# Community Affairs Committee

## Examination of Additional Estimates 2007-2008

## Additional Information Received

## CONSOLIDATED VOLUME 1

## HEALTH AND AGEING PORTFOLIO

**Outcomes: Whole of Portfolio and Outcomes 1 to 3**

**26 MAY 2008**

# ADDITIONAL INFORMATION RELATING TO THE EXAMINATION OF ADDITIONAL EXPENDITURE FOR 2007-2008

Included in this volume are answers to written and oral questions taken on notice and tabled papers relating to the additional estimates hearings on 20 and 22 February 2008

*** Please note that 24 June 2008 is the proposed date for answers to be tabled in the Senate where this date is indicated**

# HEALTH AND AGEING PORTFOLIO

| Senator | Quest. No. | Whole of portfolio | Vol. 1 Page No. | Date tabled in the Senate or presented out of session* |
|---|---|---|---|---|
| Colbeck | 50 | General staffing baseline | 1 | 15.05.08 |
| Minchin | 88 | Appointments, grants, requests to move funds & election promises | | 24.06.08 |
| | | **Outcome 1: Population Health** | | |
| | T1 tabled at hearing | Pregnancy counselling funded organisation roles and yearly funding allocation | 3 | 20.03.08 |
| | T2 tabled at hearing | Membership of the Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis (MACASHH) – February 2008 | | 20.03.08 |
| | Letter 29.02.08 | Letter from Dr Penny Allbon, Director, AIHW dated 29 Feb 08 correcting a statement made at the estimates hearing on 20 Feb 08 | | 20.03.08 |
| Birmingham | 51 | Peer-reviewed research on consumer behaviour around food labels | | 15.05.08 |
| Colbeck | 70 | Radioactive waste facility | | 15.05.08 |
| Colbeck | 85 | regulatory processes organs and tissue | | 15.05.08 |
| Stott Despoja | 1-4 | Pregnancy counselling helpline | | 15.05.08 |
| Adams | 54 | Breastscreen Australia participation | | 15.05.08 |
| Allison | 37 | Actions against Jim Selim for breaches of the *Therapeutic Goods Act 1989* | | 15.05.08 |
| Boyce | 47 | Australian Institute of Health and Welfare (AIHW) staff numbers | | 15.05.08 |
| Boyce | 48 | Owner of Australian Institute of Health and Welfare (AIHW) building | | 15.05.08 |
| Boyce | 49 | Data collections | | 15.05.08 |
| Colbeck | 20-21 | Social inclusion | | 15.05.08 |
| | | **Outcome 2: Access to Pharmaceutical Services** | | |

## Outcome 3: Access to Medical Services

| | | | | |
|---|---|---|---|---|
| | T3 tabled at hearing | The Lancet Oncology author statements [tabled by Senator Polley] | 28 | 20.03.08 |
| | T4 tabled at hearing | GP super clinic sites | | 20.03.08 |
| | T5 tabled at hearing | National Health and Hospitals Reform Commission terms of reference | | 20.03.08 |
| Boyce | 43 | Professional Services Review (PSR) Budget and staffing | | 15.05.08 |
| Milne | 65 | PET | | 15.05.08 |
| Adams | 69 | Radiation therapy | | 15.05.08 |
| Colbeck | 19 | Allied workers | | 15.05.08 |
| Milne | 66 | Medical Services Advisory Committee (MSAC) | | 15.05.08 |
| Polley | 68 | Medical Services Advisory Committee (MSAC) | | 15.05.08 |
| Milne | 67 | Medical Services Advisory Committee (MSAC) | | 15.05.08 |

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-050

OUTCOME: Whole of Portfolio

Topic: GENERAL STAFFING BASELINE

Hansard Page: CA 15

Senator Colbeck asked:

Could you give the committee a general staffing baseline across the agency?

Answer:

The table below provides information on the total staff headcount figures by classification for the Health and Ageing portfolio as at 29 February 2008. The headcount figures include staff in Therapeutic Goods Administration, Office of the Gene Technology Regulator and National Industrial Chemicals Notification and Assessment Scheme.

| **Classification** | **Total** |
|---|---|
| Secretary | 1 |
| Holder of Public Office | 4 |
| Senior Executive Band 3 | 5 |
| Senior Executive Band 2 | 21 |
| Senior Executive Band 1 | 93 |
| Executive Level 2 | 614 |
| Executive Level 1 | 1338 |
| APS6 | 1373 |
| APS5 | 734 |
| APS4 | 391 |
| APS3 | 180 |
| APS2 | 55 |
| APS1 | 10 |
| Cadet | 4 |
| Graduate | 104 |
| Legal | 47 |
| Medical | 50 |
| Professional | 2 |
| Public Affairs | 30 |
| Research Scientist | 5 |
| **Total** | **5061** |

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 & 22 February 2008

Question: E08-088

OUTCOME: Whole of Portfolio

Topic: APPOINTMENTS, GRANTS, REQUESTS TO MOVE FUNDS & ELECTION PROMISES

Written Question on Notice

Senator Minchin asked:

a) All appointments which have been made by the Government (through Executive Council, Cabinet and Ministers) to Statutory Authorities, Executive Agencies and Advisory Boards, with a brief outline of the respective appointee's credentials.

b) A list of all vacancies which remain to be filled by Ministerial (including Cabinet and Executive Council) appointments.

c) All grants which have been approved by Ministers from funds within each portfolio. In the future I propose that, departments, as a matter of course, should supply this information before each round of Senate Estimates.

d) Provide a list of requests to the Department of Finance to move funds within each portfolio.

e) In addition, I request that the Government provide me with a complete list of election promises made during the campaign and which Department is responsible for the administration of each of these commitments.

Answer:

a) Refer to part (1) of the response to Senate Question on Notice No. 117.

b) Refer to answer being provided to Senator Minchin's Parliamentary Question on Notice 127.

c) Refer to answer being provided to Senator Minchin's Parliamentary Question on Notice 127.

d) Refer to part (4) of the response to Senate Question on Notice No. 129.

e) Refer to answer being provided to Senator Minchin's Parliamentary Question on Notice 163.

**T1**

## ATTACHMENT B: FUNDED ORGANISATION ROLES AND YEARLY FUNDING ALLOCATION

| **Funded Organisation** | **Funded Role** | **2007/08 Funding (GST excl., per annum)** |
|---|---|---|
| Australian Federation of Pregnancy Support Services (AFPSS, trading as Pregnancy Help Australia) | To facilitate the provision of practical pregnancy and parenting support services to women and their partners experiencing a pregnancy, vocational training and education in pregnancy support and community outreach for high need population groups. | $314,287.09 |
| Australian Episcopal Conference of the Roman Catholic Church (AECRCC) | To provide vocational training and education in natural family planning to health and other professionals, and reproductive health and education services to high need population groups. | $976,978.00 |
| Multicultural Centre for Women's Health (MCWH, formerly Working Women's Health) | To provide culturally appropriate sexual and reproductive health training to bilingual community and health educators as well as sexual and reproductive education services to newly arrived or isolated women from diverse cultures in the workplace. | $121,074.36 |
| Sexual Health & Family Planning Australia (SH&FPA) | To provide the Commonwealth with a better understanding of Australia's emerging national sexual and reproductive health issues and priorities in primary care settings. | $106,504.36 |
| Caroline Chisholm Society (CCS) | To provide practical pregnancy support services to women and their partners experiencing an unplanned pregnancy. These services may include: material aid (baby goods and equipment); financial counselling; early parenting courses and referrals for housing assistance and pension support payments. | $52,020.00 |
| Foundation for Human Development (FHD) | To provide practical pregnancy support services to women and their partners experiencing an unplanned pregnancy. These services may include: material aid (baby goods and equipment), as well as physical, financial, emotional and other support to pregnant women in need. | $52,020.00 |

**T2**
**Membership of the Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis (MACASHH) – February 2008.**

| **Name** | **Appointment Dates** |
|---|---|
| The Hon Michael Wooldridge | 1 July 2007 – 30 Jun 2010 |
| Professor Frank Bowden | 1 July 2007 – 30 Jun 2010 |
| Professor Robert Batey | 1 July 2007 – 30 Jun 2010 |
| Associate Professor Cindy Shannon | 1 July 2007 – 30 Jun 2010 |
| Mr Nicholas Hobson DFC AFC | 1 July 2007 – 30 Jun 2010 |
| Ms Angela Assaf | 1 July 2007 – 30 Jun 2010 |
| Professor Sharon Lewin | 1 July 2007 – 30 Jun 2010 |
| Mr Don Baxter | 1 July 2007 – 30 Jun 2010 |
| Father Michael Kelly SJ | 1 July 2007 – 30 Jun 2010 |

T2

# Terms of Reference of the Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis (MACASHH)

The Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis is the key advisory body to the Minister for Health and Ageing on policies and national strategies in relation to HIV/AIDS, Indigenous sexual health, sexually transmissible infections (STIs) and viral hepatitis. The Committee is responsible for establishing alliances such as those between HIV/AIDS and hepatitis C prevention and the prevention of illicit drug use, and for coordination of a whole-of-government response to HIV/AIDS and hepatitis C.

