,471	130,283,908
6	RABEPRAZOLE	486,786	18,942,004	864,542	33,451,099	1,141,132	43,743,625
7	MELOXICAM	663,799	14,884,745	973,400	22,548,914	1,732,160	39,483,197
8	ETANERCEPT	0	0	6,525	12,240,040	12,875	24,233,858
9	EFORMOTEROL with BUDESONIDE	37,849	1,712,514	279,306	12,834,225	464,286	24,440,881
10	ALENDRONIC ACID	1,445,217	74,623,621	1,701,990	87,403,280	1,894,038	96,720,775

Note: Cost figures are on a cash basis and therefore are not consistent with the figures used for the Annual Report and Budget purposes which are reported on an accrual accounting basis.

Table Two - Highest volume Increase PBS Drugs by Generic name
Year ending June 2003 to Year ending June 2005

		Year Ending Jun 03		Year Ending Jun 04		Year Ending Jun 05	
Rank	Drug	Script volume	Govt Cost $	Script volume	Govt Cost $	Script volume	Govt Cost $
1	ESOMEPRAZOLE	944,849	48,861,880	2,051,597	100,249,623	2,745,394	130,782,301
2	ATORVASTATIN	5,848,277	314,430,315	6,629,408	368,554,153	7,629,221	433,526,445
3	MELOXICAM	663,799	14,884,745	973,400	22,548,914	1,732,160	39,483,197
4	SIMVASTATIN	5,056,541	294,159,174	5,526,791	333,669,341	5,849,104	344,032,752
5	TIOTROPIUM BROMIDE	97,217	7,006,564	578,834	42,315,436	885,784	64,398,798
6	RABEPRAZOLE	486,786	18,942,004	864,542	33,451,099	1,141,132	43,743,625
7	CLOPIDOGREL	1,023,755	81,173,216	1,369,634	108,117,378	1,665,471	130,283,908
8	ESCITALOPRAM	0	0	93,486	2,223,485	627,708	15,593,122
9	IRBESARTAN with HYDROCHLOROTHIAZIDE	2,243,913	51,711,014	2,640,518	60,775,672	2,811,442	64,840,819
10	PANTOPRAZOLE	1,845,851	77,953,816	2,037,525	85,330,042	2,375,124	95,142,299

Note: Cost figures are on a cash basis and therefore are not consistent with the figures used for the Annual Report and Budget purposes which are reported on an accrual accounting basis.

Table Three - Highest Government cost increase PBS Drugs by Drug Group
Year ending June 2003 to Year ending June 2005

		Year Ending Jun 03		Year Ending Jun 04		Year Ending Jun 05	
Rank	ATC Group Level 2	Script volume	Govt Cost $	Script volume	Govt Cost $	Script volume	Govt Cost $
1	SERUM LIPID REDUCING AGENTS	13,320,021	731,459,087	14,709,118	835,541,042	16,215,278	918,740,374
2	DRUGS FOR ACID RELATED DISORDERS	11,291,472	428,527,814	12,266,029	480,817,576	13,147,448	504,362,281
3	ANTITHROMBOTIC AGENTS	3,936,792	123,746,618	4,540,455	154,544,380	5,158,431	177,220,579
4	AGENTS ACTING ON RENIN-ANGIOTENSIN SYSTEM	17,775,765	366,439,144	19,376,940	402,709,093	19,901,853	419,765,729
5	ANTINEOPLASTIC AGENTS	378,693	147,183,954	406,132	167,801,228	439,848	199,821,921
6	PSYCHOLEPTICS	7,245,658	227,409,173	7,224,566	247,431,938	7,299,988	272,719,845
7	IMMUNOSUPPRESSIVE AGENTS	185,869	23,350,934	215,165	39,396,300	259,251	67,148,120
8	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	9,485,438	322,017,132	9,523,344	348,071,969	9,409,505	365,128,310
9	DRUGS FOR TREATMENT OF BONE DISEASES	1,966,630	110,739,959	2,439,353	135,028,145	2,835,103	153,758,487
10	PSYCHOANALEPTICS	11,104,099	317,253,523	12,000,862	350,523,725	12,595,291	360,111,529

Note: Cost figures are on a cash basis and therefore are not consistent with the figures used for the Annual Report and Budget purposes which are reported on an accrual accounting basis.

Table Four - Highest volume increase PBS Drugs by Drug Group
Year ending June 2003 to Year ending June 2005

		Year Ending Jun 03		Year Ending Jun 04		Year Ending Jun 05	
Rank	ATC Group Level 2	Script volume	Govt Cost $	Script volume	Govt Cost $	Script volume	Govt Cost $
1	SERUM LIPID REDUCING AGENTS	13,320,021	731,459,087	14,709,118	835,541,042	16,215,278	918,740,374
2	AGENTS ACTING ON RENIN-ANGIOTENSIN SYSTEM	17,775,765	366,439,144	19,376,940	402,709,093	19,901,853	419,765,729
3	DRUGS FOR ACID RELATED DISORDERS	11,291,472	428,527,814	12,266,029	480,817,576	13,147,448	504,362,281
4	PSYCHOANALEPTICS	11,104,099	317,253,523	12,000,862	350,523,725	12,595,291	360,111,529
5	ANTITHROMBOTIC AGENTS	3,936,792	123,746,618	4,540,455	154,544,380	5,158,431	177,220,579
6	DRUGS FOR TREATMENT OF BONE DISEASES	1,966,630	110,739,959	2,439,353	135,028,145	2,835,103	153,758,487
7	ANTIDIABETIC THERAPY	4,630,466	152,633,689	4,931,545	167,446,211	5,245,377	191,338,930
8	OPHTHALMOLOGICALS	5,964,619	83,438,278	6,233,638	89,823,235	6,576,334	94,755,247
9	BETA BLOCKING AGENTS	4,342,791	57,038,283	4,628,098	67,136,235	4,946,575	76,258,362
10	ANALGESICS	10,588,558	130,774,063	10,914,950	141,925,677	11,183,969	153,387,586

Note: Cost figures are on a cash basis and therefore are not consistent with the figures used for the Annual Report and Budget purposes which are reported on an accrual accounting basis.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-269

OUTCOME 2: Medicines and Medical Services

Topic: DIABETES TYPE I & II

Hansard Page: CA 23

Senator Barnett asked:

In terms of Diabetes I and II can an analysis be done of the prescription drugs that are used and can an analysis be done of the cost over a three year period? Also for oral anti-diabetic drugs, insulin and statins.

Answer

The table below provides volume and cost data for the most recent three financial years on therapies which may be used to treat type I and II diabetes. This includes a total for antidiabetic therapy, broken down into insulins, such as insulin aspart (NovoRapid ®) and oral treatments such as pioglitazone hydrochloride (Actos ®) and rosiglitazone maleate (Avandia ®). It also includes data on serum lipid reducing agents (statins) which include the drugs atorvastatin (Lipitor ®) and simvastatin (Zocor®).

PBS Drugs for Antidiabetic Therapy and Serum Lipid Reduction

Year ending June 2003 to Year ending June 2005

	Year Ending Jun 03		Year Ending Jun 04		Year Ending Jun 05	
ATC Group	Script volume	Govt Cost $	Script volume	Govt Cost $	Script volume	Govt Cost $
TOTAL ANTIDIABETIC THERAPY	4,630,466	152,633,689	4,931,545	167,446,211	5,245,377	191,338,930
INSULINS AND ANALOGUES	513,601	101,364,181	533,158	107,867,073	559,977	115,381,926
ORAL BLOOD GLUCOSE LOWERING DRUGS	4,116,865	51,269,507	4,398,387	59,579,138	4,685,400	75,957,004
SERUM LIPID REDUCING AGENTS	13,320,021	731,459,087	14,709,118	835,541,042	16,215,278	918,740,374

*Note: Cost figures are on a cash basis and therefore differ from figures used for the Annual Report and Budget purposes which are reported on an accrual accounting basis.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-270

OUTCOME 2: Medicines and Medical Services

Topic: OBESITY RELATED DRUGS

Hansard Page: CA 23

Senator Barnett asked:

Can a similar analysis be done of obesity related prescription drugs for the past three years? Your best estimate if that is possible.

Answer:

There are no drugs available on the Pharmaceutical Benefits Scheme which specifically treat obesity. However, there are a number of drugs which treat the complications of obesity such as high blood pressure, Type 2 Diabetes and hyperlipidemia (high lipid levels). Data on the volume and cost of anti-diabetic drugs are provided in the response to Question E05000269.

The table provides data on the volume and cost of antihypertensives and serum lipid reducing agents for the three years ending June 2003 to 2005.

Obesity related prescription drugs
Year ending June 2003 to Year ending June 2005

	ANTIHYPERTENSIVES		SERUM LIPID REDUCING AGENTS	
	Script volume	Govt Cost $	Script volume	Govt Cost $
Year Ending Jun 03	737,039	10,378,235	13,320,021	731,459,087
Year Ending Jun 04	726,253	10,166,040	14,709,118	835,541,042
Year Ending Jun 05	726,247	10,131,964	16,215,278	918,740,374

*Note: Cost figures are on a cash basis and therefore differ from the figures used for the Annual Report and Budget purposes which are reported on an accrual accounting basis.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-271

OUTCOME 2: Medicines and Medical Services

Topic: DIABETES AND OBESITY

Hansard Page: CA 23

Senator Barnett asked:

Provide estimates for the next year or two or three? Can some sort of estimate of the cost be done? (for obesity related prescription drugs)

Answer:

The table below provides the estimate of projected costs and script volumes over the next three financial years for drugs which treat the complications of obesity. Antihypertensives, serum lipid reducing agents and antidiabetic drugs are considered to be major contributors to the treatment of obesity related illness.

Obesity and antidiabetic related prescription drugs estimates to Year ending June 2008

	ANTIHYPERTENSIVES SERUM LIPID REDUCING AGENTS and ANTIDIABETIC DRUGS	
	Script Volume	Govt Cost $
Year Ending Jun 06	24.00 million	1,191.15 million
Year Ending Jun 07	24.30 million	1,389.80 million
Year Ending Jun 08	25.85 million	1,568.20 million

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-272

OUTCOME 2: Medicines and Medical Services

Topic: SCRIPT VOLUMES

Hansard Page: CA 22

Senator Barnett asked:

Script Volumes - breakdown on a state by state and territory by territory basis for the last 3 years?

