# Community Affairs
# Legislation Committee

## Examination of Budget Estimates 2004-2005

## Additional Information Received

## VOLUME 3

### Outcomes: whole of portfolio and Outcome 1

## HEALTH AND AGEING PORTFOLIO

### FEBRUARY 2005

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 2004-2005

Included in this volume are answers to written and oral questions taken on notice and tabled papers relating to the budget estimates hearings on 2 and 3 June 2004

# HEALTH AND AGEING PORTFOLIO

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**Senate Community Affairs Legislation Committee**

**ANSWERS TO ESTIMATES QUESTIONS ON NOTICE**

**HEALTH AND AGED CARE PORTFOLIO**

**Australian Government**
**Department of Health and Ageing**

Ms Diana Fayle
Projects Coordinator
Vision 2020 Australia
Suite 1
15-31 Pelham Street
CARLTON VIC 3053

Dear Ms Fayle

The Commonwealth Department of Health & Ageing is willing to accept your proposal and provide $20,000 Sponsorship in relation to the Vision 2020 Australia National Vision Forum, to be held in Canberra on 24 and 25 March 2004, on the terms and conditions set out below and in the General Conditions for Services set out in Attachment A (except where indicated otherwise in this letter).

**Purpose of the Forum**
To help progress the development of a National Vision 2020 Plan by drawing together input from the community and eye health sector.

**1. The Services**

1.1 The Commonwealth Department of Health & Ageing will provide a sponsorship sum of $20,000 to Vision 2020 Australia to assist in:

A. Conducting a survey of community and eye health sector stakeholders to help identify key issues, achievements, directions for the future, potential areas of focus and priorities and possible models for a national plan.
B. Providing a discussion paper based on findings of the survey.
C. Conducting a National Vision Forum with Vision 2020 Australia partners, key non-government stakeholders and agencies, and Australian and State/Territory government agencies, to be held in Canberra on 24 and 25 March 2004.
D. Preparing a paper outlining the outcomes of the Forum and recommendations to be forwarded to the Department of Health and Ageing for consideration.

1.2 Vision 2020 Australia will provide the Commonwealth Department of Health & Ageing with:

A. A copy of the results of the survey in paragraph 1.1A no later than close of business Monday 22 March 2004.
B. The discussion paper in paragraph 1.1B no later than close of business Monday 22 March 2004.
C. An opportunity for Commonwealth officers as agreed to attend the National Vision Forum in paragraph 1.1C.
D. The paper in paragraph 1.1D no later than close of business 30 April 2004.

**2. Issues**

2.1 Use of the Department of Health and Ageing name and logo at the Forum and on Forum promotional materials as follows:

- Any reference to the Department of Health and Ageing in relation to the Forum will refer to the Department as: Sponsor, National Vision Forum;
- Naming rights to the Scene-Setting Panel Session. The benefits of naming rights to the session will include:
  - Acknowledgment of session sponsorship in the program
  - Verbal acknowledgment of sponsorship by session chairperson
  - Slide of corporate logo screened in session room;
- Health & Ageing logo and 100 word promotional paragraph published in the Forum registration brochure and handbook;
- Health & Ageing logo included on the Forum web page with opportunity to link back to sponsor's web page;
- Health & Ageing logo featured on official Forum slides acknowledging sponsors;
- Signage in main Forum plenary room – specifications to be advised at a later date*;* and
- Delegate list provided to the Department of Health and Ageing no later than 22 March 2004 and an updated list on disk after the Forum, subject to authorisation from delegates for their name to appear on a Delegates List to be distributed at the Forum and for use as deemed appropriate by Vision 2020 Australia.

2.2 Intellectual Property in Contract Material – Clause 5 of Attachment A applies with the exception that the intellectual property in the following materials remains vested in Vision 2020 Australia:

- The survey in paragraph 1.1A;
- The results of the survey in paragraph 1.1A;
- The discussion paper in paragraph 1.1B; and
- The outcomes paper in paragraph 1.1D.

**3. Timing**

3.1 All materials and documents on which the Department of Health & Ageing logo appear must be provided to the Department at the address below (see 8.1) for approval prior to printing and circulation.

## 4. Specified Personnel

4.1 Management of delivery of the services in this agreement must be undertaken by:

Ms Diana Fayle
Projects Coordinator
Vision 2020 Australia
Suite 1
15-31 Pelham Street
CARLTON VIC 3053

Telephone 03 9656 2020
Facsimile 03 9656 2040
E-mail dfayle@vision2020australia.org.au or dfayle@bigpond.net.au

## 5. Fees

5.1 The total fee for the Services is twenty thousand dollars ($20,000) excluding GST. Sixteen thousand ($16,000) being payable upon signing the contract and with receipt of a correctly rendered tax invoice to the Commonwealth. Four thousand ($4,000) being payable on the provision to the Commonwealth of the Outcomes Paper from the Forum and with receipt of a correctly rendered tax invoice to the Commonwealth.

## 6. Allowances

N/A.

## 7. Invoices

7.1 The fees for Services as outlined in Item 5.1 above will be payable by the Commonwealth to the Contractor upon receipt of a correctly rendered Tax Invoice provided by the Contractor.

## 8. Commonwealth Assistance

N/A

## 9. Project Officer

9.1 The person for the time-being holding, occupying or performing the duties of Senior Adviser, Office for an Ageing Australia, currently Gillian King Rodda, available on telephone number 02 6289 5276 or via the address and facsimile number set out below, shall be the Project Officer, with responsibility for general liaison with the Contractor, supervising performance, approving payment of the Contractor's fees, and accepting and issuing any written notifications under the Contract on behalf of the Commonwealth.

Office for an Ageing Australia

Australian Government Department of Health and Ageing
MDP 10
GPO Box 9848
CANBERRA ACT 2601

***Fax: 02 6282 4412***

Email: gillian.king.rodda@health.gov.au

**10. Acceptance**

10.1 A duplicate of this letter is enclosed with an endorsement that provides for notification of acceptance. If you agree to provide the Services as set out in this letter your acceptance must be notified by signing, dating and returning the enclosed duplicate letter to this Department. This letter, Attachment A and your notification of acceptance will form the entire agreement between the parties for the provision of the Services ('the Contract').

Yours sincerely

Mark Thomann
Assistant Secretary
Office for an Ageing Australia

March 2004

**Endorsement on duplicate letter:**

Vision 2020 Australia agrees to provide the Services described in this letter in accordance with the terms and conditions set out in and attached to this letter and marked as Attachment A.

Dated .....

SIGNED by or on behalf of Vision 2020 Australia by ABN

..... .....

Ms Carley Nicholls, Executive Director, Vision 2020 Australia

who warrants that she has authority to sign this Acceptance

.....

(signature)

in the presence of:

.....

Witness

# ATTACHMENT A

# GENERAL CONDITIONS FOR SERVICES

## 1. Interpretation

1.1 In these Conditions, unless the contrary intention appears:

| | |
|---|---|
| Contractor | means the party who by the Contract undertakes to provide the Services and includes the officers, employees, agents and subcontractors of the Contractor; |
| Contract | means the Contract under which the Services are to be provided to the Commonwealth including these general conditions; |
| Contract Material | means all Material:<br>(a) created for the purposes of the Contract;<br>(b) provided or required to be provided to the Commonwealth as part of the Services;<br>or<br>(c) derived at any time from the Material referred to in paragraphs (a) or (b); |
| Department | means the Department of Health & Ageing |
| Intellectual Property | means all intellectual property rights including but not limited to the following rights:<br>(a) patents, copyright, rights in circuit layouts, registered designs, trademarks and any right to have confidential information kept confidential; and<br>(b) any application or right to apply for registration of any of the rights referred to in paragraph (a); |
| Material | includes information and the subject matter of any category of Intellectual Property rights; |
| Services | means the services to be performed by the Contractor under the Contract. |

## 2. Performance of the Services

The Commonwealth will be entitled, in addition to any other right it may have, to delay payment of any instalment of fees or allowances until the Contractor has completed to the satisfaction of the Commonwealth that part of the Services to which the payment relates.

## 3. SUBCONTRACTORS

The Contractor agrees not to subcontract the performance of any part of the Services without prior approval in writing from the Department.

## 4. MATERIAL PROVIDED BY THE COMMONWEALTH

The Contractor agrees to ensure that any Material provided by the Department to the Contractor for the purposes of the Contract is used strictly in accordance with any conditions, restrictions or directions given by the Department.

## 5. Contract Material

5.1 Intellectual Property in all Contract Material, and ownership of all documents, devices, articles or medium ('copies') in which Contract Material is or will be embodied, vests or will vest in the Commonwealth. Upon the expiration or termination of this Agreement the Contractor agrees to deliver to the Commonwealth or otherwise deal with all copies as directed by the Department.

5.2 Clause 5.1 does not affect the ownership of Intellectual Property in any existing Material which is agreed in writing between the Contractor and the Department to be excepted from that clause (including, but not limited to, the documents specified in paragraph 2.2 of the letter accompanying this document) , but the Contractor grants to the Commonwealth a permanent, irrevocable, royalty-free, world-wide, non-exclusive licence (including a right of sublicence) to use, reproduce, adapt and exploit such existing Material in conjunction with the other Contract Material.

## 6. DISCLOSURE OF INFORMATION

6.1 The Contractor agrees not to disclose to any person other than the Commonwealth, any Confidential Information relating to the Contract or the Services without prior written approval of the Department. This obligation will not be taken to have been breached where the information referred to is legally required to be disclosed and will survive the expiration or termination of the Contract.

6.2 'Confidential Information' means information that is by its nature confidential, or is designated by the Commonwealth as confidential, or the Contractor knows or ought to know is confidential, but does not include information which is or becomes public knowledge other than by breach of the Contract or by any other unlawful means, is in the possession of the Contractor without restriction in relation to disclosure before the date of receipt from the Commonwealth, or has been independently developed or acquired by the Contractor.

## 7. PROTECTION OF PERSONAL INFORMATION

The Contractor agrees to comply with the Information Privacy Principles contained in the *Privacy Act 1988* to the extent that the content of those principles apply to the types of activities the Contractor is undertaking under the Contract, as if the Contractor were an agency as defined in that Act.

## 8. CONFLICT OF INTEREST

8.1 The Contractor warrants that, to the best of its knowledge after making diligent inquiry, at the date of entering into this Contract no conflict with the interests of the Commonwealth exists or is likely to arise in the performance of the Services. If, during the performance of the Services a conflict of interest arises, or appears likely to arise, the Contractor agrees to notify the Department immediately in writing of that conflict, make full disclosure of all relevant information relating to the conflict, and take such steps as the Department may reasonably require to resolve or otherwise deal with the conflict.

## 9. CONDUCT AT COMMONWEALTH PREMISES

The Contractor agrees that when using the Commonwealth's premises or facilities for the purposes of the Services, it will comply with all reasonable directions and procedures relating to occupational health, safety and security in operation at those premises or in regard to those facilities (including the Commonwealth's smoke-free work-place policy) whether specifically drawn to the attention of the Contractor or as might reasonably be inferred from the circumstances.

## 10. INDEMNITY

10.1 The Contractor agrees to indemnify the Commonwealth from and against any liability incurred by the Commonwealth, or loss of or damage to property of the Commonwealth, or loss or expense incurred by the Commonwealth in dealing with any claim against it (including legal costs and expenses on a solicitor/own client basis), arising from any act or omission by the Contractor in connection with the Contract, any breach by the Contractor of its obligations or warranties under the Contract, or the use by the Commonwealth of the Contract Material.

10.2 The Contractor's liability under the indemnity will be reduced proportionately to the extent that any negligent act or omission of the Commonwealth contributed to the relevant liability, loss or damage, or loss or expense.

10.3 In this clause, "Commonwealth" includes officers, employees and agents of the Commonwealth.

10.4 This indemnity will survive the expiration or termination of the Contract.

## 11. INSURANCE

Subject to the Department agreeing in writing to vary this obligation, the Contractor agrees, for so long as any obligations remain in connection with the Contract:

(a) to effect and maintain the following insurance for all the Contractor's obligations under the Contract, including those which survive the expiration or termination of the Contract:

(i) public liability policy insurance to the value of at least $5 million ($5,000,000) in respect of each claim;

(ii) professional indemnity insurance to the value of at least $5 million ($5,000,000) in respect of each claim; and

(iii) workers' compensation insurance as required by law; and

(b) upon request, provide proof of insurance acceptable to the Commonwealth.

## 12. TERMINATION AND REDUCTION FOR CONVENIENCE

12.1 The Commonwealth may, at any time by notice in writing, terminate the Contract or reduce the scope of the Services immediately. Upon receipt of such a notice the Contractor agrees to stop work as specified in the notice, take all available steps to minimise loss resulting from that termination and to protect Contract Material, and continue work on any part of the Services not affected by the notice.

12.2 Where there has been a termination under clause 12.1, the Commonwealth will be liable only for:

(a) payments and assistance under the Contract for Services rendered before the effective date of termination; and

(b) reasonable costs incurred by the Contractor and directly attributable to the termination.

12.3 Where there has been a reduction in the scope of the Services, the Commonwealth's liability to pay fees or allowances, meet costs or provide facilities and assistance under the Contract will, unless there is agreement in writing to the contrary, abate in accordance with the reduction in the Services.

12.4 The Commonwealth will not be liable to pay compensation under clause 12.2(b) in an amount which would, in addition to any amounts paid or due, or becoming due, to the Contractor under the Contract, together exceed the full price of the Services ordinarily payable under the Contract.

12.5 The Contractor will not be entitled to compensation for loss of prospective profits.

## 13. TERMINATION FOR DEFAULT

13.1 Where a party fails to satisfy any of its obligations under the Contract, the other party if it considers that the failure is:

(a) not capable of remedy, may, by notice in writing, terminate the Contract immediately;

(b) capable of remedy, may, by notice in writing, require that the failure be remedied within the time specified in the notice and, if not remedied within that time, may terminate the Contract immediately by giving a second notice.

13.2 The Commonwealth may also, by notice in writing, terminate the Contract immediately (but without prejudice to any prior right of action or remedy which either party has or may have) if the Contractor:

(a) being a corporation, comes under one of the forms of external administration referred to in chapter 5 of the Corporations Law, or an order has been made for the purpose of placing the corporation under external administration; or

(b) being an individual, becomes bankrupt or enters into a scheme of arrangement with creditors.

## 14. Contractor's Access to Premises

14.1 The Contractor agrees to give to the Project Officer, or to any persons authorised in writing by the Project Officer, reasonable access to:

(a) premises occupied by the Contractor where the Services are being performed; and

(b) Material in the possession or control of the Contractor which is relevant to the Services,

and permit those persons to inspect the premises or Material and copy the Material.

14.2 The Contractor agrees to provide all reasonable assistance requested by the Commonwealth in respect of any inquiry into or concerning the Services or this Contract.

## 15. Year 2000

The Contractor shall ensure that neither performance nor functionality of any information technology, including embedded electronic systems, in relation to the Contract is affected by dates prior to, during and after the year 2000.

## 16. Taxes, Duties and Government Charges

16.1 Subject to this clause, all taxes, duties and government charges ("Taxes") imposed or levied in Australia or overseas in connection with this Contract will be paid by the Contractor, or as the Contractor might arrange.

16.2 Without limiting clause 16.1, the Contractor will pay Goods and Services Tax ("GST") on the goods, services and other supplies made under this Contract ("the Supplies") to the extent that they are 'taxable supplies' within the meaning of the *A New Tax System (Goods and Services Tax) Act 1999* ("the GST Act").

16.3 In relation to any GST payable under clause 16.2, the Contractor will issue the Commonwealth with a 'tax invoice' in accordance with the GST Act together with, or as a part of, each invoice submitted for payment in accordance with clause 6.1 of the letter.

16.4 The amounts payable by the Commonwealth to the Contractor for the Supplies as determined under clause 4 of the letter are fixed regardless of any assumptions about the extent to which the Supplies are taxable supplies.

## 17. General

17.1 No variation of the Contract is binding unless it is agreed in writing between the Department and the Contractor.

17.2 The Contractor agrees not to represent itself, and to use its best endeavours to ensure that persons engaged or employed by the Contractor do not represent themselves, as being employees or agents of the Commonwealth.

17.3 If a party does not exercise (or delays in exercising) any of its rights under the Contract, that failure or delay does not operate as a waiver of those rights.

17.4 The Contractor must not assign, in whole or part, its rights and obligations under the Contract without the prior written approval of the Department.

17.5 The Department and the Contractor must attempt to settle by negotiation any dispute in relation to the Contract before resorting to external legal proceedings.

17.6 The laws in the Australian Capital Territory apply to the Contract.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-171

OUTCOME: Whole of Portfolio

Topic: MINISTERIAL APPOINTMENTS

Written Question on Notice

Senator McLucas asked:

Please provide a list of all positions appointed by the Minister or those the Minister has the authority to appoint. Identify the role and/or duties and remuneration associated with each appointed position, the current office holder/s and the duration of their term of office including the expiry date of the current term of office.

Answer:

Information in relation to statutory agencies, statutory offices and major companies in the Portfolio is attached.

Given the large number of appointments for which the Minister is responsible, the Department is not in a position to divert the substantial resources required to answer this question concerning committees, councils and advisory boards.

# Ministerial Appointments

**Aged Care Standards Accreditation Agency (ACSAA)**

| Role | Current Office Holder | Remuneration (Note 1) | Start Date | End Date |
|---|---|---|---|---|
| Chairperson | Mr James Harrowell | $38,180 | 17/06/2004 | 16/06/2007 |
| Director | Mr Shane Fracchia | $20,080 | 07/11/2002 | 14/11/2005 |
| Director | Dr Michael Bollen | $20,080 | 17/06/2004 | 16/06/2007 |
| Director | Ms Rhonda Parker | $20,080 | 17/06/2004 | 16/06/2007 |
| Director | Dr Joseph Ibrahim | $20,080 | 07/11/2002 | 14/11/2005 |
| Director | Mr John Lang | $20,080 | 20/09/2001 | 17/09/2004 |
| Director | Ms Mary Lyttle | $20,080 | 21/11/2003 | 20/11/2006 |
| Director | Prof. Rhonda Nay | $20,080 | 24/06/2002 | 18/06/2005 |
| Director | Mr Peter Toohey | $20,080 | 21/11/2003 | 20/11/2006 |
| Director | Mr Paul Wilmot | $20,080 | 21/11/2003 | 20/11/2006 |

**Australian Institute of Health and Welfare (AIHW)**

| Role | Current Office Holder | Remuneration | Start Date | End Date |
|---|---|---|---|---|
| Director | Dr Richard Madden | Classification Band C (Note 2) | 08/01/2001 | 06/01/2006 |

**Australian Hearing Services (AHS)**

| Role | Current Office Holder | Remuneration * | Start Date | End Date |
|---|---|---|---|---|
| Chairperson | Mr Michael Shepherd | $45,930 | 14/04/2002 | 13/04/2005 |
| Director | Mr Michael Batchelor | $20,080 | 24/06/2002 | 18/06/2005 |
| Director | Prof. Field Rickards | $20,080 | 24/06/2002 | 18/06/2005 |
| Man. Director | Ms Anthea Green | Classification Band C | 23/10/2002 | 22/10/2005 |

**Food Standards Australia New Zealand (FSANZ)**

| Role | Current Office Holder | Remuneration * | Start Date | End Date |
|---|---|---|---|---|
| Chairperson | The Hon. Robert Knowles | $50,000 | 01/07/2002 | 30/06/2006 |
| Member | Ms Elaine Attwood | $16,910 | 01/07/2002 | 30/06/2005 |
| Member | Prof. Kenneth Buckle | $16,910 | 01/07/2002 | 30/06/2005 |
| Member | Dr John Craven | $16,910 | 01/07/2002 | 30/06/2005 |
| Member | Dr. Laurence Eyres | $16,910 | 01/07/2004 | 30/06/2007 |
| Member | Prof. Christopher Hudson | $16,910 | 01/07/2004 | 30/06/2005 |
| Member | Mr Peter Milne | $16,910 | 01/07/2002 | 30/06/2005 |
| Member | Prof. Kerin O'Dea | $16,910 | 01/07/2002 | 30/06/2005 |
| Member | Ms Hikihiki Pihema | $16,910 | 01/07/2002 | 30/06/2006 |
| Member | Mr Owen Symmans | $16,910 | 01/07/2002 | 30/06/2006 |
| Member | Dr Heather Yeatman | $16,910 | 01/07/2004 | 30/06/2005 |

**General Practice Education and Training Limited (GPET)**

Appointees to the GPET Board are currently being considered by the Minister.

**Health Services Australia Board (HSA)**

| Role | Current Office Holder | Remuneration * | Start Date | End Date |
|---|---|---|---|---|
| Chairperson | Mr Rae Taylor | $38,180 | 22/03/2004 | 21/03/2006 |
| Director | Mr Richard Basham | $20,080 | 22/09/2001 | 21/09/2004 |
| Director | Mr Warwick Wilkinson | $20,080 | 13/03/2004 | 12/03/2006 |

**National Blood Authority**

| Role | Current Office Holder | Remuneration * | Start Date | End Date |
|---|---|---|---|---|
| Gen. Manager | Dr Alison Turner | Classification Band C | 18/08/2003 | 17/08/2007 |
| Chairperson | Prof. Richard Smallwood | $640/day | 01/07/2003 | 30/06/2006 |
| Member | Mr Ken Baker | PS – Not Remunerated | 01/07/2003 | 30/06/2006 |
| Member | Dr Christopher Brook | PS – Not Remunerated | 01/07/2003 | 30/06/2006 |
| Member | Mr Philip Davies | PS – Not Remunerated | 01/07/2003 | 30/06/2006 |
| Member | Ms Prudence Ford | PS – Not Remunerated | 01/07/2003 | 30/06/2006 |
| Member | Dr Peter Lewis-Hughes | PS – Not Remunerated | 01/07/2003 | 30/06/2006 |
| Member | Mr Russell McGowan | $483/day | 01/07/2003 | 30/06/2006 |

**National Health and Medical Research Council (NHMRC)**

| Role | Current Office Holder | Remuneration * | Start Date | End Date |
|---|---|---|---|---|
| Chairperson | Prof. John Shine | $60,210 | 22/05/2003 | 31/12/2005 |
| CEO | Prof. Alan Pettigrew | $164,130 (Note 3) | 01/01/2001 | 31/12/2005 |
| Member | Prof. Ian Anderson | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Prof. Judith Black | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Dr David Boadle | PS – Not Remunerated | 22/05/2003 | 31/12/2005 |
| Member | Dr Kerry Breen | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Prof. Donald Cameron | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Dr Paul Dugdale | PS – Not Remunerated | 22/05/2003 | 31/12/2005 |
| Member | Prof. John Findlay | PS – Not Remunerated | 14/05/2003 | 31/12/2005 |
| Member | Dr Gerard Fitzgerald | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Dr Janet Greeley | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Prof. Adele Green | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Dr Steven Guthridge | PS – Not Remunerated | 22/05/2003 | 31/12/2005 |
| Member | Dr Robert Hall | PS – Not Remunerated | 22/05/2003 | 31/12/2005 |
| Member | Prof. Brendon Kearney | PS – Not Remunerated | 22/05/2003 | 31/12/2005 |
| Member | Ms Michele Kosky | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Prof. Linda Kristjanson | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Dr Brian Lloyd | PS – Not Remunerated | 22/05/2003 | 31/12/2005 |
| Member | Prof. John Horvath | PS – Not Remunerated | 21/11/2003 | 31/12/2005 |
| Member | Prof. Anthony McMichael | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Prof. Kerin O'Dea | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Mr Lionel Quartermaine | $307 /day (3hr meeting) | 23/06/2003 | 31/12/2005 |
| Member | Dr Chris Roberts | $307 /day (3hr meeting) | 23/06/2003 | 31/12/2005 |
| Member | Dr Sarah Robertson | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Assoc. Prof. Peter Sainsbury | PS – Not Remunerated | 22/05/2003 | 31/12/2005 |
| Member | Dr Jillian Sewell | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Prof. Trang Thomas | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Dr David Whiteman | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |
| Member | Prof. Judith Whitworth | $307 /day (3hr meeting) | 22/05/2003 | 31/12/2005 |

**National Institute of Clinical Studies (NICS)**

| Role | Current Office Holder | Remuneration * | Start Date | End Date |
|---|---|---|---|---|
| Deputy Chair | Dr Sally Redman | $60,210 | 01/06/2004 | 31/05/2007 |
| Director | Dr Chris Baggoley | $10,910 | 01/06/2004 | 31/05/2007 |
| Director | Dr Rachel David | $10,910 | 01/06/2004 | 31/05/2007 |
| Director | Assoc. Prof. Joy Vickerstaff | $10,910 | 01/06/2004 | 31/05/2007 |
| Director | Prof. John Horvath | PS – Not Remunerated | 14/07/2004 | 31/05/2007 |
| Director | Prof. Timothy Davis | $10,910 | 14/07/2004 | 31/05/2007 |
| Director | Prof. Donald Nutbeam | $10,910 | 14/07/2004 | 31/05/2007 |
| Director | Dr Jim Sullivan | $10,910 | 14/07/2004 | 31/05/2007 |
| Director | Dr Bruce Ingram | $10,910 | 14/07/2004 | 31/05/2007 |
| Director | Ms Kate Carnell | $10,910 | 14/07/2004 | 31/05/2007 |

**Private Health Insurance Administration Council (PHIAC)**

| Role | Current Office Holder | Remuneration * | Start Date | End Date |
|---|---|---|---|---|
| Commissioner | Mr Garry Richardson | $60,210 | 21/07/2001 | 20/07/2004 |
| Deputy Commissioner | Mr Graham Rogers | $35,130 | 01/06/2002 | 31/10/2004 |
| Member | Mr Peter Annand | $35,130 | 29/05/2003 | 28/05/2006 |
| Member | Ms Sue Carter | $35,130 | 29/05/2003 | 28/05/2006 |
| Member | Miss Rebecca Davies | $35,130 | 01/06/2002 | 01/11/2004 |

**Private Health Insurance Ombudsman**

| Role | Current Office Holder | Remuneration * | Start Date | End Date |
|---|---|---|---|---|
| Ombudsman | Mr John Powlay | $180,860 | 18/11/2002 | 17/11/2005 |

**Professional Services Review**

| Role | Current Office Holder | Remuneration * | Start Date | End Date |
|---|---|---|---|---|
| Director | Dr John Holmes | $234,370 | 22/10/2003 | 31/12/2004 |

Note 1 Remuneration – Members are entitled to Tier 1 or Tier 2 travel allowance when travelling on official business.