*The Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis will*:

1. Provide advice to the Minister for Health and Ageing on policies and national strategies in relation to HIV/AIDS, hepatitis C and other viral hepatitis issues, Indigenous sexual health, and sexually transmissible infections.
2. Examine the information, education and prevention needs of people from culturally and linguistically diverse backgrounds in advising upon the development of future strategies.
3. Contribute to the effectiveness of Australia's response to HIV/AIDS, hepatitis C and other viral hepatitis infections, Indigenous sexual health, and sexually transmissible infections.
4. Oversee and consolidate the advice of the disease-specific subcommittees on HIV/AIDS and STIs, viral hepatitis, and Indigenous Australians sexual health.
5. Provide independent and strategic advice to the Australian Government, intergovernmental committees and other bodies, and parliamentary parties as appropriate.
6. Consult and liaise with other stakeholders, public health advisory bodies, the research sector and relevant peak non-government organisations.
7. Build and maintain partnerships across the range of sectors concerned in addressing issues related to HIV/AIDS, hepatitis C and other viral hepatitis issues, Indigenous sexual health and STIs.
8. Work closely with the National Public Health Partnership (NPHP) and other national expert advisory bodies to develop and implement effective strategies, policies and programs to address HIV/AIDS, hepatitis C and other viral hepatitis infections, Indigenous sexual health and STIs.
9. Develop a 3-year Work Plan.
10. Report annually to the Minister for Health and Ageing.

Australian Government
Australian Institute of Health and Welfare

*Better information and statistics for better health and wellbeing*

Mr Elton Humphrey
Secretary
Senate Community Affairs Committee
Parliament House
CANBERRA ACT 2066

Dear Mr Humphrey

**Request for Amendment to Evidence Provided at the Additional Estimates Hearing on 20 February 2008: AIHW (Outcome: Better health and wellbeing for Australians through better health and welfare statistics**

I am writing to correct a statement that I made at the Additional Estimates hearing of the Senate Community Affairs Committee on 20 February 2008.

Senator Boyce asked the following question:

> But you have just been through an arbitration case with them and whatever?

My response was as follows:

> We have, and it was arbitrated by a representative from the Australian Valuation Office.

The response was accurate based on my recollection at the time of the title of the organisation which appointed the arbitrator. I have now established that the correct title of the organisation that appointed the arbitrator was the Australian Property Institute. I would appreciate it if you could arrange for the record to be amended accordingly.

Yours sincerely

Dr Penny Allbon
Director, AIHW
29 February 2008

26 Thynne Street, Fern Hill Park, Bruce ACT - GPO Box 570, Canberra ACT 2601
phone 02 6244 1000 - facsimile 02 6244 1299 - web www.aihw.gov.au

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-051

OUTCOME 1: Population Health

Topic: PEER-REVIEWED RESEARCH ON CONSUMER BEHAVIOUR AROUND FOOD LABELS

Hansard Page: CA35

Senator Birmingham asked:

Would FSANZ be able to draw the Committee's attention to the particular links for peer-reviewed research on consumer behaviour around food labels.

Answer:

***Research commissioned under the FSANZ Evaluation Strategy***

Research under the evaluation strategy is generally reviewed by the Evaluation Stakeholder Advisory Group

**Food Labelling Issues: Qualitative research with consumers**

Labelling Standards, an assessment of the impact on consumers

http://www.foodstandards.gov.au/newsroom/publications/foodlabellingissuesconsumerresearchdecember2001/index.cfm

**Food labelling issues: Quantitative Research on food labelling issues for consumers in Australia and New Zealand**

Labelling Standards, an assessment of the impact on consumers

http://www.foodstandards.gov.au/newsroom/publications/foodlabellingissuesquantitativeresearchconsumersjune2003/index.cfm

**Food Labelling Issues: Qualitative consumer study related to nutrition content claims on food labels**

A study conducted to gain qualitative information on nutrient content claims on food labels from consumers to assist FSANZ in the future development and review of food labelling standards, codes of practice and guidelines.

http://www.foodstandards.gov.au/newsroom/publications/consumerstudyrelatedtonutritioncontentclaimsjuly2003/index.cfm

**Food Labelling Issues: Qualitative consumer study related to food-type dietary supplement labelling**

A study conducted to gain qualitative information on food-type dietary supplement labelling from consumers to assist FSANZ in the future development and review of food labelling standards, codes of practice and guidelines.

http://www.foodstandards.gov.au/newsroom/publications/consumerstudyrelatedtofoodtypedietarysupplementlabellingjuly2003/index.cfm

**Food Labelling Issues: Quantitative consumer survey related to allergen labelling on food products**

Allergen Labelling Standard, an assessment of the impact on consumers

http://www.foodstandards.gov.au/newsroom/publications/allergensurvey/index.cfm

**Food Labelling Issues: Qualitative consumer study related to food labelling of infant foods**

FSANZ has undertaken a review (Proposal P274) of the minimum age labelling so that infant food labelling reflects the revised Australian guidelines, and also takes into account New Zealand policy.

http://www.foodstandards.gov.au/newsroom/publications/foodlabellingofinfantfoodsapril2004/index.cfm

**Food Labelling Issues: Qualitative research on participants' perceptions and use of nutrition, health and related claims on packaged foods and associated advertising material**

http://www.foodstandards.gov.au/newsroom/publications/evaluationreportseries/healthclaimsqualitat3069.cfm

**Food Labelling Issues: Quantitative research on consumers' perceptions and use of nutrition, health and related claims on packaged foods**

http://www.foodstandards.gov.au/newsroom/publications/evaluationreportseries/healthclaimsquantita3070.cfm

***Research commissioned as part of the standard development process***

These studies have not been peer-reviewed.

**Analysis of fortification of foods with calcium research**

See Attachment 4 of the Second Review Report for Application A424 – Fortification of Foods with Calcium

http://www.foodstandards.gov.au/_srcfiles/SSR%20A424%20Calcium%20fortification.pdf

**Consumer aspects of plant sterol enriched foods**

See Attachment 3 of the Second Review Report for Application A433 – Phytosterol Esters derived from Vegetable Oils in Breakfast Cereals, Application A434 – Phytosterol Esters derived from Vegetable Oils in Low-fat Milk & Yoghurt. Application A508 – Phytosterols derived from Tall Oils as Ingredients in Low-fat Milk.

http://www.foodstandards.gov.au/_srcfiles/A434%20Phytosterols%20in%20low%20fat%20milk%20SRR%20FINAL.pdf

**Formulated Beverages Survey**

See Attachment 3 of the First Review Report for Application A470 – Formulated Beverages.

http://www.foodstandards.gov.au/_srcfiles/A470%20Formulated%20bevs%20FRR%20FINAL.pdf

**Country of origin labelling print size consumer research**

Application A579 – Country of Origin - Print Size for Unpackaged Food in Display Cabinets

http://www.foodstandards.gov.au/_srcfiles/A579%20CoOL%20Print%20Size%20Phase%202%20consumer%20research.pdf

**Consumer research on percentage daily intake**

Proposal P293 –Nutrition, Health & Related Claims

http://www.foodstandards.gov.au/_srcfiles/P293%20PFAR%20Att%202%20-%20Technical%20Report%20Consumer%20Research.pdf

**Consumer research on no added sugar claims**

Proposal P293 –Nutrition, Health & Related Claims

http://www.foodstandards.gov.au/_srcfiles/P293%20PFAR%20Att%204%20-%20Consumer%20research%20no%20added%20sugar%20claim.pdf

***Forthcoming commissioned research***

Consumer Attitudes Survey 2007: A benchmark survey of consumers' attitudes to food issues. (reviewed by Evaluation Stakeholder Advisory Group – public release expected April 2008)

An investigation into the impact of nutrition content claims on packaging in relation to consumer purchase intentions, nutrition attitude and health benefits. (peer-reviewed – public release expected April 2008)

Consumer use of nutrition content claims in shopping environments. (peer-reviewed – public release expected April 2008)

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-070

## OUTCOME 1: Population Health

Topic: RADIOACTIVE WASTE FACILITY

Hansard Page: CA 44

Senator Colbeck asked:

Do you have any information on the government's direction in respect of the proposed low-level [Commonwealth Radioactive] waste [Management] facility?

Answer:

No, as this is a matter for the Resources, Energy and Tourism portfolio.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 22 February 2008

Question: E08-085

OUTCOME 1: Population Health

Topic: REGULATORY PROCESSES ORGANS AND TISSUE

Hansard Page: CA 16

Senator Colbeck asked:

Has any progress been made on the amendment of legislation for guidelines around organ and tissue regulatory processes?

Answer:

The Commonwealth Department of Health and Ageing (the Department) is finalising an options paper for the consideration of Health Ministers during the first half of 2008 on the regulation of solid organs and reproductive tissues. The paper is based on the findings of a review process managed by the Department in consultation with state and territory governments and key stakeholders.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 & 22 February 2008

Question: E08-001

OUTCOME 1: Population Health

Topic: PREGNANCY COUNSELLING HELPLINE

Written Question on Notice

Senator Stott Despoja asked:

a) Considering the helpline only received 2,238 calls in its first seven months of operation, how is the Federal Government planning on monitoring the effectiveness of the National Pregnancy Support Helpline, given the figures suggest women have already shunned the service?

b) Does the Department have figures identifying the demographic of callers? If so, what are they?

c) For how long will the helpline be monitored?

d) To what does the Department attribute small numbers of callers to the Helpline?

e) Will the Helpline continue if the numbers of calls remain low?

f) Are there a minimum number of calls required for the Helpline to be considered worthwhile?

g) How many people have claimed the Medicare rebate for the Helpline?