Answer:

PBS processing by State and Territory (excluding Doctors Bag)
Year ending June 2003 to Year ending June 2005
Volume of prescriptions

	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Australia
Year Ending Jun 03	55,407,095	39,733,159	28,933,428	13,594,071	13,908,981	4,527,363	543,642	1,871,431	158,519,170
Year Ending Jun 04	57,522,388	41,577,645	30,517,672	14,028,160	14,544,454	4,745,820	559,466	1,939,520	165,435,125
Year Ending Jun 05	58,612,737	42,766,141	32,070,184	14,283,055	14,822,026	4,769,403	588,185	1,965,279	169,877,010

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-273

OUTCOME 2: Medicines and Medical Services

Topic: CO-PAYMENT EFFECT OF FORWARD ESTIMATES

Hansard Page: CA 20

Senator Mclucas asked:

How do the increased co-payments affect the forward estimates?

Answer:

The increase in co-payments will result in Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) savings of approximately $890 million over four years. The table presents the year by year and total savings.

PBS COPAYMENTS CHANGES - 1 JANUARY 2005 START DATE

Savings by year	**2004-05**	**2005-06**	**2006-07**	**2007-08**	**4 Year Total**
	$'000	**$'000**	**$'000**	**$'000**	**$'000**
PBS	113,413	250,362	235,560	234,978	834,313
RPBS	7,154	15,792	15,180	15,142	53,268
Grand Total	**120,567**	**266,154**	**250,740**	**250,120**	**887,581**

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-274

OUTCOME 2: Medicines and Medical Services

Topic: PRESCRIBING PATTERNS

Hansard Page: CA 20

Senator McLucas asked:

Identify any other changes in prescribing patterns? Breakdown the major drug categories. The statins - biggest expenditure group. Look at pattern for the statins and one or two of the highest cost or highest volume groups - script variants. Decline in the use of statins over that period, which was not anticipated but shows up in the figures.

Answer:

The table below indicates increases or decreases in script numbers (by date of supply) for financial years since 2000-01 for all Pharmaceutical Benefits Scheme (PBS) drugs dispensed through community pharmacies. The table also indicates increases or decreases for the following high-volume therapeutic main groups:

- A02 DRUGS FOR ACID RELATED DISORDERS (includes proton pump inhibitors);
- C09 AGENTS ACTING ON RENIN-ANGIOTENSIN SYSTEM (comprises ACE inhibitors, Angiotensin II antagonists and their various respective combination products);
- C10 SERUM LIPID REDUCING AGENTS (predominantly statins); and
- N06 PSYCHOANALEPTICS (includes antidepressants such as the selective serotonin reuptake inhibitors).

Table: Percentage increases/(decreases) in script numbers since the previous financial year

	2001-02	2002-03	2003-04	2004-05
PBS overall				
concessional patients	5.8	1.2	4.6	1.4
general patients	(2.9)	(3.8)	6.5	5.8
A02				
concessional patients	14.4	8.0	7.7	4.6
general patients	13.2	8.8	10.4	7.0
C09				
concessional patients	15.5	10.4	10.2	6.8
general patients	12.3	10.3	12.2	9.2
C10				
concessional patients	10.0	8.7	11.0	7.9
general patients	3.9	6.6	12.5	11.0
N06				
concessional patients	8.1	5.2	7.0	2.3
general patients	5.1	6.9	10.9	6.5

Script numbers for general patients are the sum of those recorded for the PBS as well as the estimated number of under co-payment scripts (where no government benefit applies because the dispensed price is below the general co-payment level). The under co-payment data is not captured by Medicare Australia.

Key points from this data are:

- There are fluctuations across years in growth rates for script volumes across the therapeutic groups and between concessional and general patients.
- The recent trend (since the second half of 2004) has seen a decrease in the rate of growth for concessional and general patients for all PBS drugs dispensed through community pharmacies and in each of the therapeutic main groups listed in the table above.
- As a general rule, the rate of increase in script numbers for concessional patients has been less than that for general patients since 2001-02.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-283

OUTCOME 2: Medicines and Medical Services

Topic: PBS/MBS ACCESS

Written Question on Notice

Senator Crossin asked:

What percentage of Indigenous people pay the general copayments for their medicines?

Answer:

The capacity of the Medicare database to provide information on the percentage of Aboriginal and Torres Strait Islander peoples who pay the Pharmaceutical Benefits Scheme (PBS) general patient co-payment is dependent on them identifying themselves and/or dependants to Medicare as Indigenous.

A Voluntary Indigenous Identifier (VII) was introduced to the Medicare database from November 2002. Australians can elect to voluntarily identify as Indigenous on the several Medicare forms, not just the enrolment form. As at October 2005 there were approximately 100,000 VIIs. While this represents about 22% of the entire Indigenous population, this sample is not random nor necessarily representative and therefore the data cannot be extrapolated to the whole Indigenous population.

Of the 100,000 VIIs about 33,000 accessed the PBS in 2004 and 3,742 received a script as a general patient. The remainder are concession card holders. (Note: these figures do not include prescriptions which are priced under the general patient's co-payment amount of $28.60. Medicare Australia does not collect data on prescriptions where there is no Government subsidy involved).

Special arrangements are also in place to supply PBS medicines to approved remote area Aboriginal and Torres Strait Islander Health Services (AHSs) under the provisions of section 100 of the *National Health Act of 1953*. Under these arrangements, clients of approved AHSs are able to receive medicines at the point of consultation, without the need for a prescription form, and without charge. In 2004-05 1.15 million PBS items were supplied under these arrangements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-311

OUTCOME 2: Medicines and Medical Services

Topic: EXTENSION OF S100 TO URBAN AND RURAL & GOVT. RESPONSE TO S100 EVALUATION

Written Question on Notice

Senator Crossin asked:

a) Why hasn't the Department implemented the Australian Pharmaceutical Advisory Council (APAC) endorsed proposal for the extension of the Section 100 supply scheme for pharmaceuticals to urban and rural Aboriginal Health Services? This was endorsed by APAC in June 2004- over 12 months ago.
b) Costing for this program is commensurate with the underspend for this population (even without taking into consideration the greater burden of disease as it could be argued that funding should be three times higher per head than for the average Australian). Therefore, what has been the hold-up for the implementation of this proposal given that it is evidence-based?
c) Why hasn't the Dept responded to the Section 100 evaluation conducted by the CRCATH completed in July 2004?

Answer:

a) A response to the *Evaluation of PBS medicine supply arrangements for remote area Aboriginal Health Services under S100 of the National Health Act* is currently with Government for consideration.

b) See response to a), above

c) See response to a), above.

Topic: Review of Aged Care GP Panels

Question: Who were the members on the advisory group for the Panels Review and what capacity were they fulfilling on the Group?

Aged Care GP Panels initiative - Implementation Advisory Group
List of member organisations

- Rural Doctors Association Australia: Dr Ken Mackey
- Australian Medical Association: Ms Kristen Connell
- Council on the Ageing (National Seniors): Mr Jim Purcell
- Aged Care Association Australia: Mr Rod Young
- Aged and Community Services Australia: Mr Greg Mundy
- Australian Society for Geriatric Medicine: Dr Michael Dorevitch
- Geriaction: Ms Kate Hurrell
- Australian Divisions of General Practice: Ms Kate Carnell
- Adelaide North East Division of General Practice: Dr Peter Ford
- Brisbane North Division of General Practice: Dr Ann McBryde
- Mornington Peninsula Division of General Practice: Dr John Siemienowicz
- Department of Health and Ageing: Ms Lisa McGlynn

Members of the group participated in an advisory capacity, to assist the Department in developing the Aged Care GP Panels initiative, including providing advice and feedback on the implementation of the initiative.

With respect to the 12 month review, the Group has provided advice on:

- Options for funding flexibility;
- Performance indicators;
- Increased participation of geriatricians; and
- Models of good practice on Panels.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-075

OUTCOME 3: Aged Care and Population Ageing

Topic: RESIDENT CLASSIFICATION SCALE REVIEWS

Written Question on Notice

Senator McLucas asked:

(a) Please provide RCS review figures for the six months ending June 2005.

(b) What is the proportion of the residents of aged care facilities values of downgrades/upgrades?

Answer:

(a) For the six months ending June 2005 there were 10,705 Resident Classification Scale reviews conducted.

(b) 36% were downgraded and 5% were upgraded.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-083

OUTCOME 3: Aged Care and Population Ageing

Topic: ACCOMMODATION BONDS PROTECTION

Written Question on Notice

Senator McLucas asked:

(a) Is the Department aware of the Aged Care Complaints Resolution Scheme Determination Review which found that the Woolgoolga and District Retirement Village Ltd was in breach of the Aged Care Act because it would not refund the balance of an accommodation bond to Mr Pratt, and

That the Secretary be encouraged to initiative a review of Section 57-21(3)(b) of the Act having regard to accepted prudent commercial practice as outlined in the commentary in the Department's Residential Care Manual.

(b) Has the Secretary initiated this review? If not, why not?

Answer:

(a) Yes.

(b) Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-084

OUTCOME 3: Aged Care and Population Ageing

Topic: ACCOMMODATION BONDS PROTECTION

Written Question on Notice

Senator McLucas asked:

The Government is introducing new legislation to guarantee residents' bonds will be repaid if an aged care provider becomes bankrupt or insolvent. The Government will repay the bond, but then will recover these payments by pursuing the defaulting provider, and if necessary, levying all aged care providers who hold bonds. What other methods of protecting bonds were considered?

Answer:

The options for protecting bonds considered included insurance based arrangements, trust fund arrangements, pre- and post-payment guarantee schemes and strengthened prudential arrangements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-085

OUTCOME 3: Aged Care and Population Ageing

Topic: ACCOMMODATION BONDS PROTECTION

Written Question on Notice

Senator McLucas asked:

Do you think the new legislation, including the clause to levy all aged care providers who hold bonds if a provider defaults on a bond, fair to those providers who are solvent?

Answer:

The guarantee scheme proposed by the Government was developed in close consultation with the aged care industry and consumers through the Conditional Adjustment Payment (CAP) and Prudential Reference Group and the Minister's Implementation Taskforce, and was supported as the preferred option.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-089

OUTCOME 3: Aged Care and Population Ageing

Topic: CONCESSIONAL RESIDENT RATIO

Written Question on Notice

Senator McLucas asked:

How many concessional residents were in the aged care system in financial year 2004/05?