Note 2 Classification Band C – total remuneration determined by the Remuneration Tribunal falls within the range of $190,000 - $319,300 p.a.

Note 3 Base salary only. The Remuneration Tribunal does not publish details of total remuneration.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-281

OUTCOME: Whole of Portfolio

Topic: TRAVEL

Hansard Page: CA 26-29-2.6

Senator McLucas asked:

a) How many double-ups would you have for the same staff taking overseas travel in any financial year?

b) For the current financial year, please provide details of international travel undertaken where the travel was in response to an invitation.

c) For Ms Halton's overseas travel in the current financial year, please provide a list of the number of trips and the purpose of the travel.

d) For the years that can be disaggregated, please provide the number of overseas trips and domestic trips for non-employees that were funded by the Department of Health and Ageing.

e) What is the year to date expenditure for domestic travel?

Answers:

a) The number of staff with two or more trips undertaken in the financial year to date April 2004 is 22.

b) There were two trips undertaken during the financial year to date April 2004 that were the result of an invitation. The details of these two trips are:

- destination: Macau - As part of an Austrade organised HR Management forum, facilitated by Acumen Consulting Pty Ltd, the Macau Government sought the inclusion of a senior public sector manager, with relevant experience, for inclusion in the forum delegation. The Department was approached to provide a representative with the required experience. The Department nominated and sent the Assistant Secretary People Branch.

- destination: France – The Chief Information Officer was invited to attend an IBM Chief Information Officer Conference which discussed the application of internet and e-business models. The conference also exhibited cutting edge information technology solutions.

c) Ms Halton has travelled overseas on four occasions. The purpose of travel was as follows:

- to participate in the OECD (Organisation for Economic Co-operation and Development) Health Ministers' Ministerial Group;

- to Chair the OECD Working Group on Health, attend the Australia-New Zealand Food Regulation Ministerial Council meeting and to sign the Framework Convention on Tobacco Control;

- to Chair the OECD Working Group on Health; and

- to participate in the OECD Ministerial Council Meeting, to attend the World Health Assembly and to attend the Executive Board of the World Health Organisation.

d)

| Financial Year | Domestic Trips Non-employees | Overseas Trips Non-employees |
|---|---|---|
| 2001-2002 | 7,846 | 103 |
| 2002-2003 | 6,679 | 46 |
| 2003-Apr 04 | 5,254 | 30 |

Note 1): The disaggregation of non-employee trips for Commonwealth Rehabilitation Service Australia are not available and consequently are not included in the above table.

e) The financial year to date April 2004 domestic travel expenditure is $12,301,844.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-282

OUTCOME: Whole of Portfolio

Topic: PROCUREMENT OF SOFTWARE

Written Question on Notice

Senator Humphries asked:

Has the choice of Microsoft software been a measure that has:

(a) Saved money;
(b) Provided flexibility and capacity for the department, or
(c) Both of the above

Answer:

(a) We have not undertaken a definitive evaluation of the savings associated with the use of Microsoft software by the Department of Health and Ageing. At the time the Department chose the Microsoft suite of products there was little whole of life cost differentiation between the two competing products.

(b) The Microsoft software suite has greatly increased both the flexibility and capability of the Department.

(c) As above.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-074

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ALCOHOL HARM REDUCTION STRATEGY

Written Question on Notice

Senator Harradine asked:

What is the Department doing to address the problem of preteen and teen young people bingeing on sweet-tasting "alco-pops"? Does the Department support a review of the alcohol beverage advertising code to stop promotion of such alcoholic drinks to young women?

Answer:

The Department has been involved in the review of the Alcohol Beverages Advertising Code (ABAC), conducted by the National Committee for the Review of Alcohol Advertising, on behalf of the Ministerial Council on Drug Strategy. The Government funded a project to evaluate alcohol advertising and promotion in light of the recent revisions to the ABAC procedures.

In addition, the Government has funded a project to determine the palatability of a range of alcoholic and non-alcoholic beverages among young people, whether this pattern changes with age and the extent to which marketing affects palatability ratings.

Furthermore, the 2004 National Drug Strategy Household Survey, which is currently underway, will provide detailed empirical data relating to alcohol consumption patterns and preferences in the population. This survey, with its large sample size (25,000) will produce reliable information on the extent of high risk drinking in teenagers and the beverage preferences of this group.

The findings of these projects will determine whether any further reviews of the advertising code are required.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Questions: E04-076

OUTCOME 1: Population Health and Safety

Topic: SEXUALLY TRANSMISSIBLE INFECTIONS

Written Question on Notice

Senator Harradine asked:

(a) What is the rate of sexually transmitted infection in teenagers?

(b) Does the Department agree that there is a lack of information about rates of STIs and pregnancy terminations among teenagers, as reported in the Medical Journal of Australia of August 2003?

Answer:

(a) The following data has been adapted from the *HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia, Annual Surveillance Report, 2003.*

**Rate of diagnosis of sexually transmissible infections (STIs) in people aged 15 – 19 years, 2002 (per 100,000 population)**

| **STI** | *RATE* |
|---|---|
| Chlamydia | 128.5 |
| Gonorrhoea | 32.9 |
| Syphilis | 8.2 |

(b) Notifications of STIs are recorded through the National Notifiable Diseases Surveillance System (NNDSS). This data is the basis for the Report mentioned above. Notification data provided include a unique record reference number, State or Territory identifier, disease code, date of onset, date of notification to the relevant health authority, sex, age, Indigenous status and postcode of residence.

Some States and Territories, (South Australia, Western Australia, the Australian Capital Territory and the Northern Territory) require notification to State health authorities of induced abortion.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Questions: E04-077

OUTCOME 1: Population Health and Safety

Topic: SEXUALLY TRANSMISSIBLE INFECTIONS

Written Question on Notice

Senator Harradine asked:

Does the Department agree that there should be universal screening of sexually active teenagers for the genital infection Chlamydia trachomatis?

Answer:

The Australian Government is committed to reducing the transmission of STIs and is currently developing a new National HIV/AIDS and STIs Strategy that will identify priority areas for action. This includes consideration of ways to address the genital infection Chlamydia trachomatis.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-078

OUTCOME 1: Population Health and Safety

Topic: SEXUALLY TRANSMISSIBLE INFECTIONS

Written Question on Notice

Senator Harradine asked:

What strategies has the Department developed or funded, or intends to develop or fund, to prevent high risk sexual behaviour in teenagers?

Answer:

The Government has funded a number of different education resources for use with teenagers. The most significant is the *Talking Sexual Health* package for senior high school students commissioned in 1998. The package included a national framework for guiding approaches and curriculum development in sexuality and sexual health education, a professional development resource for teacher training, classroom materials for students in years 9 and 10, and a parents' resource.

In addition, the Government also provides recurrent funding to the Australian Research Centre in Sex, Health and Society to conduct, amongst other things, the National Survey of Secondary Students and Sexual Health. This Survey is conducted every five years and involves students from years 10 and 12 in all States and Territories.

In 2003-04, the Government is contributing approximately $14.3 million directly through the Family Planning Program and $2 million indirectly to family planning activities under the Public Health Outcome Funding Agreements for a range of sexual and reproductive health programs.

Furthermore, development and implementation of the new National HIV/AIDS and STIs Strategy will examine ways to reduce the incidence of these diseases through education and prevention activities.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-079

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

(a) Can the Department please provide copies of training and protocols established by the Pharmacy Guild of Australia for dispensing Postinor-2?

(b) What proportion of pharmacists are members of the Pharmacy Guild?

(c) Have other groups made protocols or training available? If so, please provide copies of protocol or training material.

(d) What proportion of pharmacists has undertaken training in the dispensing of Postinor-2?

(e) Is the Department concerned by a Sun Herald claim that Postinor-2 was sold, without proper advice to the customer, by a beauty consultant at one pharmacy?

Answer:

(a) &(c)

Yes. This material is attached for the information of the Committee. The Department's understanding is that the development of protocols and educational materials for the supply of Postinor-2 by pharmacists was initiated by a group titled The Joint Guild / PSA (The Pharmacy Guild of Australia and the Pharmaceutical Society of Australia) Scheduling Committee. Work on the development of protocols and guidelines was progressed, on behalf of the PSA, through the Pharmaceutical Council of Western Australia (PCWA) in consultation with the Family Planning Association of Western Australia. The distributor of Postinor-2 in Australia, Schering Pty Ltd, has also made educational materials available to pharmacists. The Department has been advised that all materials developed by the PSA were disseminated to PSA members (approximately 9,500 pharmacists) in December 2003 and January 2004, while Schering Pty Ltd wrote to all pharmacies in December 2003 advising of the availability of its educational material. Additionally, this Schering letter was reproduced as a "full-page" journal advertisement in the

December issues of the *Australian Journal of Pharmacy* and the *Australian Pharmacist*.

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

(b) The Department of Health and Ageing has been advised that there are some 4,500 independent community pharmacies in Australia. Almost 90% of the pharmacist proprietors are members of The Pharmacy Guild of Australia.

(d) The PSA has advised that it distributes nationally policy statements, protocols and distance education materials while face-to-face training is provided by the individual PSA State Branches. Continuing Education (CE) questions relating to emergency contraception were published in the PSA educational booklet distributed to members in December 2003 and in the January 2004 issue of the *Australian Pharmacist*. While CE participation in most States and Territories is voluntary (except for South Australia), 545 pharmacists returned the CE questions from the educational booklet and 384 pharmacists returned the CE questions from the *Australian Pharmacist* journal article. Face-to-face Postinor-2 pharmacist training was provided by the PSA State Branches and the PCWA. Summary information on training attendances provided by the PSA is presented below:

Queensland - total attendees 302.
Victoria - total attendees approximately 600.
South Australia - approximately 250 attendees.
New South Wales - over 950 attendees.
Western Australia - approximately 1000 attendees representing approximately 80% of
practising pharmacists in the State.
Tasmania - 81 attendees.

(e) Yes. Such an occurrence would, prima facie, be a breach of the relevant State or Territory controls on the access to medicines.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-080

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

(f) Is the Department concerned by reports (Sunday Herald Sun, 28 March 2004; The West Australian, 3 April2004) that girls as young as 13 are buying the morning-after pill over the counter at Victorian pharmacies?

(g) Is the Department concerned about a report in the Sun Herald (30 May) that many pharmacists are ignoring guidelines about dispensing Postinor-2 and that only two out of ten pharmacists investigated by that newspaper were following recommended protocols?

(h) Is the Department concerned by a Sun Herald claim that Postinor-2 was sold, without proper advice to the customer, by a beauty consultant at one pharmacy?

Answer:

(b) Yes. A survey of jurisdictional representative members of the National Drugs and Poisons Schedule Committee in March 2004, however, did not identify any complaints to any relevant State or Territory authorities concerning such sales that would support media claims.

(c) Yes. Such behaviour may be contrary to the expectations of appropriate professional practice held by the relevant State and Territory pharmacist registration authorities.

(d) Yes. Such an occurrence would, prima facie, be a breach of the relevant State or Territory controls on access to medicines.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-081

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

I note in the Consumer Medicine Information (CMI) pamphlet for Postinor-2 it states "you should consult your doctor before you take it if [you have a range of medical conditions] …".
In light of reports that girls as young as 13 who may not be aware that they have such conditions and who may not even read the CMI material prior to taking the drug purchased over the counter, does the Department consider that the health of these women may be compromised through over the counter provision? Are pharmacists instructed to give women this advice?

Answer:

The National Drugs and Poisons Schedule Committee considered that the health of women would not be compromised by availability of Postinor-2 for 'Pharmacist Only' supply. The materials provided by the distributor and by the Pharmaceutical Society of Australia to pharmacists both include check lists for use by pharmacists that are useful aids to discovering the existence of such medical conditions.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-082

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

(a) I note the CMI also states "you should see you doctor within 3 weeks of taking Postinor-2." Are pharmacists instructed to advise women of this CMI recommendation?

(b) What proportion of women purchasing Postinor-2 subsequently visit a doctor for a check-up within these 3 weeks?

Answer:

(a) Yes. Advice to this effect is available to pharmacists in the Product Information as well as the Consumer Medicine Information document for Postinor-2 as a 'Pharmacy Only Medicine'. Such advice is also included in the distributor's and the Pharmaceutical Society's pharmacist support materials.

(b) The Department is not aware of any available data.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-083

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

I note the CMI states "Postinor-2 is not recommended for children. There is only limited information available on Postinor-2 when taken by women aged 14 -16 years.

(a) Again, in light of the earlier question regarding 13-year-olds, how will those in this age group be properly apprised of this information through over-the-counter sale?

(b) What is the Department doing to protect these young women from harm?

Answer:

(a) & (b)

Advice to this effect is available to pharmacists in the Product Information as well as the Consumer Medicine Information document for Postinor-2 as a 'Pharmacy Only Medicine'. The pharmacist would be expected to take this into account when giving advice, as is required for a 'Pharmacist Only Medicine'.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-084

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

(c) Do any of the materials remind pharmacists of the importance of allowing women to make a fully informed decision to use Postinor-2 and include in the information that the drug can prevent the implantation of a human embryo? Leaving aside debate over whether this can be defined as an abortion, many women would have ethical concerns over the drug's mode of action and should be offered the information.

(d) The National Drugs and Poisons Schedule Committee "acknowledged a reduction in abortion rate was desirable, [but] it may not be easy to link it to the availability of EC through conventional epidemiological data". Does the Department therefore agree with manufacturer Schering's training materials, which assert that Postinor-2 has been made available through pharmacies "because of public health concerns about the high number of unwanted pregnancies and abortion occurring in Australia"?

Answer:

(a) Both the Product Information and Consumer Medicine Information for Postinor-2 as a 'Pharmacist Only Medicine' include information about the mode of action of this product.

(b) Schering has not accurately reported the Committee's reasons. Postinor-2 was recommended as a 'Pharmacy Only Medicine' by the National Drugs and Poisons Schedule Committee for the following reasons:

i)Enabling timely access to levonorgestrel for EC.
ii) A well-established safety and efficacy profile.
iii) Levonorgestrel for EC use has been available in several countries for a number of years including use as a product not requiring a medical practitioner's prescription.
iv) The purpose is considered suitable for Schedule 3 listing and the product satisfies the criteria for Schedule 3 listing.

v) The distributors undertaking to provide appropriate training materials and educational materials for pharmacies.
vi) The pharmacist being required to provide professional advice and counselling to consumers to ensure that the product is used safely and effectively.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-085

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

(a) The National Drugs and Poisons Schedule Committee made the assessment that making Postinor-2 available over the counter would not lead to "more extensive use in women and teenagers". Please provide monthly statistics for Postinor-2 sales across Australia since the drug was first made available on prescription.

(b) The Sun Herald (30 May) reports that sales of Postinor-2 have doubled since 1 January. Does this mean that the National Drugs and Poisons Schedule Committee, which made the assessment that making Postinor-2 available over the counter would not lead to "more extensive use in women and teenagers", was in error?

Answer:

(a) The Record of Reasons for the June 2003 meeting of the National Drugs and Poisons Schedule Committee actually states: “The Committee gave consideration as to whether wider over-the-counter availability would lead to a tendency for levonorgestrel to be used as a primary form of contraception and result in a more extensive use in women and teenagers.” The distributor of Postinor-2 in Australia, in response to the Therapeutic Goods Administration’s request for sale statistics to enable this question to be answered, advised that it wishes to retain its sales statistics in confidence.

(b) It is not clear from The Sun-Herald article whether the reported increase in sales of Postinor-2 indicates use as the primary form of contraception.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-086

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

(a) Do pharmacists have a right of conscientious objection to providing morning-after pills such as Postinor-2?

(b) Are you aware of Schering training materials that repeat on a number of occasions that pharmacists who have an ethical objection "should advise customers of an appropriate alternative source of supply that is available within the time period for Postinor-2 to be effective"?

(c) Wouldn't referring to an alternate supply actually facilitate the supply of Postinor-2 and therefore be against that same pharmacist's conscience?

(d) Are you aware of reports in the UK of pharmacists, exercising their conscience, being pilloried for refusing to supply or refer customers to suppliers of morning-after pills? Does the Department consider such harassment appropriate in Australia?

Answer:

(c) Yes.

(d) Yes.

(e) That is a matter for the individual pharmacist.

(f) The Therapeutic Goods Administration is aware of only a single United Kingdom media item dated 22 May 2001, where it was reported that British pharmacists who refuse to dispense such medications feared discrimination.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-089

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

(a) To satisfy the National Drugs and Poisons Schedule Committee, Schering offered to provide training materials for pharmacists to help them dispense Postinor-2. The materials provided advice to pharmacist of appropriate questions to ask, but not of what might be appropriate responses to answers. For example, one suggested question is "is Postinor-2 for your own use?

(b) No direction or discussion is given as to whether it is appropriate to supply the drug to a third party. Isn't such material inadequate for helping pharmacists to make dispensing decisions? Isn't Schering just paying lip service to its commitment to the National Drugs and Poisons Schedule Committee and attempting to maximise sales?

Answer:

(a)&(b)

The National Drugs and Poisons Schedule Committee considered that training protocols provided by Schering Pty Ltd, together with other training materials etc provided to pharmacists, were adequate.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-090

OUTCOME 1: Population Health and Safety

Topic: HUMAN EMBRYONIC STEM CELLS

Written Question on Notice

Senator Harradine asked:

Please advise as to progress with implementing changes to the provision of information in Consumer Medicine Information and Product Information on the use in pharmaceuticals of human embryos, human embryonic stem cells or any other material sourced from a human embryo or human embryonic stem cell.

Answer:

The new requirement applies to medicines registered on or after 1 July 2004.

The pharmaceutical industry has been advised that it is a requirement from 1 July 2004 to include a declaration in relation to this matter in the data that is submitted to the Therapeutic Goods Administration (TGA).

The TGA has also separately contacted all sponsors of applications currently in process, and advised that a declaration would also be required from them.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-019

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ILLICIT DRUG STRATEGY

Written Question on Notice

Senator Denman asked:

Is the Department able to provide a breakup of the funding (see Portfolio Budget Statement page 71) to be provided to each of the following programmes over the four year period of the forward estimates, covering both that provided for in the forward estimates and the newly allocated funding:

(i) Continued Drug Use Monitoring Initiative
(ii) National Comorbidity Initiative
(iii) National Psychostimulants Initiative

Answer:

The following table provides a breakup of the funding:

| | **2004-05 ($m)** | **2005-06 ($m)** | **2006-07 ($m)** | **2007-08 ($m)** |
|---|---|---|---|---|
| (i) Continued Drug Use Monitoring | **1.099** | **1.107** | **1.004** | 1.003 |
| (ii) National Comorbidity Initiative | **2.700** | 1.732 | 1.766 | 1.801 |
| (iii) National Psychostimulants Initiative | **0.999** | 1.018 | 1.037 | 1.059 |

The funding in bold was included in the forward estimates. The unbolded funding was newly allocated in the 2004-05 Budget.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-020

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ILLICIT DRUG STRATEGY

Written Question on Notice

Senator Denman asked:

What measures are proposed to be continued or implemented within each initiative during (a) 2004-05 and (b) in subsequent years covered by the forward estimates?

Answer:

Following a comprehensive consultation process involving the Australian National Council on Drugs, the Alcohol and other Drugs Council of Australia, the Mental Health Council of Australia and other key stakeholders, an implementation plan has been developed for the National Comorbidity Initiative (Attachment A) and the National Psychostimulants Initiative (Attachment B). The 2004-2005 Budget allocated additional funding to these initiatives. The implementation plans will be reviewed and modified as required.

**Attachment A**

# NATIONAL COMORBIDITY INITIATIVE

As part of the National Illicit Drug Strategy the Australian Government has allocated $9.7 million (over the period 2003-04 to 2007-08) to the National Comorbidity Initiative. The Initiative aims to improve coordination across psychiatric/mental health services and drug treatment services, develop best practice guidelines for service delivery, and increase professional education and training.

The Australian Government has undertaken a comprehensive consultation process with the Australian National Council on Drugs, the Alcohol and other Drugs Council of Australia, the Mental Health Council of Australia and other key stakeholders in developing an implementation plan for the Initiative. This process has identified the following four areas of activity:

1. **Raising awareness of comorbidity among clinicians/health workers and promoting examples of good practice resources/models**

    - fund a forum of key stakeholders from around Australia to discuss the comorbidity of mental health and substance misuse, particularly in the area of youth and early psychosis. The Mental Health Council of Australia convened a Comorbidity Forum in Sydney on 21 May 2004.
    - disseminate and promote information on comorbidity, good practice models, clinical guidelines, training resources, and research findings through recognised pathways such as peak bodies (for example Australian Divisions of General Practice, ADCA, ANCD and RACGP) relevant conferences/forums, national websites (such as Primary Mental Health Centre Australian Resource Centre, Australian Drug Information Network, beyondblue and Health Online), peak journals/newsletters (such as Australian Doctor/Medical Observer and 'Of Substance'). The monograph 'comorbid mental disorders and substance use disorders: epidemiology, prevention and treatment' was released by the Parliamentary Secretary, the Hon Trish Worth MP, on 20 May 2004.
    - develop a quality assurance framework including accreditation of services and core competencies for staff for non-government organisations.

2. **Providing support to general practitioners and other health workers to improve treatment outcomes for comorbid patients**

    - explore the feasibility of undertaking a range of projects with Australian Government funded programs in the areas of drug and alcohol, mental health and allied health. For example, organisations already funded for drug and alcohol treatment services (Non Government Organisation Treatment Grants Programme), mental health services (National Mental Health Strategy), and allied health services (More Allied Health Services Program), could be contracted to trial models of shared care/case management linking primary care to specialist settings including integrated patterns of service delivery.
    - review the provision of specialist telephone support services to general practitioners on clinical aspects of treatment of comorbidity and determine if a stand alone service should be developed, or expansion of current services.
    - conduct a qualitative study of treatment experiences of drug treatment clients with

comorbidity and complex vulnerabilities to identify the barriers and incentives to treatment and treatment models, policies and practices to improve treatment outcomes for clients. LMS Consulting, in consortium with the National Centre on HIV Social Research and the Australian Injecting and Illicit Drug Users League, have been commissioned to undertake this project.

- evaluate selected current treatment approaches to comorbidity, to determine the efficacy of the models of treatment.
- trial the implementation of a mental health screening tool and integrated intervention within drug treatment services to assist clinicians to address mental health problems, including the development of a skills training system. The Turning Point Alcohol and Drug Centre have been commissioned to undertake this project.

3. Facilitating resources and information for consumers

- review and if applicable wide dissemination of the "Self-Help Manual for People Living with Substance Use and Mental Health Problems". This manual has been developed by JenCo Consulting and is currently being peer reviewed;
- the development and wide dissemination of a book of case studies of real life stories from ordinary Australians who have experienced what it is like to have, or be exposed to someone that has, a drug and alcohol and mental health problem. The case studies could cover the individual, their family and friends and a frontline worker perspective. This approach has been successfully utilised in other areas (for example homelessness) and will go some way to breaking down the barriers and stigma associated with drug and alcohol and mental health disorders. LMS Consulting have been commissioned to undertake this project;
- the development and wide dissemination (including GP waiting rooms) of an information brochure for consumers on comorbidity and how to find help. A tender process is being finalised for this project; and
- the development of a care plan policy which incorporates consumer involvement in planning, including consideration of access to existing services such as the voucher system.

**4. Improving data systems and collection methods within the mental health and alcohol and other drugs sectors to manage comorbidity more effectively**

- determine suitable data sources and data sets which identify work force and work flow issues in the management of patients with complex comorbidities; and
- explore ways of improving data systems and collection methods to deliver key information on people presenting with comorbidity at population, program and individual. The Australian Institute of Health and Welfare have been commissioned to undertake this project.

**Attachment B**

# NATIONAL PSYCHOSTIMULANTS INITIATIVE

As part of the National Illicit Drug Strategy the Australian Government has allocated $5.1 million (over the period 2003-04 to 2007-08) to the National Psychostimulants Initiative. The Initiative aims to address problems associated with the increased availability and use of psychostimulants in Australia.

The Australian Government has undertaken a comprehensive consultation process with the Australian National Council on Drugs, the Alcohol and other Drugs Council of Australia and other key stakeholders in developing an implementation plan for the Initiative. This process has identified the following three areas of activity:

1. **Identification and dissemination of good practice models and approaches for the treatment of psychostimulant use**

   - the evaluation and trialing of current treatment approaches to determine the efficacy in achieving positive outcomes for psychostimulant users and good practice approaches that can be widely disseminated;
   - the conduct of a trial of assertive community follow-up treatment for methamphetamine-induced psychosis. This study seeks to optimise the management of acute psychosis presentations and reduce the risk of relapse following treatment. The Drug and Alcohol Services Council of South Australia have been commissioned to undertake this project; and
   - the promotion and dissemination of: (i) information on psychostimulants (for example the updated National Drug Strategy Monograph on Models of Intervention and Care for Psychostimulant Users and clinical guidelines for general practitioners, police, ambulance officers and emergency personnel); (ii) good practice models; (iii) training resources; and (vi) research findings - through recognised pathways (such as Australian Divisions of General Practice, Alcohol and other Drugs Council of Australia and Australian National Council on Drugs), relevant conferences/forums, national websites (for example Australian Drug Information Network and Health Online), and peak journals/newsletters (such as Australian Doctor/Medical Observer and 'Of Substance'). The National Drug Strategy Monograph Series No. 51 2nd Edition 'Models of intervention and care for psychostimulant users' was released by the Parliamentary Secretary, the Hon Trish Worth MP, on 20 May 2004.