Answer:

a) The Department regularly monitors McKesson Asia Pacific Pty Limited's (McKesson's) performance against the contract requirement to deliver non-directive counselling. Operation of the Helpline and receipt of funding is conditional on the operator continuing to meet this requirement.

   The Department also actively monitors McKesson's performance through quarterly reporting against the contract. McKesson has in place a process to record, manage, investigate and resolve complaints in accordance with their Feedback and Complaints Management Procedure.

   An evaluation of the Helpline is planned to take place after the first 12 months of its operation.

b) The Department is provided with general information on the age and gender of callers to the Helpline. The Department also has information on the origin of calls broken down to state/territory and capital city/outside capital city. This information is contained in the quarterly reports provided by McKesson Asia Pacific Pty Limited covering the period May to December 2007. The Department is not provided with any information that identifies individual callers.

**Gender of caller**

- 11% of calls were from men
- 88% of calls were from women
- Gender was not recorded for 1% of calls

**Age of caller (**Of calls where age was recorded):

- 0 – 17 years = 11.5%
- 18 – 24 years = 30.5%
- 25 – 29 years = 18.4%
- 30 – 39 years = 30.4%
- 40 – 49 years = 7.4%
- 50 – 59 years = 1.3%
- 60 – 69 years = 0.5%

Information on the age or gender of a caller is not recorded for calls which are non-target, or out of scope. Non-target calls include enquiry calls from the media and students, hang ups and wrong numbers. Information on the age of clients can only be recorded where clients provide this information to the counsellor.

**Origin of calls**

| Capital City | |
|---|---|
| Sydney | 21.0% |
| Brisbane | 7.5% |
| Melbourne | 21.9% |
| Canberra (ACT) | 2.1% |
| Hobart | 1.0% |
| Adelaide | 6.5% |
| Perth | 8.0% |
| Darwin | 0.6% |

| Outside Capital City | |
|---|---|
| NSW | 11.3% |
| QLD | 8.9% |
| VIC | 7.5% |
| SA | 1.6% |
| WA | 1.0% |
| NT | 0.3% |

c) The Department will maintain the regular monitoring of the service against the contract requirements for the life of the contract.

d) The Helpline is in its first year of operation and to date there has only been low level communication activity. Currently there are listings in white and yellow pages and a small number of posters and wallet cards advising of the Helpline number have been distributed.

e) An evaluation of the Helpline is due to be undertaken after the first 12 months of operation of the service. This may inform any future consideration of the Helpline.

f) No. A minimum number of calls has not been identified for this purpose.

g) None. Counselling through the Helpline is provided at no cost to the caller. There is no Medicare Benefits Schedule rebate for this service.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 & 22 February 2008

Question: E08-002

OUTCOME 1: Population Health

Topic: PREGNANCY COUNSELLING HELPLINE

Written Question on Notice

Senator Stott Despoja asked:

Is the AFPSS still in receipt of funding from the Department? If so what are they contracted to do, given that they no longer provide the 1300 service?

Answer:

Yes.

The Australian Federation of Pregnancy Support Services (AFPSS) is contracted to facilitate the provision of practical pregnancy and parenting support services to women and their partners experiencing pregnancy, vocational training and education in pregnancy support and community outreach for high need population groups.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 & 22 February 2008

Question: E08-003

OUTCOME 1: Population Health

Topic: PREGNANCY COUNSELLING HELPLINE

Written Question on Notice

Senator Stott Despoja asked:

a) Is the Department aware that the Australian Federation of Pregnancy Support Services (Pregnancy Help Australia) helpline still contains a phone message that says while it no longer provides phone counselling, it can provide contact numbers for pregnancy support services in States that provide 'support, referral and counselling' – yet the numbers provided are anti-abortion, therefore unable to 'refer'?

b) Does the Department consider this appropriate?

Answer:

(a) The Australian Federation of Pregnancy Support Services (AFPSS) has amended its answering message in light of its contracted agreement to provide an answering message that reflects the practical pregnancy and parenting support services provided by the Federation. The current message is as follows:

> "*You have reached Pregnancy Help Australia on 1300 13 93 13. This line no longer provides direct counselling to clients. However we can direct you to contact information for a Pregnancy Help Agency in your state which can provide you with help and practical support.*"

(b) This message accurately reflects activities funded under the current agreement with the AFPSS.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 & 22 February 2008

Question: E08-004

OUTCOME 1: Population Health

Topic: PREGNANCY COUNSELLING HELPLINE

Written Question on Notice

Senator Stott Despoja asked:

Will the Government endeavour to set up another national pregnancy counselling helpline, in consultation with key non-directive pro-choice services?

Answer:

This would require a future policy decision by the Government.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-054

OUTCOME 1: Population Health

Topic: BREASTSCREEN AUSTRALIA PARTICIPATION

Hansard Page: CA18

Senator Adams asked:

Do you have figures for the take-up of people on the outside of that target age group that are coming forward to ask to have a mammogram done?

Answer:

BreastScreen Australia offers free mammographic screening to well women without symptoms of breast cancer aged 50-69 years. Women aged 40-49 and 70 years and older are also eligible to attend, but are not actively recruited.

A breakdown of the proportion of women screened by BreastScreen Australia from 1 January 2003 to 31 December 2004 (two year period) is as follows:

| Age Group | Participation | Percentage of all BreastScreen participants |
|---|---|---|
| 40-49 years | 268,345 | 16.5% |
| 70 years and over | 214,287 | 13.2% |
| 50-69 years (target group) | 1,144,483 | 70.3% |

The latest published data available on the proportion of women screened by BreastScreen Australia outside the target age group are provided in the Australian Institute of Health and Welfare *BreastScreen Australia Monitoring Report 2003-2004* published in April 2007.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-037

OUTCOME 1: Population Health

Topic: ACTIONS AGAINST JIM SELIM FOR BREACHES OF THE *THERAPEUTIC GOODS ACT 1989*

Hansard Page: CA41, CA42

Senator Allison asked:

a) How much has the Department incurred to date in legal costs as a result of action being taken against Mr Selim?

b) Can you advise if at any stage there has been negotiation with Mr Selim over compensation?

c) What charges have been laid that remain outstanding? In what courts are they?

Answer:

a) The legal proceedings arising from the investigation by the Therapeutic Goods Administration (TGA) in 2003 into the manufacture of Travacalm tablets and other therapeutic products by Pan Pharmaceuticals Ltd (Pan) remains ongoing and involves eight defendants including Mr Selim. The associated legal costs to date have not been incurred by nor attributed to the Department nor is it possible, because some matters have been heard concurrently, to determine with any degree of accuracy the proportion of legal costs that might be attributable to the action against any individual involved in these proceedings.

b) Mr Selim is currently defending a civil claim bought against him by the Liquidator of Pan. In the same proceedings Mr Selim has bought a cross-claim against the Commonwealth alleging negligence and misfeasance and he is seeking substantial damages. Comcover, as the Commonwealth's insurer, is responsible for managing the Commonwealth's response in these proceedings. Working with Comcover, the Department is vigorously defending the claims on the basis that the TGA was carrying out the functions given to it under the *Therapeutic Goods Act 1989* the objects of which include to ensure the safety of therapeutic goods supplied in Australia. The Department has not made an offer of compensation to Mr Selim in relation to these proceedings.

c) A total of 269 charges have been laid following the TGA investigation into the manufacture by Pan Pharmaceuticals Ltd (Pan) of Travacalm tablets and other therapeutic products.

Of these 142 charges involving four defendants have been finalised:

- Convictions have been recorded against both Pan and a former employee in relation to manufacturing a counterfeit medicine and intentionally inflicting Grievous Bodily Harm. The company was fined a total of $3 million; the former employee was sentenced to and served 18 months periodic detention.

- Mr Selim was acquitted of a charge relating to procuring the destruction of evidence. Following a submission by Defence Counsel the trial Judge directed the jury to acquit Mr Selim. An appeal by the Commonwealth Director of Public Prosecutions (CDPP) was subsequently dismissed on 19 November 2007.

- One defendant has pleaded guilty to charges related to aiding and abetting the manufacture and export of counterfeit therapeutic goods and forging Commonwealth documents. A term of imprisonment imposed at the District Court of New South Wales (Sydney) has been suspended upon the person entering a $1,000 recognizance and an undertaking to be of good behavior for a period of 15 months.

96 charges involving four defendants are currently before the Courts:

- One defendant has pleaded guilty to charges concerning the manufacture and export of counterfeit therapeutic goods and is awaiting sentence in the District Court of New South Wales.

- A committal hearing involving three defendants charged with the manufacture and export of counterfeit therapeutic goods has commenced in the Burwood Local Court (Sydney).

Committal hearings commenced on 31 March 2008 at the Burwood Local Court in relation to a total of 31 charges:

- Two defendants are expected to appear in relation to charges concerning the forging of Commonwealth documents.