Answer:

As at 30 June 2005, there were 59,517 concessional and assisted residents in permanent residential aged care.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-091

OUTCOME 3: Aged Care and Population Ageing

Topic: CONCESSIONAL RESIDENT RATIO

Written Question on Notice

Senator McLucas asked:

Is the regional concessional target a published document and if not why not? If yes, can it be provided?

Answer:

The regional concessional resident ratios are published in the Residential Care Manual, a source document for management and staff of residential care facilities. This manual is available on the Department of Health and Ageing's web site at www.health.gov.au

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-092

OUTCOME 3: Aged Care and Population Ageing

Topic: CONCESSIONAL RESIDENT RATIO

Written Question on Notice

Senator McLucas asked:

What is the rationale for setting the regional target as the target for providers to achieve?

Answer:

The regional concessional resident ratios were introduced to ensure that all residents, including the financially disadvantaged, receive fair access to care. The regional ratios require homes to meet a minimum target ratio for concessional and assisted residents. Acknowledging the differing demographics across Australia, the regional ratios are based on socio-economic data from a number of sources on incomes, assets, home ownership, marital status and living arrangements prior to entry into care.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-094

OUTCOME 3: Aged Care and Population Ageing

Topic: CONCESSIONAL RESIDENT RATIO

Written Question on Notice

Senator McLucas asked:

Is the Department aware of situations where the current policy is actually operating as a perverse incentive where providers cannot achieve the 40% target (as) it is not in their interest to actually seek any concessional residents?

Answer:

No.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-095

OUTCOME 3: Aged Care and Population Ageing

Topic: CONCESSIONAL RESIDENT RATIO

Written Question on Notice

Senator McLucas asked:

a) Is the Department aware that with the introduction of the new Centrelink/DVA asset testing arrangements providers are now being penalised because they fall below the 40% rule as a new resident initially advises they are concessional but the asset test deems them as not concessional meaning a provider then loses the higher supplement on all concessional residents within that facility?

b) Is there any indication that the scenario above may lead to providers being reluctant to accept new admissions until the concessional status of a resident is known?

Answer:

a) The department is not aware of any specific cases where a provider has been penalised because they fell below the 40% rule as a result of accepting a resident before an assets assessment was completed.

b) Some providers may be reluctant to accept new admissions until the concessional status of a resident is known. However, priority is given to assessments where a person enters care before submitting a request for an assessment, or where the potential resident is in a hospital waiting for a place in a service, or has been offered a place in permanent residential aged care.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-241

OUTCOME 3: Aged Care and Population Ageing

Topic: Fire Safety Declarations

Hansard Page: CA 68/79

Senator McLucas asked:

Could I get a copy of that declaration at some stage?

Answer:

A generic copy is attached for your information.

Australian Government

Department of Health and Ageing

Fire Safety Declaration 2005

Must be provided by: **01/03/06**

Period ending 31 December 2005

Part A Fire Safety Declaration

The Fire Safety Declaration seeks assurance that all obligations under State, Territory and local government legislation relating to fire safety have been met.

Approved providers are required to make the declaration in relation to compliance as at 31 December 2005 and also in relation to continuing compliance throughout the period from1 January 2005 to 31 December 2005.

This declaration does not form part of your certification requirements relating to fire safety. While aspects of certification deal with fire and safety issues, approved providers must be aware that achieving certification does not provide an assurance that the service meets its obligations under State, Territory and local government laws in relation to fire safety.

Approved providers with more than one residential aged care service must complete a separate Fire Safety Declaration form for each service.

It is an approved provider's responsibility under the *Aged Care Act 1997* to complete and return the declaration to the Department of Health and Ageing by 1 March 2006 Approved providers also have a responsibility to comply with all State, Territory and local government laws relating to fire safety.

Failure to return the declaration or provide all of the requested information may result in compliance activity for breach of the approved providers' responsibilities under the *Aged Care Act 1997*. Please note that the Department may also provide information contained in the completed declaration to relevant authorities.
All questions contained in the declaration must be completed.

This form must not be amended, as it is an approved form under the *Aged Care Act 1997*.

Details of Service

Name of Residential Aged Care Service

«SERVICE_NAME»

Address of Residential Aged Care Service

«SERVICE_ADDRESS_LINE_1»
«SERVICE_SUBURB» «SERVICE_STATE»
«SERVICE_POST_CODE»

Residential Aged Care Service ID (RACS ID)

«RAC_SERVICE_ID»

Building Classification: **«BCA_CLASS»**

Telephone Number of Residential Aged Care Service

«SERVICE_PHONE»

Details of approved provider

Name of approved provider	Contact Person
«PROVIDER_NAME»	
Address of approved provider	Contact person position/title
«PROVIDER_ADDRESS_LINE_1_POSTAL» «PROVIDER_ADDRESS_LINE_2_POSTAL» «PROVIDER_SUBURB_POSTAL» «PROVIDER_STATE_POSTAL»	Telephone number of contact person

(Please check the above information and amend if incorrect. This will enable the Department to update its records)

Question 1

This question requires an Approved Provider of a residential aged care service to declare whether all of the obligations imposed by all relevant State, Territory and local government legislation relating to fire safety have been met, including any maintenance of fire safety services.

The Fire Safety Declaration does not in any way change an Approved Provider's obligation to comply at all times with all applicable State, Territory and local government fire safety legislation.

Q1A Did the service comply with all applicable State, Territory and local government legislation relating to fire safety, including the maintenance of fire safety services on 31 December 2005?

Yes ☐ ☐ **No** *If no, please provide details of the non-compliance, including any action taken to resolve the matter(s).*

If insufficient space, please attach details

Q1B Did the service comply with all applicable State, Territory and local government legislation relating to fire safety, including the maintenance of fire safety services at all times during the period from 1 January 2005 to 31 December 2005?

Yes ☐ ☐ **No** *If no, please provide details and period of non-compliance, including any action taken to resolve the matter(s) and complete question 1C. If yes, please proceed to question 1C.*

If insufficient space, please attach details

Q1C Do you hold all relevant fire safety documentation required by State, Territory and local government legislation relating to fire safety?

Note: You are not required to provide copies of documentation as part of this declaration.

Yes ☐ ☐ **No** *If no, please provide details of the non-compliance, including any action taken to resolve the matter(s)*

If insufficient space, please attach details

Question 2

The aim of this question is to determine if any fire safety dispensations have been granted or alternative solutions approved by a building authority in the period from 1 January 2005 to 31 December 2005. Any alternative fire safety solution must comply with the performance requirement of the Building Code of Australia.

Q2 During the period 1 January 2005 to 31 December 2005, have any fire safety dispensations been granted or alternative solutions approved by a building authority or certifier?

Yes ☐ *If yes, please provide details* **No** ☐

If insufficient space, please attach details

Part B One Off Payment Information

Q3 Accountability for payment of $3,500 per recipient of residential aged care services

In June 2004, Approved Providers of residential aged care services were provided with a 'One Off Payment' of $3,500 per recipient of residential aged care services as part of the 2004 Federal Budget initiatives.

In accordance with the information that was provided to Approved Providers on 15 June 2004, residential aged care services are required to indicate how the payment has been applied. Please

indicate below by placing a tick in the appropriate box or boxes how the funds have been or are intended to be utilised.

This information may have been provided as part of your 2004 Fire Safety Declaration; however, if you have not previously confirmed that the funds have been Fully Expended, you **must** complete Questions 3 and 4 as set out below.

Q3A As at the date of this declaration, the payment has been:

❑ Fully expended

❑ Partially expended

❑ Yet to be expended

(Please tick one box)

Q3B Please tick one or more of the following boxes as applicable

The Payment has been/will be used for:

- ❑ updating or improving fire safety standards, including upgrading existing fire safety equipment to meet State and Territory and local government regulatory requirements, to achieve a score of at least 19/25 against the 1999 Certification Assessment Instrument;
- ❑ installation of fire sprinklers;
- ❑ updating or improving fire safety equipment;
- ❑ engaging the services of professional fire safety consultants to advise on possible improvements in fire safety measures to ensure the money is appropriately utilised;
- ❑ improving the level of staff fire safety training;
- ❑ investing in building upgrades to meet the benchmarks of the 10 year forward plan for certification;
- ❑ ensuring that high care residents, including residents who are ageing in place, are accommodated in buildings of the appropriate building classification.

Where fire safety requirements (including compliance with all State/Territory/local government fire safety requirements) and 2008 certification requirements have been met the payment has been/ will be used to:

- ❑ improve the quality and range of residential aged care services as defined under the *Aged Care Act 1997*; and/or
- ❑ retire debt relating to residential care in respect of which a subsidy is payable under the *Aged Care Act 1997.*

Q3C Funds not used for the service for which they were allocated

If any of the funds paid in respect of this service have been used or are intended to be used by another service operated by the approved provider, please provide below details of the service to which the funds have been applied. This information must include the RACS ID number, service name, and how the funds have been utilised.

RACS ID	Service Name	Used For:

(If used for «SERVICE_NAME» do not complete this table)

Q3D Leased – Freehold Buildings

Are the buildings utilised by the service for the provision of residential aged care leased or freehold?

Leased ☐ **Freehold** ☐

Part C 2008 Space and Privacy targets

Q4 Progress toward 2008 Space and Privacy targets

As part of the ten-year forward plan for certification, residential aged care services are required to meet space and privacy targets for the number of residents per room, and access to showers and toilets, by December 2008.

In meeting the requirements for the provision of toilet and bathing facilities, an Approved Provider must demonstrate that the distribution of these facilities across the service ensures equitable access by all residents. This expectation applies to both **'new'** and **'existing'** residential aged care services.

The privacy and space requirements for **new** services apply to buildings for which plans were submitted for approval after July 1999.

Ratio for New Buildings

- An average for the whole residential aged care service of no more than 1.5 residents per room and no individual room may accommodate more than two (2) residents.
- No more than three (3) residents per toilet, including those off common areas, and no more than four (4) residents per shower or bath.
- Staff toilets and showers will not be counted when these averages are calculated.

The privacy and space requirements for **existing** services apply to buildings for which plans were submitted for approval prior to July 1999.

Ratio for Existing Buildings

- A maximum of four (4) residents in any room by 31 December 2008.
- A maximum of six (6) residents per toilet, including those off common areas.
- A maximum of seven (7) residents per shower.