2. **Providing support and training to general practitioners and other health workers to improve treatment outcomes for psychostimulant users**

   - the conduct of national training workshops for clinicians and other health care workers, in drug and alcohol treatment services, on recognised treatment approaches for psychostimulant use (eg: brief cognitive behavioural interventions). JenCo Consulting have been commissioned to undertake the training workshops;
   - the conduct of several pilots, through selected Divisions of General Practice, to provide information and training workshops to general practitioners and other health care workers (for example practice nurses) on psychostimulants (utilising the new Alcohol and Other Drugs: A Handbook for Health Professionals); and

- the conduct of an evaluation of the guidelines for management of acute psychotimulant toxicity with police and ambulance services in a range of jurisdictions. The evaluation would include the new sedation protocol for acute psychostimulant toxicity that is currently being trialed at the Gold Coast Hospital.

**3. Providing information for at-risk youth and families**

- the identification and dissemination of information and resources on psychostimulants for young people, their families, and friends and those contemplating use. This would include a plain English guide including general information about psychostimulants, the consequences of psychostimulant use and associated harm. In addition, this resource will include information on issues such as dealing with the extremes of user behaviour and problems and where to seek help. The Alcohol and other Drugs Council of Australia are undertaking a scoping study to identify current resources around psychostimulants - particularly directed at young people and families. The aim is to determine gaps in information development around psychostimulants for these target groups; and
- research into the feasibility of using peer education approaches among groups of young people at risk of initiating or increasing psychostimulant use.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-021

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ILLICIT DRUG STRATEGY

Written Question on Notice

Senator Denman asked:

What did the evaluations undertaken by the Department reveal about the effectiveness of each of these initiatives in the period for which they have been funded to date?

Answer:

The National Psychostimulants Initiative and the National Comorbidity Initiative were first allocated funding as part of the 2003-04 Budget. This funding was for the 2003-04 and 2004-05 financial years. The Department has not yet undertaken an evaluation of these Initiatives as they are still in the first year of operation. As part of the 2004-05 Budget, these two Initiatives have been allocated funding up to and including 2007-08. A review of these measures will now occur by the end of 2007-08.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-022

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ILLICIT DRUG STRATEGY

Written Question on Notice

Senator Denman asked:

Does the Department have available any figures which would indicate the effectiveness of measures funded under the National Illicit Drug Strategy and if so, can a copy be provided ?

Answer:

There are a number of indicators to suggest that the measures funded under the National Illicit Drug Strategy have been effective. These include:

- fewer people using illicit drugs - the 2001 National Drug Strategy Household Survey reported a 23% reduction in the proportion of people using illicit drugs;
- fewer people dying of overdoses - the Australian Bureau of Statistics has reported 364 deaths in 2002, compared to 958 in 1999;
- more parents talking to their children about drugs - 78% of parents spoke to their children about drugs during the 2001 National Illicit Drugs Campaign;
- more people accessing treatment - a 2001 census of drug treatment services confirmed that the number of people treated for drug and alcohol problems has increased considerably since 1995. In 2002-03 there were more than 27,000 treatments provided to drug users through the treatment services funded under the Non Government Organisation Treatment Grants Programme, which is up from around 19,000 in 1999-2000;
- more people being diverted from gaol to treatment - all States and Territories have now established Diversion Programs and more than 50,000 diversions have occurred;
- new treatment options available for the management of opioid dependency;
- more national information on drug use and markets - through the Illicit Drug Reporting System and Drug Use Monitoring in Australia projects; and
- law enforcement efforts continue to disrupt heroin importation markets with record drug seizures - over 9 tonnes of illicit drugs have been seized since the introduction of the National Illicit Drug Strategy.

These figures have been sourced from published and unpublished reports.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-023

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ILLICIT DRUG STRATEGY

Written Question on Notice

Senator Denman asked:

(a) To which organisations will funding be provided during 2004-05 under the Non Government Organisation Treatment Grants Program in respect of:

(i) new treatment services;
(ii) existing treatment services; and
(iii) the expansion of existing treatment services.

(b) What is the amount of each grant to each organisation for each such service?

Answer:

(a) There are a total of 177 organisations that have been allocated funding in the 2004-05 financial year under the Non Government Organisation Treatment Grants Programme (NGOTGP). They are summarised below and listed individually in Attachments A, B and C.

i) In April 2004, 29 new treatment services were allocated funding under the NGOTGP, with 9 in NSW, 9 in VIC, 3 in WA, 3 in SA, 2 in QLD, 2 in NT and 1 in the ACT (as per Attachment A). These new services have been allocated a total of $9,502,751.00 from 2004 to 2006.

ii) In October 2003, 113 existing treatment services were allocated funding under the NGOTGP, with 31 in VIC, 22 in NSW, 20 in WA, 19 in QLD, 9 in SA, 5 in NT, 5 in TAS and 2 in the ACT (as per Attachment B). These services have been allocated a total of $47,728,087.00 from 2004 to 2006.

iii) In March 2004, 35 existing treatment services were allocated funding under the NGOTGP for expansions of their services, with 9 in NSW, 6 in WA, 6 in QLD, 5 in VIC, 4 in TAS, 3 in SA, 1 in NT and 1 in the ACT (as per Attachment C). These services have been allocated a total of $8,495,929.50 from 2004 to 2006.

(b) Under the NGOTGP a total of $65,726,767.50 has been allocated to 177 treatment services across Australia. The amount each service has been allocated has been included in Attachments A, B and C.

Attachment A:
New Treatment Services

| State | Name of Organisation | Grant Total |
|---|---|---|
| ACT | ADFACT Canberra Alliance for Harm Minimisation and Advocacy | $231,642.00 |
| NSW | Blacktown Alcohol and other Drugs Family Services Inc.(BADFS) | $357,356.00 |
| NSW | Daruk Aboriginal Community-Controlled Medical Service | $355,028.00 |
| NSW | Eleanor Duncan Aboriginal Medical Centre | $206,350.00 |
| NSW | Glebe House Limited | $211,574.00 |
| NSW | Manly Drug Education and Counselling Centre (MDECC) | $176,545.00 |
| NSW | Society of St. Vincent de Paul | $341,106.00 |
| NSW | Teen Challenge NSW Inc | $671,596.00 |
| NSW | The Haymarket Foundation Ltd | $192,579.00 |
| NSW | Weigelli Centre Aboriginal Corporation | $242,337.00 |
| NT | Centacare NT | $374,500.00 |
| NT | Drug and Alcohol Services Association | $237,435.00 |
| QLD | Teen Challenge | $210,046.00 |
| QLD | We Help Ourselves (WHOS) | $1,358,495.00 |
| SA | DRUG ARM SA | $283,392.00 |
| SA | Vietnamese Community in Australia/SA | $266,927.00 |
| SA | Young Women's Christian Association of Adelaide Inc | $578,470.00 |
| VIC | North Yarra Community Health (NYCH) | $192,167.00 |
| VIC | Odyssey House Victoria | $595,523.00 |
| VIC | Orygen Research Centre | $396,906.00 |
| VIC | Peninsula Community Health Service & Frankston Community Health Service | $381,524.00 |
| VIC | Taskforce Community Agency Inc. | $222,274.00 |
| VIC | The Salvation Army - Kardinia Network | $176,263.00 |
| VIC | Uniting Care - Moreland Hall | $207,203.00 |
| VIC | Uniting Care - Moreland Hall | $197,494.00 |
| VIC | Youth Substance Abuse Service (Latrobe Valley) | $198,019.00 |
| WA | B-Attitudes Inc | $240,000.00 |
| WA | MercyCare (Mercy Community Services Inc.) | $200,000.00 |
| WA | Noongar Alcohol & Substance Abuse Service | $200,000.00 |
| | **TOTAL** | **$9,502,751.00** |

**Number of Services** **29**

Attachment B:
Existing Treatment Services

| State | Name of Organisation | Grant Total |
|---|---|---|
| ACT | Ted Noffs Foundation | $2,156,042.00 |
| ACT | Toora Womens Incorporated | $488,112.00 |
| NSW | Aboriginal Medical Service Cooperative Ltd | $801,508.00 |
| NSW | Calvary Health Care, Riverina-O'Connor House AOD Service | $1,292,864.00 |
| NSW | Kamira Farm Inc | $140,900.00 |
| NSW | Kamira Farm Inc | $416,138.00 |
| NSW | Kedesh Rehabilitation Services | $621,567.00 |
| NSW | Ngaimpe Aboriginal Corporation | $162,887.00 |
| NSW | Odyssey House McGrath Foundation | $1,881,266.00 |
| NSW | Odyssey House McGrath Foundation | $190,315.00 |
| NSW | Peninsula Community Centre Inc | $83,612.00 |
| NSW | Salvation Army - Oasis Youth Support Network | $233,045.00 |
| NSW | Salvation Army - Youth link | $149,341.00 |
| NSW | South Sydney Youth Services | $579,424.00 |
| NSW | Ted Noffs Foundation Inc | $1,069,124.00 |
| NSW | The Buttery Inc | $1,216,193.00 |
| NSW | The Lyndon Community | $1,051,578.00 |
| NSW | The Salvation Army - Shoalhaven Bridge | $245,525.00 |
| NSW | The Station Ltd | $146,811.00 |
| NSW | Triple Care Farm - Mission Australia | $145,596.00 |
| NSW | We Help Ourselves (WHOS) | $1,204,561.00 |
| NSW | We Help Ourselves (WHOS) | $1,650,060.00 |
| NSW | Wollongong Crisis Centre | $455,929.00 |
| NSW | Youth off the Streets | $862,307.00 |
| NT | Banyan House | $411,553.00 |
| NT | Banyan House | $355,700.00 |
| NT | Central Australian Aboriginal Congress | $378,000.00 |
| NT | Ngaanyatjarra Pitjantjatjara Yankunyjatjara (NPY) Women's Council Aboriginal Corporation | $604,187.00 |
| NT | NT AIDS and Hepatitis C Council | $490,560.00 |
| QLD | Alcohol and Drug Foundation - Kingston | $315,700.00 |
| QLD | Alcohol and Drug Foundation Queensland - Spring Hill | $382,500.00 |
| QLD | Brisbane Youth Service | $316,772.00 |
| QLD | Drug Arm QLD | $517,000.00 |
| QLD | Drug Users Network Education Support Inc (DUNES) | $220,849.00 |
| QLD | Gold Coast Alcoholics Recovery Project T/A Goldbridge | $752,353.00 |
| QLD | Gold Coast Drug Council Inc (Mirikai) | $477,967.00 |
| QLD | Mamu Health Service | $483,339.00 |
| QLD | Mater Mothers' Hospital | $296,993.00 |
| QLD | Queensland Intravenous AIDS Association (QuIVAA) | $874,416.00 |
| QLD | St Lukes Nursing Service | $483,125.00 |
| QLD | St Vincent's Community Services - Cairns (Ozcare) | $401,982.00 |
| QLD | St Vincents' Community Services Brisbane (OzCare) | $442,667.00 |
| QLD | Sunshine Coast Injectors Voice and Action Association (SCIVAA) | $417,213.00 |
| QLD | Tablelands Alcohol and Drug Service (auspice Wuchopperen) | $672,153.00 |
| QLD | The Salvation Army Fairhaven | $321,000.00 |
| QLD | The Salvation Army Fairhaven (Womens) | $249,000.00 |
| QLD | The Salvation Army Fairhaven - Townsville | $215,798.00 |

| | | |
|---|---|---|
| QLD | Youth Empowered Towards Independence (YETI) | $624,571.00 |
| SA | Aboriginal Drug and Alcohol Council of SA Inc | $655,857.00 |
| SA | Adelaide Central Mission - Kuitpo | $273,028.00 |
| SA | Adelaide Central Mission - Streetlink | $310,625.00 |
| SA | Anglicare SA (Archway) | $115,446.00 |
| SA | Baptist Community Services SA Inc | $134,458.00 |
| SA | Mission Australia - Hindmarsh | $579,360.00 |
| SA | Nunkuwarrin Yunti of SA Inc | $141,310.00 |
| SA | Offenders Aid and Rehabilitation Servcies SA Inc (OARS) | $422,246.00 |
| SA | The Salvation Army, Towards Independence | $291,270.00 |
| TAS | Anglicare Tasmania Inc. | $239,814.00 |
| TAS | Community Connections Inc. | $281,026.00 |
| TAS | The Link Youth Health Services | $205,985.00 |
| TAS | The Salvation Army | $241,800.00 |
| TAS | Youth and Family Focus Inc. | $222,264.00 |
| VIC | Anglicare Victoria | $325,125.00 |
| VIC | Australia Vietnamese Women's Welfare Association | $230,009.00 |
| VIC | Eastern Drug and Alcohol Service (YSAS Northern) | $386,816.00 |
| VIC | Flat Out | $380,968.00 |
| VIC | General Practitioners Association of Geelong (Clockwork Young Peoples Health Service Auspiced by GPAG) | $289,090.00 |
| VIC | Goulburn Valley Community Health Service Inc. | $204,663.00 |
| VIC | Inner South Community Health Service | $224,654.00 |
| VIC | Jesuit Social Services | $656,163.00 |
| VIC | Knox Community Health Service | $218,249.00 |
| VIC | Latrobe Community Health Service Inc. | $262,428.00 |
| VIC | MacKillop Family Services | $447,574.00 |
| VIC | Maroondah Social and Community Health Service Inc (Eastern Access Community Health) | $494,595.00 |
| VIC | Mitchell Community Health Service | $232,384.00 |
| VIC | Ngwala Willumbong Coopoerative Ltd | $376,532.00 |
| VIC | Northern District Community Health Centre (in cooperation with Echuca Regional Health) | $763,471.00 |
| VIC | Salvation Army (Victoria) Property Trust - Eastcare | $198,951.00 |
| VIC | San Remo and District Health Centre inc (Bass Coast Community Health Service) | $190,029.00 |
| VIC | Self Help Addiction Resource Centre Inc (SHARC) | $383,008.00 |
| VIC | Someone Who Cares Inc | $77,809.00 |
| VIC | Sunbury Community Health Centre Inc | $225,929.00 |
| VIC | Sunraysia Community Health Service Inc. | $165,945.00 |
| VIC | The Buoyancy Foundation of Victoria | $216,749.00 |
| VIC | The Salvation Army - Bridgehaven | $1,272,958.00 |
| VIC | The Salvation Army - VIC | $198,951.00 |
| VIC | The Windana Society | $192,933.00 |
| VIC | Turning Point Alcohol and Drug Centre Inc. | $180,295.00 |
| VIC | Uniting Care - Ballarat | $247,535.00 |
| VIC | Upper Hume Community Health Service - Wodonga | $218,983.00 |
| VIC | Windana Society Inc | $124,163.00 |
| VIC | Youth Substance Abuse Service (YSAS) | $580,018.00 |
| VIC | Youth Substance Abuse Service (YSAS) | $386,816.00 |
| WA | Agencies for South West Accommodation | $240,000.00 |
| WA | Daughters of Charity | $328,772.00 |
| WA | Drug Arm WA Inc | $300,000.00 |

| | | |
|---|---|---|
| WA | Drug Arm WA Inc | $186,373.00 |
| WA | Goldfields Centrecare | $196,656.00 |
| WA | Holyoake (Art Theraplay Program) | $280,000.00 |
| WA | Holyoake (Prison to Parole) | $227,147.00 |
| WA | Holyoake (Wheatbelt) | $374,950.00 |
| WA | Mission Australia | $550,000.00 |
| WA | Mission Australia | $183,842.00 |
| WA | North East Regional Youth Council (Swan City Youth Service) | $214,996.00 |
| WA | Outcare Inc | $239,503.00 |
| WA | Palmerston Association Inc - Great Southern Region | $240,000.00 |
| WA | Palmerston Association Inc - South West Metro | $210,000.00 |
| WA | Salvation Army - Bridge Program | $148,500.00 |
| WA | St John of God | $240,000.00 |
| WA | WA Council on Addictions - Cyrenian House | $375,000.00 |
| WA | Warburton Community Inc | $218,473.00 |
| WA | Western Australian Substance Users' Association (WASUA) | $195,490.00 |
| WA | Women's Health Care Association | $360,000.00 |

| | |
|---|---|
| **TOTAL** | **$47,728,087.00** |

**Number of Services** **113**

**Attachment C:**

Expansion of Existing Treatment Services

| State | Name of Organisation | Grant Total |
|---|---|---|
| ACT | Ted Noffs Foundation | $391,361.00 |
| NSW | Kedesh Rehabilitation Services | $246,207.00 |
| NSW | Ngaimpe Aboriginal Corporation | $128,268.00 |
| NSW | The Lyndon Community | $691,339.00 |
| NSW | The Salvation Army Property Trust (NSW) | $501,452.00 |
| NSW | The Salvation Army Property Trust NSW (Salvation Army Youthlink) | $319,600.00 |
| NSW | We Help Ourselves (WHOS) | $293,484.00 |
| NSW | Wollongong Crisis Centre (WCC) | $104,052.00 |
| NSW | Alcohol and Drug Foundation - Kathleen York House | $295,485.00 |
| NSW | Jarrah House | $344,050.00 |
| NT | Banyan House | $348,065.00 |
| QLD | Gold Coast Alcoholics Recovery Project Inc: Goldbridge | $149,207.00 |
| QLD | Gold Coast Drug Council Inc (Mirikai) | $223,675.00 |
| QLD | Queensland Intravenous AIDS Association (QuIVAA) | $240,186.00 |
| QLD | Sunshine Coast Injectors Voice and Action Association (SCIVAA) | $116,120.50 |
| QLD | Addiction Help Agency Cairns Inc | $518,675.00 |
| QLD | Drug Arm QLD | $344,539.00 |
| SA | Nunkuwarrin Yunti of SA Inc | $64,436.00 |
| SA | Offenders Aid and Rehabilitation Services SA Inc (OARS) | $44,226.00 |
| SA | The Salvation Army, Towards Independence | $219,799.00 |
| TAS | The Link Youth Health Service Inc | $183,862.00 |
| TAS | The Salvation Army (Tasmania) | $240,342.00 |
| TAS | Holyoake Tasmania | $163,834.00 |
| TAS | Launceston City College | $215,210.00 |
| VIC | Inner South Community Health Service Inc | $189,235.00 |
| VIC | The Windana Society and Sacred Heart Mission | $181,989.00 |
| VIC | Turning Point Alcohol and Drug Centre Inc. | $258,101.00 |
| VIC | Uniting Care - Ballarat | $196,864.00 |
| VIC | Upper Hume Community Health Service - Wodonga | $191,313.00 |
| WA | Mission Australia (WA) | $220,000.00 |
| WA | Palmerston Inc - South Metropolitan Community Drug Service Team | $200,000.00 |
| WA | Palmerston Inc. Great Southern Community Drug Service Team | $149,520.00 |
| WA | WA Council on Addictions Inc | $200,000.00 |
| WA | WA Council on Addictions Inc | $121,433.00 |
| WA | Western Australian Substance Users' Association (WASUA) | $200,000.00 |
| | **TOTAL** | **$8,495,929.50** |
| | **Number of Services** | **35** |
| | **Grand Total Services** | **177** |
| | **Grand Total Funding** | **$65,726,767.50** |

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-024

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ILLICIT DRUG STRATEGY

Written Question on Notice

Senator Denman asked:

> What measures does the Department propose during 2004-05 to evaluate the effectiveness the National Drug Strategic Framework?

Answer:

The new National Drug Strategy 2004-2009 took effect from 1 July 2004.

A cross-jurisdictional working group has commenced the work of identifying effectiveness measures for the life of the Strategy.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-025

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ILLICIT DRUG STRATEGY – DRUG DEPENDENT PERSONS

Written Question on Notice

Senator Denman asked:

(a) Since 1996-97 has the Government initiated, conducted or supported any programmes which are designed to encourage drug dependent persons to enter or return to the workforce?

(b) If so, what funding (i) has been spent and (ii) is currently allocated for such programmes ? Has there been any evaluation of the success and benefits of such programmes and if so, what did it reveal ?

(c) If not, are their particular reasons why such programmes have not been initiated, conducted or supported ?

Answer:

(a) The State and Territory Governments are primarily responsible for the provision of drug and alcohol treatment and support services in their jurisdictions.

The Non Government Organisation Treatment Grants Programme (NGOTGP) provides funding to supplement State and Territory Government activities by providing funding to establish and operate new treatment services, and expand or enhance existing treatment services for users of illicit drugs. The NGOTGP does not provide funding specifically for initiatives that encourage drug dependent persons to enter or return to the workforce. However, many of the treatment services do provide their clients with a broad range of support services, some of which include support and assistance to enter or return to the workforce.

The Australian Government Department of Employment and Workplace Relations aims to maximise the ability of unemployed Australians to find work. This includes programs such as the Job Network, Job Placement and Work for the Dole. There are also a range of career and training programs.

(b) Not applicable.

(c) See answer to (a) above.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-026

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ILLICIT DRUG STRATEGY – DRUG DEPENDENT PERSONS

Written Question on Notice

Senator Denman asked:

(a) Since 1996-97 has the Government initiated, conducted or supported any programmes which are designed to improve literacy and/or numeracy amongst drug dependent persons?

(b) If so, what funding (i) has been spent and (ii) is currently allocated for such programmes ? Has there been any evaluation of the success and benefits of such programmes and if so, what did it reveal?

(c) If not, are their particular reasons why such programmes have not been initiated, conducted or supported ?

Answer:

(a) The State and Territory Governments are primarily responsible for the provision of drug and alcohol treatment and support services in their jurisdictions.

The Non Government Organisation Treatment Grants Programme (NGOTGP) provides funding to supplement State and Territory Government activities by providing funding to establish and operate new treatment services, and expand or enhance existing treatment services for users of illicit drugs. The NGOTGP does not provide funding specifically for initiatives designed to improve literacy and/or numeracy skills for drug dependent persons. However, many of the treatment services do provide their clients with a broad range of support services, some of which include improving literacy and/or numeracy skills.

The Australian Government Department of Employment and Workplace Relations aims to maximise the ability of unemployed Australians to find work. This includes a range of career and training programs.

(b) Not applicable.

(c) See answer to (a) above.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-027

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ILLICIT DRUG STRATEGY

Written Question on Notice

Senator Denman asked:

(a) In answer to question E03-109 relating to the Supplementary Budget Estimates in November 2003, the Department indicated that the information sought was not yet available. Can the information now be provided?

(b) In the answer to the same question, the Department indicated that a "detailed implementation strategy for this initiative is currently being finalised". Has the strategy been finalised? If so, can a copy be provided?

(c) If not, particularly as the Initiative has been extended, can reasons be provided why this has not been possible and when is it envisaged that the strategy will be finalised and available?

Answer:

(a) The National Psychostimulants Initiative aims to address problems associated with the availability and use of psychostimulants in Australia. The Department has consulted with the Australian National Council on Drugs, the Alcohol and other Drugs Council of Australia, and other stakeholders on the implementation of the Initiative. This process identified the following priority areas:

- identification and dissemination of good practice models and approaches for the treatment of psychostimulant use;
- providing support and training to general practitioners and other health workers to improve treatment outcomes for psychostimulant users; and
- providing information for at-risk youth and families.

A number of projects have commenced including the following:

- the Drug and Alcohol Services Council of South Australia is undertaking a trial of assertive community follow-up treatment for methamphetamine-induced psychosis. The study seeks to optimise the management of acute psychosis presentation and reduce the risk of relapse following treatment.

- JenCo Consulting are conducting a series of one-day workshops for frontline workers from various settings across Australia in delivering the brief cognitive behavioural intervention for psychostimulant users.

- the Alcohol and other Drugs Council of Australia is undertaking a scoping study to identify current resources around psychostimulants - particularly directed at young people and families. The aim is to determine gaps in information development around psychostimulants for these target groups.

Tender processes have commenced for a range of other projects.

(b) An implementation plan for the National Psychostimulants Initiative is at Attachment A. Additional funding was allocated to the Initiative as part of the 2004-2005 Budget. The implementation plan will be reviewed and amended as required.

(c) Not applicable.

**Attachment A**

## NATIONAL PSYCHOSTIMULANTS INITIATIVE

As part of the National Illicit Drug Strategy the Australian Government has allocated $5.1 million (over the period 2003-04 to 2007-08) to the National Psychostimulants Initiative. The Initiative aims to address problems associated with the increased availability and use of psychostimulants in Australia.

The Australian Government has undertaken a comprehensive consultation process with the Australian National Council on Drugs, the Alcohol and other Drugs Council of Australia and other key stakeholders in developing an implementation plan for the Initiative. This process has identified the following three areas of activity:

1. Identification and dissemination of good practice models and approaches for the treatment of psychostimulant use

- the evaluation and trialing of current treatment approaches to determine the efficacy in achieving positive outcomes for psychostimulant users and good practice approaches that can be widely disseminated;

- the conduct of a trial of assertive community follow-up treatment for methamphetamine-induced psychosis. This study seeks to optimise the management of acute psychosis presentations and reduce the risk of relapse following treatment. The Drug and Alcohol Services Council of South Australia have been commissioned to undertake this project; and

- the promotion and dissemination of: (i) information on psychostimulants (eg: the updated National Drug Strategy Monograph on Models of Intervention and Care for Psychostimulant Users and clinical guidelines for general practitioners, police, ambulance officers and emergency personnel); (ii) good practice models; (iii) training resources; and (vi) research findings - through recognised pathways (eg: Australian Divisions of General Practice, Alcohol and other Drugs Council of Australia, Australian National Council on Drugs etc), relevant conferences/forums, national websites (eg: Australian Drug Information Network, Health Online etc), and peak journals/newsletters (eg: Australian Doctor/Medical Observer, 'Of Substance' etc). The National Drug Strategy Monograph Series No. 51 2nd Edition 'Models of intervention and care for psychostimulant users' was released by the Parliamentary Secretary, the Hon Trish Worth MP, on 20 May 2004.