- One defendant is expected to appear in relation to using forged Commonwealth documents.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-047

OUTCOME 1: Population Health

Topic: AUSTRALIAN INSTITUTE OF HEALTH AND WELFARE (AIHW) STAFF NUMBERS

Hansard Page: CA 46

Senator Boyce asked:

What is your full-time equivalent (of staff numbers at the AIHW)?

Answer:

As at 31 January 2008 there were 204.1 full-time equivalent staff at the AIHW.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-048

OUTCOME 1: Population Health

Topic: OWNER OF AUSTRALIAN INSTITUTE OF HEALTH AND WELFARE (AIHW) BUILDING

Hansard Page: CA 47

Senator Boyce asked:

Are you able to tell me who the building owner is?

Answer:

The name of the new owner of the main building occupied by the AIHW is Wolin Investments Pty Limited.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-049

OUTCOME 1: Population Health

Topic: DATA COLLECTIONS

Hansard Page: CA 49

Senator Boyce asked:

Is it correct that you have five new data collection activities that are beginning in the 2007-08 year?

Answer:

Yes, the AIHW can confirm that during 2007-08 it has been working to develop or enhance data collections in relation to: quality and safety in health care; monitoring of bowel cancer screening; child protection services; palliative care agencies and patients; and young people in nursing homes.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 & 22 February 2008

Question: E08-020

OUTCOME 1: Population Health

Topic: SOCIAL INCLUSION

Written Question on Notice

Senator Colbeck asked:

What early intervention programs does the Government have to encourage healthy ageing and living?

Answer:

The Australian Government currently has the following intervention programs to encourage healthy ageing and living:

- The National Heart Foundation's Walking Program
    - Funding of $1.5 million over three years (2007-10) has been allocated for the walking program. The program provides free access to coordinated walking groups across Australia and enhanced support networks for people who are socially isolated, including older people.

- Lifescripts
    - Lifescripts provide general practice with the tools and resources to address the top five lifestyle risk factors for chronic disease (smoking, poor nutrition, alcohol misuse, physical inactivity and unhealthy weight) with their patients. These resources can be used with adults of all ages, including older people.

- Healthy Active Australia Community and School Grants Program
    - $76.7 million over four years is currently allocated to provide one-off grants of between $10,000 and $200,000 to not-for-profit organisations and schools to fund physical activity and healthy eating initiatives in communities and schools across Australia. The target groups for the grants include adults and older Australians.

- The National Falls Prevention in Older People Initiative
    - The National Falls Prevention in Older People Initiative aims to reduce the harm from falls in people aged 65 and over (55+ for Aboriginal and Torres Strait Islander peoples), living in the community and aged care homes, as well as those being treated in hospitals.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 & 22 February 2008

Question: E08-021

OUTCOME 1: Population Health

Topic: SOCIAL INCLUSION

Written Question on Notice

Senator Colbeck asked:

a) Can the Department outline the number of healthy lifestyle programs being funded over the past two years?

b) What are the names of those programs?

c) How long do the programs run for?

d) Have there been any programs cut?

e) If programs have been cut, why have they been cut?

f) Have the outcomes of those programs been measured?

Answer:
a) See Attachment A.

b) See Attachment A.

c) See Attachment A.

d) No programs listed in Attachment A have been cut.

e) Not applicable.

f) See Attachment A.

**ATTACHMENT A**

| (b) Name of program | (c) Length of program | (d) Program cut? | (e) Reason for cut | (f) Has outcome of program been measured? |
|---|---|---|---|---|
| Walk to Work Day | 2000-2010 | No | n/a | An event report is provided after each Walk to Work Day. In addition, the current contract includes an evaluation component which will be provided at the end of the program. |
| Walk Safely to School Day | 2000-2010 | No | n/a | An event report is provided after each Walk Safely to School Day. In addition, the current contract includes an evaluation component which will be provided at the end of the program. |
| *Get Moving* social marketing campaign | 3 months (2006) | No | n/a | Yes, an evaluation report was provided in January 2007. |
| Around Australia in 40 Days Walking Challenge | 3 months (2007) | No | n/a | Participation of schools and students was measured. |
| Bluearth (physical activity promotion to children and youth) | July 2007 to June 2008 | No | n/a | The contract requires a final report outlining the progress and achievements made under the project. |
| National Heart Foundation's Walking Program | 3 years (2007-10) | No | n/a | The contract includes an evaluation component which will be completed at end of the program. |
| Lifescripts | Commenced 2003-04 and is currently being evaluated | No | n/a | Yes, program uptake was measured in 2006-2007. Demonstration Divisions are currently undergoing data collection and evaluation. |
| Healthy Active Australia Community and School Grants Program | 1 July 2007 to 30 June 2010 | No | n/a | No, the Program is currently being implemented. |
| Building a Healthy Active Australia Healthy School Communities Grants Program | 1 July 2004 – 1 December 2005 (Extended to 22 December 2006) | No | n/a | Data on the uptake of the program has been collected. |
| Healthy Active Ambassador Program | September 2006 to June 2008 | No | n/a | No |

13

TABLED BY SENATOR POLLEY AT DOHA ESTIMATES 20.02.08

THE LANCET Oncology

## Author Statements

Please insert the relevant text under the subheadings below. The completed form should be signed by all authors. Please fax the signed copy to: +44 207 424 4557 and mail the original to The Lancet Oncology, 32 Jamestown Road, London NW1 7BY, UK.

Manuscript title: _____

_____

Corresponding author: _____

Submission category:
Article ☐ Review ☐ Meta-analysis ☐ Historical Review ☐ Personal View ☐ Health-care Research ☐ Essay ☐ Case Report ☐ Clinical Picture ☐ Reflection & Reaction ☐ Debate ☐

Does your manuscript have a reference number? No ☐ Yes ☐ If yes, enter number here _____

Authors' contributions
[Please insert here the contribution each author made to the manuscript, eg, literature search, figures, writing etc. If all authors contributed equally, please state this.]

Conflict of interest
[Please declare any conflicts of interest relevant to what you write. This includes employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications and travel grants.] If there are no conflicts of interest, please state that there are none.

Role of the funding source
[Please disclose any funding sources and their role, if any, in the writing of the manuscript or the decision to submit it for publication. Examples of involvement include data collection, analysis or interpretation; trial design; patient recruitment; or any other aspect pertinent to the study. Please also comment whether you have been paid to write this article by a pharmaceutical company or other agency.]

I agree with the plan to submit to *The Lancet Oncology*; the contents of the manuscript; and to being listed as an author. I have had access to all the data in the study (for original research articles).

Name: _____ Signature: _____ Date: _____

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Name: _____ Signature: _____ Date: _____

Name: _____ Signature: _____ Date: _____

Name: _____ Signature: _____ Date: _____

T4
***GP Super Clinic Sites***

The following is a list of publicly announced sites for the GP Super Clinics for each State and Territory:

| | |
|---|---|
| **NEW SOUTH WALES**<br>1. Blue Mountains – up to $5 million<br>2. Southern Lake Macquarie - up to $2.5 million<br>3. Grafton - up to $5 million<br>4. North Central Coast - up to $2.5 million<br>5. Port Stephens - up to $2.5 million<br>6. Queanbeyan - up to $5 million<br>7. Riverina - up to $1 million<br>8. Shellharbour - up to $2.5 million | **QUEENSLAND**<br>1. Bundaberg - up to $5 million<br>2. Cairns - up to $5 million<br>3. Gladstone - up to $5 million<br>4. Ipswich - up to $2.5 million<br>5. Mt Isa - up to $2.5 million<br>6. Redcliffe - up to $5 million<br>7. Brisbane Southside - up to $7.5 million<br>8. Strathpine - up to $2.5 million<br>9. Townsville - up to $5 million |
| **NORTHERN TERRITORY**<br>1. Palmerston - up to $10 million | **TASMANIA**<br>1. Burnie - up to $2.5 million<br>2. Devonport - up to $5 million<br>3. Hobart Eastern shores - up to $7.5 million |
| **SOUTH AUSTRALIA**<br>1. Modbury - up to $12.5 million<br>2. Onkaparinga - up to $12.5 million<br>3. Playford North - up to $7.5 million | **VICTORIA**<br>1. Ballan - up to $1 million<br>2. Bendigo - up to $5 million<br>3. Berwick/La Trobe - up to $2.5 million<br>4. Geelong - up to $7 million<br>5. Wallan – up to $1 million |
| **WESTERN AUSTRALIA**<br>1. Midland – up to $5 million<br>2. Wanneroo – up to $5 million | |

T5

## NATIONAL HEALTH AND HOSPITALS REFORM COMMISSION
### Terms of Reference

Australia's health system is in need of reform to meet a range of long-term challenges, including access to services, the growing burden of chronic disease, population ageing, costs and inefficiencies generated by blame and cost shifting, and the escalating costs of new health technologies.

The Commonwealth Government will establish a National Health and Hospitals Reform Commission to provide advice on performance benchmarks and practical reforms to the Australian health system which could be implemented in both the short and long term, to address these challenges.