Q4A New or Existing Service

Based on the above criteria, is your service a 'New' or 'Existing' building?

New ☐ **Existing** ☐

Q4B Compliance with 'New' Standards

If your service is a new building, does the service fully comply with the required ratio for new buildings?

Yes ☐ **No** ☐

Q4C Compliance with the 2008 Target

If no to Q4B, do you anticipate meeting these requirements by 31 December 2008?

Yes ☐ **No** ☐ *(If no, please provide details of why the requirements will not be met by 31 December 2008)*

If insufficient space, please attach details

Part D Approved Provider Declaration

- **I am a person who is registered with the Department of Health and Ageing as a 'key personnel' of the Approved Provider for the purpose of the *Aged Care Act 1997*;**
- **I am authorised by the Approved Provider to make this declaration;**
- **I have answered all questions contained in this form;**
- **I certify that the particulars given in this declaration and any attachments are correct; and**
- **I understand that giving false or misleading information to the Commonwealth is a serious offence.**

Name **Telephone Number**

Position/title

Signature **Date**

/ /

Sanctions may be imposed under the *Aged Care Act 1997* if an Approved Provider fails to provide a fully completed and signed declaration or provides false or misleading information. In addition, this information may be passed to the Aged Care Standards and Accreditation Agency and State/Territory fire or other authorities.

Please return this declaration by 1 March 2006 to:

Forms Administration
PO Box 5008
Nowra Delivery Centre NSW 2541
Telephone (02) 4447 8022

Forms Administration undertakes the processing of the Fire Safety Declaration on behalf of the Department of Health and Ageing. If you have any questions concerning the processing of the form please contact (02) 4447 8022. If you have any questions of a technical nature, please contact the Department on (02) 6289 1583

Please fill in the time boxes if your business employs fewer than 20 people.
The information you provide will assist the Australian Government to design better forms.

Time taken to complete this form:

Hrs **Min**

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-242

OUTCOME 3: Aged Care and Population Ageing

Topic: FIRE SAFETY DECLARATIONS

Hansard Page: CA 79

Senator McLucas asked:

Have all facilities been sending in their acquittals?

Answer:

Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-244

OUTCOME 3: Aged Care and Population Ageing

Topic: SIR JAMES BY THE BAY / EXTRA SERVICE

Hansard Page: CA 70

Senator McLucas asked:

a) When was Sir James by the Bay assessed and approved as an extra service provider?

b) Were they provided with extra service status prior to opening?

Answer:

a) Sir James by the Bay was granted Extra Service approval on 25 November 2002.

b) Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-307

OUTCOME 3: Aged Care and Population Ageing

Topic: SIR JAMES BY THE BAY – VISITS BY THE AGED CARE STANDARDS AND ACCREDITATION AGENCY

Hansard Page: CA 68

Senator McLucas asked:

Can I also get a list of each spot check or support contact provided by the Agency to Sir James by the Bay since its inception? Include which ones were advised visits and which ones were unannounced visits?

Answer:

The following unannounced and announced visits or support contacts were conducted at Sir James by the Bay:

2003 (5 May to 31 December 2003)	1 visit	Announced
2004	2 visits	Both announced
2005 (1 January to 2 November 2005)	27 visits	26 announced 1 unannounced

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-240

OUTCOME 3: Aged Care and Population Ageing

Topic: FIRE SAFETY AND 2004 ONE-OFF PAYMENT

Hansard Page: CA 91

Senator McLucas asked:

To finish off the fire safety and certification issue, can you provide the committee with a copy of the letter (notifying them of the payment and the conditions), that was sent out to residential aged care providers with the $3,500 per bed?

Answer:

Copies of the two letters sent to approved providers on 15 and 22 June 2004 are attached.

Australian Government

Department of Health and Ageing

Dear Approved Provider

I am writing to advise you of the accountability arrangements for the payment of $3,500 per recipient of residential aged care services in recognition of the forward plan for improved building standards for aged care homes by 2008 pursuant to certification requirements, in particular improved fire safety, as announced in the Australian Government's recent Budget.

The payment will be made to eligible approved providers in the second part of June 2004. Further information on the Government's expectations about the expenditure of the funds and associated accountability arrangements is set out in the Attachment to this letter.

I will write to approved providers again in the next few days providing details of payment arrangements.

Yours sincerely

Stephen Dellar
Assistant Secretary
Residential Program Management Branch
15 June 2004

Attachment

Expenditure and Accountability Requirements in relation to the Payment of $3,500 per Recipient of Residential Aged Care Services

Eligible expenditure

The payment may be used to

- update or improve fire safety standards, including upgrading existing fire safety equipment to meet State and Territory and local government regulatory requirements, to achieve a score of at least 19/25 against the 1999 Certification Assessment Instrument, including
  - ♦ installation of fire sprinklers
  - ♦ updating or improving fire safety equipment
  - ♦ engaging the services of professional fire safety consultants to advise on possible improvements in fire safety measures to ensure the money is appropriately utilised.
  - ♦ improving the level of staff fire safety training.
- Invest in building upgrades to meet the benchmarks of the 10 year forward plan for certification (see Appendix - *Ten Year Forward Plan for all Certified Residential Aged Care Services*).
- Ensure that high care residents, including residents who are ageing in place, are accommodated in buildings of the appropriate building classification.

Where fire safety requirements (including compliance with all State/Territory/local government fire safety requirements) and 2008 certification requirements are met the payment shall be used to

- improve the quality and range of residential aged care services as defined under the *Aged Care Act 1997*; and/or
- retire debt relating to residential care in respect of which a subsidy is payable under the *Aged Care Act 1997*.

Details of the benchmarks incorporated in the 10 year forward plan for certification are set out in *Building Quality for Residential Care Services - Certification* (also known as the Certification Information Pack) distributed to all homes in April 2004 and also available from the Department's website at www.health.gov.au/acc/certification/index.htm

Accountability

- The annual fire safety declaration will include a requirement for providers to show how the payment has been applied, including improving services and retiring debt.
  - ♦ Should a provider fail to complete and return the declaration by the due date or to provide all requested information, the Department can institute compliance action under the *Aged Care Act 1997*. The Department may also

undertake a review of certification under section 39-4 of the *Aged Care Act 1997*. The provision of false or misleading information is an offence under the *Criminal Code Act 1995*.

- Providers will be required to provide evidence to the Department of Health and Ageing of an assessment of the home against the 1999 Certification Assessment Instrument, by a professional approved by the Department to undertake such inspections, which shows that the home scores at least 19/25 for fire safety and 60/100 overall.
  - ♦ If such evidence is not provided by December 2005, this may result in a review of the home's certification under the *Aged Care Act 1997*.

Details of the process to engage professionals to undertake inspections against the 1999 Certification Assessment Instrument are set out in the Certification Information Pack.

The one-off payment and capital grants

The Government makes available capital grants to assist approved providers undertake necessary capital works where the approved provider can demonstrate that it is unable to fund the works from any other sources of funding, including debt finance. These grants are made available through the annual Aged Care Approvals Round. Where a provider applies for a capital grant in relation to fire safety or 2008 certification issues in the Aged Care Approvals Round 2004 it will be required to demonstrate that the one-off payment has been, or will be, applied to achieving fire safety standards and 2008 certification requirements before a grant for those purposes will be considered. If fire safety and 2008 certification requirements have been met, the applicant will be required to demonstrate why this one-off payment is not available to be applied to the capital works for which a grant is sought.

Obtaining further information: Further information may be obtained by contacting the Department on 1800 500 853.

Appendix

Ten Year Forward Plan for all Certified Residential Aged Care Services

Since 1999, for residential aged care services to be certified they must achieve a score of at least 19/25 for Section 1 (Safety) and a score of 60/100 overall as measured by the 1999 Certification Assessment Instrument.

Residential aged care services are also required to meet the targets set within the ten year forward plan for certification as agreed between the stakeholders of the aged care sector including approved providers and the Australian Government.

With all buildings and building works, approved providers are, irrespective of certification, required to meet the requirements of relevant building authorities, including State/Territory legislation, and any applicable provisions of the Building Code of Australia.

The ten year forward plan identifies targets for fire and safety to be met by 2003 and for privacy and space to be met by 2008.

Fire and Safety Targets

To meet the fire and safety targets a service must achieve a mandatory score of at least 19/25 for Section 1 of the 1999 Certification Assessment Instrument.

Privacy and Space Targets

The privacy and space requirements for residential aged care buildings relate to the number of residents per room, and access to showers and toilets. The privacy and space requirements differ for buildings constructed after the introduction of the 1999 Instrument in July 1999 (new buildings) and buildings constructed prior to that date (existing buildings).

In meeting the requirements for the provision of toilet and bathing facilities, an approved provider must demonstrate that the distribution of these facilities across the service ensures an equitable access by all residents. This expectation applies to both **'new'** and **'existing'** residential aged care services.

New Buildings

For new buildings there is to be an average for the whole residential aged care service of no more than 1.5 residents per room.

No individual room may accommodate more than 2 residents.

There is also a mandatory standard of no more than three residents per toilet, including those off common areas, and no more than four residents per shower or bath. Staff toilets and showers will not be counted when these averages are calculated.

Existing Buildings

There is a requirement for a maximum of four residents in any room by 31 December 2008. It is expected however, that the aged care sector strive to meet the optimal targets of a maximum of two residents per room by this time.

There is also a mandatory standard of a maximum of six residents per toilet, including those off common areas, and a maximum of seven residents per shower.

Culturally appropriate care

Exceptions may be approved where the approved provider can make a case to the Department of Health and Ageing that a higher number of residents per room is culturally appropriate on an ongoing basis.

Australian Government

Department of Health and Ageing

Dear Approved Provider

I am writing to advise you of the payment arrangements for the payment of $3,500 per recipient of residential aged care services in recognition of the forward plan for improved building standards for aged care homes by 2008, in particular improved fire safety, as announced in the Australian Government's recent Budget.

The payment will be made to eligible approved providers in the second part of June 2004. Further information on the method of calculation of the payment and payment arrangements is set out in the Attachment to this letter.

I wrote to providers on 15 June advising of the Government's expectations about the expenditure of the funds and associated accountability arrangements. If you did not receive that letter please ring 1800 500 853 to arrange for a copy to be sent to you.