**2. Providing support and training to general practitioners and other health workers to improve treatment outcomes for psychostimulant users**

- the conduct of national training workshops for clinicians and other health care workers, in drug and alcohol treatment services, on recognised treatment approaches for psychostimulant use (eg: brief cognitive behavioural interventions). JenCo Consulting have been commissioned to undertake the training workshops;

- the conduct of several pilots, through selected Divisions of General Practice, to provide information and training workshops to general practitioners and other health care workers (eg: practice nurses) on psychostimulants (utilising the new Alcohol and Other Drugs: A Handbook for Health Professionals); and

- the conduct of an evaluation of the guidelines for management of acute psychotimulant toxicity with police and ambulance services in a range of jurisdictions. The evaluation would include the new sedation protocol for acute psychostimulant toxicity that is currently being trialed at the Gold Coast Hospital.

**3. Providing information for at-risk youth and families**

- the identification and dissemination of information and resources on psychostimulants for young people, their families, and friends and those contemplating use. This would include a plain English guide including general information about psychostimulants, the consequences of psychostimulant use and associated harm. In addition, this resource will include information on issues such as dealing with the extremes of user behaviour and problems and where to seek help. The Alcohol and other Drugs Council of Australia are undertaking a scoping study to identify current resources around psychostimulants - particularly directed at young people and families. The aim is to determine gaps in information development around psychostimulants for these target groups; and

- research into the feasibility of using peer education approaches among groups of young people at risk of initiating or increasing psychostimulant use.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-028

OUTCOME 1: Population Health and Safety

Topic: NATIONAL COMORBIDITY INITIATIVE

Written Question on Notice

Senator Denman asked:

(a) In answer to question E03–110 relating to the Supplementary Budget Estimates in November 2003, the Department indicated that the information sought was not yet available. Can the information now be provided?

(b) In the answer to the same question, the Department indicated that "a detailed implementation strategy for this initiative is currently being finalised." Has the strategy been finalised? If so, can a copy be provided?

(c) If not, particularly as the initiative has been extended, can reasons be provided why this has not been possible and when it is envisaged that the strategy will be finalised and available?

Answer:

(a) The National Comorbidity Initiative aims to improve service co-ordination and treatment outcomes for people with coexisting mental health and substance use disorders. The Department consulted with the Australian National Council on Drugs, the Alcohol and Other Drugs Council of Australia, the Mental Health Council of Australia and other key stakeholders on the implementation of the Initiative. This process identified the following priority areas:

- facilitating resources and information for consumers;
- providing support to general practitioners and other health workers to improve treatment outcomes for comorbid clients;
- improving data systems and collection methods within the mental health and alcohol and other drugs sectors to manage comorbidity more effectively; and
- raising awareness of comorbidity among clinicians/health workers and promoting examples of good practice resources/models.

A number of projects have commenced as part of the National Comorbidity Initiative including the following:

- the Mental Health Council of Australia convened a Comorbidity Forum on 21 May 2004 with key stakeholders from around Australia to discuss the comorbidity of

mental health and substance misuse, particularly in the area of youth and early psychosis.

- LMS Consulting are undertaking the "Family Stories" project which will involve the development of a book of case studies of real life stories from ordinary Australians who have experienced what it is like to have, or be exposed to someone that has, a drug and alcohol and mental health problem.

- LMS Consulting, in consortium with the National Centre on HIV Social Research and the Australian Injecting and Illicit Drug Users League, are conducting a qualitative study of treatment experiences of drug treatment clients with comorbidity and complex vulnerabilities to identify barriers and incentives to treatment and treatment models, policies and practices to improve treatment outcomes for clients.

- The Australian Institute of Health and Welfare is reviewing data collections relating to people with coexisting substance use and mental health disorders.

Tender processes have commenced for a range of other projects.

(b) An implementation plan for the National Comorbidity Initiative is at Attachment A. Additional funding was allocated to the Initiative as part of the 2004-2005 Budget, the implementation plan will be reviewed and amended as required.

(c) Not applicable.

**Attachment A**

# NATIONAL COMORBIDITY INITIATIVE

As part of the National Illicit Drug Strategy the Australian Government has allocated $9.7 million (over the period 2003-04 to 2007-08) to the National Comorbidity Initiative. The Initiative aims to improve coordination across psychiatric/mental health services and drug treatment services, develop best practice guidelines for service delivery, and increase professional education and training.

The Australian Government has undertaken a comprehensive consultation process with the Australian National Council on Drugs, the Alcohol and other Drugs Council of Australia, the Mental Health Council of Australia and other key stakeholders in developing an implementation plan for the Initiative. This process has identified the following four areas of activity:

1. **Raising awareness of comorbidity among clinicians/health workers and promoting examples of good practice resources/models**

    - fund a forum of key stakeholders from around Australia to discuss the comorbidity of mental health and substance misuse, particularly in the area of youth and early psychosis. The Mental Health Council of Australia convened a Comorbidity Forum in Sydney on 21 May 2004.
    - disseminate and promote information on comorbidity, good practice models, clinical guidelines, training resources, and research findings through recognised pathways such as peak bodies (for example Australian Divisions of General Practice, ADCA, ANCD and RACGP) relevant conferences/forums, national websites (such as Primary Mental Health Centre Australian Resource Centre, Australian Drug Information Network, beyondblue and Health Online), peak journals/newsletters (for example Australian Doctor/Medical Observer and 'Of Substance'). The monograph 'comorbid mental disorders and substance use disorders: epidemiology, prevention and treatment' was released by the Parliamentary Secretary, the Hon Trish Worth MP, on 20 May 2004.
    - develop a quality assurance framework including accreditation of services and core competencies for staff for non-government organisations.

2. **Providing support to general practitioners and other health workers to improve treatment outcomes for comorbid patients**

    - explore the feasibility of undertaking a range of projects with Australian Government funded programs in the areas of drug and alcohol, mental health and allied health. For example, organisations already funded for drug and alcohol treatment services (Non Government Organisation Treatment Grants Programme), mental health services (National Mental Health Strategy), and allied health services (More Allied Health Services Program), could be contracted to trial models of shared care/case management linking primary care to specialist settings including integrated patterns of service delivery.
    - review the provision of specialist telephone support services to general practitioners on clinical aspects of treatment of comorbidity and determine if a stand alone service should be developed, or expansion of current services.

- conduct a qualitative study of treatment experiences of drug treatment clients with comorbidity and complex vulnerabilities to identify the barriers and incentives to treatment and treatment models, policies and practices to improve treatment outcomes for clients. LMS Consulting, in consortium with the National Centre on HIV Social Research and the Australian Injecting and Illicit Drug Users League, have been commissioned to undertake this project.
- evaluate selected current treatment approaches to comorbidity, to determine the efficacy of the models of treatment.
- trial the implementation of a mental health screening tool and integrated intervention within drug treatment services to assist clinicians to address mental health problems, including the development of a skills training system. The Turning Point Alcohol and Drug Centre have been commissioned to undertake this project.

**3. Facilitating resources and information for consumers**

- review and if applicable wide dissemination of the "Self-Help Manual for People Living with Substance Use and Mental Health Problems". This manual has been developed by JenCo Consulting and is currently being peer reviewed;
- the development and wide dissemination of a book of case studies of real life stories from ordinary Australians who have experienced what it is like to have, or be exposed to someone that has, a drug and alcohol and mental health problem. The case studies could cover the individual, their family and friends and a frontline worker perspective. This approach has been successfully utilised in other areas (eg: homelessness) and will go some way to breaking down the barriers and stigma associated with drug and alcohol and mental health disorders. LMS Consulting have been commissioned to undertake this project;
- the development and wide dissemination (including GP waiting rooms) of an information brochure for consumers on comorbidity and how to find help. A tender process is being finalised for this project; and
- the development of a care plan policy which incorporates consumer involvement in planning, including consideration of access to existing services such as the voucher system.

**4. Improving data systems and collection methods within the mental health and alcohol and other drugs sectors to manage comorbidity more effectively**

- determine suitable data sources and data sets which identify work force and work flow issues in the management of patients with complex comorbidities; and
- explore ways of improving data systems and collection methods to deliver key information on people presenting with comorbidity at population, program and individual. The Australian Institute of Health and Welfare have been commissioned to undertake this project.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-029

OUTCOME 1: Population Health and Safety

Topic: NATIONAL TOBACCO STRATEGY

Written Question on Notice

Senator Denman asked:

What funding is allocated within
(a) Investment in Preventative Health; and
(b) in any other programmes for initiatives within the National Tobacco Strategy?

Answer:

(a) $2.2 million per year has been allocated to tobacco harm reduction measures for the years 2002-03 to 2005-06.

(b) Since 1997 the National Tobacco Campaign (NTC) has spent a total of $24.93 million on the Campaign (including media buys, research, production, etc). This figure includes expenditure up to the end of financial year 2003-04.

The Australian Government provides broadbanded (or pooled) funding through the Public Health Outcome Funding Agreements to assist States and Territories achieve a number of nationally agreed outcomes. One of these outcome areas is smoking prevention. In 2003-04 a total of $128.9 million in broadbanded funding was provided to States and Territories for a range of purposes including smoking cessation programs.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-030

OUTCOME 1: Population Health and Safety

Topic: NATIONAL TOBACCO STRATEGY

Written Question on Notice

Senator Denman asked:

What specific initiatives and programmes are planned to:
(a) reduce the use of tobacco; and
(b) otherwise reduce minimise tobacco harm?

Answer:

(a) & (b) The Australian Government is committed to smoking cessation initiatives such as the introduction of graphic health warnings on cigarette packets, the review of the *Tobacco Advertising Act 1992*, funding of the Centre for Excellence in Indigenous Tobacco Control, and ongoing funding through the Public Health Outcome Funding Agreements with State and Territory Governments. The Government continues to support the National Tobacco Campaign through use of the "Every Cigarette is Doing you Damage" advertising coinciding with World No Tobacco Day 2004.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-031

OUTCOME 1: Population Health and Safety

Topic: NATIONAL TOBACCO STRATEGY

Written Question on Notice

Senator Denman asked:

In reference to the Performance Information for Administered Items on page 84 of the PBS:

(b) When is it envisaged that plans for the national policy post June 2004 will be formalised?

(c) What research has been undertaken or committed in order to acquire the "sound evidence base" envisaged for the policy?

(d) What are the new and emerging trends in tobacco control to be responded to?

(e) Apart from the national policy, what other further developments of the Strategy are envisaged?

Answer:

(a) The final draft of the National Tobacco Strategy (NTS) 2004-09 is due to be submitted to the next meeting of the Ministerial Council on Drug Strategy (MCDS), scheduled for November 2004.

(b) The NTS 2004-09 has been drafted on the basis of the findings of studies and reviews of evidence on proposed tobacco control interventions commissioned by the Australian Government over the past four years, an analysis of strategies in other English-speaking countries, and findings of extensive international literature. A complete list of the evidence base will be included in the final NTS document.

(c) New and emerging trends will be identified as priority areas in the new NTS and will be considered once the NTS is endorsed by the MCDS.

(d) The Australian Government will consider all proposed priority areas in the final Strategy once it has been endorsed by the MCDS.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-032

OUTCOME 1: Population Health and Safety

Topic: REVIEW OF HEALTH WARNING LABELLING ON TOBACCO PRODUCTS

Written Question on Notice

Senator Denman asked:

(a) What is the anticipated cost to the Commonwealth of the measure to include graphic health warnings on tobacco products in (i) 2004-05 and (ii) in future years covered by the forward estimates? From which program will this be funded?

(b) Some concern has been expressed by retailers that the planned measures may include the placement of material within their premises, so graphic that it may make visits to their premises unpleasant to customers. What is the extent to which retailers will be expected to place this material? Will it be limited to tobacco product packaging or will retailers be required to place other materials such as posters within their premises?

Answer:

(a) (i) and (ii). There will be no cost to the Department of Health and Ageing for the inclusion of graphic health warnings on tobacco products. There may be some costs incurred by the Australian Competition and Consumer Commission in its role as regulator.

(b) The proposed amendments to the Trade Practices (Consumer Product Information Standard) (Tobacco) Regulations 1994 made under the *Trade Practices Act 1974*, will only require the proposed graphic health warnings to appear on tobacco product packaging.

Any requirement for posters or other displays is dependent upon individual State and Territory point-of-sale legislation.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-033

OUTCOME 1: Population Health and Safety

Topic: TOBACCO USE AMONGST HIGH RISK GROUPS

Written Question on Notice

Senator Denman asked:

(a) Has the Department undertaken or is it otherwise aware of any research or statistics which might indicate whether any or each of the following groups of people are more likely to smoke cigarettes than other members of the community:
(i) severely drug dependent persons;
(ii) people with serious mental illness;
(iii)Indigenous Australians?

(b) If so, what are the indications from such research and statistics?

Answer:

(a) and (b)

(i) The Australian Institute of Health and Welfare report *Statistics on Drug Use in Australia 2002* indicates that there is an association between smoking and use of other substances. It states that "across the drugs reported in 2001, the prevalence of use of other drugs in the past 12 months was higher for tobacco smokers than non-smokers...there was about a fourfold greater use of marijuana/cannabis and any illicit drug among smokers compared with non-smokers."

(ii) The *2001 National Health Survey* undertaken by the Australian Bureau of Statistics indicated that a higher proportion of current smokers reported a mental or behavioural problem (14% compared with 10% of ex-smokers and 9% of adults who had never smoked). The *1997 National Survey of Mental Health and Well-Being* found that people with a psychotic disorder were more likely to be smokers than the general population.

(iii) The recently released Australian Bureau of Statistics Indigenous Social Survey found that 48.6% of Indigenous persons Australia wide are daily smokers.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-034

OUTCOME 1: Population Health and Safety

Topic: TOBACCO USE AMONGST HIGH RISK GROUPS

Written Question on Notice

Senator Denman asked:

(a) Are there any specific initiatives or programmes currently operating which are specifically designed or have elements which target smoking in these groups? If so, can information be provided?

(b) If not, are there any reasons why not?

Answer:

(a) Delivery of specific smoking cessation programmes, including targeted programmes, is generally a matter for States and Territories through their various Quit organisations. However, given the burden of smoking on Indigenous health, the Australian Government has provided funding to establish a Centre of Excellence in Indigenous Tobacco Control at the University of Melbourne. It is hoped that this will develop into a source of national leadership and coordination in this field.

(b) The Australian Government has generally funded whole of population anti-smoking strategies. These have included one of the most sustained and intensive anti-smoking campaigns in Australia's history, maintenance of the price of cigarettes through taxation, prohibition of tobacco advertising, effective health warnings and promotion of smoking cessation through the Quitline.

The Australian Government also provides broadbanded (or pooled) funding through the Public Health Outcome Funding Agreements to assist States and Territories achieve a number of nationally agreed outcomes. One of these outcome areas is smoking prevention. In 2003-04 a total of $128.9 million in broadbanded funding was provided to States and Territories for a range of purposes including smoking cessation programs.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-035

OUTCOME 1: Population Health and Safety

Topic: TOBACCO USE AMONGST HIGH RISK GROUPS

Written Question on Notice

Senator Denman asked:

Are there any specific initiatives or programmes currently operating which are specifically designed or have elements which target smoking in any other groups which may have been identified as high risk? If so, can information be provided?

Answer:

The Australian Government funds whole of population anti-smoking strategies. These have included one of the most sustained intensive anti-smoking campaigns in Australia's history, maintenance of the price of cigarettes through taxation, prohibition of tobacco advertising, effective health warnings and promotion of smoking cessation via the Quitline.

The Australian Government also provides broadbanded (or pooled) funding through the Public Health Outcome Funding Agreements to assist States and Territories achieve a number of nationally agreed outcomes. One of these outcome areas is smoking prevention. In 2003-04 a total of $128.9 million in broadbanded funding was provided to States and Territories for a range of purposes including smoking cessation programs.

State and Territories are responsible for funding and delivering smoking cessation support services (Quitlines), including targeted programs for particular groups. The manner in which these services are delivered varies between jurisdictions.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-193

OUTCOME 1: Population Health and Safety

Topic: TOBACCO

Hansard Page: CA 72-3.6

Senator Crossin asked:

(a) What are the smoking rates amongst Indigenous people in the Northern Territory?

(b) Can you tell me what Quit programs are available for Indigenous people?

Answer:

(a) The recently released Australian Bureau of Statistics Indigenous Social Survey found that 50.7% of Indigenous persons in the Northern Territory are daily smokers.

(b) Quit programs are the responsibility of State and Territory Governments.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2-3 June 2004

Question: E04-036

OUTCOME 1: Population Health and Safety

Topic: CANNABIS USE

Written Question on Notice

Senator Denman asked:

Does the Department have any figures available to it which might estimate that number of Australians who have smoked cannabis during the last available 12 month period? If so, can these be provided – nationally and by State and Territory?

Answer:

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

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

**Table 1.** Recent use (last 12 months) of cannabis: number of Australians aged 14 years and over, States and Territories, 2001 (source: 2001 National Drug Strategy Survey State and Territory Findings)

| STATE/TERRITORY | **2001** |
|---|---|
| NSW | 636,451 |
| Vic | 462,884 |
| Qld | 369,853 |
| WA | 268,024 |
| SA | 176,444 |
| Tas | 45,281 |
| ACT | 37,480 |
| NT | 37,031 |
| National | 2,031,748[1] |

1. National figure does not equal the sum of State and Territory figures due to rounding.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2-3 June 2004

Question: E04-037

OUTCOME 1: Population Health and Safety

Topic: CANNABIS USE

Written Question on Notice

Senator Denman asked:

How many deaths have occurred in Australia in each of the following periods, which have been attributed solely or predominantly to cannabis use:

(a) in the last available 12 month period;

(b) in the last available 5 year period; and

(c) in the last available 10 year period.

Answer:

(a) (b) and (c)

The Department is not aware of any published data on the number of deaths in Australia that have been attributed solely or predominantly to cannabis use.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-042

OUTCOME 1: Population Health and Safety

Topic: NALTREXONE IMPLANTS

Written Question on Notice

Senator Denman asked:

(a) Is it true that naltrexone implants are stamped "not to be used in human subjects"?

(b) Is the Department aware whether trials with naltrexone implants have proceeded in Australia, including trials involving human subjects?

Answer:

(a) The Therapeutic Goods Administration is unaware of such a stamp.

(b) The National Health and Medical Research Council approved a clinical trial of naltrexone implants through its 2003-04 Grants Program. Associate Professor Gary Hulse from the University of Western Australia was awarded a funding grant of $400,000 (over two years) to conduct a trial of naltrexone implants and naltrexone tablets.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-043

OUTCOME 1: Population Health and Safety

Topic: NALTREXONE IMPLANTS

Written Question on Notice

Senator Denman asked:

Have naltrexone implants been approved as yet by the TGA? If not, is there any date by which the TGA is expected to consider the matter?

Answer:

Naltrexone implants are not registered or approved for any use in Australia. In order to enable naltrexone implants to be registered, a sponsor company would need to submit an application to the Therapeutic Goods Administration (TGA) with supporting documentation to demonstrate the quality, safety and efficacy for the proposed usage. The TGA cannot consider the registration of naltrexone implants until an application is received.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-044

OUTCOME 1: Population Health and Safety

Topic: NON RE-USABLE INJECTING EQUIPMENT

Written Question on Notice

Senator Denman asked:

What is the total amount (and over what period) that the Commonwealth Government (a) has expended and (b) has allocated for initiatives or programmes to develop non re-useable injecting equipment for injecting drug users?

Answer:

(a) In the 2002-03 budget, an allocation of $27.5 million was provided to fund a product development and implementation strategy for the introduction of retractable needle and syringe technology into Australia. Expenditure during that year was $65,497.

The Government then redirected some $8.7 million over 2003-04 ($3.3million) and 2004-05 ($5.4million) from this initiative to other Health and Ageing initiatives which seek to reduce the demand for illicit drugs. Expenditure for the 2003-04 financial year for the Retractable Needle and Syringe Technology Initiative is approximately $500,000.

Delays have been experienced due to:

- the need to seek human ethics clearance for the research prior to the commencement of actual trials of the retractable technology with injecting drug users. The Pilot studies have now commenced and will be completed within this financial year;
- negotiations with Needle and Syringe Programs regarding their role in the Pilot Studies, including issues related to insurance cover; and
- the emerging nature of the technology and the availability of retractable needles and syringes, and the consequent need to conduct some product testing prior to adopting particular needles for use in the trial.

(b) The revised allocation of $17.5 million will be spent over three years on the implementation of the Retractable Needle and Syringe Initiative. The allocation is shown below.

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

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-045

OUTCOME 1: Population Health and Safety

Topic: NON RE-USABLE INJECTING EQUIPMENT

Written Question on Notice

Senator Denman asked:

Has any evaluation taken place as to the effectiveness of such initiatives or programmes? If so, what did this reveal? If not, why not?

Answer:

Health Outcomes International has been contracted to conduct an evaluation of the Retractable Needle and Syringe Technology Initiative.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-046

OUTCOME 1: Population Health and Safety

Topic: NON RE-USABLE INJECTING EQUIPMENT

Written Question on Notice

Senator Denman asked:

Has any view been formed as to the likelihood or success of the value of such initiatives or programmes?

Answer:

Health Outcomes International has been contracted to conduct an evaluation of the Retractable Needle and Syringe Technology Initiative. Until all components under the current Initiative are complete, the Department of Health and Ageing is unable to formulate a view or speculate on the outcome of the Initiative.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-047

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ALCOHOL HARM REDUCTION STRATEGY

Written Question on Notice

Senator Denman asked:

Which strategic partnerships will be developed and strengthened under this programme in (a) 2004-05 and (b) in future years covered by the forward estimates?

Answer:

(a) and (b)

The Department has worked with a range of stakeholders to disseminate the communication materials for the National Health & Medical Research Council Australian Alcohol Guidelines. These include State and Territory Governments, the alcohol beverage and hospitality industry and health care providers (for example general practitioners, health promotion workers, and drug and alcohol workers) to deliver the materials in settings where people seek treatment and where they consume alcohol.

The Department will continue to work with these groups in 2004-05. In addition, the Department plans to develop targeted materials based on the Guidelines for groups at particular risk, including young people, women, older people, people with a mental health disorder, and people with a health condition made worse by alcohol consumption (for example diabetes and epilepsy). It is planned to develop partnerships with relevant groups to distribute these materials through existing networks and in settings where members of these groups congregate.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-048

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ALCOHOL HARM REDUCTION STRATEGY

Written Question on Notice

Senator Denman asked:

What materials are planned to be disseminated 2004-05?

Answer:

The following materials will continue to be distributed:

- consumer brochures
- consumer booklets
- coasters
- posters
- a series of 25 Fact Sheets.

Resources that are planned for development and distribution in 2004-05 are:

- Alcohol guidelines brochures for indigenous communities and health services (currently being finalised)
- polycarbonate glasses with standard drinks measures
- new look posters and consumer brochures for further distribution through industry networks
- targeted materials based on the Guidelines for groups at particular risk, including young people, women, older people, people with a mental health disorder, people with a health condition made worse by alcohol consumption (diabetes, epilepsy etc).
- a communicator's guide to assist health educators, health care providers and teachers etc convey the Guidelines messages to different audiences.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-049

OUTCOME 1: Population Health and Safety

Topic: NATIONAL ALCOHOL HARM REDUCTION STRATEGY

Written Question on Notice

Senator Denman asked:

Has any evaluation taken place as to the effectiveness of the Strategy to date? If so, what did this reveal? If not, why not?

Answer:

An evaluation of the effectiveness of the National Alcohol Harm Reduction Strategy was undertaken in 2003 in accordance with the Department of Finance guidelines for lapsing programs as part of the Department's advice to the government in the 2004-05 Budget context. The funding for the Strategy was confirmed for a further four years in the Budget.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Questions: E04-012

OUTCOME 1: Population Health and Safety

Topic: NATIONAL OBESITY TASKFORCE

Written Question on Notice

Senator Denman asked:

(a) What initiatives and programmes are planned for the National Obesity Taskforce in 2004-05?

(b) In particular what initiatives and programmes are planned or envisaged for:

(i) the national action agenda on childhood obesity; and
(ii) the development of further advice on strategies to reduce obesity in adults and older Australians.

Answer:

*(a)* *The National Obesity Taskforce is currently drafting an implementation strategy for* Healthy Weight 2008 – Australia's Future – The National Action Agenda for Children and Young People and Their Families.

In addition, the Building a Healthy, Active Australia Initiative announced on the 29 June 2004, provides $116 million over four years to address the growing problem of declining physical activity and poor eating habits of Australian children and contains the following four measures:

1. Active After-school Communities - $90 million to establish an after school physical activity programme in schools and approved outside school hours care services, with about 150,000 children expected to participate. This Initiative will be managed by the Australian Sports Commission.
2. Active School Curriculum - New conditions of funding will require education authorities to include in their curriculum at least two hours of physical activity per week for children in primary school and junior high school. This Initiative will be managed by the Education, Science and Training Portfolio.

3. Healthy School Communities - $15 million for grants of up to $1,500 to community organisations linked with schools, such as parents and citizens' associations, to initiate activities to promote healthy eating. This Initiative will be managed by the Health Portfolio.

4. Healthy Eating and Regular Physical Activity – Information for Australian Families - $11 million to give Australian families practical help and information about how to make healthy eating and physical activity part of their everyday lives. This Initiative will be managed by the Health Portfolio.

(b)(i) In line with the recommendations of the Australian Health Ministers' Council the National Obesity Taskforce is currently drafting an implementation strategy for *Healthy Weight 2008 – Australia's Future – The National Action Agenda for Children and Young People and Their Families*.