1. By April 2008, the Commission will provide advice on the framework for the next Australian Health Care Agreements (AHCAs), including robust performance benchmarks in areas such as (but not restricted to) elective surgery, aged and transition care, and quality of health care.
2. By June 2009, the Commission will report on a long-term health reform plan to provide sustainable improvements in the performance of the health system addressing the need to:
    a. reduce inefficiencies generated by cost-shifting, blame-shifting and buck-passing;
    b. better integrate and coordinate care across all aspects of the health sector, particularly between primary care and hospital services around key measurable outputs for health;
    c. bring a greater focus on prevention to the health system;
    d. better integrate acute services and aged care services, and improve the transition between hospital and aged care;
    e. improve frontline care to better promote healthy lifestyles and prevent and intervene early in chronic illness;
    f. improve the provision of health services in rural areas;
    g. improve Indigenous health outcomes; and
    h. provide a well qualified and sustainable health workforce into the future

The Commission's long-term health reform plan will maintain the principles of universality of Medicare and the Pharmaceutical Benefits Scheme, and public hospital care.

The Commission will report to the Commonwealth Minister for Health and Ageing, and, through her to the Prime Minister, and to the Council of Australian Governments and the Australian Health Ministers' Conference.

The Commonwealth, in consultation with the States and Territories from time to time, may provide additional terms of reference to the Commission.

The Commission will comprise a Chair, and between four to six part-time commissioners who will represent a wide range of experience and perspectives, but will not be representatives of any individual stakeholder groups.

The Commission will consult widely with consumers, health professionals, hospital administrators, state and territory governments and other interested stakeholders.

The Commission will address overlap and duplication including in regulation between the Commonwealth and States.

The Commission will provide the Commonwealth Minister for Health and Ageing with regular progress reports.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-043

OUTCOME 3: Access to Medical Services

Topic: PROFESSIONAL SERVICES REVIEW (PSR) BUDGET AND STAFFING

Hansard Page: CA 92

Senator Boyce asked:

'What I wanted to do was look at their baseline budget at the current time and their current staffing.'

Answer:

**PSR Budget (from Portfolio Budget Statements 2007-08)**

Budgeted departmental income statement (for the period ended 30 June)

| | Budget estimate 2007-08 $'000 | Forward estimate 2008-09 $'000 | Forward estimate 2009-10 $'000 | Forward estimate 2010-11 $'000 |
|---|---|---|---|---|
| **INCOME** | | | | |
| **Revenue** | | | | |
| Revenues from Government | 6,148 | 5,964 | 6,213 | 6,286 |
| Other | 50 | 50 | 50 | 50 |
| ***Total revenue*** | 6,198 | 6,014 | 6,263 | 6,336 |
| **Total income** | 6,198 | 6,014 | 6,263 | 6,336 |
| **EXPENSE** | | | | |
| Employees | 2,284 | 2,460 | 2,534 | 2,610 |
| Suppliers | 3,674 | 3,285 | 3,409 | 3,460 |
| Grants | | | | |
| Depreciation and amortisation | 240 | 269 | 320 | 266 |
| ***Total expenses*** | 6,198 | 6,014 | 6,263 | 6,336 |
| **Surplus (Deficit) before income tax** | - | - | - | - |
| **Income tax expense** | | | | |
| **Surplus/(Deficit)** | | | | |

**PSR Staffing – as at 17 March 2008**

| **Position/Classification Level** | **Number** |
|---|---|
| Director | 1 |
| Senior Executive Service Band 1 | 1 |
| Executive Level 2 (EL2) | 4 |
| Executive Level 1 (EL1) | 8* (3 new EL1s to commence at PSR in March/April 2008) |
| APS6 | 2 |
| APS5 | 2* (1 staff member to commence at PSR in March/April 2008) |
| APS4 | 3* (1 staff member on Maternity Leave to February 2009) |
| APS3 | 3 |
| APS2 | 2 |
| **Total** | **26** |

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-065

OUTCOME 3: Access to Medical Services

Topic: PET

Hansard Page: CA 60

Senator Milne asked:

I understand that the government received a report in 2003 that demonstrated that PET improved the treatment in more than 50 per cent of bowel cancer patients and reduced the cost of care by approximately $4,000 per patient. That report was authorised by MSAC health economist Dr Terri Jackson and the Peter MacCallum Cancer Centre. The research protocol was approved and the research was funded by the department's consultative committee for diagnostic imaging. But when it had paid $79,212 in fact to compile the data showing PET reduced patient suffering and saved money.

(a) Why did the department decide to proceed with additional data collection such that it did not report to MSAC until June 2006?

(b) Who made the decision to go out after extra data collection?

(c) Specifically in relation to that, what I am really getting to is this: why did the government incur the cost and delay of restudying some cancer indications when other important areas had not been evaluated by MSAC?

Answer:

(a, b and c)
The Consultative Committee on Diagnostic Imaging (CCDI) was established to assist the Government to implement the Diagnostic Imaging Reform Package announced in the 1996 Budget. The Budget package included a series of measures, which included a research program to improve the understanding of the role and value of diagnostic imaging in patient care.

In late 1999 the CCDI offered a grant of $79,212 to Monash University for "A cost consequence study of care following cancer staging with and without the use of F-18 FDG PET scanning". The research team was Dr Terri Jackson, Professor Rodney Hicks and Dr Michael MacManus. The research commenced in February 2000. A final report was presented to the Department in July 2003.

This research was overtaken by a separate process when the Government accepted advice contained in the 2000 Review of PET, to support a "data collection" on the grounds that there was 'insufficient evidence from which to draw definitive conclusions about the clinical effectiveness and cost effectiveness of PET'. It recommended that interim funding be provided to enable the collection of clinical, cost and demographic data to support PET's further evaluation.

The data collection commenced on 1 August 2002. While many clinical indications were discussed by MSAC and the Supporting Committee, the indications included in the data collection program were agreed on the basis of MSAC's judgement of clinical need and where the evidence base was considered strongest.

The CCDI supported report was not available when the recommendations of the PET Review were finalised nor at the time when the resultant data collection exercise started in August 2002.

It would not have been appropriate to stop the 'data collection' program and for MSAC to re-assess PET for some indications based on the results of one, non-peer reviewed research paper. Furthermore the Commonwealth funded data collection program had a number of advantages over the Monash study in that it:

- included data from multiple rather than one PET facility;
- covered a larger number of clinical indications;
- had larger patient numbers; and
- was a prospective trial of new PET scans for patients from 2002 onwards, rather than a retrospective study which analysed outcomes from patients that had PET scans between November 1996 and April 1999.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-069

OUTCOME 3: Access to Medical Services

Topic: RADIATION THERAPY

Hansard Page: CA 63

Senator Adams asked:

Radiation therapy internships and undergraduate program

a) How many?

b) Can you tell me how popular it is?

Answer:

a) Since 2006, the Commonwealth has contributed to funding 163 radiation therapist internships through the 2004-05 *Strengthening Cancer Care* Budget measure. These positions have been allocated to both public and private radiation therapy facilities.

   The Commonwealth has also funded 79 undergraduate places in radiation therapy through the 2004-05 *Strengthening Cancer Care* Budget measure. These places have been allocated across the following universities: Queensland University of Technology, Royal Melbourne Institute of Technology, University of Newcastle and the University of South Australia. This funding is being administered by the Department of Education, Employment and Workplace Relations (formerly Department of Education Science and Training).

b) The program has proved to be popular. Since 2006, the number of internships the Commonwealth has contributed to has increased (42 in 2006, 57 in 2007 and 64 in 2008). The number of facilities accepting the funding has also increased.

   Commonwealth funding for the undergraduate places has been fully utilised by the four universities each year.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 & 22 February 2008

Question: E08-019

OUTCOME 3: Access to Medical Services

Topic: ALLIED WORKERS

Written Question on Notice

Senator Colbeck asked:

The current system of funding in residential aged care provides for treatment by qualified allied health practitioners for daily living and maintenance needs only. Aged care funding does not cover treatment after injury from say a fall or adverse incident. Medicare funding provides for treatment by a GP but funding for treatment by a registered allied health practitioner is only available in very limited circumstances under chronic disease management. Will Government outline how it intends to fund post injury allied health treatment for frail aged Australians?

Answer:

Currently, if a GP has contributed to a multidisciplinary care plan for an aged care resident using MBS item 731, the resident is then eligible for Medicare rebates for certain allied health services, including those relevant to treatment following an adverse incident or fall. Up to five allied health services are available each calendar year.

For low care residents, aged care facilities are required to assist with accessing health practitioner and therapy services, including arranging for the practitioner or therapist to visit the facility if necessary. However, the resident can be asked to bear the cost of the service. Where the GP has contributed to care planning under item 731, low care residents are eligible for Medicare rebatable allied health services.

While most high care residents should already be receiving all the necessary care and services to meet their assessed care needs at no additional cost over and above the resident fee, those who require intensive long term rehabilitation services following serious injury, surgery or trauma are also able to access the Medicare rebates for allied health services once their GP has contributed to care planning under item 731.