Yours sincerely

Stephen Dellar
Assistant Secretary
Residential Program Management Branch
22 June 2004

Attachment

Payment Arrangements in relation to the Payment of $3,500 per Recipient of Residential Aged Care Services

Amount to be paid

The payment of $3 500 for each recipient of residential aged care will be calculated on the basis of whichever is the greater of the following:

(a) the number of care recipients in respect of whom the approved provider of the service was eligible for residential care subsidy on 31 March 2004;

(b) the daily average number of care recipients in respect of whom the approved provider of the service was eligible for residential care subsidy during the payment period ending on 30 April 2004.

In June 2004 a payment of $3,500 will be paid to each approved provider in respect of the daily average number of residents in respect of whom a subsidy is payable in April 2004. Payment is being made under the *Aged Care (Consequential Provisions) Act 1997*.

All residents for whom a subsidy is payable will be included in the calculation of the April 2004 daily average, including:

Extra service residents
Respite residents
Residents on leave for whom a subsidy is payable (eg pre-entry leave, hospital leave, social leave)
Residents assessed at RCS 8

The following will not be included

Occupants of flexibly-funded places
Residents on leave for whom a subsidy is not payable
Respite residents for whom a subsidy is not payable
Provisional allocations
Off-line allocations.

The April 2004 daily average number of residents will be calculated on the basis of information held by the Department at the time the payment is certified within the Department.

If the April 2004 daily average number of residents changes after this date, adjustments to the payment will be made. All entitlements will be finalised in 2005. During 2004-05 a comparison will be done between the average daily occupancy during April 2004 with the number of residents as at 31 March 2004, and final entitlements will be calculated and paid to approved providers eligible to receive residential care subsidies under the *Aged Care Act 1997*. Repayment of any overpayments will be sought as a debt to the Commonwealth. It will not be possible to deduct overpayments from future advances made under the *Aged Care Act 1997*.

Who will be paid?

The approved provider which the Department's records show holds the allocated places on the date the payments are certified will receive the payment. The payment will be made to the account nominated by the approved provider for the payment of residential care subsidies in respect of each of its residential aged care services.

Obtaining further information: Further information may be obtained by contacting the Department on 1800 500 853.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-078

OUTCOME 3: Aged Care and Population Ageing

Topic: AGED CARE FUNDING INSTRUMENT (ACFI) TRIAL

Written Question on Notice

Senator McLucas asked:

The current Resident Classification Scale is founded on a 'needs based assessment'. The model under the trial is a 'dependency based assessment'. There is no question regarding therapy such as diversional therapy or physiotherapy.

(a) Can you inform me how these needs for diversional therapy and physiotherapy will be assessed in the ACFI trial?
(b) Was consultation undertaken with the Health Professions Council of Australia or any professional allied health association?
(c) If allied health professional such as physiotherapists, diversional therapists or occupational therapists were not included in the consultation process when developing the ACFI, can you please explain why?
(d) When will the results and reports of the trial be available?

Answer:

(a) The Aged Care Funding Instrument (ACFI) is designed to measure resident dependency as a basis for calculating basic subsidy payments to residential aged care services. Under the Quality of Care Principles of the *Aged Care Act 1997,* it is the responsibility of the service provider to ensure that all residents receive appropriate treatment and therapies. The Aged Care Standards and Accreditation Agency monitors aged care homes to ensure that the expected outcomes under the Accreditation Standards are met.

(b) The Health Professions Council of Australia (HPCA) is represented on the Aged Care Advisory Committee which has discussed the ACFI and the development of the new funding model, including a paper prepared by the HPCA. The department has also corresponded with the HPCA, its affiliates and other allied health and complementary peak bodies in relation to the ACFI and the national trial, and departmental officers have discussed ACFI related issues with them.

(c) See (b) above.

(d) In the new year.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-087

OUTCOME 3: Aged Care and Population Ageing

Topic: INDIGENOUS AGED CARE

Written Question on Notice

Senator McLucas asked:

Funding was provided for a Department of Health and Ageing Training Resource Officer for Indigenous Support (TROICAS) in Queensland. This position was originally created to aid Indigenous aged care facilities meet Accreditation Standards, but funding was discontinued in June 2004.

a) Could you please advise how much has been spent on consultants and wages, airfares and accommodation for Department staff to help indigenous specific aged care facilities meet Accreditation Standards since the TROICAS position was defunded.

Answer:

a) $92,200 was provided for a consultant to assist the Mornington Island Aged Persons Hostel on Mornington Island, Queensland.

   Departmental officers undertake routine visits to aged care homes, including those with a predominance of indigenous residents, as part of the normal operations of the department.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-088

OUTCOME 3: Aged Care and Population Ageing

Topic: CULTURALLY AND LINGUISTICALLY DIVERSE

Written Question on Notice

Senator McLucas asked:

If funding is provided to an aged care service for CACP and EACH packages for Culturally and Linguistically Diverse (CALD) communities, how does the Department ensure these services are actually provided to people from CALD communities and are complied with over time?

Answer:

Aged care places are issued subject to specified conditions. Section 63-1(d) of the *Aged Care Act 1997* makes it an approved provider responsibility to comply with any conditions of allocation.

Where relevant, a condition of allocation will specify that priority is given to specified Cultural and Linguistically Diverse Communities.

Providers are required, under the Act, to seek approval to change any conditions of allocation.

The department will investigate any complaint that a provider is not meeting any of its conditions of allocation.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-098

OUTCOME 3: Aged Care and Population Ageing

Topic: CAMPBELL RESEARCH CONSULTING

Written Question on Notice

Senator McLucas asked:

Campbell Research Consulting were engaged by the Department to undertake an evaluation of the aged care accreditation system which they commenced in February. Nearly $1.5 million was allocated for this research. Has the research been completed, and if so, can an interim or final report of the findings be provided.

Answer:

No.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-096

OUTCOME 3: Aged Care and Population Ageing

Topic: DEMENTIA RESEARCH

Written Question on Notice

Senator McLucas asked:

Could the Department please provide an update on how the specific funding for dementia services research which was provided in the 2005 Budget measure Dementia – A National Health Priority was allocated? (See Question E05-117 in Outcome 3 from June 2005 Budget Estimates).

Answer:

Allocation of funding for dementia research will occur through a competitive process in 2006. A pre-notice to alert researchers appeared in the National Press on 26 November 2005.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-233

OUTCOME 3: Aged Care and Population Ageing

Topic: CENTRAL SYDNEY AREA HEALTH SERVICE – INNER WEST COMMONWEALTH CARER RESPITE CENTRE

Hansard Page: CA 96/97

Senator McLucas asked:

In relation to Central Sydney Area Health Service's Inner West Commonwealth Carer Respite Centre I want a list of previous providers and successful tenderers.

Answer:

South West Sydney Area Health Service was the provider of the South West Sydney Region Commonwealth Carer Respite Centre until 30 September 2005. Sydney Anglican Home Mission Society trading as Anglicare has been the provider of the South West Sydney Region Commonwealth Carer Respite Centre from 1 October 2005.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-234

OUTCOME: 3: Aged Care and Population Ageing

Topic: UNICARE, RED HILL, QLD – RESPITE FOR CARERS

Hansard Page: CA 96

Senator McLucas asked:

In respect of Unicare Red Hill in Queensland, it seems that this organisation has lost its funding and two aged care services have received funding instead. How do we expect that these aged care providers will be able to provide appropriate respite for parents of children with disabilities?

Answer:

There are a number of alternative service providers in the North Brisbane Home and Community Care region in which Unicare was located. This includes seven services providing respite that include carers of younger people with disabilities as part of their target group. Overall, the National Respite for Carers Program funding in the North Brisbane region has increased from $4.6 million in 2004-05 to $5.9 million in 2005-06.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-236

OUTCOME: 3: Aged Care and Population Ageing

Topic: RESPITE FOR CARERS IN QUEANBEYAN AND ACT

Hansard Page: CA 95

Senator McLucas asked:

What hours are those programs (Baptist Community Services and Carers ACT Home from Home) open on a Saturday?

Answer:

These services are open on a Saturday as follows:

1. Baptist Community Services - from 10.00 am to 3.00 pm.
2. Carers ACT Home from Home - from 8.00 am to 8.00 pm.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-246

OUTCOME 3: Aged Care and Population Health

Topic: SIR JAMES BY THE BAY - COMPLAINTS

Hansard Page: CA 68

Senator McLucas asked:

I wonder whether I could get on notice the dates that each of the complaints were received by the department and exactly when each of those matters were referred to the agency. Was it one referral to the agency or did the department refer five separately and, with the subsequent information, call the agency?

Answer:

Specific detail in relation to complaints is protected information under the *Aged Care Act 1997*.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-245

OUTCOME 3: Aged Care and Population Ageing

Topic: SIR JAMES BY THE BAY – 2005 CHRONOLOGY

Hansard Page: CA 68-69-72

Senator McLucas asked:

Could I ask for a chronology of interactions between the department and Sir James by the Bay and the agency and Sir James by the Bay? Has the provider appealed or sought a review of the sanctions that have been imposed?

Going back to Sir James by the Bay, the chronology that you provide to the committee will need to identify the three to four month delay from April this year till August from the first complaints being made to the first action being taken on those complaints.

Answer:

The information sought is protected information under the *Aged Care Act 1997* as it relates to the affairs of an Approved Provider. Complaints and information contacts with the Complaints Resolution Scheme (the Scheme) between 1 January 2005 and 2 November 2005 relating to Sir James by the Bay were assessed and action taken in accordance with processes under the Scheme. The Department has protocols with the Aged Care Standards and Accreditation Agency (the Agency) which also provide for the referral of information to the Agency. During the period 1 January to 2 November 2005, the Agency and the Department and Health and Ageing undertook a total of 36 visits to Sir James by the Bay.

The Approved Provider has not lodged an appeal or sought a review of the decision to impose sanctions.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-081

OUTCOME 3: Aged Care and Population Ageing

Topic: ACCOMMODATION BONDS PROTECTION

Written Question on Notice

Senator McLucas asked:

(a) What is the total monetary amount of bonds held for residents in aged care facilities held in Australia?

(b) What mechanism does the Department use to ascertain what entity holds the bond money?

Answer:

(a) Accommodation bonds worth approximately $4.3 billion were held for residents in aged care facilities on 30 June 2005. The estimate is derived from data collected in the Department's 2005 Survey of Aged Care Homes and includes an adjustment for non-respondents.