(b)(ii) The National Obesity Taskforce has commenced work on a review of the evidence for intervention, and the development of a framework to address overweight and obesity in adults and older Australians.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-013

OUTCOME 1: Population Health and Safety

Topic: NATIONAL OBESITY TASKFORCE

Written Question on Notice

Senator Denman asked:

(a) In what ways will the Department support the work of the National Obesity Taskforce in 2004-05?

(b) What funding is allocated for this work and in what areas will such funding be spent?

Answer:

(a) To support the work of the National Obesity Taskforce in 2004-05, the Department will continue to chair and provide secretariat support to the Taskforce.

(b) The National Obesity Taskforce Secretariat is funded by the Department. Departmental funds in the order of $250,000 are spent on:
- salaries for secretariat staff;
- airfares, accommodation and catering associated with meetings, and
- provision of expert advice.

The answer to question E04-217 gives current Australian Government activity and expenditure across portfolios which support the intent of the report of the National Obesity Taskforce, *Healthy Weight 2008 – Australia's Future – The National Action Agenda for Children and Young People and Their Families.*

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-014

OUTCOME 1: Population Health and Safety

Topic: NATIONAL OBESITY TASKFORCE

Written Question on Notice

Senator Denman asked:

Is any funding currently allocated for the implementation of any programmes or initiatives in relation to the reduction of obesity? If so, in what amount and for which programmes or initiatives?

Answer:

The Building a Healthy, Active Australia Initiative, announced on the 29 June 2004, provides $116 million over four years to address the growing problem of declining physical activity and poor eating habits of Australian children and contains the following four measures:

5. Active After-school Communities - $90 million to establish an after school physical activity programme in schools and approved outside school hours care services, with about 150,000 children expected to participate. This initiative will be managed by the Australian Sports Commission.

6. Active School Curriculum - New conditions of funding will require education authorities to include in their curriculum at least two hours of physical activity per week for children in primary school and junior high school. This initiative will be managed by the Education, Science and Training Portfolio.

7. Healthy School Communities - $15 million for grants of up to $1,500 to community organisations linked with schools, such as parents and citizens' associations, to initiate activities to promote healthy eating. This initiative will be managed by the Health Portfolio.

8. Healthy Eating and Regular Physical Activity – Information for Australian Families - $11 million to give Australian families practical help and information about how to make healthy eating and physical activity part of their everyday lives. This initiative will also be managed by the Health Portfolio.

A list of current Australian Government project/programs that support the intent of Healthy Weight 2008 – Australia's Future – The National Action Agenda for Children and Young People and Their Families across a range of agencies is attached.

# NUTRITION, PHYSICAL ACTIVITY AND OBESITY INITIATIVES

**Medicare rebates** are available for services rendered by medical practitioners treating patients for obesity in the private setting in accordance with accepted clinical practice. Funding is also provided by the Australian Health Care Agreements for admitted services and outpatient treatment clinics by public hospitals.

Recent Australian Government policies have increased the emphasis on preventing chronic disease and contributing risk factors, including obesity, within the primary care system.

**Enhanced Primary Care (EPC)** Medicare items (introduced in November 1999) provide more preventive care for older Australians and better coordinated care for patients with chronic conditions and complex care needs. While obesity is not itself considered a chronic medical condition for the purposes of EPC items, patients who are eligible for multidisciplinary care may have complications to their chronic medical condition (eg diabetes) arising from obesity. A care plan for such patients should address their health and care needs, including management of their weight and its impact on their chronic medical condition.

**Indigenous adult health checks** under Medicare (estimated $7.5 million over four years from 2003-04) were introduced from 1 May 2004. They are available every two years for indigenous people aged 15 to 54 years to help prevent and treat chronic illness. Indigenous people have a higher rate of overweight and obesity than the general population and are up to 2.6 times more likely to die from coronary heart disease.

**Focus on Prevention** measures in the 2003-04 Budget will increase the emphasis on prevention in general practice. "Lifestyle scripts" (estimated $4.3 million over three years) are one of the tools being developed for general practitioners to address health risk factors with patients, including overweight or obesity, poor nutrition and physical inactivity. The *Clinical Guidelines for Managing Overweight and Obesity* recently released by the National Health and Medical Research Council will also be an important part of this approach.

The **30% Rebate** on private health insurance premiums may also assist with combating obesity as a number of private health insurance funds provide benefits for weight management programs.

Australia's commitment to the **World Health Organisation's** *Global Strategy on Diet, Physical Activity and Health* for 2004-05 is $150,000.

**National Health and Medical Research Council (NHMRC) research grants** contributed $9.1 million for research into obesity from 2000-2004 (including over $2.2 million in 2004).

**National Guidelines for diet and physical activity** have been developed and been disseminated widely. They provide evidence-based guidance for use by health professionals and 50,000 related consumer resources are distributed each month.

- *Dietary Guidelines for Australian Adults (2003)*
- *Dietary Guidelines for Children and Adolescents in Australia (2003)*
- *Dietary Guidelines for Older Australians (1999)*
- *National Physical Activity Guidelines for Australians (1999)*
- Physical Activity recommendations for Children and Youth (in development)

There is also a wide range of Australian Government programs and initiatives to improve nutrition, increase physical activity and fight overweight and obesity – listed below.

### *Be Active Australia* – Draft National Physical Activity for Health Action Plan

**Target Group(s):** All Australians.

**Funding** $25,000 for development of the Plan in 2003-04.

**Description:** A priority of the National Obesity Taskforce, this Action Plan will identify a set of national level actions to be addressed by the health sector, including collaboration with other sectors, to support inactive Australians to be sufficiently active for a health benefit. The Plan will guide and inform a more coordinated, collaborative and strategic approach at the national level.

## Rural Chronic Disease Initiative (RCDI)

**Target Group(s):** Whole of population.

**Funding** $14.2 million total funding, provided under Regional Health Strategy *More* Doctors, Better Services (2000 – 2004).

***Description:*** *Community grants for projects that invest in innovative chronic disease and injury prevention management approaches, develop and distribute high quality information on chronic disease and injury or support and develop skills and leadership at the local level. 29 projects funded for 12 - 18 months.*

Building Healthy Communities *is a step-by-step practical guide for community driven health projects in rural Australia. It has been produced using the experiences and lessons learnt from the RCDI projects and will be a very valuable legacy of the initiative*.

## National Child Nutrition Program

**Target Group(s):** Children (0-12 years of age) and pregnant women.

**Funding** $15 million from 1999-2000. Around half the projects are nearing completed and the rest will be finalised by early 2005.

**Description**: Community grants program targeting the nutrition and long term eating patterns of children and pregnant women designed to improve the nutrition-related knowledge and skills of children and their parents, build capacity in communities to promote better nutritional health, and improves access to and availability of nutritious foods. 109 projects across Australia were funded. High priority was given to projects in rural and remote communities, Aboriginal and Torres Strait Islander communities and lower socioeconomic communities. The second round of funding (23 projects), announced in November 2001, had a specific focus on high need Indigenous communities.

## Public Health Education and Research Program (PHERP) Innovations funding

### *Sentinel Site for Obesity Prevention*

**Target Group(s):** Children and Adolescents: 0 to 5 years, 2 to 12 years and 12 to 18 years.

**Funding** $449,340 from the Australian Government (June 2002 to December 2005) plus $651,160 from Deakin University.

**Description**: Trial of community development and intervention programs in Barwon South West to build the knowledge, skills and evidence necessary to prevent obesity among children and adolescents.

## Walk Safely to School Day (4 April 2004)

**Target Group(s):** Primary School Aged Children.

**Funding** $150,000 for the 2004 event ($35,000 between 2001-2003).

**Description**: The department contributed funding to a national community awareness event promoting health (physical activity), road safety and public transport, and the environment. This event encourages parents and carers to walk to school with primary school aged children, and reinforce safe pedestrian behaviour.

## Walk to Work Day (October 2003)

**Target Group(s):** All adults.

**Funding** $373,000 for the 2003 event. $65,000 between 2000-2002.

**Description**: The department contributes funding to an annual community awareness campaign run by the Pedestrian Council of Australia (PCA) to promote walking as an alternative to private vehicles, for health and environmental reasons.

## Walk to Work Day and Walk Safely to School Day (2004-07)

**Target Group(s):** All adults and primary school aged children.

**Funding** Up to $1.5 million over 3 years (2004-05, 2006-07, 2006-07).

**Description**: Funding has been approved for annual Walk to Work Day and Walk Safely to School Day, national community awareness campaigns run by the Pedestrian Council of Australia (PCA) to promote walking as a way to increase physical activity for health.

## Clinical Practice Guidelines for the Management of Overweight and Obesity

**Target Group(s):** General practitioners treating patients for overweight and obesity.

**Funding** $136,000 in 2000-2003.

**Description**: Development by the National Health and Medical Research Council of evidence-based guidelines and related information resources for the management of overweight and obesity in children, adolescents and adults by general practitioners. Published in November 2003:

- *Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults*
- *Clinical Practice Guidelines for the Management of Overweight and Obesity in Children and Adolescents*
- *Overweight and Obesity in Adults and in Children and Adolescents: A Guide for General Practitioners*

## Aboriginal and Torres Strait Child and Maternal Health Exemplar Site Initiative

**Target Group(s):** Aboriginal and Torres Strait Islander children and families.

**Funding** $397,000 over two financial years, commencing in 2002-03.

**Description:** Identified Aboriginal Community Controlled Health Services selected as a "best practice" sites in the delivery of child and maternal health services. The initiative will identify dimensions of effective service delivery in order to inform the development of national, regional and local policy development.

## Ngaanyatjarra Pitjantjatjara Yankunytjatjara Women's Council Nutrition Project

**Target Group(s):** Aboriginal and Torres Strait Islander Mothers, babies and other carers.

**Funding** $120,000 in 2003-04.

**Description:** Nutrition project for mothers, babies and other carers in the remote Central Australian region. This is a unique style of project that has been funded with up to $74,000 annually since 1998.

## Diabetes Prevention Pilot Initiative

**Target Group(s):** Young Aboriginal and Torres Strait Islanders, people in the general community who have diabetes.

**Funding** $658,000 over 2 years from July 2004.

**Description:** The Diabetes Prevention Pilot Initiative aims to improve the prevention and detection of Type 2 Diabetes, by funding community based demonstration initiatives that involve implementation of recommendations from the NHMRC Guidelines on the Prevention and Detection of Type 2 Diabetes.

In accordance with the guidelines, projects aim to increase physical activity, improve diet and achieve a healthy weight for people at risk of developing diabetes.

## National Diabetes Improvement Projects (NDIP)

**Target Group(s):** Aboriginal and Torres Strait Islanders, culturally and linguistically diverse people, people in rural and remote areas, adolescents with diabetes, women who have or have had Gestational Diabetes Mellitus.

**Funding** $1,010,386 from June 2003 to January 2005.

**Description**: 18 National Diabetes Improvement Projects (NDIP) commenced mid-2003 to improve services for people with diabetes. Designed to provide funding for local communities to trial new and innovative strategies to enhance the early detection and management of diabetes. 11 of the projects include an element of healthy lifestyle as part of the self management focus.

## Australian Institute of Health and Welfare (AIHW) Statistics

**Target Group(s):** Students, interested members of the public, academics, media, other government and non-government agencies.

**Funding** $84,526 in 2002-2004.

**Description**: Statistical bulletins on overweight and obesity to increase the accessibility of data for researchers and policy makers. Released in 2003/04:

- *Health, wellbeing and body weight*
- *Obesity trends in older Australians*
- *Are all Australians gaining weight?*
- *A growing problem: Trends and patterns in overweight and obesity among adults in Australia, 1980 to 2001*

## Australian Government Breastfeeding Initiatives

**Target Group(s):** Mothers, fathers, pregnant and lactating women, children 0-5 years.

**Funding** The Australian Breastfeeding Association will receive $100,000 in Australian Government funding for 2004-05, extending the previous three year funding agreement.

**Description**: Children who are breastfed are less likely to become obese, and breastfeeding can help mothers return to their pre-pregnancy weight.

The Australian Breastfeeding Association provide education resources and promote breastfeeding in the community.

## Smoking Nutrition Alcohol and Physical Activity (SNAP) Framework for General Practice

**Target Group(s):** General Practice.

**Funding** $107,660.

**Description**: The Royal Australasian Collage of General Practice SNAP Practice Guide was printed and distributed to general practitioners.

## Communication Strategies

**Target Group(s):** Students, general public, academics, media, government agencies, NGOs.

**Funding** Nil.

**Description**: ***Healthy and Active*** website contains practical tips for families and children on how to choose healthy foods and be more active. It was launched in November 2003 as part of the Australian Government's response to the National Obesity Taskforce's national agenda for children and families, *Healthy Weight 2008*. www.healthyandactive.gov.au

***PaperWeight*** is the Department of Health and Ageing's newsletter on overweight and obesity, distributed electronically twice a year. It draws attention to issues about overweight and obesity and initiatives within the Government and non-government sectors to address. http://www.health.gov.au/pubhlth/strateg/hlthwt/paperweight.htm

***Bone Health for Life*** website ($66,000 funding) provides practical advice for women and health professionals to improve bone health and prevent or manage osteoporosis. It provides strong encouragement for exercise and its many health benefits. www.bonehealthforlife.org.au

# OTHER PORTFOLIOS

## Stronger Families and Communities Strategy 2004-2008
***(Department of Family and Community Services)***

The Prime Minister and the Minister for Children and Youth Affairs recently announced $365.8 million over four years for the Stronger Families and Communities Strategy. This program is expected to include opportunities to address health issues, including obesity and related risk factors, in children and families. One example is described below.

***Under the "Early Childhood - Invest To Grow" funding stream***

**Target Group(s):** Indigenous parents and young children.

**Funding** **$**500,000 over four years.

**Description**: The National Aboriginal Sports Corporation Australia (NASCA) will develop and pilot a model for improving access to information and support for Indigenous parents and young children, in consultation with health care professionals and Indigenous communities. The model will then be rolled out in up to 40 communities.

## Healthy Kids Australia Newsletter

***(Department of Family and Community Services / Australian Sports Commission)***

**Target Group(s):** Parents and carers of children 0-12. Newsletters are distributed through all child care centres across Australia and through the Playgroup Association and the Active Australia Schools network.

**Funding** $145,000 for 2003-04. Funded from July 2002 to June 2004.

**Description:** Quarterly newsletter with simple, easy-to-read information, practical nutritional advice and sources of further information for parents to help their kids be healthy. The key message is that healthy eating habits and high activity levels reduce the likelihood of childhood obesity/overweight. Active children have higher self esteem, do better at school, stay active as adults and stay healthy through life.

## Out of School Hours Sports Program

**(*Australian Sports Commission / State agencies*)**

**Target Group(s):** Primary school aged children.

**Funding** $220,000 in 2003-04 to pilot the program in five states.

**Description**: Pilot sites in Victoria, South Australia, NSW, WA and the Northern Territory. Entry-level and modified sporting experiences are being used to provide structured physical activity programs to children in after-school care centres by linking existing infrastructure to the community. There has been a strong take-up rate and support from families for the pilot project.

## Targeted Sports Participation Growth Program (*TSPGP*)

**(*DCITA / Australian Sports Commission*)**

**Target Group(s):** Juniors, Women, Adults, Metropolitan, Regional.

**Funding** $11.53 million over the life of the project (commenced 2002).

**Description**: The TSPGP focuses on increasing participation in organised sport, particularly at the club level. The policy also seeks to find new ways of establishing partnerships between sport and business to enhance the sustainability of participation growth. The program targets a small number of sports for special support, to grow their business by expanding active membership of clubs and associations.

## Indigenous Sport Program

***(DCITA / Australian Sports Commission)***

**Target Group(s):** Indigenous Australians.

**Funding** $13.1 million from ASC and ATSIS in 2003-04.

**Description**: The Indigenous Sport Unit has engaged 16 National Sporting Organisations (NSOs) and assisted them in the development, implementation, monitoring and evaluation of specific initiatives aimed at increasing participation in all areas of sport by Indigenous Australians.

## Australia Cycling: the National Strategy, 1999 – 2004

***(Australian Bicycle Council / Department of Transport and Regional Services)***

**Target Group(s):** Policy and decision makers across all levels of government, members of the community and relevant professionals.

**Funding** $100,000 in 2003-04 for two projects, *Parameters to Prioritise Cycle Infrastructure Proposals* and *Whole of life costings of cycle projects.*

**Description:** The Australian Bicycle Council (ABC) is a national inter-governmental committee that manages and coordinates implementation of *Australia Cycling - The National Strategy 1999-2004*. The ABC's objective is to increase safe cycling and remove impediments to cycling to achieve its vision: *Increased cycling for transport and recreation to enhance the well-being of all Australians*.

### Cycle Connect

***(Department of the Environment and Heritage)***

**Target Group(s):** Adults who are able to incorporate cycling into their regular travel.

**Funding** $2.4m over two financial years (2004-05 and 2005-06).

**Description**: Active transport infrastructure initiative to provide secure parking, mostly in the form of bike lockers, at suburban bus and train stations to encourage commuters to cycle rather than drive to the station. There will be two rounds of grants, for 2004-05 and 2005-06. Proposals have been received from state and local governments offering matched funding and in-kind contributions.

## Active Australia Schools network

***(Australian Sports Commission)***

**Target Group(s):** Schools.

**Funding** $420,000 in 2003-04.

**Description**: The Active Australia Schools Network (AASN) is for schools across Australia that share an interest in sport and physical activity and value the contribution of 'being active' to the overall health and well being of young people and communities. The AASN supports schools make links with local sporting organisations as a way of providing great opportunity for young people to access quality sports programs. It also facilitates professional development for teachers delivering sports programs within the schools curriculum.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-017

OUTCOME 1: Population Health and Safety

Topic: NATIONAL OBESITY TASKFORCE

Written Question on Notice

Senator Denman asked:

(a) How is it envisaged that the national approach to obesity, Healthy Weight by 2008 will be developed and implemented?

(b) Is it envisaged that the process will involve any other Commonwealth Government departments and agencies, including for example the Australian Sports Commission and the Department of Education, Science and Training? If so, which departments and agencies and how are/would they be involved?

Answer:

(a) At the November 2003 Australian Health Ministers' Conference, Health Ministers asked the National Obesity Taskforce to lead and coordinate the implementation of *Health Weight 2008 – Australia's Future - The National Action Agenda for Children and Young People and their Families*. The National Obesity Taskforce is currently drafting an implementation plan for consideration by Health Ministers.

(b) On 29 June 2004, the Prime Minister announced the Building a Healthy, Active Australia Initiative. This Initiative provides $116 million over four years to address the growing problem of declining physical activity and poor eating habits of Australian children and contains the following four measures:

1. Active After-school Communities - $90 million to establish an after school physical activity programme in schools and approved outside school hours care services, with about 150,000 children expected to participate. This Initiative will be managed by the Australian Sports Commission.
2. Active School Curriculum - New conditions of funding will require education authorities to include in their curriculum at least two hours of physical activity per week for children in primary school and junior high school. This Initiative will be managed by the Education, Science and Training Portfolio.

3. Healthy School Communities - $15 million for grants of up to $1,500 to community organisations linked with schools, such as parents and citizens' associations, to initiate activities to promote healthy eating. This Initiative will be managed by the Health Portfolio.
4. Healthy Eating and Regular Physical Activity – Information for Australian Families - $11 million to give Australian families practical help and information about how to make healthy eating and physical activity part of their everyday lives. This Initiative will be managed by the Health Portfolio.

The Building a Healthy, Active Australia Initiative is consistent with the recommendations of the report of the National Obesity Taskforce, *Health Weight 2008 – Australia's Future - The National Action Agenda for Children and Young People and their Families.*

A range of programs exist across Australian Government Departments, including Family and Community Services, the Australian Sports Commission and the Department of Education, Science and Training that commits significant government funding, which contributes to tackling the issues of overweight and obesity. Please refer to Question on Notice E04-217 for details.

The development of responses to obesity will continue to be across jurisdictions and portfolios.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-018

OUTCOME 1: Population Health and Safety

Topic: NATIONAL OBESITY TASKFORCE

Written Question on Notice

Senator Denman asked:

(a) Is it envisaged that resourcing and/or funding from departments and agencies other than DOHA will be made available during 2004-05 or in future periods in
(i) developing and implementing Healthy Weight by 2008; or
(ii) supporting the work of the National Obesity Taskforce?

(b) If so, which department and agencies and what sort of resourcing and what amounts of funding?

Answer:

(a) Yes. The Building a Healthy, Active Australia Initiative is consistent with the recommendations of the report of the National Obesity Taskforce, *Health Weight 2008 – Australia's Future - The National Action Agenda for Children and Young People and their Families* and supports the work of the National Obesity Taskforce.

(b) On 29 June 2004, the Prime Minister announced the Building a Healthy, Active Australia Initiative. This Initiative provides $116 million over four years to address the growing problem of declining physical activity and poor eating habits of Australian children and contains the following four measures:

9. Active After-school Communities - $90 million to establish an after school physical activity program in schools and approved outside school hours care services, with about 150,000 children expected to participate. This Initiative will be managed by the Australian Sports Commission.
10. Active School Curriculum - New conditions of funding will require education authorities to include in their curriculum at least two hours of physical activity per week for children in primary school and junior high school. This Initiative will be managed by the Education, Science and Training Portfolio.
11. Healthy School Communities - $15 million for grants of up to $1,500 to community organisations linked with schools, such as parents and citizens'

associations, to initiate activities to promote healthy eating. This Initiative will be managed by the Health Portfolio.

12. Healthy Eating and Regular Physical Activity – Information for Australian Families - $11 million to give Australian families practical help and information about how to make healthy eating and physical activity part of their everyday lives. This Initiative will be managed by the Health Portfolio.

A list of current Australian Government project/programs that support the intent of *Healthy Weight 2008 – Australia's Future – The National Action Agenda for Children and Young People and Their Families* across a range of agencies is provided in Question on Notice E04-217.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-015

OUTCOME 1: Population Health and Safety

Topic: OBESITY

Written Question on Notice

Senator Denman asked:

What definitions of obesity and related categories of excess weight is the Department using in its work and in particular in support of the work of the National Obesity Taskforce?

Answer:

The Department of Health and Ageing and the National Obesity Taskforce use the following definitions for adults and for children in categorising overweight and obesity.

Definitions of Overweight and Obesity for Adults

Two measures are used:

- Body Mass Index (BMI) is the ratio of weight (in kilograms) divided by height (in metres) squared.
  Overweight - BMI of 25 and above, but less than 30.
  Obesity - BMI of 30 and above.

- Waist circumference - for adults it is also recommended that waist circumference as a measurement of central or abdominal obesity, be taken in conjunction with BMI (particularly those people with a BMI less than 35) as increased abdominal obesity has shown to be related to disease risk. The waist circumference cut-offs detailed below and which indicate risk of metabolic complications associated with obesity, are used by the Department as recommended by the World Health Organisation.

| | | |
|---|---|---|
| Caucasian Males: | increased risk | 94 to 101cm |
| | substantially increased | 102 cm and above |
| Caucasian Females: | increased risk | 80 to 87 cm |
| | substantially increased | 88 cm and above |

Definitions of Overweight and Obesity for Children and Adolescents

In children, BMI changes substantially with age, rising steeply in infancy, falling during the preschool years and then rising again during adolescence and early adulthood. For this reason, child and adolescent BMI is classified differently to adult BMI.

The Australian standard definitions for measuring overweight and obesity in children and adolescents at the population level are based on the work of Cole et al (recognised by the World Health Organisation and the International Obesity Taskforce) which allocates a BMI equivalent score for children depending on age. These definitions assist in more accurate monitoring and surveillance of overweight and obesity in children and adolescents at the population level.

There are also separate recommendations for measuring weight individually at the clinical practice level for children and adolescents. In health care settings such as hospitals, clinics and in general practice, it is recommended that calculated BMI for children and adolescents be compared with a suitable growth reference such as the US Centers for Disease Control 2000 BMI - for-age chart. A BMI greater than the 85th percentile is indicative of being overweight, while a BMI greater than the 95th percentile is indicative of being obese. These percentiles are arbitrary and do not relate to morbidity in the way the BMI cut-points do in adults. For these reasons it is recommended that changes over time will provide more meaningful information. These charts are available on the CDC website at: http://www.cdc.gov/growthcharts/

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-016

OUTCOME 1: Population Health and Safety

Topic: OBESITY

Written Question on Notice

Senator Denman asked:

(a) Has the Department undertaken or accessed any research which would indicate, or by any other means determine, the current levels of obesity in the Australian population?

(b) If so, can these figures be provided:

(i) nationally, including by age group;
(ii) by State and Territory, including by age group; and
(iii) by any other demographic classification such as ethnicity or occupation?

(c) If not, what are the reasons why?

Answer:

(a) In the 2002-03 financial year the Population Health Division of the Department commissioned the Australian Institute of Health and Welfare (AIHW) to provide a series of bulletins and fact sheets on overweight and obesity in Australia. The aim of commissioning the work was to summarise information from a range of existing sources on the following:

(i) prevalence, trends and patterns in overweight and obesity amongst Australian adults;
(ii) differentials in overweight and obesity among adult Australians;
(iii) characteristics of overweight and obesity in adult Australians; and
(iv) prevalence and trends in overweight and obesity among Australian children and adolescents.

(b) The data contained in the bulletins and fact sheets cover a number of different surveys, survey years and contain both measured and self reported information. The Ageing and Aged Care Division of the Department also commissioned research from the AIHW on obesity trends in older Australians - people aged 55 years and over.