The Government is committed to developing a National Primary Health Care Strategy, with an increased focus on multidisciplinary care from primary care teams. This includes developing a long term strategy for delivering allied health care. The adequacy of allied health services for frail aged Australians will be considered in the development of the National Primary Health Care Strategy.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-066

OUTCOME 3: Access to Medical Services

Topic: Medical Services Advisory Committee (MSAC)

Hansard Page: CA 60

Senator Milne asked:

Can the department provide data on the number of new surgical procedures placed on the MBS in the six years before and subsequent to MSAC's commencement?

Answer:

In the six years subsequent to MSAC's commencement (1999-2004) 39 procedures were funded following the Minister's endorsement of MSAC recommendations. Of these, 12 were surgical procedures.

The Department of Health and Ageing cannot reasonably identify the number of new surgical procedures listed on the MBS in the six years prior to MSAC's commencement (1993-1998) as this information is not readily available and its compilation would involve a significant diversion of resources.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2007-2008, 20 February 2008

Question: E08-068

OUTCOME 3: Access to Medical Services

Topic: MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

Hansard Page: CA 60

Senator Polley asked:

From our report that our committee looked into, I think it is fair to say that the majority of people on this committee, if not all, believe there was an issue relating to how the department sets up and protects the integrity of those people taking part in those reviews. I was wondering, as we suggested at the previous hearing, whether anything is being put in place to protect the professional integrity of those professional people in terms of, when a report is handed down, whether they have the opportunity to review that and either have their name removed from or sign off on the reports.

(d) To be helpful to me and others, could you then step me through what changes have been made that are appropriate now, as opposed to when that particular report was handed down?

(e) What are the processes and protections that have been put in place that was undertaken to be done so by the department?

(f) With all due respect, in relation to minutes of meetings, we have heard evidence over a number of years in relation to the assertion that minutes had been changed. With all due respect, I do not have a lot of confidence in minutes that have been taken. I guess what I am looking for is: is there an authority statement that the department has developed for those professionals to sign off on?

Answer:

The Department has taken four steps to address situations where Advisory Panel members may have dissenting views: (1) preparing guidelines for minute taking at meetings; (2) clarifying the role of Advisory Panels to members when they are appointed; (3) ensuring that Advisory Panel members clearly express their assent or otherwise to the report that is conveyed to MSAC, and conveying this information to MSAC; and (4) making provision for a general disclaimer as a standard part of all MSAC reports.

(1) Guidelines for minute taking

The Department has acknowledged that the quality of minute taking in the past was not what it should have been (Submission to the Senate Community Affairs Legislation Committee Inquiry 'A Matter Relating to the PET Review of 2000', 3 September 2007). However, the Department is not aware that any agreed and formally approved minutes of a meeting of MSAC or its Supporting Committees / Advisory Panels were subsequently changed.

Minutes of MSAC and its Advisory Panels are now recorded and approved in accordance with standard meeting procedures, and with particular regard for recording conflicts of interest and dissenting views.

'Guidelines for taking minutes of meetings of MSAC and its Advisory Panels' are applied accordingly (See Attachment A).

(2) Clarifying the role of Advisory Panel members

MSAC Advisory Panel members are now better informed about their role. The two guideline documents for Advisory Panels - 'Guidelines for Chairs of MSAC Advisory Panels' (See Attachment B), and 'Guidelines for Members of MSAC Advisory Panels' (See Attachment C) – have been revised and strengthened.
These guidelines outline the roles and responsibilities of Advisory Panel members (attached).

'Guidelines for Chairs of MSAC Advisory Panels' require the Chair to explain at the first Advisory Panel meeting the respective roles of MSAC and the Advisory Panels.

The 'Guidelines for Members of MSAC Advisory Panels' state:

> *The A[dvisory] P[anel]'s role is to provide guidance to ensure the evaluation of the evidence is clinically relevant and takes into account consumer interests.*

(3) Managing and documenting assent/dissent

The 'Guidelines for Chairs of MSAC Advisory Panels' require the Chair to:

*Seek advice from the MSAC medical advisor or MSAC if major conflict arises between members and the evaluators over the review parameters, or the inclusion/exclusion of interpretation of studies or data;*

When an assessment is completed, the Advisory Panel Chair – who is always a member of MSAC – asks all members to indicate whether or not they agree with the draft assessment report. If dissent cannot be resolved, then those views are documented in the minutes.

Once the final assessment report has been edited, the project manager seeks final clearance from Advisory Panel members via e-mail, so that a written account of members' assent or otherwise is placed on file. In August 2007, a form was used to record members' sign-off for an Advisory Panel that considered Positron Emission Tomography for melanoma, ovarian and colorectal cancers. This process will be strengthened and formalized as routine practice once there has been further consultation on the content of a standard pro forma.

The ‘Guidelines for Members of MSAC Advisory Panels’ state that one of the Advisory Panels’ tasks is to advise MSAC of ‘*details of dissenting view(s) (if any) held by member(s).*’ The guidelines further state:

*Dissenting views held by AP members relating to the report findings may also be conveyed to the MSAC at this time, together with any other matter the A[dvisory] P[anel] believes should be drawn to the MSAC’s attention. While the MSAC carefully considers the A[dvisory] P[anel]’s advice and any dissenting position, it is not bound by these views in reaching its recommendation.*

The ‘Guidelines for Chairs of MSAC Advisory Panels’ require the Chair to:

*Provide a verbal update on the evaluation to MSAC, including any dissenting views held by A[dvisory] P[anel] members relating to the report’s findings or any other matter the AP believes should be drawn to the MSAC’s attention.*

(4) General disclaimer

All MSAC reports now include the statement: *MSAC recommendations do not necessarily reflect the views of all individuals who participated in the MSAC evaluation.*

**Attachment A**

# MEDICAL SERVICES ADVISORY COMMITTEE

# GUIDELINES FOR TAKING MINUTES OF MEETINGS OF MSAC AND ITS ADVISORY PANELS

## 1. Introduction

1.1 Minutes are a permanent record of a meeting. Their purpose is to provide a true and accurate record of decisions made at a meeting, and the rationale for those decisions.

1.2 These guidelines apply to MSAC meetings, MSAC Executive meetings, and MSAC Advisory Panels. They apply equally to face-to-face meetings and teleconference meetings. The term 'meeting' is used below to apply to both meeting formats.

1.3 The guidelines should be read in conjunction with the Department of Health and Ageing's 'Committee Servicing Manual'.

## 2. Minute taker

2.1 The Minute taker is nominated by the Department and is a person with sufficient subject matter knowledge to be able to accurately record decisions and the rationale leading to the decision. This may mean that there are different minute takers for different items.

## 3. Content of Minutes

3.1 Minutes of meetings should record the following information:

(i) The date, time and place of the meeting;

(ii) The names of attendees, including Committee / Advisory Panel / Executive members, any supporting officials, and any apologies;

(iii) The name(s) of any invited observers;

(iv) The agenda item and agenda number that is being minuted.

(v) An outline of discussion and debate about all agenda items in sufficient detail that describes the rationale for decisions/agreed action at a meeting;

(vi) Decisions made, including voting numbers and details of members who abstained from voting, with reasons;

(vii) Any conflict of interest disclosures, and how these were managed (see below); and

(viii) Any dissenting views amongst members on any item, and how these were managed (see below).

3.2 The Chair should ensure that all decisions are clearly expressed for the purpose of being recorded in the minutes. The minute taker should assist the Chair in this regard.

## 4. Conflicts of interest

4.1 The management of conflicts of interest is further detailed in 'Guidelines for the disclosure and management of conflicts of interest for members of the Medical Services Advisory Committee (MSAC) and MSAC Advisory Panels'.

4.2 At the commencement of every meeting, the Chair must provide an opportunity for members to declare an interest in any activity of, or matters being considered. This is a standing agenda item for all meetings.
Where a disclosure is made, the member's disclosure, together with the agreed action that was taken following the disclosure, should be fully documented in the minutes of the meeting.

## 5. Dissenting views

5.1 At MSAC meetings, any dissenting view about a recommendation, action or resolution on any agenda item must be recorded.

5.2 At MSAC meetings, any dissenting views amongst Advisory Panel members will be noted in the agenda paper for that item, including the nature and extent of the dissenting view.

5.3 The management of dissent in MSAC Advisory Panel meetings is detailed in the document 'Guidelines for Chairs of MSAC Advisory Panels'.

## 6. Approval of minutes

6.1 Draft minutes should be completed within 30 days from the date that the meeting took place. The Chair will be asked to review the minutes. Within 45 days of the date that the meeting took place, all members will be afforded an opportunity to raise any concerns about the content of the minutes with the Chair.

6.2 At the subsequent meeting, members will be asked to approve the minutes of the previous meeting as a true and accurate record. The minutes, with any amendments agreed at that meeting, will be approved, and such approval formally recorded (including any dissenting views).

6.3 Approved minutes, together with the original agenda and agenda papers, are to be placed on an appropriate file and securely stored.

Attachment C

# MEDICAL SERVICES ADVISORY COMMITTEE

# GUIDELINES FOR MEMBERS OF MSAC ADVISORY PANELS

## 1. Introduction

1.1 The Medical Services Advisory Committee (MSAC) appreciates your acceptance of its invitation to join the Advisory Panel (AP) for this assessment. The AP provides a clinical and consumer perspective to the consideration of the available evidence relating to the safety, effectiveness and cost-effectiveness of the technology or treatment under consideration. The findings of the assessment are the basis on which the MSAC formulates its recommendations to the Minister for Health and Ageing.