(b) Under the *Aged Care Act 1997*, approved providers are required to submit an annual Prudential Compliance Statement that includes a declaration of whether they held any accommodation bonds during the financial year. The Government has recently introduced three bills into Parliament to strengthen the prudential arrangements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-086

OUTCOME 3: Aged Care and Population Ageing

Topic: ACCOMMODATION BONDS PROTECTION

Written Question on Notice

Senator McLucas asked:

(a) How many providers have defaulted in the past?

(b) If no providers have ever defaulted, what is being protected?

Answer:

(a) To date there has not been an instance where a resident's bond balance has not been repaid.

(b) The amount paid by residents as bonds will receive increasing protection as a result of the Australian Government prudential arrangements and guarantee scheme.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-093

OUTCOME 3: Aged Care and Population Ageing

Topic: CONCESSIONAL RESIDENT RATIO

Written Question on Notice

Senator McLucas asked:

a) What savings does the government achieve by reducing the supplement to providers who fall below the 40% target?

b) What would be the impact on government outlays if the 40% target was replaced by the regional target?

Answer:

a) The higher rate payable to services achieving the 40% ratio is to encourage greater access for concessional residents. It is not considered a savings measure.

b) It is not possible to provide a definitive amount.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-090

OUTCOME 3: Aged Care and Population Ageing

Topic: CONCESSIONAL RESIDENT RATIO

Written Question on Notice

Senator McLucas asked:

a) Is there a regional concessional resident target?

b) Is the regional target different to the national target?

Answer:

a) and b)

Yes. The Secretary has determined under section 14-5(4) of the *Aged Care Act 1997* concessional resident ratios for each of the 72 planning regions. There is no provision in the *Aged Care Act 1997* for the Secretary to determine a national target.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-239

OUTCOME 3: Aged Care and Population Ageing

Topic: Certification Compliance

Hansard Page: CA 91

Senator McLucas asked:

Confirmation that the 1999 instrument set in place the `2008 target. Provide a copy of the 1999 instrument to the Committee.

Answer:

The *1999 Certification Assessment Instrument* is located on the Department of Health and Ageing's website at http://www.health.gov.au/internet/wcms/publishing.nsf/Content/ageing-certification-download-assessin-cnt.htm.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-243

OUTCOME 3: Aged Care and Population Ageing

Topic: CERTIFICATION COMPLIANCE

Hansard Page: CA 79

Senator McLucas asked:

After the end of December 2005, could you provide the committee, with an analysis of the numbers? Could you give general proportions, of these non-compliance ones in some groupings?

Answer:

As at 10 February 2006, 2,354 homes (or 80%) met the Fire and Safety requirements of the 1999 Certification Assessment Instrument. Further information can be found on the Department of Health and Ageing's web-site - http://www.health.gov.au/internet/wcms/publishing.nsf/Content/Certification

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-079

OUTCOME 3: Aged Care and Population Ageing

Topic: CONDITIONAL ADJUSTMENT PAYMENT (CAP) COMPLIANCE

Written Question on Notice

Senator McLucas asked:

a) How many aged care facilities have complied with the Conditional Adjustment Payment financial reporting which was due on 31 October?

b) I understand that residents, prospective residents, families and the Department will be able to view the financial reports of aged care facilities. Is this correct?

c) How will that occur?

d) How will residents and prospective residents know what [sic] they can see the financial reports of the aged care facility?

e) What penalties will apply if an aged care facility fails to comply with the CAP financial reporting deadline of 31 October?

Answers:

a) As at close of business on 21 November 2005, 965 approved providers of residential aged care had lodged an Annual Notice (due on 31 October 2005) indicating compliance with the CAP financial reporting requirements.

b) Yes.

c) A resident (or their representative) or a potential resident (or their representative) may request a copy of the audited financial report from the approved provider.

d) Fact Sheets for residents and for approved providers have been prepared which provide information on residents', prospective residents' or their representatives' right to access approved providers' audited financial statements. The Fact Sheets are available on the Department's website. The Department has sent the Fact Sheet for residents to providers with a request that it be disseminated to residents, prospective residents and/or their representatives.
As the Department updates its publications aimed at consumers, they will include a reference to the right to obtain a copy of providers' or prospective providers' audited financial reports. For example, the next print run of the publication *5 Steps to Entry*

into Residential Aged Care will be updated to include a reference to the ability of residents and potential residents (and their representatives) to request their providers' audited financial report.

e) In order to receive CAP funding, providers must satisfy the three conditions of CAP. If a provider does not comply (with respect to a facility) with the CAP financial reporting deadline, CAP is not paid (with respect to the facility in question). Once a provider complies, CAP payments (with respect to the facility in question) will resume in the next payment period (ie the next calendar month).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-080

OUTCOME 3: Aged Care and Population Ageing

Topic: ACCREDITATION DVD

Senator McLucas asked:

The Aged Care Standards and Accreditation Agency Ltd (ACSAA) produced a DVD earlier this year.

(a) Who was sent the DVD?
(b) What featured in the DVD?
(c) What was the purpose of the DVD?
(d) How much did it cost to make the DVD?
(e) How much did it cost to distribute the DVD?
(f) Has any evaluation been undertaken as to the effectiveness of the DVD? If so, can the Committee be provided with this evaluation

Answer:

(a) The DVD was sent to Australian Government funded aged care facilities and key stakeholder groups. More than 700 copies were distributed to delegates at the national ACSA (Canberra) and ACAA (Brisbane) conferences in September and October.
(b) The DVD featured the stories of two families who had been through the process of finding an aged care home for a parent. It also featured interviews with various aged care staff – CEO, registered nurse, care manager, about the Accreditation Standards and the role of the Agency.
(c) The purpose of the DVD was to explain to residents and potential residents (consumers) and their families, about the system of accreditation and the Agency.
(d) $66,313.50, including DVD replication, cover design and cases.
(e) $11,535.51.
(f) The annual survey in The Standard newsletter in February, will include a question about methods of communication, and seek feedback about the DVD.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-082

OUTCOME 3: Aged Care and Population Ageing

Topic: ACCOMMODATION BONDS PROTECTION

Written Question on Notice

Senator McLucas asked:

(c) Does the *Aged Care Act 1997* outline who should receive interest earned on accommodation bonds during the period between the resident leaving the facility and the balance of the bond being returned to the resident/estate?

(d) If not, doesn't this create conflict between residents/families if there is a delay in the refund of the bond balance?

(e) Will the new legislation aimed at protecting accommodation bonds fix this potential conflict?

Answer:

(a)(b)(c)

The new legislation to strengthen protection of resident's accommodation bonds includes provisions that require approved providers to pay interest on accommodation bond balances from the date a resident leaves a service until the bond is repaid. The amount of interest will be detailed in the User Rights Principles and will include a penalty rate if the bond balance is not refunded within the legislated timeframe. The legislation will make it clear that the interest, like the bond balance, will be paid to the care recipient or the care recipient's estate. Issues relating to an estate are a matter for the families and/or the executor of the resident's estate.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-097

OUTCOME 3: Aged Care and Population Ageing

Topic: RATIO OF AGED CARE PLACES

Written Question on Notice

Senator McLucas asked:

Could the Department please explain why the projected allocations of residential aged care places and Community Aged Care Packages is 11,093 in 2004-05, 2006 (indicative) only 6,193 and in 2007 only 6,366? (See Question E05-198 in Outcome 3 from June 2005 Budget Estimates.)

Answer:

The indicative numbers are published in order to give the aged care industry an increased capacity to plan for future local care provision. These indicative numbers of places are intended to achieve and then maintain the new ratio of 108 operational places per 1,000 people aged 70 and over.

This ratio was increased from 100 aged care places per 1,000 people aged 70 and over in 2004. The new ratio and the release of indicative places were included in the Government's initiatives in the $2.2 billion 2004-05 aged care budget package.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-235

OUTCOME 3: Aged Care and Population Ageing

Topic: COMPETITIVE TENDERING

Hansard Page: CA92/93

Senator McLucas asked:

Are services for children with disabilities in Kingaroy provided from Maryborough? I am looking for how much money is available (in Kingaroy) and how much respite can be purchased with that money.

Answer:

The National Respite for Carers Program (NRCP) funded the South Burnett Community Access service in Kingaroy to provide respite for carers of the frail aged and younger people with disabilities in Kingaroy. Funding for the South Burnett Community Access service has grown from $139,000 in 2004-05 to $170,000 in 2005-06 and will grow to $200,400 by 2007-08. Respite services are also available through Home and Community Care (HACC) and State disability funding. This includes respite services for carers of younger people with disabilities in Kingaroy available through the Blue Care South Burnett region.

In addition, Commonwealth Carer Respite Centres (CCRCs) are able to broker respite from local services for carers across the HACC region in which the CCRC is located. The Central Region CCRC in which Kingaroy is located has a number of outlets in the region, including in Bundaberg, Rockhampton, Longreach, Emerald and Hervey Bay, and can assist carers of younger people with disabilities in Kingaroy. This is on the basis of assessed relative need.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-237

OUTCOME 3: Aged Care and Population Ageing

Topic: COMPETITIVE TENDERING

Hansard Page: CA92/93

Senator McLucas asked:

Can the department provide me with a list of all the auspiced organisations – their addresses, the types of services in broad terms and the geographical area that they cover – that were funded prior to 30 June 2005 under the National Respite for Carers Program, the Commonwealth Carelink Centres program, the Continence Aids Assistance Scheme – and I recognise that is a slight different funding system – and the Carer Information and Support program. I want a complete list of them.

Answer:

Organisations funded under the National Respite for Carers Program, the Commonwealth Carelink Program and the Carer Information and Support Program during the financial year ending 30 June 2005 are at Attachment A.

Intouch Pty Ltd (a Division of PQ Lifestyles) was funded under the Continence Aids Assistance Scheme in the financial year ending 30 June 2005.

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

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-238

OUTCOME: 3: Aged Care and Population Ageing

Topic: COMPETITIVE TENDERING – Second part

Hansard Page: CA 93/94

Senator McLucas asked:

Could I also have a list of the other services funded after 1 July for the four programs mentioned above including a hard copy of what's on the web site. I do understand the Continence Aids Assistance Program is funded in a different way, but if you could give me some explanation of how those services are funded that would also be useful.

Answer:

Organisations funded from 1 July 2005 under the National Respite for Carers Program, the Commonwealth Carelink Program and the Carer Information and Support Program are at Attachment A. A copy of the list on the Department's web-site of organisations funded from 1 July 2005 under the National Respite for Carers Program and the Commonwealth Carelink Program to operate Commonwealth Carer Respite Centres and Commonwealth Carelink Centres and to provide respite services is at Attachment B.