**(i) nationally, including by age group**

| **1995 National Child and Adolescent Rates of Overweight and Obesity** | |
|---|---|
| Combined national rates amongst children | |
| Boys aged 5 - 17 years | 15.3% of boys were overweight 4.7% were obese |
| Girls aged 5 - 17 years | 16% of girls were overweight 5.5% were obese |
| By age group | |
| Boys 2- 4 years | 14.6% of boys were overweight 2.2% were obese |
| Girls 2- 4 years | 18.5% of girls were overweight 4.2% were obese |
| Boys 5 - 9 years | 10.4% of boys were overweight 4.3% were obese |
| Girls 5 - 9 years | 14.9% of girls were overweight 7.1% were obese |
| Boys 10 - 14 years | 18.3% of boys were overweight 4.1% were obese |
| Girls 10 - 14 years | 16.9% of girls were overweight 4.9% were obese |
| Boys 15 - 17 years | 18% of boys were overweight 6.1% were obese |
| Girls 15 - 17 years | 11.4% of girls were overweight 3.2% were obese |
| | |
| Survey of NSW primary school children in 2001* | |
| Boys | 26.2% of boys were overweight and obese |
| Girls | 28.4% of girls were overweight and obese |
| | |
| 2003 Victorian study of primary school children aged 7 -11 years* | 26.7% overweight or obese, with 7.9% being obese |

*Further breakdowns not provided in AIHW publications.

| **National Adult Rates of Overweight and Obesity by Age Group** | |
|---|---|
| Combined national prevalence - 25 years and over | Almost 60% (or around 7.5 million) Australians are either overweight or obese. Of these, 21% or about 2.5 million were obese. |
| By age group | |
| 20 - 24 years | 23.8% overweight 9.5% were obese |
| 25 - 44 years | 31.5% overweight 15.6% were obese |
| 45 - 64 years | 39.5% overweight 20.8% were obese |
| 65 years and over | 37.9% overweight 15.7% were obese |

**(ii) by State and Territory, including by age group***

| **Prevalence of Overweight and Obesity by State/Territory Among Persons 20 years and Over** | |
|---|---|
| New South Wales | 33.9 overweight 16.9% were obese |
| Victoria | 34.6% overweight 15.5% were obese |
| Queensland | 34.5% overweight 18.5% were obese |
| Western Australia | 35.2% overweight 15.1% were obese |
| South Australia | 35.1% overweight 17.6% were obese |
| Tasmania | 34.3% overweight 16.5% were obese |
| Australian Capital Territory | 34% overweight 13.5% were obese |
| Northern Territory | Results not available |

* Data by age group not provided in the AIHW resources commissioned by the Department.

**(iii) by any other demographic classifications such as ethnicity or occupation***

| **Prevalence of Overweight and Obesity Amongst Different Adult Populations** | |
|---|---|
| Ethnicity - overseas born | 31.7% overweight 14.7% were obese |
| Indigenous | 32.4% overweight 31.3% were obese |
| Labour force status - employed | 35.2% overweight 16.2% were obese |
| Labour force status - unemployed | 28% overweight 18.4% were obese |
| Labour force status - not in the labour force | 27.4% overweight 18.7% were obese |
| Socioeconomic status - least disadvantaged group | 33.8% overweight 12.5% were obese |
| Socioeconomic status - most disadvantaged group | 31.3% overweight 21.1% were obese |
| Income - highest equivalent | 36.4% overweight 14.3% were obese |
| Income - least equivalent | 30.5% overweight 19.1% were obese |
| Education - post school qualifications | 35.5% overweight 14.9% were obese |
| Education - no school qualifications | 33.3% overweight 19% were obese |

* The prevalence of overweight and obesity by specific occupations are not available as the analysis of overweight and obesity by labour force status used the standard Australian Bureau of Statistics categories of 'employed', 'unemployed' and 'not in the labour force'.

Categories used in the various surveys limit the capacity of the AIHW to further delineate groups within certain Australian sub-populations.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-217

OUTCOME 1: Population Health and Safety

Topic: OBESITY

Written Question on Notice

Senator McLucas asked:

Rather than get you to explain all the different activities that the department is doing and the funding involved, I wonder if you could provide me with a list on notice of what current expenditures support the intent of the Healthy Weight 2008 document plan and its subsequent action plan?

Answer:

The Building a Healthy, Active Australia Initiative, announced on the 29 June 2004, provides $116 million over four years to address the growing problem of declining physical activity and poor eating habits of Australian children and contains the following four measures:

13. Active After-school Communities - $90 million to establish an after school physical activity programme in schools and approved outside school hours care services, with about 150,000 children expected to participate. This initiative will be managed by the Australian Sports Commission.

14. Active School Curriculum - New conditions of funding will require education authorities to include in their curriculum at least two hours of physical activity per week for children in primary school and junior high school. This initiative will be managed by the Education, Science and Training Portfolio.

15. Healthy School Communities - $15 million for grants of up to $1,500 to community organisations linked with schools, such as parents and citizens' associations, to initiate activities to promote healthy eating. This initiative will be managed by the Health Portfolio.

16. Healthy Eating and Regular Physical Activity – Information for Australian Families - $11 million to give Australian families practical help and information about how to make healthy eating and physical activity part of their everyday lives. This initiative will also be managed by the Health Portfolio.

A list of current Australian Government project/programs that support the intent of *Healthy Weight 2008 – Australia's Future – The National Action Agenda for Children and Young People and Their Families* across a range of agencies is attached.

[See attachment to Question E04-014]

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-196

OUTCOME 1: Population Health and Safety

Topic: FUNDING FOR THE NATIONAL DRUG STRATEGY

Hansard Page: CA 76-3.6

Senator Crossin asked:

What funds has the government committed to implement the National Drugs Strategy?

Answer:

The new National Drug Strategy 2004-2009 took effect from 1 July 2004. This is a policy framework to inform the ongoing policy and investment decisions of all levels of government, including using current funding, rather than a funding document.

Since 1997, the Australian Government has committed more than $1 billion to Tough on Drugs, including more than $771 million through the Health and Ageing portfolio.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-055

OUTCOME 1: Population Health and Safety

Topic: SEXUAL HEALTH, HIV/AIDS AND HEPATITIS C STRATEGIES

Written Question on Notice

Senator Denman asked:

(a) What are the timelines for the development of the proposed new HIV/AIDS and hepatitis C strategies?

(b) Is it anticipated that these will be developed and released in stages or only as a complete strategy?

(c) How will the strategies be developed and what consultation processes are envisaged?

(d) Is it envisaged whether the HIV/AIDS strategy will incorporate strategies in relation to other sexually transmissible infections?

(e) In view of the fact that these are not the only sexual health issues facing the nation, what is the reasoning behind not having a more expansive and embracing national sexual health strategy?

Answer:

(a) The current National HIV/AIDS and Hepatitis C Strategies have been extended until 31 December 2004. The new National HIV/AIDS and Sexually Transmissible Infections (STIs) and Hepatitis C Strategies are scheduled to take effect from 1 January 2005.

(b) These two Strategies are being developed separately but within a similar timeframe. The Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis will provide advice on the release process.

(c) The Australian Government is developing the new National Strategies with advice from the Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis and its Subcommittees. The consultation process is still being devised, however there will be extensive consultation in association with the Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis. Organisations/agencies to be consulted will include the Intergovernmental Committee on HIV/AIDS, Hepatitis C and Related Diseases, Australian Government agencies, States and Territories, community organisations and other interested stakeholders.

(d) The National HIV/AIDS and STIs Strategy will incorporate a broadening focus on STIs for the first time.

(e) Currently effort is focused on the development and implementation of the new National HIV/AIDS and STIs Strategy as these diseases continue to be an important challenge to Australians' health and well-being. The reported incidence of STIs, in particular, has been rising in recent years.

The Australian Government is also committed to improving the sexual health of Australians through other programs. In 2003-04, the Government is contributing approximately $14.3 million directly through the Family Planning Program and $2 million indirectly to family planning activities under the Public Health Outcome Funding Agreements for a range of sexual and reproductive health approaches, abstinence being one approach. This funding provides a comprehensive range of information, education, professional training, counselling and clinical services in sexual and reproductive health to the Australian community.

Also the Australian Government provides funding to Andrology Australia of approximately $1 million per year. Andrology Australia develops and implements professional and community education programs about men's sexual and reproductive health issues such as prostate and testicular cancer and infertility.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-058

OUTCOME 1: Population Health and Safety

Topic: SEXUAL HEALTH, HIV/AIDS AND HEPATITIS C STRATEGIES

Written Question on Notice

Senator Denman asked:

Does the Department have any figures (a) on a national basis and (b) by State and Territory of the cost to the public purse of the failure to prevent or treat at an early stage sexually transmissible infections other than HIV/AIDS and hepatitis C? If so, can these be provided?

Answer:

The Department does not have this information.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-059

OUTCOME 1: Population Health and Safety

Topic: SEXUAL HEALTH, HIV/AIDS AND HEPATITIS C STRATEGIES

Written Question on Notice

Senator Denman asked:

Is the Department aware of any reports or research which might indicate the social cost and effect of the failure to prevent or treat at an early stage sexually transmissible infections other than HIV/AIDS and hepatitis C? If so, can these or references by provided?

Answer:

The *Burden of Disease and Injury in Australia* report, (Australian Institute of Health and Welfare, 1999) estimates that the attributable burden of sexually transmitted diseases (other than HIV/AIDS and hepatitis) in Australia, in 1996, was 1,904 disability-adjusted life years.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-060

OUTCOME 1: Population Health and Safety

Topic: SEXUAL HEALTH, HIV/AIDS AND HEPATITIS C STRATEGIES

Written Question on Notice

Senator Denman asked:

Can the Department provide details of the type and level of improved responsiveness that it plans to or anticipates being able to provide to limit the spread of HIV/AIDS and hepatitis C and to minimise the social and personal impact of these diseases?

Answer:

The new National Hepatitis C and HIV/AIDS and Sexually Transmissible Infections Strategies are currently being developed. It is envisaged that after completion of the Strategies, existing programs will be amended or new initiatives developed as necessary, in response to new priority areas for action.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-061

OUTCOME 1: Population Health and Safety

Topic: CHLAMYDIA

Written Question on Notice

Senator Denman asked:

(a) Does the Department have annual figures on (i) a national and (ii) state and territory basis on the reported incidence of chlamydia infections? If so, can these be provided? If not, is there a particular reason why such figures are not kept or available?
(b) Does the Department have access to figures for previous years which would indicate trends in these figures? If so, can these be provided?
(c) Does the Department have any figures or is it aware of any research or reports which would indicate the effect that failure to treat chlamydia appropriately is leading to increased infertility rates?
(d) Does the Department have any evidence or a view on whether any of the figures so provided are affected by an increase (or decrease) in detection or reporting as opposed to an increase (or decrease) in the actual incidence? If so, can these be provided?

Answer:

(a) and (b)

The latest and most comprehensive data is contained in the *HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia, Annual Surveillance Report, 2003*. The following table has been adapted from Table 3.1.1.on page 58 of the Report and addresses parts (a) and (b) of the question.

**Number of reported diagnoses of chlamydia, 2000-2002, by State/Territory and year**

| **STATE/ TERRITORY** | **2000** | **2001** | **2002** |
|---|---|---|---|
| ACT | 245 | 301 | 460 |
| NSW | 3,557 | 4,389 | 5,527 |
| NT | 1,000 | 1,200 | 1,451 |
| QLD | 4,931 | 5,449 | 6,449 |
| SA | 1,023 | 1,457 | 1,741 |
| TAS | 332 | 375 | 478 |
| VIC | 3,338 | 3,853 | 4,972 |
| WA | 2,597 | 2,736 | 2,967 |
| **TOTAL** | **17,023** | **19,760** | **24,045** |

(c) Widely accepted expert medical opinion is that undiagnosed and untreated chlamydia is the major cause of pelvic inflammatory disease in women and may lead to infertility.

(d) The Department does not have the data to infer whether the apparent increase in chlamydia infections is due to increases in detection and reporting or alternatively is an actual increase. Such evidence is difficult to obtain.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-062

OUTCOME 1: Population Health and Safety

Topic: CHLAMYDIA

Written Question on Notice

Senator Denman asked:

(a) Which Departmental programme and/or initiatives currently provide funding or other support to (i) education about and research into, and (ii) prevention of and treatment programme for chlamydia?

(b) What specific funding is provided for these programmes in (i) the year 2004-05 and (ii) over the forward estimates?

Answer:

(a) The Government provides ongoing funding to four National Research Centres in HIV, Hepatitis and Sexually Transmissible Infections (STIs). In 2004-05, two of the Centres, the National Centre in HIV Epidemiology and Clinical Research (NCHECR) and the National Centre in HIV Social Research (NCHSR), will be involved in research activities which will provide data on chlamydia in the context of research on sexually transmissible infections or sexual health.

The Government also provides funding for chlamydia treatment through the Pharmaceutical Benefits Scheme. However, it is not possible to precisely quantify this expenditure as the antibacterials used are not exclusively used for the treatment of chlamydia.

In 2003-04, the Government is contributing approximately $14.3 million directly through the Family Planning Program and $2 million indirectly to family planning activities under the Public Health Outcome Funding Agreements for a range of sexual and reproductive health programs.

The Family Planning Organisations provide clinical services and implement a broad range of sexual and health education strategies aimed at promoting responsible sexual behaviour, rather than focusing on one particular strategy or program.

Furthermore, through development and implementation of the new National HIV/AIDS and STI Strategy, support will be provided to education, research, prevention and treatment of STIs, including chlamydia. The Strategy will identify priority areas for action to address chlamydia.

(b) The available data is not able to be broken down to give separate information about differing sexually transmitted diseases such as chlamydia.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-063

OUTCOME 1: Population Health and Safety

Topic: PUBLIC HEALTH OUTCOME FUNDING AGREEMENTS (PHOFAs) - SEXUAL HEALTH

Written Question on Notice

Senator Denman asked:

Can the Department please provide the details as to the amount of funding which will be provided to each State and Territory under the Public Health Outcome Funding Agreements in the area of broadbanded or other funding for sexual and reproductive health programmes and initiatives in (a) 2004-05 and (b) – (e) in each subsequent year of the proposed five year agreements?

Answer:

The Australian Government's offer to jurisdictions for renewed Public Health Outcome Funding Agreements fully commits the current forward estimates for all components of the agreements. Under broadbanded arrangements, it is the responsibility of individual jurisdictions to use the flexibility provided by pooled funding to make local service funding decisions within the total pool of funds allocated to them, in line with local needs and priorities.

The table below summarises the proposed allocations to jurisdictions for all components.

## Offers to States and Territories for the Renewed PHOFA 2004-05 to 2008-09

| | NSW | VIC | QLD | WA | SA | TAS | ACT | NT | Total |
|---|---|---|---|---|---|---|---|---|---|
| **2004-05** | **49,651,938** | **37,222,942** | **26,691,935** | **13,968,841** | **11,996,001** | **5,570,068** | **3,333,662** | **3,765,129** | **152,200,516** |
| **2005-06** | **47,468,649** | **38,256,242** | **30,852,799** | **14,288,869** | **11,860,840** | **5,452,842** | **2,955,200** | **3,956,884** | **155,092,325** |
| **2006-07** | **48,284,284** | **38,942,348** | **31,689,909** | **14,610,296** | **12,005,319** | **5,514,789** | **2,983,867** | **4,008,267** | **158,039,079** |
| **2007-08** | **49,188,734** | **39,674,385** | **32,553,552** | **14,954,223** | **12,167,823** | **5,570,466** | **3,018,712** | **4,071,966** | **161,199,861** |
| **2008-09** | **50,111,553** | **40,420,204** | **33,435,603** | **15,305,370** | **12,332,933** | **5,626,906** | **3,054,163** | **4,137,127** | **164,423,859** |
| **Total offer over 5 years** | **244,705,158** | **194,516,121** | **155,223,799** | **73,127,600** | **60,362,915** | **27,735,071** | **15,345,605** | **19,939,372** | **790,955,641** |

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-064

OUTCOME 1: Population Health and Safety

Topic: PUBLIC HEALTH OUTCOME FUNDING AGREEMENTS (PHOFAs) - SEXUAL HEALTH

Written Question on Notice

Senator Denman asked:

(a) Should any State or Territory not sign off on its Public Health Outcome Funding Agreement by 30 June 2004 when direct funding from the Commonwealth to existing providers ends, is there any contingency plan in place to enable services to be continued? If so, can the details be provided?

(b) What process will the Department use to ensure that under this new arrangement, the extent and quality of sexual and reproductive health services is maintained and guaranteed?

Answer:

(a) The Minister for Health and Ageing wrote to State and Territory Health Ministers on 7 June 2004 proposing an extension of the current PHOFAs for a period of three months (from 1 July 2004 to 30 September 2004) to allow additional time for consideration and negotiation of the Australian Government's offer. The proposed extension would continue current arrangements for Family Planning payments to South Australia and the Australian Capital Territory and vaccine funding for all jurisdictions.

The current direct agreements between the Australian Government and family planning organisations in Western Australia, the Northern Territory, Tasmania, New South Wales, Queensland and Victoria will also be extended to 30 September 2004 to provide their current level of funding plus indexation.

(b) The new agreements (2004-09) will include an agreed performance information framework. States and Territories will be required to report against the performance indicators specified in the agreements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-219

OUTCOME 1: Population Health and Safety

Topic: PUBLIC HEALTH OUTCOME FUNDING AGREEMENTS (PHOFAs)

Hansard Page: CA 50-3.6

Senator McLucas asked:

Is it possible to do a disaggregation of those funds by State and by program for the 2003-04 year and the 2004-05 year from the budget paper. That would then identify where the immunisation money has come out and the family planning money has gone in.

Answer:

Comparison of funding provided under Current PHOFA 2003-04 (Year 5) and Proposed Offer for renewed PHOFA 2004-05 (Year 1) and Australian Immunisation Agreement 2004-05 (Year 1).

| **2003-2004** | | **2004-2005[5] Proposal** | |
|---|---|---|---|
| | **$m** | | **$m** |
| **Within PHOFAs** | | **Within PHOFAs** | |
| Broadbanded base | 128.9 | Base | 131.5 |
| Family Planning (SA and ACT)[1] | 2.1 | Family Planning (all States) | 15.4 |
| Victorian Cytology Service[2] | 5.2 | Victorian Cytology Service | 5.3 |
| Immunisation[3] | 147.9 | | |
| **Outside PHOFAs** | | **Outside PHOFAs** | |
| Family Planning (Other States)[4] | 13.0 | Immunisation[6] | 155.5 |
| **Total** | **297.1** | **Total** | **307.7** |

[1] Family Planning payments for SA and ACT were provided as quarantined funding in the current PHOFAs 1999-00 to 2003-04

[2] Provided as quarantined funding in 1999-00 to 2003-04 PHOFAs

[3] Funding through the 1999-00 to 2003-04 PHOFAs for the purchase of vaccines based on the funding formula - cohort x vaccine price x coverage x doses

[4] Family Planning payments for all States and Territories except SA and ACT were provided through a direct contract between the Australian Government and the relevant State/Territory Family Planning Organisation in 2003-04

[5] All PHOFA funding is proposed to be broadbanded in the 2004-05 to 2008-09 agreements

[6] Funding to be provided through the Australian Immunisation Agreements to each State/Territory government where funding for the purchase of vaccines is based on the funding formula - cohort x vaccine price x doses x coverage

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-212

OUTCOME 1: Population Health and Safety

Topic: EXPENDITURE - PSYCHOSTIMULANTS AND COMORBIDITY

Hansard page CA122

Senator Moore asked:

Can we get detail about how expenditure has been going on psychostimulants and comorbidity?

Answer:

There are a number of projects that have commenced as part of the National Comorbidity Initiative and the National Psychostimulants Initiative.

National Comorbidity Initiative

A total of $171,363 has been expended on the National Comorbidity Initiative to date. This comprises the following projects:

- $35,350 for the Mental Health Council of Australia to convene a Comorbidity Forum of key stakeholders from around Australia to discuss the comorbidity of mental health and substance misuse, particularly in the area of youth and early psychosis. The Forum was held in Sydney on Friday 21 May 2004. A total of $30,000 has been paid in the 2003-04 Financial Year.

- $116,580 for LMS Consulting to undertake the "Family Stories" project which will involve the development of a book of case studies of real life stories from ordinary Australians who have experienced what it is like to have, or be exposed to someone that has, a drug and alcohol and mental health problem. A total of $43,636 has been paid in the 2003-04 Financial Year.

- $268,398 for LMS Consulting, in consortium with the National Centre on HIV Social Research and the Australian Injecting and Illicit Drug Users League, to conduct a qualitative study of treatment experiences of drug treatment clients with comorbidity and complex vulnerabilities to identify barriers and incentives to treatment and treatment models, policies and practices to improve treatment outcomes for clients. A total of $72,727 has been paid in the 2003-04 Financial Year.

- $99,231 for the Australian Institute of Health and Welfare to review data collections relating to people with coexisting substance use and mental health disorders. A total of $25,000 has been paid in the 2003-04 Financial Year.

Tender processes have commenced for a range of other projects.

**National Psychostimulants Initiative**

A total of $108,469 has been expended on the National Psychostimulants Initiative to date. This comprises the following projects:

- $218,494 for the Drug and Alcohol Services Council of South Australia to undertake a trial of assertive community follow-up treatment for methamphetamine-induced psychosis. The study seeks to optimise the management of acute psychosis presentation and reduce the risk of relapse following treatment. A total of $50,000 has been paid in the 2003-04 Financial Year.

- $52,500 for JenCo Consulting to conduct a series of one-day workshops for frontline workers from various settings across Australia in delivering the brief cognitive behavioural intervention for psychostimulant users. A total of $47,727 has been paid in the 2003-04 Financial Year.

- $23,000 for the Alcohol and other Drugs Council of Australia to undertake a scoping study to identify current resources around psychostimulants - particularly directed at young people and families. The aim is to determine gaps in information development around psychostimulants for these target groups. A total of $10,742 has been paid in the 2003-04 Financial Year.

Tender processes have commenced for a range of other projects.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-215

OUTCOME 1: Population Health and Safety

Topic: POLIO VACCINES

Hansard Page: CA 42-3.6

Senator McLucas asked:

Please provide references on the link between the possibility and timing of polio eradication and countries' consideration of oral or injected polio vaccine.

Answer:

The literature discusses a number of complex issues for countries to consider when deciding if the immunisation program should move from oral polio vaccine (OPV) to inactivated polio vaccine (IPV), and if so, when such a move should occur.

The United Kingdom has chosen to delay the replacement of OPV with IPV until global eradication of polio is nearer. The link http://www.advisorybodies.doh.gov.uk/jcvi/mins060204.htm refers to the Joint Committee on Vaccination and Immunisation (JCVI) minutes of its 6 February 2004 meeting. JCVI is the equivalent of the Australian Technical Advisory Group on Immunisation (ATAGI) in the United Kingdom.

Other references of interest include:

- World Health Organization. Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries. *Weekly epidemiological record* 2003;78(28):241-52.

- Aylward RB, Cochi SL. Framework for evaluating the risks of paralytic poliomyelitis after global interruption of wild poliovirus transmission. *Bulletin of the World Health Organization* 2004;82(1):40-6.

These articles were written prior to the latest evidence on the recent spread of the virus in west and central Africa.

The World Health Organization (WHO) released a media statement on 22 June 2004 warning of the likelihood of the largest polio outbreak seen in recent years to occur in west and central Africa, stemming from the cessation of immunisation in the northern Nigerian state of Kano. The media statement can be found at http://www.who.int/mediacentre/releases/2004/pr45/en/print.html

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-216

OUTCOME 1: Population Health and Safety

Topic: IMMUNISATION - VACCINES

Hansard Page: CA 42-3.6

Senator McLucas asked:

Vaccines – Why is there a $3m underspend in ACIR payments – refer to PBS – If that is not right, could you write me a note to that effect?

Answer:

There are two reasons why Australian Childhood Immunisation Register (ACIR) payments to immunisation providers in 2004-05 are expected to be approximately $3 million lower than the payments in 2003-04 (note that this is not an underspend but a reduction in the estimate between years). In 2003-04, one-off payments to immunisation providers were made for the catch-up component of the National Meningococcal C Vaccination Program that commenced in 2003. As well, in September 2003 the 18 month dose of DTPa vaccine was removed from the Australian Standard Vaccination Schedule and National Immunisation Program. The removal of this vaccine means that children no longer require this vaccination at 18 months of age.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-175

OUTCOME 1: Population Health and Safety

Topic: EXTENSION OF INVESTMENT IN PUBLIC HEALTH

Written Question on Notice

Senator McLucas asked:

Please provide a breakdown by activity and year for the extension of funding to be provided in this area.

Answer:

Departmental and Administered funding for the Investment in Preventative Health budget measure by activity and year is presented in the following table:

**Approximate split of funding by activity**

| **Measure : Investment in Preventive Health** | **2004-05 ($m)** | **2005-06 ($m)** | **2006-07 ($m)** | **2007-08 ($m)** | **TOTAL ($m)** |
|---|---|---|---|---|---|
| Investment in Preventive Health - Immunisation | 11.0 | 11.2 | 11.4 | 11.6 | **45.2** |
| Investment in Preventive Health - Injury Prevention | 1.4 | 1.4 | 1.5 | 1.5 | **5.8** |
| Investment in Preventive Health - Cancer Control | 1.4 | 1.4 | 1.4 | 1.5 | **5.7** |
| Investment in Preventive Health - Men's Health | 1.1 | 1.1 | 1.1 | 1.1 | **4.4** |
| Investment in Preventive Health - Environmental Health | 1.2 | 1.2 | 1.2 | 1.2 | **4.8** |
| Investment in Preventive Health - Tobacco | 2.3 | 2.4 | 2.4 | 2.4 | **9.5** |
| Investment in Preventive Health - Public Hlth Information Development Plan (Strengthening Evidence Base) | 4.0 | 4.1 | 4.2 | 4.3 | **16.6** |
| Investment in Preventive Health - Health*Insite* website (Internet Redevelopment) | 1.4 | 1.5 | 1.5 | 1.6 | **6.0** |
| **TOTAL : Investment in Preventive Health** | **23.8** | **24.3** | **24.7** | **25.2** | **98.0** |

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-176

OUTCOME 1: Population Health and Safety

Topic: BOWEL CANCER SCREENING

Written Question on Notice

Senator McLucas asked:

The Government will provide $7.4 million over 4 years to continue the current pilots in bowel cancer screening.