1.2 Members of an AP are appointed for their knowledge, skills and/or experience relevant to the treatment or technology under review, rather than representing a particular constituency or organisation.

## 2. Roles and responsibilities of contracted evaluators

2.1 The specialised research tasks associated with these scientific assessments are undertaken by an evaluation team contracted by the MSAC for their skills and experience in this field. The evaluation team has responsibility for the scientific and editorial content of the draft assessment report prepared for the MSAC.

2.2 The specific tasks the evaluation team undertakes are to:

(i) define the research question(s) in consultation with the AP;

(ii) prepare a draft evaluation protocol to address the agreed research question(s) and outline the methods to be used;

(iii) search the literature to find relevant studies;

(iv) appraise and select studies according to the inclusion and exclusion criteria;

(v) summarise and synthesise included/relevant studies;

(vi) evaluate the validity, strength and applicability of results;

(vii) prepare a costing and economic analysis;

(viii) obtain and incorporate expert opinion in the report where appropriate;

(ix) develop conclusions in consultation with the AP;

(x) advise MSAC of any evaluation issues it should take into account when forming its recommendation;

(xi) prepare all agenda papers and forward them to AP members at least 5 days prior to a meeting. After the first meeting, papers and messages are usually distributed via e-mail; and

(xii) prepare the report for publication.

2.3 The evaluation team also performs some secretariat functions for each Advisory Panel including: confirming dates and times for each AP meeting, minute taking and the preparation and distribution of agenda papers.

## 3. Roles and responsibilities of the Advisory Panel (AP)

3.1 The Advisory Panel is chaired by an MSAC member whose role is to guide the assessment process. The AP's role is to provide guidance to ensure the evaluation of the evidence is clinically relevant and takes into account consumer interests. A copy of the Advisory Panel Chair guidelines is attached.

3.2 The specific tasks of the AP are to:

(i) assist in formulating the research question(s) to be addressed including the identification of patient group(s), intervention(s), comparator(s) and clinical outcome(s);

(ii) advise on other relevant details required for the assessment eg the nature of the procedure, any existing treatments, clinical need, clinical pathways, likely impact of the intervention, appropriate use of the technology, diagnostic accuracy, costs etc;

(iii) advise the evaluators about any relevant information sources eg published papers, trials, data registries, unpublished data, conference proceedings and other experts;

(iv) confirm the list of proposed studies or papers for inclusion;

(v) assist in the interpretation of results and development of conclusions;

(vi) advise on other broader considerations which the MSAC takes into account – including but not limited to access and equity issues;

(vii) advise on any specific training requirements;

(viii) advise on possible implementation issues;

(ix) where requested by the AP Chair, consult with peer(s) to obtain advice on matters relating to a review in progress or to identify a suitable peer reviewer for a completed draft report; and

(x) provide advice to the MSAC. This may include comment on:

- the safety, effectiveness and cost-effectiveness of the service being reviewed;
- any other considerations which MSAC should take into account;
- any restrictors that should be considered if funding is recommended; and,
- details of dissenting view(s) (if any) held by member(s).

## 4. Roles and responsibilities of Departmental staff

4.1 The MSAC Medical Adviser undertakes the following roles:

(i) examines applications and references received and advises the MSAC Secretariat and MSAC Executive about the eligibility of applications for assessment;

(ii) assists evaluators and the AP Chair in determining the scope of the evaluation, including the research questions to be answered;

(iii) assists in the development of the Clinical Flowchart;

(iv) attends meetings of the AP to assist with complex issues; and

(v) advises on the development of the economic analysis.

4.2 The Project Manager undertakes the following roles:

(i) is the central coordinator of the review process;

(ii) is the primary contact for applicants, evaluators, AP members and AP Chair;

(iii) records the Minutes of each meeting and distributes them to all Members of the AP, the AP Chair, and the Evaluators;

(iv) attends all meetings of the AP; and

(v) ensures that all AP members complete and sign the template (attached to these Guidelines) regarding their formal sign-off of the draft assessment report prior to its consideration by MSAC. If substantive are made to the draft, formal sign-off may again be required.

4.3 The Secretariat facilitates payment of sitting fees and bookings of air travel, meeting venues and teleconferences.

## 5. Conflict of nterest

5.1 Conflict of interest is a standing agenda item at all AP meetings /teleconferences. At the commencement of each meeting, the AP Chair will invite members to declare any personal, professional or financial matters which may directly impact on their consideration of the treatment or technology under review. Members should be mindful of the importance of all potential conflicts of interest and should therefore err on the side of caution when making any declaration. The minutes of the meeting or teleconference will document any declarations.

## 6. Confidentiality

6.1 All members are required to sign a Deed of Confidentiality requiring them to maintain the confidentiality of any information that is not public knowledge and to which they have access by virtue of their membership to the AP. This is

done to protect confidential or commercial-in-confidence information received by members and to prevent the MSAC findings being prematurely released or decisions pre-empted.

6.2 Members should also exercise due care in the storage of any confidential information relating to an assessment until the status of the information changes, which generally occurs when it moves into the public domain. Commercial-in-confidence information, such as trial data or costings, can be returned to the Secretariat for appropriate disposal.

6.3 The confidentiality and non-disclosure agreements binding AP members does allow for appropriate consultation with experts outside the AP. With the approval of the MSAC Chair, a member or members may consult with a specified peer or peers to obtain additional advice on matters relating to a review in progress, where such is not available within the AP. The extent of the information that the AP member(s) can disclose to a peer or peers is to be determined in consultation with the AP Chair, prior to any such discussion taking place.

6.4 The AP Chair, after discussion with the MSAC Executive, may also ask panel members to identify an appropriate professional group or individual expert who may be willing to provide peer comment on a completed draft report on a reference made to the MSAC by the Department of Health and Ageing.

## 7. Dissenting views amongst Advisory Panel members

7.1 Dissenting views held by AP members relating to the report findings may also be conveyed to the MSAC at this time, together with any other matter the AP believes should be drawn to the MSAC's attention. While the MSAC carefully considers the AP's advice and any dissenting position, it is not bound by these views in reaching its recommendation.

## 8. Advisory Panel tenure

8.1 The AP life span is generally 4-6 months during which the following milestones would be achieved:

(i) the initial meeting of the AP at the commencement of an assessment to provide the evaluators with expert advice used to complete the evaluation protocol. In those instances where an assessment is complex and involves more than three indications, more than one meeting may be required to finalise the protocol;

(ii) a meeting of the AP on completion of the first draft of the evaluation report to consider its contents section-by-section and provide comments and guidance to the evaluators. Further meetings may be necessary to provide feedback to the evaluators about changes made to the draft report; and

(iii) a final meeting to complete the draft report and formulate the AP's advice to the MSAC.

8.2 The initial meeting is usually a 3-4 hour face to face meeting in a capital city convenient for the majority of members. Subsequent meetings are usually teleconferences of 1 – 2 hours duration. In some cases a second face-to-face meeting may be held to finalise more complex evaluations.

9. Liaison with applicants and evaluation team

9.1 The list of Panel members is posted on the MSAC's website, unless members have requested otherwise. However, the name of the evaluation team is not provided to applicants or published on the website during the course of an evaluation.

9.2 If contacted by an applicant, AP members are asked not to discuss the application or evaluation with them, and should refer the inquiry to the Project Manager.

9.3 Any out-of-session requests from panel members to include additional information in the report or to include additional research data in the literature search are to be cleared through the Chair and the Project Manager. If it is agreed that the additional information/research data should be included, the Project Manager will liaise with the evaluators accordingly. Note, however, that additional information/research data will only be included if it is likely to change the outcome of the report, ie high level research data.

10. SAC consideration of draft assessment reports

10.1 Once the Advisory Panel completes its review, the draft review report is forwarded for comment to the applicant by the Project Manager. Where an applicant provides written comments, the evaluators provide a rejoinder. Draft reports are also sent to the relevant areas in the Department, the Medicare Benefits Implementation section and the MSAC Senior Medical Adviser for comment.

10.2 The draft report, and all comments received are circulated to the MSAC members as part of the agenda papers for the next MSAC meeting. At the MSAC meeting, the AP Chair provides a verbal overview of the report and the AP's views, including whether there are any dissenting views from any member of the Advisory Panel. A nominated MSAC member then critiques the report, after which other members are invited to comment.

10.3 If the draft report is accepted at an MSAC meeting, the MSAC will develop recommendations for the Minster. The report and the MSAC's recommendations are then forwarded to the Minister for his consideration.

10.4 If the MSAC agrees that the report requires further work before a decision can be made, it will be returned to the Evaluators for revision, and a further meeting of the AP may be required.

10.5 The recommendation will usually be to support or not support funding, but in a small number of cases, interim funding may be proposed. Recommendations are always indication specific and restrictions (eg by volume, site or service provider), which are suggested by the evaluation findings, may form part of a positive recommendation. These restrictions may also be incorporated in the item descriptors that will appear in the Medicare Benefits Schedule. A specific timeframe for the review of an interim funding decision may also form part of a recommendation.