Under the Continence Aids Assistance Scheme, there is a single service provider, Intouch Pty Ltd (a Division of PQ Lifestyles), funded after 1 July 2005. Intouch provides continence aids to eligible clients nationally.

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

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-076

OUTCOME 3: Aged Care and Population Ageing

Topic: PROVISIONAL ALLOCATIONS

Written Question on Notice

Senator McLucas asked:

Please provide:

(a) the number of revoked provisional places for 2004-05.

(b) provisional aged care places by Aged Care Planning Region which were revoked by the Department from aged care providers over 2004-05.

(c) the number of provisional aged care places by Aged Care Planning Region which were returned to the Department from aged care providers in 2004-05.

(d) the number of provisional places, by Aged Care Planning Region, that are over 1 year old, 2 years old, 3 years old 4 years old 5 years old, 6 years old etc.

Answer:

(a) In the period from 1 July 2004 to 30 June 2005 there were no revocations of provisionally allocated residential aged care places.

(b) See (a).

(c) In the period from 1 July 2004 to 30 June 2005 there were 109 provisionally allocated residential mainstream places surrendered under section 15.6 of the Act.

(d) Provisional allocations are closely monitored by the Department of Health and Ageing. Approved providers are required to submit quarterly reports to the Department on their progress towards bringing provisional allocations into operation. At 30 June 2005, there were 10,955 provisionally allocated mainstream residential aged care places which were allocated prior to 2004-05, that is, aged one year or more (Table 1). The most common reasons given by approved providers for delays with provisional allocations aged two years or older across Australia at 30 June 2005 are in relation to planning approvals, appeals, land availability and site problems.

Table 1

Provisionally allocated residential mainstream aged care places at 30 June 2005: Places one year or more old by year of allocation under the *Aged Care Act 1997*

		Year of Allocation					
State	**Aged Care Planning Region**	**1997/99**	**1999/00**	**2000/01**	**2001/02**	**2002/03**	**2003/04**
NSW	Central Coast			70	142	199	179
	Central West			6			6
	Far North Coast			40	110	57	34
	Hunter				30	110	82
	Illawarra			58	115	147	154
	Inner West		57	40	20	12	45
	Mid North Coast			10	180	85	179
	Nepean			45	40	60	
	New England				8	13	16
	Northern Sydney			15	14	131	47
	Orana Far West						34
	Riverina/Murray						48
	South East Sydney		50		92	165	264
	South West Sydney			16	64	116	84
	Southern Highlands			67	47	26	
	Western Sydney			70	52	60	49
VIC	Barwon-South Western		15	30	59	150	231
	Eastern Metro		11	40	34	168	382
	Gippsland			20	40	91	130
	Grampians			4	25		
	Hume				70	110	30
	Loddon-Mallee			25	30	30	30
	Northern Metro			51	141	84	189
	Southern Metro				47	169	455
	Western Metro		45	125	124	96	228
QLD	Brisbane North					28	111
	Brisbane South					126	108
	Cabool				39		66
	Darling Downs					3	5
	Far North						20
	Fitzroy			40	58		22
	Logan River Valley					125	61
	Mackay						6
	North West					10	0
	Northern					30	0
	South Coast			15	135	106	59
	Sunshine Coast				80	50	84
	West Moreton						10
	Wide Bay					16	96

State	Aged Care Planning Region	Year of Allocation					
		1997/99	1999/00	2000/01	2001/02	2002/03	2003/04
SA	Hills, Mallee & Southern					60	50
	Metropolitan North					86	99
	Metropolitan South					20	11
	Metropolitan West			40	30	40	
	Mid North					2	15
	South East			33		40	
	Yorke, Lower North & Barossa				18		
WA	Goldfields						8
	Great Southern					20	15
	Kimberley	5		5	12		
	Metropolitan East					35	
	Metropolitan North			40	16	183	233
	Metropolitan South East				30	20	35
	Metropolitan South West			70	118		31
	Pilbara		4	20		9	
	South West			30	0	32	30
	Wheatbelt				25		
TAS	North Western				12	14	
	Northern						49
	Southern				29	24	112
NT	Alice Springs						10
	Darwin			24	13	3	
ACT	ACT				65	36	107

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-077

OUTCOME 3: Aged Care and Population Ageing

Topic: COMMUNITY VISITORS SCHEME

Written Question on Notice

Senator McLucas asked:

There was a recent funding review of the Community Visitors Scheme (CVS) by the Allen Consulting Group. The CVS aims to enrich the Quality of Life of Residents of Aged Care facilities who are socially isolated and would benefit from a visitor.

a) Could the Committee please be provided with a copy of the review of the Community Visitors Scheme and its recommendations?

b) Could I also please be provided with any other documents relating to the review of funding for the CVS?

c) Could you also please provide a timeframe for responding to the review?

Answer:

a) The report will be released after it has been fully considered.

b) Relevant documentation is contained within the consultant's report.

c) The timeframe for responding to the review is subject to Ministerial consideration.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-232

OUTCOME 3: Aged Care and Population Ageing

Topic: COMMONWEALTH CARELINK PROGRAM

Hansard Page: CA 97

Senator McLucas asked:

Is an analysis or evaluation of the Commonwealth Carelink Program available to this committee? I would like the data you are receiving, the number of contacts, that sort of information. I am trying to get an indication of the levels of usage. If there is any sort of evaluative tool, that would be helpful. Could you give me something that compares the years in terms of number of calls?

Answer:

Commonwealth Carelink Program total client contact data for the period 1 July 2001 to 30 June 2005 and analysis by type for period 1 July 2004 to 30 June 2005 is attached.

Total Number of Commonwealth Carelink Centre Client Contacts from 1 July 2001 - 30 June 2005

2001-02	87,000
2002-03	145,000
2003-04	200,000
2004-05	235,000

Person Contacting a Centre
1 July 2004 - 30 June 2005

Who contacts a Centre?

Care recipient	27%
Carer	8%
Family member/sign. other	22%
GP	2%
Not Adequately Stated	11%
Other	5%
Other Health Professional	4%
Practice Staff	1%
Service Provider	17%
Student	3%
TOTALS	**100%**

Referral to a Centre
1 July 2004 - 30 June 2005

Who referred you to a Centre?

GP	1%
Not adequately stated	15%
Other	10%
Other Health Professional	2%
Practice Staff	1%
Press Advertisement	6%
Promotional Material	32%
Service Provider	16%
Telephone Directory	10%
Word of Mouth	7%
TOTALS	**100%**

Contact Type
1 July 2004 - 30 June 2005

Type of contact

Email	2.1%
Fax	0.5%
Mail	0.4%
Other	14.2%
Phone	69.1%
Walk in	13.8%
TOTALS	**100.0%**

Type of Assistance Sought
1 July 2004 - 30 June 2005

Type of Assistance

HACC or HACC-like services	61%
Residential Accommodation	6%
CACPs, Coordinate Accommodation, & Extended Care	2%
Disability	2%
Assessment	7%
GPs, medical, palliative care	3%
Other service type	19%
TOTALS	**100%**

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-228

OUTCOME 4: Primary Care

Topic: AGED CARE GP PANELS INITIATIVE

Hansard Page: CA 47

Senator McLucas asked:

(a) Can we get a list of the membership of the advisory group?
(b) And in what capacity they are there?

Answer:

a)

Aged Care GP Panels initiative - Implementation Advisory Group
List of member Organisations

- Rural Doctors Association Australia: Dr Ken Mackey
- Australian Medical Association: Ms Kristen Connell
- Council on the Ageing (National Seniors): Mr Jim Purcell
- Aged Care Association Australia: Mr Rod Young
- Aged and Community Services Australia: Mr Greg Mundy
- Australian Society for Geriatric Medicine: Dr Michael Dorevitch
- Australian Divisions of General Practice: Ms Kate Carnell
- Adelaide North East Division of General Practice: Dr Peter Ford
- Brisbane North Division of General Practice: Dr Ann McBryde
- Mornington Peninsula Division of General Practice: Dr John Siemienowicz
- Department of Health and Ageing: Ms Lisa McGlynn

b) Members of the group participated in an advisory capacity, to assist the department in developing the Aged Care GP Panels initiative, including providing advice and feedback on the implementation of the initiative.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-226

OUTCOME 4: Primary Care

Topic: MENTAL HEALTH

Written Question on Notice

Senator Moore asked:

a) Can you tell me how many people got their Service Incentive Payment (SIP) each year?
b) How many GPs have reached their cap (each year)?

Answer:

	2002-03	2003-04	2004-05
No of GPs eligible to receive a SIP	2,482	3,450	4,108
No of GPs who received a SIP	888	1,412	1,849
No of SIPs	5,695	13,908	16,748
*No of GPs who reached the cap of 67 SIPs	8	17	20

*Figures are based on date of service including data processed to the end of July 2005.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-227

OUTCOME 4: Primary Care

Topic: CMA HEALTH ASSESSMENTS

Hansard Page: CA 46

Senator McLucas asked:

a) How many annual health care assessments have been done for residents of aged care?
b) What is the expenditure?

Answer:

a) and b)

The Medicare item for Comprehensive Medical Assessments was introduced on 1 July 2004.

The table shows a quarterly breakdown of the number of services and expenditure on Comprehensive Medical Assessments from 1 July 2004 to 30 September 2005.

Quarters	Number of Services	Expenditure ($m)
Jul – Sep 04	6,570	0.99
Oct – Dec 04	7,089	1.07
Jan – Mar 05	5,647	0.99
Apr – Jun 05	5,165	0.93
Jul – Sep 05	7,436	1.34
Total	31,907	5.32

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-318

OUTCOME 4: Primary Care

Topic: CERVICAL PIP

Written Question on Notice

Senator Crossin asked:

a) An evaluation of the Practice Incentive Program (PIP) Cervical Screening Initiative was undertaken by the DoHA in 2004. Did this evaluation investigate how effectively this Federal Budget initiative was accessed by Aboriginal Community Controlled Health services? If not – why not?
b) Do you have an appreciation of whether this program was accessible to ACCHSs given that they are significant providers of primary health care (including Pap smears) to Aboriginal women?
c) I understand that NACCHO alerted the DOHA, prior to the evaluation, that ACCHSs might have difficulty accessing this initiative. In this case, why didn't the evaluation include a survey of ACCHSs to ascertain access to the program?