(a) When is it expected that the pilot phase of this work will be complete?
(b) What is required to move beyond pilots to the roll-out of a national screening program?
(c) What is the timeline for this?

The April 2004 progress report for the bowel cancer screening pilot program states that a cost effectiveness study for the pilot is being sponsored by the Medical Services Advisory Committee. This work is being undertaken by the Medical Technology Advisory Group, an independent research company.

(d) When will this report on cost effectiveness be completed?

Answer:

(a) The final invitations to participate in the Pilot were mailed in June 2004. The final data download will be undertaken in September 2004, by which time most of the participants in the Pilot will have completed their journey through the screening pathway. A final report on the Pilot will be prepared for Government by November 2004.

(b) To move to a national rollout of a screening program would require a budgetary decision by Government to fund a national program following consideration of the report on the Pilot.

(c) This is a matter for the Government to decide.

(d) The report is due to the Department in September 2004, which will enable its findings to be incorporated into the final report.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-194

OUTCOME 1: Population Health and Safety

Topic: CERVICAL CANCER

Hansard Page: CA 74-75-3.6

Senator Crossin asked:

(a) What is happening around the country in terms of Indigenous women accessing and having a pap smear?

(b) What is being done to encourage more Indigenous women to have Pap smears where there is no access to a female doctor, for example?

(c) Has the Commonwealth given any consideration to perhaps tying any sort of funding to a requirement that state or territories keep this sort of data [cervical cancer screening rates for Indigenous women] on record?

Answer:

(a) State and Territory programs are responsible for implementation of the National Cervical Screening Program. Programs specifically target Indigenous women by developing resources including posters, brochures and kits that are culturally appropriate. Indigenous Project Officers also travel to centres in their state, both rural and urban, to educate local health professionals and communities of the importance of Indigenous women participating in screening. Mobile clinics staffed by females provide Pap smear services to Indigenous women and the women can also access Aboriginal Medical Services or mainstream practices.

To better ensure access to cervical screening by Indigenous women, the National Advisory Committee to the National Cervical Screening Program established the Aboriginal and Torres Strait Islander Women's Forum in February 2000. The aim of the Forum is to increase the participation of Indigenous women in screening by making the services more accessible and appropriate for them. One of the projects undertaken by the Forum was the development of a set of standards and guidelines to assist the delivery of an appropriate cervical screening service for Indigenous women. The resultant document, *Principles of Practice, Standards and Guidelines for Providers of Cervical Screening Services for Indigenous Women*, shaped through national consultation, was endorsed in 2003 and published and distributed from March 2004.

(b) State and Territory programs provide mobile clinics with female staff, and the Royal Flying Doctor Service is aware of the need, and provides for, female doctors to be available for Indigenous women seeking Pap smears. Trained Nurse Practitioners are also available in some centres. The *Principles of Practice, Standards and Guidelines for Providers of Cervical Screening Services for Indigenous Women* supports and encourages mainstream practices to address the need for female health practitioners to be available for Indigenous women.

(c) The National Advisory Committee to the National Cervical Screening Program has considered the issue of collecting data on screening rates for Indigenous women. The Aboriginal and Torres Strait Islander Women's Forum also has a strong interest in collecting this data as it would be a way to chart their progress. The issue of identification remains under discussion between the Australian Government and the National Aboriginal Community Controlled Health Organisation.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-195

OUTCOME 1: Population Health and Safety

Topic: HEPATITIS B

Hansard Page: CA 75-3.6

Senator Crossin asked:

(a) What percentage of the Indigenous population is hepatitis B positive?

(b) What percentage of the Indigenous population has been vaccinated against hepatitis B?

Answer:

(a) The available sources of information are one off surveys of specific groups of Indigenous Australians. Such surveys use hepatitis B surface antigen (HBsAg) as a marker of recent infection of hepatitis B. In 1989, a serological survey among school children (4-19 years of age) in the Kimberley Region in Western Australia found that 6.1% of Indigenous children were positive for HBsAg.[1] In 1992, a further study showed that 8.2% of Northern Territory Indigenous school children (9-17 years of age) were HBsAg positive.[2]

Data from the National Notifiable Diseases Surveillance System indicates that the rate of new infections with hepatitis B infection are 4-5 times higher in Indigenous Australians compared with non-Indigenous Australians.

(b) Recent data from the Australian Childhood Immunisation Register shows that among children who turned 1 and 2 in January 2004, the vaccination coverage rates of Aboriginal or Torres Strait Islander children were 93.5% and 98.15% respectively.

**References**

1. Gill SJ, Bucens M, Hatton M, Carey M, Quadros FC. Markers of hepatitis B virus infection in schoolchildren in the Kimberley, Western Australia. The medical Journal of Australia 1990;153:34-37.

2. Gardner DI, Wan X, Simms AD, Worswick D, Burrell JC, Mathews JD. Hepatitis B virus markers in children and staff in Northern Territory Schools. Med J Aust 1992;156:638-641

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 2 & 3 June 2004

Question: E04-209

OUTCOME 1: Population Health and Safety

Topic: INDIGENOUS REPRESENTATION ON THE COMMUNICABLE DISEASE NETWORK AUSTRALIA STEERING GROUP

Hansard Page: CA 106-3.6

Senator Crossin asked:

Is there Indigenous representation on the Communicable Diseases Network of Australia's steering group [i.e. the steering committee established "to look at issues around developing not only a better sense of the data but also a more consistent approach to definitions and survey methodology as well as screening methodology and treatment protocols"]? Please provide a copy of the terms of reference of the steering committee.

Answer:

It is noted that the question was asked to staff of the Office of Aboriginal and Torres Strait Islander Health as part of a broader discussion about the review of the Indigenous Eye Health Program and specifically about trachoma control. Therefore, it is assumed that the steering committee referred to by Senator Crossin, is the Communicable Diseases Network Australia's (CDNA's) Trachoma Steering Group.

CDNA comprises Australian Government and State and Territory Government technical expertise in communicable diseases and seeks to ensure collaboration and communication on national communicable disease issues. CDNA has a number of disease-specific subcommittees including the Trachoma Steering Group. Membership of the Trachoma Steering Group is drawn from the CDNA and has representation from the Department's Population Health Division and Office for Aboriginal and Torres Strait Islander Health. The Trachoma Steering Group currently does not include Indigenous representation. CDNA is seeking advice from key organisations, including the National Aboriginal Community Controlled Health Organisation, as to how they can best be engaged in the development of national trachoma reporting and management guidelines.

The Terms of Reference for the Trachoma Steering Group, endorsed by CDNA in December 2003, are attached.

**ATTACHMENT**

## Trachoma Steering Group of the Communicable Diseases Network Australia

**Purpose:**
The Steering Group is to provide recommendations to the Communicable Diseases Network Australia (CDNA) on standards for surveillance and reporting of trachoma and a mechanism to develop a nationally consistent approach to the public health management of trachoma in Australia.

**Membership:**
Membership is drawn from CDNA with Northern Territory, Western Australia, South Australia and Population Health Division of the Australian Government Department of Health and Ageing participating together with the Office for Aboriginal and Torres Strait Islander Health.

**Terms of Reference:**
The Steering Group will advise and recommend to CDNA the following:

1. Establish best practice guidelines to achieve consistency in diagnosis and reporting of trachoma. This would include consideration of such issues as:
   - the role of ligase chain reaction (LCR)/polymerase chain reaction (PCR) testing in diagnosis;
   - standardised reporting for clinical diagnoses;
   - guidelines for regional data collection including protocols for collation of a national data-set through:
     - standardisation of numerators and denominators; and
     - development of a trachoma data-set that is harmonised with the World Health Organization (WHO) proforma.

2. Options for a consultation process to reach a consensus on guidelines and principles for the public health management of trachoma. The Steering Group will oversee the preferred consultation process and will seek to ensure that State and Territory public health units and other stakeholders are engaged with this process.

3. National guidelines for the public health management of trachoma in Australia for CDNA endorsement. These would take into account WHO guidelines, current literature, and the consultation process. They would include attention to:
   - screening and treatment protocols across all regions;
   - appropriate timing and frequency of screening and treatment under varying circumstances;
   - treatment approaches (mass / family / opportunistic);
   - appropriate referral mechanisms;
   - protocols for engagement with communities; and
   - the role of local primary health care services.

***Endorsed by Communicable Diseases Network Australia December 2003***

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-141

OUTCOME 1: Population Health and Safety

Topic: NATIONAL NUTRITION SURVEY

Written Question on Notice

Senator Allison asked:

(a) What work or planning has been undertaken by the Department into conducting a follow-up to the 1995 National Nutritional Survey?
(b) If none, why not; if some, when and how will this planning be pursued?

Answer:

(a) and (b)
The Department of Health and Ageing is contributing funding to an investigation of the most cost-effective approach to data collection on nutrition, through a project of the National Public Health Partnership's Strategic Inter-Governmental Nutrition Alliance. This project will develop a framework and business case for an ongoing national food and nutrition monitoring and surveillance system in Australia. This work will inform any decision on a follow-up survey across jurisdictions.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-218

OUTCOME 1: Population Health and Safety

Topic: NATIONAL NUTRITION SURVEY

Hansard Page: CA 46-3.6

Senator McLucas asked:

Discussing the 1995 Survey.

Was that the first time that the Survey had occurred?

Answer:

No.

Prior national surveys funded by the Australian Government include:

- *1985 National Dietary Survey of Schoolchildren* conducted by the Australian Council for Health, Physical Education and Recreation. The Survey was funded by the National Health and Medical Research Council and also supported by Kellogg's (Australia) Pty Ltd, and

- *1983 National Dietary Survey of Adults* conducted by the National Heart Foundation of Australia. The Survey extended the National Heart Foundation Risk Factor Prevalence Survey with a grant from the Department of Health to form the National Dietary Survey.

Prior studies did not use identical methodology to the *1995 National Nutrition Survey*. The *1995 National Nutrition Survey* was a more comprehensive survey and was conducted using a sub-sample of the National Health Survey (ABS).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-220

OUTCOME 1: Population Health and Safety

Topic: APPROVAL PROCESSES FOR HEPATITIS C PUBLICATIONS

Hansard Page: CA 51-3.6

Senator McLucas asked:

Could I get a list of the period of time that each approval process had to go through, including the ones that are not complete?

Answer:

Attachment A is a list of hepatitis C publications produced by Non-Government Organisations, funded through the *Hepatitis C Education and Prevention Initiative 2003-2004.* Under this Initiative, the Australian Hepatitis Council and the Australian Injecting and Illicit Drug Users organisations produce a series of hepatitis C educational resources.

The list includes those resources submitted for approval from July 2003.

**Attachment A**

| Organisation | Document | Submission Date | Approval Status |
|---|---|---|---|
| **Australian Hepatitis Council (AHC)** | Hepatitis Chronicle Issue #13 | • 22 September 2003 (incorrect format)<br>• 10 November 2003 – resubmitted in correct format. | Approved |
| **Australian Hepatitis Council (AHC)** | Advocacy Manual & Training Materials | 3 October 2003 | Under negotiation. |
| **Australian Injecting and Illicit Drug Users League (AIVL)** | JunkMail – Issue number 7 | 28 January 2004 | With AIVL for final editing prior to final approval. |
| **Australian Injecting and Illicit Drug Users League (AIVL)** | Hepatitis See – Issue number 15 | 30 January 2004 | With AIVL for final editing prior to final approval. |

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-142

OUTCOME 1: Population Health and Safety

Topic: FAMILY PLANNING

Written Question on Notice

Senator Allison asked:

What funding arrangements or processes will be put in place to monitor the total amount of funds that the State and Territory family planning organisations receive under the PHOFAs and how these funds are expended?

Answer:

The agreements will include an agreed performance information framework. States and Territories will be required to report against the performance indicators relating to family and reproductive health specified in the agreements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-144

OUTCOME 1: Population Health and Safety

Topic: TOBACCO

Written Question on Notice

Senator Allison asked:

(a) Could the Department indicate whether the introduction of flavoured cigarettes, such as chocolate and mint and cherry cheesecake, would be possible in Australia?

(b) What steps has the Department taken to investigate whether any companies are considering introducing these products into Australia?

(c) Has the Department undertaken any work into what initiatives could be put in place to counteract the introduction of these products?

Answer:

(a) Australian Government legislation does not currently prohibit flavoured cigarettes.

(b) The Department is not aware of any companies currently seeking to introduce these products into Australia.

(c) The Department is currently seeking advice from Australian Competition and Consumer Commission (ACCC) on this matter.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-145

OUTCOME 1: Population Health and Safety

Topic: ILLICIT DRUG USE

Written Question on Notice

Senator Allison asked:

How does the increasing rate of illicit drug use overall amongst younger people reflect on the 'Tough on Drugs' approach? Do we need to look at alternative ways of addressing drug use and abuse?

Answer:

The National Drug Strategy Household Survey is the most reliable source of data on drug use in the general population in Australia. As the Survey is conducted triennially, the 2001 Survey results provide the most recent data.

The 2001 National Drug Strategy Household Survey revealed a 23% decrease overall in recent use of illicit drugs by Australians aged 14 years and over, from 22% in 1998 to 16.9% in 2001.

In relation to young people, results from the Survey revealed that use of illicit drugs in the previous 12 months by this group had also decreased. The Survey showed that the proportion of males aged 14–19 years who had used an illicit drug in the previous 12 months had decreased from 38.3% in 1998 to 28.8% in 2001. The Survey also showed that the proportion of females aged 14-19 years who had used an illicit drug in the previous 12 months had decreased from 37.1% in 1998 to 26.6% in 2001.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-146

OUTCOME 1: Population Health and Safety

Topic: ILLICIT DRUG USE

Written Question on Notice

Senator Allison asked:

What proportion of the money allocated to the National Illicit Drug Strategy in the current budget is allocated to preventative measures?

Answer:

As part of the 2004-05 Budget more than $135 million was allocated to the Health and Ageing Portfolio for the period 2004-05 to 2007-08 to continue a range of measures to prevent and reduce illicit drug use in Australia.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-147

OUTCOME 1: Population Health and Safety

Topic: ILLICIT DRUG USE

Written Question on Notice

Senator Allison asked:

What evidence does the Department have on the cost-effectiveness of preventative measures for reducing the level of drug use? As opposed to law enforcement approaches?

Answer:

The Department is not aware of research that compares the cost-effectiveness of prevention measures and law enforcement. Within the context of the National Drug Strategy, prevention refers to measures that prevent or delay the onset of drug use as well as measures that protect against risk and prevent and reduce the harms associated with drug supply and use. The National Drug Strategy provides the framework for a coordinated, integrated approach to drug issues in the Australian community. The Strategy encompasses supply reduction, demand reduction and harm reduction measures.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-148

OUTCOME 1: Population Health and Safety

Topic: ILLICIT DRUG USE

Written Question on Notice

Senator Allison asked:

What measures does the Department have in place to respond to the increasing rate of ecstasy use among young people?

Answer:

According to the 2001 National Drug Strategy Household Survey, the proportion of the population aged 14 years and over that had recently used ecstasy/designer drugs increased from 2.4% in 1998 to 2.9% in 2001. Recent use of ecstasy/designer drugs by males aged 14-19 years increased from 3.3% in 1998 to 5.7% in 2001, and for females aged 14-19 years recent use increased from 3.0% in 1998 to 4.3% in 2001.

The National Psychostimulants Initiative aims to address problems associated with the increased availability and use of psychostimulants in Australia. The Department has consulted with the Australian National Council on Drugs, the Alcohol and other Drugs Council of Australia, and other stakeholders on the implementation of the Initiative. This process identified the following priority areas:

- identification and dissemination of good practice models and approaches for the treatment of psychostimulant use;
- providing support and training to general practitioners and other health workers to improve treatment outcomes for psychostimulant users; and
- providing information for at-risk youth and families.

In implementing the priority areas, consideration will be given to implications for young people.

The Alcohol and other Drugs Council of Australia are undertaking a scoping study to identify current resources around psychostimulants - particularly directed at young people and families. The aim is to determine gaps in information development relating to psychostimulants for these target groups.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-121

OUTCOME 1: Population Health and Safety

Topic: HERBICIDE, CONTAMINATION AND FARMING PRACTICES

Written Question on Notice

Senator Cherry asked:

How does the OGTR reconcile its failure to impose any conditions on Bayer and Monsanto that will prevent or limit the persistence or contamination of GMOs in the environment with section 49(2)(c ) of its acts which requires you to have regard to provisions "for limiting the dissemination or persistence of the GMO or its genetic material in the environment?

Answer:

Section 49(2) of the *Gene Technology Act 2000* requires the Gene Technology Regulator to consider a number of factors in order to determine whether the genetically modified organism (GMO) may pose significant risks to human health and safety and the environment.

The Gene Technology Regulator did have regard to provisions for limiting the dissemination and persistence of the GMOs and their genetic material in the environment in the assessment of the two genetically modified (GM) canolas to which you refer. The potential for dissemination and persistence is acknowledged by the Gene Technology Regulator in the risk assessment and risk management plans that were prepared in respect of the licence applications for these GMOs. However, the assessment by the Gene Technology Regulator concluded that these GM canolas will not pose any greater risks to human health and safety or the environment than conventional canola. Therefore no risk management conditions were required in relation to dissemination or persistence of the GMOs or their genetic material in the environment.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-122

OUTCOME 1: Population Health and Safety

Topic: HERBICIDE, CONTAMINATION AND FARMING PRACTICES

Written Question on Notice

Senator Cherry asked:

In previous testimony you were asked about evidence from overseas indicating that American farmers were not complying with requirements designed to reduce the likelihood of resistance developing to Bt. You said at the time that "we have systems in place that will assist" in ensuring that doesn't occur in Australia (CA 108, 5/11/03). You referred specifically to cotton in that answer. In imposing conditions on the release of Bt cotton, you clearly determined that controlling resistance was a matter within your jurisdiction. In approving commercial release of canola, you have imposed no measures to prevent resistance, why is that?

Answer:

Regulation of agricultural chemicals is principally the responsibility of the Australian Pesticides and Veterinary Medicines Authority (APVMA) under the *Agricultural and Veterinary Chemicals Code Act 1994* (the Ag Vet Code Act). Herbicides applied to genetically modified (GM) plants and insecticidal genes in GM plants fall under the Ag Vet Code Act definition of agricultural chemical products, and are thus subject to regulation by the APVMA. The development of resistance to agricultural chemicals is part of the APVMA's assessment of agricultural chemical use. The APVMA can impose conditions on both registrations and permits. These conditions can include restrictions on use, implementation of a resistance management plan, and ongoing reporting on compliance.

The APVMA has imposed conditions on the registration of GM Bt cottons, including insecticide resistance management strategies. Therefore, conditions to manage the development of insecticide resistance have not been imposed in licences issued by the Gene Technology Regulator for field trials or commercial releases of GM Bt cottons. However, all licences for releases involving Bt cottons issued by the Gene Technology Regulator indicate the applicants' obligation to comply with any conditions imposed by the APVMA.

The Gene Technology Regulator has approved two commercial releases of GM herbicide tolerant canola. Conditions of registration for the use of the herbicides on the GM canolas are imposed by the APVMA and include procedures to manage the potential development of herbicide resistant weeds. Accordingly, no specific conditions in relation to management of herbicide resistance are included in the licences issued by the Gene Technology Regulator. The licences for commercial releases of GM canola also indicate the licence holders' obligation to comply with any conditions required by the APVMA.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-123

OUTCOME 1: Population Health and Safety

Topic: HERBICIDE, CONTAMINATION AND FARMING PRACTICES

Written Question on Notice

Senator Cherry asked:

Would you agree that the condition provisions of the Act do not require you limit your conditions to matters of environment or health and safety? (see section 62)

Answer:

Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-124

OUTCOME 1: Population Health and Safety

Topic: HERBICIDE, CONTAMINATION AND FARMING PRACTICES

Written Question on Notice

Senator Cherry asked:

Would you agree that there is currently no system in place in relation to GE canola that will prevent resistance or control herbicide regimes?

Answer:

There is a system in place to regulate the use of herbicides and to manage the risk of the development of herbicide resistance. The Australian Pesticides and Veterinary Medicines Authority assesses whether a herbicide resistance management strategy is required as part of their assessment process for applications for registration for the use of herbicides on all crops.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-125

OUTCOME 1: Population Health and Safety

Topic: HERBICIDE, CONTAMINATION AND FARMING PRACTICES

Written Question on Notice

Senator Cherry asked:

(a) The CSIRO review found the British Farm Studies evaluation relevant to Australian the basis that the "FSE clearly shows the interdependence of different groups of organisms within farm-land ecosystems". Would you agree that this is relevant to Australian cropping areas?

(b) If so, to what extent have you assessed this interdependence in your RARMP for Monsanto?

Answer:

(a) Yes. It is certainly true that there is an interdependence of different groups of organisms in farm-land ecosystems.

(b) In-crop biodiversity is considered important in the UK, as weeds are often remnant native vegetation that is critical to the survival of indigenous wildlife. In contrast, weeds in Australian cropping systems are exotic, not native, species and Australia's fauna has a much greater reliance on bushland and forest in the off-farm environment. Accordingly, weeds on Australian farms are not considered environmentally valuable and their eradication, including during the cultivation of genetically modified herbicide tolerant crops, is not important to maintaining biodiversity. The results from the UK Farm Scale study cannot be used as evidence that Roundup Ready canola will have a detrimental effect on the Australian environment.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-126

OUTCOME 1: Population Health and Safety

Topic: HERBICIDE, CONTAMINATION AND FARMING PRACTICES

Written Question on Notice

Senator Cherry asked:

(c) Obviously, Australian cropping areas involve a large diversity of ecosystems, but can you tell us to what extent native species of flora and fauna live within those cropping areas?

(d) How many of those species are threatened or vulnerable?

(e) How many survive primarily in agricultural cropping areas?

(f) If does not know - why not? (and take on notice)

Answer:

(c) Australian flora and fauna have a much greater reliance on relatively undisturbed areas of native bushland and forest for survival, than on areas in agricultural regions that are actively cropped. Cropped fields, whether genetically modified, organic or conventional, manage biodiversity to exclude, reduce or minimise any native flora and fauna that adversely affect the crop.

(d) Australian flora and fauna have a much greater reliance on native bushland and forest.

(e) To the best of our knowledge, none survive primarily within cropped fields, which are extensively and regularly disturbed. As noted in response to part (a) of this question, Australian flora and fauna have a much greater reliance on relatively undisturbed habitats for survival.

Part of the purpose of consulting with expert agencies and authorities and the public on proposals to release genetically modified organisms (GMOs) into the environment is to seek this type of information. In this regard, we especially value feedback from the Australian Government Environment Minister, local councils and the public.

These stakeholders, particularly local councils and interested members of the public, are in a relatively strong position to provide feedback regarding the presence of species of high conservation value in cropping habitats into which GMOs may be proposed for release.

The Office of the Gene Technology Regulator (OGTR) is not aware of any such species and none has been highlighted during any of the extensive consultations on the risk assessment and risk management plans that have underpinned decisions to issue licences for dealings involving the release of GMOs into the environment.

(f) As stated above, the OGTR is unaware of any such species, largely because the Australian flora and fauna have a much greater reliance on native bushland and forest for survival, than on cropping habitats.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-127

OUTCOME 1: Population Health and Safety

Topic: HERBICIDE, CONTAMINATION AND FARMING PRACTICES

Written Question on Notice

Senator Cherry asked:

CSIRO has clearly identified changed farming practices as likely to have a significant impact on ecosystems - and as an issue important in any risk assessment. What is the Office of the Gene Technology Regulator position on the environmental impact of changed farming practices in relation to the intentional release of genetically modified organisms?

Answer:

These are assessed on a case by case basis in the context of human health and safety and the environment, and in consultation with other relevant agencies and authorities.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-128

OUTCOME 1: Population Health and Safety

Topic: BIODIVERSITY STUDIES

Written Question on Notice

Senator Cherry asked:

(a) You indicated that you had looked at 400 papers and you suspected that there would be peer reviewed biodiversity studies amongst those - you were asked to take that question on notice - wondering if you have an answer to that question of how many peer reviewed biodiversity studies were part of your Risk Assessment and Risk Management Plan for GE canola?

(b) How many of those relate to Australian conditions?

Answer:

(a) There were a number of peer reviewed papers among the papers that informed the assessment of potential impacts of genetically modified (GM) canola on biodiversity. These papers looked at the effect of GM canola on biodiversity within a range contexts including toxicity, weediness, geneflow, effects on soil and effects on non-target species. In respect of DIR020, the Roundup Ready canola application by Monsanto, 495 papers were considered of which 164 were peer reviewed biodiversity papers. In respect of DIR021, the InVigor canola application by Bayer, 395 papers were considered of which 96 were peer reviewed biodiversity papers.

(b) Ten were conducted in Australia, but all of the papers identified in answer to part (a) were relevant.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-129

OUTCOME 1: Population Health and Safety

Topic: BIODIVERSITY STUDIES

Written Question on Notice

Senator Cherry asked:

(g) How many studies have been commissioned by the OGTR specifically looking at ecological impacts of GE plants in Australian conditions? (NONE)

(h) Is this because you believe we understand the impacts of GE on ecosystems?

Answer:

(a) & (b)

The Office of the Gene Technology Regulator (OGTR) has commissioned some studies on cotton. However, it should be pointed out that the OGTR is a regulatory body whose primary role is to assess licence applications, including for release of genetically modified organisms. If the Gene Technology Regulator is not satisfied that there is sufficient data on any risk to human health and safety and the environment that cannot be managed, no licence would be issued. Data can come from many sources, including existing data from previous studies, data from research conducted under licence and studies commissioned by the OGTR or others.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-130

OUTCOME 1: Population Health and Safety

Topic: BIODIVERSITY STUDIES

Written Question on Notice

Senator Cherry asked:

CSIRO has identified impacts of GE plants on soils and soil microorganisms as a poorly understood area in need of additional research?