## 11. Implementation

11.1 If the Minister supports a recommendation to fund a new medical treatment or technology, the development of the MBS item including the fee and descriptor, is undertaken by the relevant tabling committee, drawing on MSAC's findings and recommendation. These committees are the Medicare Benefits Consultative Committee, the Pathology Services Table Committee and the Consultative Committee on Diagnostic Imaging.

11.2 MSAC does not have a mandate to determine or recommend an appropriate fee for a service. However, the AP may be asked to comment on the costs used in the economic analysis. The anticipated fee and other costs are usually derived from information provided by the applicant or the referring area, but are verified as far as possible from other sources.

## 12. Advisory Panel remuneration and travel

12.1 Sitting fees are paid for attendance at meetings and teleconferences and include a component for reading time. The rate paid is that for 'Professional Committees - Health Portfolio', as set by the Remuneration Tribunal as indicated in the table below.

12.2 As sitting fees and allowances are subject to GST, members are required to nominate a payment option for GST purposes. Where a member chooses the tax invoice or invoice option, an invoice for the amounts owed must be submitted to the MSAC Secretariat before the payment can be made.

12.3 The Department of Health and Ageing arranges air travel for AP members attending face-to-face meetings. To claim reimbursement for expenses incurred in land travel to and from the meeting (taxi fares or parking costs - **excluding valet parking**), original receipts need to be retained and forwarded to the MSAC Secretariat with either a completed Incidental Expenditure form or a tax invoice, as appropriate.

**Sitting fees* (Effective from 1 July 2007)**

| ***Meeting duration*** | **Chairperson** | **Committee member** |
|---|---|---|
| More than three hours | $756.00 | $572.00 |
| Two hours or more but less than three hours | $453.60 | $343.20 |
| Less than two hours | $302.40 | $228.80 |

*Subject to GST

**Attachment**

## SIGN-OFF BY MSAC ADVISORY PANEL MEMBERS OF DRAFT ASSESSMENT REPORTS – SUGGESTED TEMPLATE FOR CONSIDERATION AND COMMENT BY MSAC EXECUTIVE

MSAC APPLICATION XXX/ REFERENCE XXX : [Title]

I confirm that I have read the draft final assessment report dated ……. 2008 on the above application/referral.

□ I am satisfied that the report is ready to be submitted to MSAC for consideration.

□ I am not satisfied that the report is ready to be submitted to MSAC for the following reasons:

…….

…….

…….

…….

……..
Signed
Member of the Advisory Panel for MSAC application [reference] XXX
/ /2008

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2007-2008, 20 February 2008

Question: E08-067

OUTCOME 3: Access to Medical Services

Topic: MSAC

Hansard Page: CA 61

Senator Milne was made the following offer (by Ms Halton):

What I think might be also useful is to give you a little bit of background on the kinds of methodologies that are used and give you some perspective on what some of that debate is about, because this is contested space.

Answer:

This response provides a basic overview of health technology assessment, as it is undertaken by the Medical Services Advisory Committee (MSAC). It draws mainly on MSAC's 'Funding for new medical technologies and procedures: application and assessment guidelines, September 2005' and 'Guidelines for the assessment of diagnostic technologies, August 2005.'

**1. Definition**

Health technology assessment is a multidisciplinary activity that seeks to assess the technical performance, safety, effectiveness and cost effectiveness of health technologies to guide policy decisions about their use and funding. Health technology assessors use explicit scientific methods derived from the evidence-based medicine movement to systematically locate, appraise, synthesise and report on the evidence to support the use of this technology. The methods used to perform systematic reviews have been developed to minimise bias and random errors in the selection and summary of evidence.

**2. Process**

MSAC evaluates new technologies and procedures for which funding is sought under the Medicare Benefits Scheme by assessing the safety, effectiveness and cost-effectiveness while taking into account issues such as access and equity.

The assessment involves not only the application of multidisciplinary, scientific method to the available data, but also consultation with clinical experts, consideration of consumer perspectives, and further engagement with the application and (in the case of references) other interested parties at specific points in the process.

A consumer perspective

The MSAC committee includes a representative of the Consumers' Health Forum of Australia (CHF).

Advisory panels also include a nominee of the CHF for each assessment. The consumer representative helps the evaluators and the panel to present the patient's perspective. Any valid studies on patients' views or experience of the technology under review may be included in the assessment. Where appropriate in the context of the assessment report, the assessment report will address consumer issues.

MSAC will pay particular attention to the impact of the technology on patient-relevant factors, including quality of life. Studies that seek to measure the effect of the technology on patients' quality of life will be included in the assessment.

Clinical expertise

MSAC harnesses clinical expertise through the committee itself, and through its advisory panels. The committee currently comprises people with a mix of clinical expertise including pathology, surgery, specialist medicine and general practice, together with clinical epidemiology, clinical trials, health economics, and health administration and planning.

Advisory panels support each assessment, by providing a clinical (and consumer) perspective to the research protocol and the evaluation of evidence. MSAC, through its executive, appoints members to panels in consultation with the relevant college(s) and/or craft group(s). Members are appointed for their knowledge, skills and/or experience of relevance to the medical service under review or its comparator.

The applicant can also suggest people who might be appointed to the advisory panel, so long as they have relevant knowledge of the procedure or technology to be assessed, and have no pecuniary interest.

Health technology assessment expertise

The Department engages organisations with expertise in the method and process of health technology assessment through periodic Requests for Tender. This process ensures that MSAC and its advisory panels are supported by the best available professional expertise in this multidisciplinary field.

## 3. Method

### Defining the research question

Accurately and appropriately determining the research question is a fundamental part of the assessment methodology. Typical questions that need to be resolved at an early stage include:

- The patient: that is, the patient group(s) and indications for whom the technology will be assessed to determine its relative effectiveness,
- The intervention, and its place in the 'clinical pathway'.
- The comparator: effectiveness and cost-effectiveness are measured in relative terms, of the technology under review as compared with another technology or clinical pathway. The appropriate comparator is the service most likely to be replaced or supplemented by the introduction of the new service.
- The outcome: that is, the health outcome or benefit that the technology (and the comparator) will be measured as having achieved.

**Assessment**

Assessors base their reviews on evidence identified through systematic literature searches, and can include: bibliographic databases; databases of clinical trials, systematic reviews and health technology assessment reports; specialised databases; and conference abstracts and presentations. On the basis of the evidence, the assessors review the safety and effectiveness, and in certain circumstances the cost-effectiveness, of the technology.

Safety

Evaluators are expected to draw on all available data to assess the adverse outcomes of a service.

Effectiveness

An analysis typically involves assessment of the level, quality, strength and magnitude of effect, and relevance of the evidence, in relation to both the technology under review and the comparator. Depending on what evidence is available, evaluators may refer to a single definitive study, or conduct a meta-analysis of a series of studies.

The *level* of evidence refers to the relative degree of bias inherent in a particular study methodology. MSAC uses the NHMRC hierarchy of levels of evidence. The Committee prefers making decisions based on data from randomised controlled trials, but recognises that medical interventions are seldom investigated with the rigor common in the pharmaceuticals research literature.

*Quality* of evidence refers to the methods used by the investigators to minimise bias within a study design and in the conduct of a study.

*Strength* of evidence is defined as the precision of the estimate of effect. It is about the degree of certainty regarding the existence of a true treatment effect, rather than the effect occurring due to chance.

The assessment of *relevance* of the evidence aims to determine how pertinent or appropriate the study design and outcomes are to the clinical question that is being considered, or to clinical practice.

Economic evaluation

Economic analysis is a set of formal, qualitative methods used to compare alternative strategies with respect to their resource use and their expected outcomes, and the relationship between these. In essence, an economic analysis will help MSAC to assess whether a technology represents value for the health dollar.

In the first instance, it is necessary to establish the clinical effectiveness of the technology. If a technology is not found to be relatively effective, then in general the assessment will not proceed to an economic analysis.

The types of economic analysis that are feasible will depend upon how the effects of the technology (and its comparator) can be measured.

- Cost minimisation: the proposed intervention is demonstrated to be at least no worse therapeutically than other interventions at the same or lower cost. That is, the outcome is shown to be at least the same, and therefore the cost becomes the key variable.

- Cost-effectiveness: the proposed intervention is demonstrated to offer more of a given outcome. That is, the outcome may vary from that of the comparator, but the outcomes can be measured in terms of the same unit outcome achieved. The summary measure of a cost-effectiveness analysis is the incremental cost per additional unit outcome achieved.
- Cost-utility: outcomes are expressed in terms of an extension of life and a utility value of that extension. Quality-adjusted life years (QALYs) are an example of this type of metric.
- Cost-benefit: all outcomes are expressed in monetary rather than physical units.

## 4. Diagnostic tests

Assessments of diagnostic tests (technologies or procedures used to confirm, exclude or classify disease) present particular methodological challenges.

The effectiveness of diagnostic tests depends on a combination of factors:

- the improvement in the overall accuracy of testing (the 'sensitivity' and 'specificity' of the test);
- the effect on therapeutic decisions; and
- the effectiveness of the therapies selected on the basis of the test results.

In respect of diagnostic tests, it can often be a challenge to demonstrate whether a more accurate test necessarily changes patient management, and thereby leads to better health outcomes for patients.