Answer:

a) & c)
The evaluation of the Practice Incentive Program (PIP) Cervical Screening Initiative surveyed a sample of Aboriginal Medical Services (AMS) which include Aboriginal Community Controlled Health Services (ACCHS). The evaluation also consulted with focus groups and a number of Divisions of General Practice that operate in rural areas with large Aboriginal populations.

b)
In 2004-05, the number of AMS participating in the PIP increased from 44 to 61. The department is working with Medicare Australia and the Royal Australian College of General Practitioners to support AMS to become accredited and participate in the PIP.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-319

OUTCOME 4: Primary Care

Topic: CERVICAL PIP

Written Question on Notice

Senator Crossin asked:

I understand that around one-third of ACCHSs are not eligible for the program on the basis of eligibility criteria. Of those that are eligible, what proportion claimed a service incentive payment from the program, and roughly what amount would have been received in outcome payments by these services?

Answer:

Of the 50 Aboriginal Medical Services (AMS) participating in the Cervical Screening Initiative in 2004-05, 33 practices received cervical screening Service Incentive Payments (SIPs) totalling $9,765. Of these, 16 AMS were paid an outcome payment totalling $26,661 or an average of $1,666 per practice.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-320

OUTCOME 4: Primary Care

Topic: CERVICAL PIP

Written Question on Notice

Senator Crossin asked:

The Evaluation has been described by the Department assessing the effectiveness of the incentive program on 'high risk' women – that is – to assess how effectively this program enhanced Pap screening of 'high risk' women. So, please tell us how effective this program was at targeting Aboriginal women as it is clear that rates of cervical cancer are much higher in Aboriginal population than non-Aboriginal.

If you are unable to report on how effective this program was in enhancing the Pap smear coverage of Aboriginal women – why are you not able to report this?

Answer:

For the purposes of the Practice Incentives Program (PIP) Cervical Screening Incentive, the 'high risk' category refers to women aged between 20 and 69 years who have not had a Pap smear for four years or more. GPs in practices participating in the Cervical Screening Incentive of the PIP can claim a Service Incentive Payment when a 'high risk' woman is screened.

In 2004-05, participating Aboriginal Medical Services (AMS) screened 279 women who had not had a Pap smear for four years or more. The number of 'at risk' Aboriginal women screened by AMS participating in PIP increased from 40 in the August 2004 quarter to 177 in the August 2005 quarter.

These figures do not include 'at risk' Aboriginal women who were screened by non-Aboriginal medical practices or Aboriginal women who were screened within the recommended two year time period.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-321

OUTCOME 4: Primary Care

Topic: CERVICAL PIP

Written Question on Notice

Senator Crossin asked:

How do you intend to evaluate more fully whether this program benefited Aboriginal women?

Answer:

The evaluation of the Practice Incentive Program (PIP) Cervical Screening Initiative conducted in 2004 by the Department of Health and Ageing surveyed a sample of Aboriginal Medical Services which include Aboriginal Community Controlled Health Services (ACCHS). The evaluation also consulted with focus groups and a number of Divisions of General Practice that operate in rural areas with large Aboriginal populations.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, November 2005

Question: E05-322

OUTCOME 4: Primary Care

Topic: CERVICAL PIP

Written Question on Notice

Senator Crossin asked:

What are some of the ways that the Department will improve THIS program so that Aboriginal women are targeted more effectively?

Answer:

The department is working with Medicare Australia and the Royal Australian College of General Practice to support more Aboriginal Medical Services (AMS) to become accredited and increase participation in the Practice Incentives Program (PIP). In 2004-05, the number of AMS participating in the PIP increased from 44 to 61.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-323

OUTCOME 4: Primary Care

Topic: CERVICAL PIP

Written Question on Notice

Senator Crossin asked:

I note that one problem with this program is that the outcomes payment system may be inequitable. GPs with clients from higher socioeconomic areas are more likely to meet the payment threshold than GPs with clients from lower SE areas. The more disadvantaged the target group – the more effort and investment required on the part of the GP to reach the outcomes payment threshold. Did evaluation of the program examine this issue?

Answer:

Yes. The evaluation also noted other factors affecting practice outcomes rates such as availability of GPs, characteristics of practices, and screening by other providers such as specialists and community health services.

The Service Incentive Payment component of the program is designed to complement the outcomes payment, by providing an incentive to GPs to screen under-screened women.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-256

OUTCOME 6: Hearing Services

Topic: HEARING SERVICES - HEARING SERVICES CONSULTATIVE COMMITTEE

Hansard Page: CA 129

Senator Crossin asked:

Can you provide me with a list of who is on that Committee?

Answer:

Mr Don Cole
Dr Robert Cowan
Mr Philip Davies
Ms Gayle Dicieri
Dr Harvey Dillon
Ms Anthea Green
Associate Professor Louise Hickson
Ms Helen King
Mr Barry MacKinnon
Mr Daniel McAullay
Ms Maureen McGrotty
Air V Marshall John Paule
Ms Jo Quayle
Mrs Margaret Robertson

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-298

OUTCOME 6: Hearing Services

Topic: HEARING SERVICES

Written Question on Notice

Senator Crossin asked:

With the extension of the Commonwealth Hearing Services Program to include indigenous people in receipt of CDEP, have funds been provided or allocated to educate people about these changes as well as how to access these services in order to improve uptake rates?

Answer:

Over the four year period from 1 December 2005, a total of $10.1 million has been allocated to provide services to Community Development Employment Program (CDEP) participants and to Indigenous people 50 years and over. The allocation includes funding for advertising and education about the changes, as well as the provision of services.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-299

OUTCOME 6: Hearing Services

Topic: HEARING SERVICES

Written Question on Notice

Senator Crossin asked:

What is the amount of funds that have been allocated to the outreach program by Australian Hearing in negotiation with the department under the CSO for 2005? Has this figure been determined for 2006? If so what is it?

Answer:

$2 million dollars was allocated to an outreach program for Indigenous Australians during the 2004/05 financial year.

A further $2 million dollars is expected to be expended through the outreach program for Indigenous Australians in the 2005/06 financial year.

A budget measure in 2005/06 provides additional funding for Indigenous Australians from 1 December 2005 in the following client categories;

- Indigenous Australians aged 50 years and over; and
- those participating in the Community Development Employment Program.

It is expected that some of these new clients will access the outreach program for Indigenous Australians.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-330

OUTCOME 6: Hearing Services

Topic: HEARING SERVICES

Written Question on Notice

Senator Crossin asked:

a) What has the Office done to inform Aboriginal CDEP holders and ACCHSs of this new eligibility?
b) Has there been an increase in uptake by Aboriginal adults since this initiative was announced in May?
c) How does the Office propose to examine and monitor uptake?

Answer:

a) Australian Hearing has developed a comprehensive communication strategy to inform Community Development Employment Program (CDEP) participants and Indigenous people who are 50 years and over of the new eligibility criteria. The strategy includes the use of posters, brochures and direct mail to key organisations including Aboriginal Medical Services, CDEP sites and Commonwealth, State, Territory and Local Government agencies; advertisements in Indigenous newspapers and newsletters, and radio advertisements on the National Indigenous Radio Service. The Office of Hearing Services and Australian Hearing have held meetings with stakeholder groups in Western Australia and the Northern Territory to assist in promoting the new eligibility criteria.

b) The commencement date for the new eligibility is 1 December 2005. There has been no change in the pattern of uptake by Aboriginal adults prior to November 2005.

c) The Office of Hearing Services will monitor uptake through the quarterly reports provided under the Memorandum of Understanding with Australian Hearing.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-347

OUTCOME 6: Hearing Services

Topic: HEARING SERVICES

Written Question on Notice

Senator Crossin asked:

What is the total amount spent on administered appropriations on ear health for 2004/05?

Answer:

Australian Government Hearing Services Program

Total expenditure on administered appropriations for the Hearing Services Program was $224.5 million during the 2004/05 financial year. Of this, $191.8 million was expended on the voucher hearing services and $32.7 million on the Community Service Obligations component of the Program.

Office of Aboriginal and Torres Strait Islander Health

The Office of Aboriginal and Torres Strait Islander Health (OATSIH) expended $2.760 million on its hearing health program during 2004/05.

Medicare and Pharmaceutical Benefits Schedules

A proportion of Medicare and Pharmaceutical appropriations for 2004/05 would be expended on ear health. It is not possible to identify specific amounts in this regard.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-348

OUTCOME 6: Hearing Services

Topic: HEARING SERVICES

Written Question on Notice

Senator Crossin asked:

Has the department been able to now analyse the adult expenditure outside the outreach program? If so what is this?

Answer:

Data is available on the number of Indigenous adult clients who access the Community Service Obligations (CSO) component of the Hearing Services Program (the Program). While eligible Aboriginal and Torres Strait Islander people are able to access hearing services under the voucher component of the Program, they are not required to identify themselves as being of Aboriginal and/or Torres Strait Islander descent. Accurate data on the level of expenditure on adult Indigenous voucher clients is therefore not available.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-344

OUTCOME 6: Hearing Services

Topic: HEARING SERVICES – VOUCHER SYSTEM

Written Question on Notice

Senator Crossin asked:

Can you please provide the criteria under the eligibility for a voucher system as will be applied from 1 January 2006?

Answer:

As of 1 January 2006, a person will be eligible for a hearing services voucher if they have reached the age of 21 years and are an Australian citizen or an Australian permanent resident and are:

- a holder of a Pensioner Concession Card; or
- a holder of a Gold Repatriation Health Card issued for all conditions; or
- a holder of a White Repatriation Health Card issued for conditions including hearing loss; or
- a person in receipt of both Sickness Allowance and a Health Care Card; or
- a dependant of a person in one of the above categories; or
- a member of the Australian Defence Force; or
- a person undergoing vocational rehabilitation under Part III of the *Disability Services Act 1986* and who is referred by their case manager.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2005-2006, 2 November 2005

Question: E05-345

OUTCOME 6: Hearing Services

Topic: HEARING SERVICES -VOUCHER SYSTEM

Written Question on Notice

Senator Crossin asked:

How many vouchers were issued in 2004/05? How many of these were used by clients accessing services through private providers?

Answer:

There were 192,000 vouchers issued in 2004/05 of which 101,000 have been serviced by private providers.