Answer:

This is a statement/question regarding the actions of CSIRO and should be referred to that agency for specific response.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-131

OUTCOME 1: Population Health and Safety

Topic: BIODIVERSITY STUDIES

Written Question on Notice

Senator Cherry asked:

Would you agree with that soil organisms regulate a number of processes in terrestrial ecosystems that are critical for productivity and ecosystem health? (see Gupta, Impacts of Genetically Modified Plants on Soil Biota Communities and Biological Processes, 2003)

Answer:

Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-132

OUTCOME 1: Population Health and Safety

Topic: BIODIVERSITY STUDIES

Written Question on Notice

Senator Cherry asked:

(i) A conference paper given by Gupta from CSIRO this year, indicated that there is increasing evidence of soil borne diseases associated with herbicide tolerant GM crops. Are you aware of this research?

> "A number of reports from overseas (both published and conference reports) raised concern over increased prevalence of soil-borne plant diseases either in Herbicide Tolerant-Genetically Modified (HT-GM) crops or in crops following HT-GM crops), e.g. severe epidemics of sudden death syndrome of soybeans caused by F. solani f.sp. glycines in the U.S. north central region. A number of different causes for such an increase in the occurrence of soil-borne diseases have been proposed, not necessarily related to genetic modification alone but alone related to the in-crop use of specific herbicides." Herbicide Tolerant Crops and Soil-Borne Plant Diseases (71).

(j) That same paper indicates that "Research from Canada indicates that endophytic and rhizosphere microbial communities of the trangenic canola cultivar Quest were different from non-transgenic cultivars grown at the same field site." (71) Do you know if the roundup ready and liberty link varieties of canola you have approved for commercial release have similar impacts on Australian soils?

(k) If yes, what published research in Australia leads to that conclusion?

(l) If not - would you agree that soil health is an environmental issue that is within your jurisdiction?

Answer:

(a) The conference paper referred to is Gupta et al (2004)[4]. This paper reports work on Bt cotton indicating changes in soil microbial communities but not whether this was beneficial or deleterious. The *Gene Technology Act 2000* seeks to protect human health and safety and the environment by minimising harm. It does not seek to prevent change.

The Gene Technology Regulator is aware of reports from overseas that raise concern over increased prevalence of soil-borne plant diseases in herbicide tolerant genetically modified (GM) crops. A comprehensive consideration of this issue is provided in Appendix 3, section 1.2.1 of the Risk Assessment and Risk Management Plan (RARMP) of DIR020/2002 for Roundup Ready® canola and Appendix 3, section 2.2.1 of the RARMP of DIR021/2002 for InVigor® canola.

(b) Studies on cultivar Quest (a Roundup Ready® canola grown in Canada) are cited in the Roundup Ready® canola RARMP (DIR 020/2002). These studies showed that there were transient changes in the root zone microbial community of the cultivar when compared to its non-GM counterpart. However, these changes did not persist over winter when the plants were removed. There was no indication from these studies that this change in the microbial community had either positive or negative impacts on plant growth.

There is no evidence that cultivation of either GM glyphosate-tolerant canola (Roundup Ready®) or GM glufosinate ammonium-tolerant canola (InVigor®) results in adverse effects on soil microflora. The RARMPs for DIR 020/2002 and DIR 021/2002 detail the available studies on the response of soil microflora to the cultivation of these plants and in each case concluded that there were no significant changes in soil microbial communities. In addition, the experience of commercial production in North America, and trials in Europe and Australia indicate that there are no apparent adverse impacts on soil health as evidenced by the growth performance of the GM canola, and on the growth of subsequent crops. Given the data from overseas that any changes in soil microbial communities are transient and manageable, the likelihood that different results would be achieved with Australian soils is unlikely.

(c) There is no published research conducted on Australian soils on the impact of herbicide tolerant GM canola on microbial populations compared to non-transgenic canola grown at the same field site. However, studies to date conclude that changes in microbial communities are dynamic and are influenced by agricultural practices. This hazard can only be considered a risk if there is a substantiated negative outcome on overall soil health that cannot be managed. Disease outbreaks overseas have not been causally linked to changes to soil community structure as a result of growing of herbicide tolerant GM crops. However, disease severity can be influenced by herbicide application.

[4] Gupta, V. V. S. R., Roget, D. K, Rovira, A. D, and Sivasithamparam, K (2004). Herbicide tolerant crops and soil-borne plant diseases, 3rd Australasian Soilborne Diseases Symposium, Feb 2004 South Australia.

If fungal diseases occurred in GM crops they could be managed as they are in non-GM crops: by selecting cultivars that have a genotype with high levels of resistance to the plant disease in question and by employing standard agricultural management practices in relation to soil hygiene.

(d) There is no evidence to date that dynamic changes in soil microbial communities have any deleterious impact on soil health. If consistent, negative changes in soil health is caused by the growth of GM crops, leading to adverse impacts on human health and safety or the environment that can not be managed, it is within the jurisdiction of the Gene Technology Regulator to cancel or suspend a licence.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-133

OUTCOME 1: Population Health and Safety

Topic: BIODIVERSITY STUDIES

Written Question on Notice

Senator Cherry asked:

Gupta also notes - as does Mark Lonsdale of CSIRO - that we may have indications of changes in soils as a result of GE plants, but we understand very little about what this means. Wouldn't you agree that this is the kind of assessment that should take place before commercial release is authorised?

Answer:

All farming practices, including cultivation of genetically modified (GM) and conventional plants and the application of inputs eg fertilisers, organic matter, herbicides or pesticides, have some impact on soil microbial communities, as detailed in QON EO4-132. Moreover, changes also occur in response to environmental conditions, on a seasonal basis, and with plant growth stage. The evidence available to date does not suggest that GM plants cause changes to soils outside the normal, extremely dynamic range. In relation to the assessment of applications for commercial release of GM glyphosate tolerant (Roundup Ready®) and glufosinate ammonium tolerant (InVigor®) canola, the Risk Assessment and Risk Management Plans for DIR 020/2002 and DIR 021/2002 detail the available studies on the response of soil microflora to the cultivation of these plants and in each case concluded that there were no significant changes in soil microbial communities. In addition, the experience of commercial production in North America, and trials in Europe and Australia indicate that there are no apparent adverse impacts on soil health as evidenced by the growth performance of the GM canola, and on the growth of subsequent crops.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-134

OUTCOME 1: Population Health and Safety

Topic: BIODIVERSITY STUDIES

Written Question on Notice

Senator Cherry asked:

A number of CSIRO documents from the Ecological Implications of Genetically Modified Organisms project indicate that predictability of harm for biological introductions into complex systems is low because of a variety of effects. Lonsdale notes scale effects, complexity of systems, number of introduced organisms, cascade effects and lag effects. Would you agree with that position?

Answer:

Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-135

OUTCOME 1: Population Health and Safety

Topic: BIODIVERSITY STUDIES

Written Question on Notice

Senator Cherry asked:

Keith Hayes notes that "many of the current appeals to the safety of GM products rely on the incredibly rare likelihood of undesired events such as bacterial gene flow. These appeals, however, are undermined by the large number of potential exposure pathways (demonstrated by the complexity of the fault tree) and extremely high exposure (billions of plants in commercial production)." (Inductive hazard analysis for GMOs, 2003). Would you agree with that statement?

Answer:

In relation to risk assessments conducted by the Office of the Gene Technology Regulator, no. For example, the risk assessment for Roundup Ready® canola recognised that although gene flow to some related brassicaceous species occurred at a very low rate, it would be inevitable in the commercial situation. The risk assessment evaluated the impact of this inevitability and concluded that the GM canola is as safe to humans and the environment as conventional canola.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-136

OUTCOME 1: Population Health and Safety

Topic: DEFINITION OF ENVIRONMENT

Written Question on Notice

Senator Cherry asked:

(a) In the definition of Environment in the GT Act, how do you understand the third part of that definition that relates to "the qualities and characteristics of locations, places and areas"?

(b) In the view of the OGTR, are 'qualities and characteristics' purely natural?

(c) If so, how is this part c different from the definitions of environment included in parts (a) and (b)?

Answer:

(a) The Office of the Gene Technology Regulator's "understanding" is that locations, places and areas have certain qualities and characteristics. These qualities and characteristics may be affected by genetically modified organisms which, potentially, could impact on them.

(b) No. Some qualities and characteristics of locations, places and areas will not be purely natural, for example a building at a location or a wheat crop in a field.

(c) Not applicable.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-137

OUTCOME 1: Population Health and Safety

Topic: DEFINITION OF ENVIRONMENT

Written Question on Notice

Senator Cherry asked:

(d) Would you agree that qualities and characteristics might include modifications to the landscape and ecosystems made by the presence of humans?

(e) If no, is there anything in the *Gene Technology Act 2000* that would support that kind of restricted reading?

Answer:

(a) & (b) Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-138

OUTCOME 1: Population Health and Safety

Topic: DEFINITION OF ENVIRONMENT

Written Question on Notice

Senator Cherry asked:

(a) Would you agree that qualities and characteristics might include the particular types of flora and fauna?

(b) Endemic species?

(f) Soil and soil types?

(g) Climate?

(h) Ecosystems?

(i) Threatened species?

Answer:

(d) Yes.

(e) Yes.

(f) Yes.

(g) Yes.

(h) Yes.

(i) Yes, but also note that the answer to part (a) includes <u>all</u> species, irrespective of their conservation status or degree of endemism.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-139

OUTCOME 1: Population Health and Safety

Topic: DEFINITION OF ENVIRONMENT

Written Question on Notice

Senator Cherry asked:

To what extent have you assessed specific qualities and characteristics of places locations and areas?

Answer:

Qualities and characteristics of places, locations and areas are components of the environment and, as such, are considered during the assessment of licence applications. Consistent with the requirements of the *Gene Technology Act 2000*, licence conditions may be imposed to protect human health and safety and the environment. These conditions seek to minimise harm, and do not seek to prevent change.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-140

OUTCOME 1: Population Health and Safety

Topic: DEFINITION OF ENVIRONMENT

Written Question on Notice

Senator Cherry asked:

Can you tell us whether there are any threatened species in the agricultural cropping areas where you have authorised commercial release of a GE plant? (unlikely to know any specifics - the answer is yes in general terms)

Answer:

Cropped fields, irrespective of whether they are planted with genetically modified crops or not, are relatively poor habitats for a majority of species. Threats to the habitat of native species that may occur in cropping regions reflect threats posed by agriculture *per se*, which are beyond the scope of assessments conducted under the *Gene Technology Act 2000.*

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-087

OUTCOME 1: Population Health and Safety

Topic: DEFINITION OF ENVIRONMENT

Written Question on Notice

Senator Cherry asked:

Can you tell us why you did not conduct any special research or commission any studies on the potential impacts of GE crops on those species - including indirect and long term impacts?

Answer:

In answering this question, an assumption has been made that the species to which you refer are the presumed threatened species referenced in Question on Notice number E04-140. As noted in response to that question, agriculture *per se* displaces Australian flora and fauna.

Any decision to issue a licence for a dealing involving the intentional release of a genetically modified organism (GMO) into the environment is based on a risk assessment and risk management plan (RARMP) that is prepared in respect of a proposed dealing. All RARMPs that are prepared by the Office of the Gene Technology Regulator, including for the 'commercial licences' that have been issued to date, rigorously assess the potential for the genetic modification to impact adversely on the environment. Hazards that are assessed in this context include increased weediness of the GMO and the associated potential for displacement of native species, and the potential for the GMO to have toxic effects on non-target species that are greater than those of the parent organism.

The technical methodology for estimating the level of risk associated with hazards such as weediness and toxicity are well-established in the scientific literature. These techniques relate to all biological organisms, not only those that may be threatened or of some other conservation status. It would be inappropriate to limit the risk assessment to impacts on threatened species only.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-088

OUTCOME 1: Population Health and Safety

Topic: HEALTH - SAFETY

Written Question on Notice

Senator Cherry asked:

(a) You have indicated in previous testimony that in relation to safety issues, you believe that the role of the OGTR is limited to investigating matters such as handling and occupational health and safety - not food safety (see CA 110, 5/11/03), is that correct?

(b) That would be because FSANZ is responsible for such matters?

(c) And would you agree that while there is nothing in your Act explicitly limiting your assessment of health and safety, you have tried to limit your assessment to matters not already covered by other agencies?

(d) Would you agree that occupational health and safety is an issue already addressed by OSHA acts in each state? (see below objects clause of NSW OSHA leg eg)

3 Objects

The objects of this Act are as follows:

(a) to secure and promote the health, safety and welfare of people at work, to protect people at a place of work against risks to health or safety
(b) arising out of the activities of persons at work,
(c) to promote a safe and healthy work environment for people at work that protects them from injury and illness and that is adapted to their physiological and psychological needs,
(d) to provide for consultation and co-operation between employers and employees in achieving the objects of this Act,
(e) to ensure that risks to health and safety at a place of work are identified, assessed and eliminated or controlled,
(f) to develop and promote community awareness of occupational health and safety issues,
(g) to provide a legislative framework that allows for progressively higher

standards of occupational health and safety to take account of changes in technology and work practices,

(h) to protect people (whether or not at a place of work) against risks to health and safety arising from the use of plant that affects public safety.

Answer:

(a) The cited Hansard reference (CA 110, 5 November 2003) does not refer to testimony regarding the role of the Office of the Gene Technology Regulator (OGTR) in relation to safety issues. However, it has previously been indicated (see CA 158, 5 November 2003) that the OGTR's role, in relation to health and safety, includes exposure to the genetically modified organism (GMO) through, for example, occupational use.

(b) Yes. The safety of commercially available foods and food products derived from GMOs is the responsibility of Food Standards Australia New Zealand (FSANZ).

(c) The *Gene Technology Act 2000* (the Act) compliments, rather than duplicates, the activities of other regulatory agencies. In this context, the Act requires consultation with key Australian Government agencies, including FSANZ, on licence applications involving an intentional release into the environment (DIR), and on the risk assessment and risk management plans that are prepared in relation to DIR applications.

(d) Yes. In consulting with State and Territory Governments on DIR applications, it would be expected that issues relating to State-based legislation would be raised.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-117

OUTCOME 1: Population Health and Safety

Topic: HEALTH - SAFETY

Written Question on Notice

Senator Cherry asked:

If OSHA legislation is covering occupational health and safety and FSANZ is addressing food safety - can you explain to this committee what is the role of the OGTR in addressing human health and safety issues under the Act?

Answer:

The object of the *Gene Technology Act 2000* (the Act) is to protect human health and safety and the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs). In fulfilling the requirements of the Act, the Gene Technology Regulator liaises closely with a number of regulatory agencies. For example, Food Standards Australia New Zealand, and the National Occupational Health and Safety Commission are consulted twice on each application for a dealing involving the intentional release of a GMO into the environment, before the licence is issued.

In terms of addressing human health and safety issues under the Act, it is significant that occupational exposure and food ingestion are <u>not</u> the only sources of exposure to potential hazards that may be posed by GMOs. For instance, humans have been exposed to genetically modified cholera intentionally, as a vaccination against pathogenic strains of this disease. In this example, exposure is via infection. For such a GMO, the advice of the Therapeutic Goods Administration is sought.

In consulting these agencies, the aim is to identify any risks posed by the GMO that require management actions that are outside the legislative scope of those expert agencies.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-119

OUTCOME 1: Population Health and Safety

Topic: HEALTH - SAFETY

Written Question on Notice

Senator Cherry asked:

(a) In earlier questions, it was pointed out that a number of CSIRO documents express concern at the degree of uncertainty that surrounds a novel biological introduction, such as a GE plant. Dr Lonsdale was cited as saying that unpredictable consequences can occur for a variety of reasons, including the complexity of the systems involved, lag times and cascade effects. Is that also possible with human health?

(b) You have previously testified that the OGTR has commissioned no research into human health effects of GM crops, correct?

(c) When asked, you also indicated you did not know whether FSANZ had conducted or commissioned any such research, correct?

(d) Are you aware of whether there is any monitoring system in place in Australia to determine whether those foods already released into the food chain are having an impact on human health?

Answer:

(a) Both environmental impacts and human health impacts require a thorough and detailed assessment.

(b) Yes, however, in relation to the impacts of genetically modified organisms on human health and safety, we consider the extensive information that exists already, and which is being augmented almost daily. Such information is available from a variety of sources including the peer-reviewed scientific literature, material from Australian Government and international agencies, and data provided by applicants.

(c) Yes.

(d) Yes. Food Standards Australia New Zealand (FSANZ) has supplied the

following answer to this question: “FSANZ maintains a general food safety monitoring and surveillance program. The Modeling, Evaluation and Surveillance Section of FSANZ is responsible for the collection of scientific data related to human nutrition and the evaluation of major changes in food regulatory measures.

In relation to genetically modified (GM) foods, FSANZ has also recently coordinated a survey of compliance with GM labelling requirements with the State and Territory enforcement agencies and the report of this survey is available on the FSANZ website at www.foodstandards.gov.au

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-120

OUTCOME 1: Population Health and Safety

Topic: CROP MANAGEMENT PLANS

Written Question on Notice

Senator Cherry asked:

(a) In previous testimony (CA 107, 5/11/03) you indicated that the crop management plans were confidential on the basis that the companies had requested the plans be deemed commercial in confidence under your legislation. You testified that they "applied for commercial confidential information on aspects of their plan because they had commercial information in them". Was that the basis for you witholding them from the public - that they contained commercial information?

(b) If so, what section of the Act allows you to withhold information on that basis? (likely to use section 185 which allows CiC if (1)(b) the information has commercial value and would, or could reasonably be expected to be destroyed or diminished if the information were disclosed.)

(c) Isn't it correct that the crop management plans (CMPs) are intended for use by farmers?

(d) In other words, then, the CiC claim made by the company could only be in reference to information that might lose commercial value up to the point at which farmers are provided with those plans?

(e) Presumably that would be after approval from the Regulator and before planting?

(f) So, if there were no moratoria in place, we could expect that farmers proposing to plant GE canola would be in receipt of those CMPs now?

(g) Without revealing any secrets, can you confirm to this committee that what was in the CMPs was time sensitive in the manner described above - in other words if it had been released between OGTR approval and commencement of planting the companies involved would have been likely to lose something of commercial value to them?

(h) And are those matters you deemed CiC in those plans still CiC in your view?

Answer:

(a) The crop management plans (CMPs) were required to be declared to be confidential commercial information (CCI) because they met two main criteria. Firstly, they contained information considered to have a commercial or other value that could reasonably be expected to be diminished if it were disclosed. Secondly, the public interest in disclosure of that information did not outweigh the prejudice that the disclosure would cause its owner. In this situation, section 185 of the *Gene Technology Act 2000* (the Act) requires information to be protected by a declaration that it is CCI. The decision to declare information CCI is made independently from the evaluation of an application for a licence. The evaluation of the licences did consider the information contained in the CMPs, but concluded that the CMPs did not impact on the risks to human health, safety and the environment.

(b) Section 187 of the Act generally requires information that has been declared to be CCI to be protected from public disclosure. Disclosure of CCI otherwise than in accordance with section 187 is an offence punishable by up to 2 years imprisonment. See also the answer to (a) above.

(c) Ultimately, yes. However, the original CMPs, in the form in which they were submitted to the Gene Technology Regulator for declaration as CCI, were indicative drafts that always required amendment to incorporate any conditions which may be imposed by the Office of the Gene Technology Regulator, Australian Pesticides and Veterinary Medicines Authority or other agency.

(d) No. There was information in the CMPs declared to be CCI that could reasonably be expected to be diminished when made public, whether by disclosure to farmers prior to planting, or to others who might reasonably be able to use that information, at some other point in time (eg competitors of the applicant).

(e) No. See the answer to (d) above. The value in the CCI could reasonably be expected to be diminished if it were disclosed at any time and not just by disclosure to farmers.

(f) One might expect that the applicant would have a version of the CMPs in place with growers of its product. However, the final CMPs (incorporating any requirements from other agencies) would not necessarily be the same as those submitted to the Gene Technology Regulator and declared to be CCI.

(g) Yes. See the answers to (a) and (d) above.

(h) This would depend on how closely the published version of the CMPs resembled the CMPs submitted to the Gene Technology Regulator for protection as CCI. See the answer to (f) above. The applicant has since finalised the CMPs. The final CMPs have not been compared with the CMPs that were submitted for consideration as CCI. Information in the CMPs that has been released by the applicant is no longer CCI and those interested may wish to request copies of the final CMPs from the companies involved.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-298

OUTCOME 1: Population Health and Safety

Topic: IRRADIATED PRODUCTS CONSUMED BY HUMANS

Written Question on Notice

Senator Cherry asked:

(a) What products that humans consume/ingest are being treated with irradiation? And for what reason are they being irradiated?

(b) Which of these products are currently labelled as irradiated?

(c) Why are some products which are irradiated allowed to be marketed without being labelled?

(d) How does Food Standards Australia New Zealand (FSANZ) justify requiring labelling on some products and not others?

Answer:

(a) Herbs and spices have permissions to be irradiated for the purposes of decontamination. Herbal infusions – fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, excluding tea can be irradiated for the purposes of controlling sprouting and pest disinfestation, including control of weeds. The following tropical fruits may only be irradiated for the purposes of pest disinfestation for a phytosanitary objective:

Bread fruit
Carambola
Custard apple
Longan
Litchi
Mango
Mangosteen
Papaya (Paw paw)
Rambutan

(b) Standard 1.5.3 - Irradiation of Food requires that all irradiated food be labelled, and all packaged food containing an irradiated ingredient or component be labelled, irrespective of how minor. Food not required to bear a label (eg unpackaged food) must have displayed with it a statement that the food ingredient or component has been treated with ionising radiation.

(c) FSANZ is unaware that there are products being irradiated which are not being labelled; however this is an issue for enforcement agencies.

(d) Standard 1.5.3 requires that all irradiated food to be labelled as described in (b).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-299

OUTCOME 1: Population Health and Safety

Topic: HOSPITAL FOOD

Written Question on Notice

Senator Cherry asked:

(a) Is/Are any hospital food/meals being irradiated in Australia?

(b) If yes, what food/meals are being irradiated?

(c) Why are these foods being irradiated?

(d) What are the alternatives to irradiating these foods?

(e) Is the food labelled irradiated?

(f) Are the consumers/patients informed that their meals are being irradiated?

Answer:

Food Standards Australia New Zealand is not aware of hospital/food meals currently being irradiated.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-300

OUTCOME 1: Population Health and Safety

Topic: MILITARY FOOD

Written Question on Notice

Senator Cherry asked:

(a) Is any food consumed by the Australian or New Zealand military irradiated?

(b) If so, which foods are being irradiated?

(c) Why are these foods being irradiated?

(d) What are the alternatives to irradiating these foods?

(e) Are the consumers of the food informed that the food is irradiated?

Answer:

Food Standards Australia New Zealand is not aware of any food consumed by the Australian or New Zealand military being irradiated.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-301

OUTCOME 1: Population Health and Safety

Topic: THERAPEUTIC PRODUCTS

Written Question on Notice

Senator Cherry asked:

What is the "food-drug interface"?

Answer:

Foods and therapeutic goods are regulated separately in Australia. Foods are regulated under the Australia New Zealand *Food Standards Code* (the Code), while therapeutic goods are regulated under the *Therapeutic Goods Act 1989* (TGAct). Unlike other countries, there is not currently any regulation of dietary supplements as a distinct category in Australia.

Products that are manufactured to dietary supplement regulations in other countries often present at the interface between foods and therapeutic goods in Australia. Some products have characteristics of both foods and therapeutic goods, which places them at the interface between regulation. Ingredients in foods may also be designated active ingredients in therapeutic goods (eg vitamins and minerals, creatine) or generally recognised foods could be presented in a therapeutic form (eg powdered and encapsulated carrot). Particular ingredients of interest at the interface include non-culinary herbs, plant extracts and other bioactive substances.

Consumers, organisations/companies, health departments and the Australian Quarantine and Inspection Service may refer products to Food Standard Australia New Zealand or the Therapeutic Goods Administration for clarification on their regulatory status.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-302

OUTCOME 1: Population Health and Safety

Topic: THERAPEUTIC PRODUCTS (NOT LABELLED AS FOOD)

Written Question on Notice

Senator Cherry asked:

Who is responsible for determining whether a product is a food or therapeutic good?

Answer:

An inter-agency foods-therapeutic goods interface group, comprising members from Food Standards Australia New Zealand, the Therapeutic Goods Administration (TGA), and the Australian Quarantine and Inspection Service (AQIS) meets to consider products for which the regulatory status is unclear. Products are considered on a case-by-case basis and the group meets as required, approximately every 3 months. The group provides advice on the appropriate regulatory status of the product. This advice is communicated to senior food officers in Australian State and Territory jurisdictions, AQIS and New Zealand who are responsible for enforcing the Australia New Zealand Food Standards Code (the Code); and the enforcement arm of the TGA. Ultimately, it is the decision of the enforcement agencies to determine, based on the advice provided by the inter-agency interface group, whether a particular product should be covered by either the Code or the *Therapeutic Goods Act 1989*.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-303

OUTCOME 1: Population Health and Safety

Topic: THERAPEUTIC PRODUCTS (NOT LABELLED AS FOOD)

Written Question on Notice

Senator Cherry asked:

What is the distinction between a food and a therapeutic good?

Answer:

The distinction between a food and a therapeutic good is often difficult to make. The *Therapeutic Goods Act 1989* (TGAct) and the Australia New Zealand Food Standards Code are used to clarify the regulatory status of a product at the interface. A number of factors are taken into account when providing advice on products including the: presentation of the product (eg whether it is likely to be taken for therapeutic use); physical form (eg capsule, powder, liquid); composition; and labelling.

Declarations may be made under section 7 of the TGAct that a particular good or class of goods is or is not a therapeutic good. Section 7 declarations are made to provide greater clarity for consumers, the food and medicines industries and regulators in determining whether a product is a food or a therapeutic good.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-304

OUTCOME 1: Population Health and Safety

Topic: 'THERAPEUTIC PRODUCTS' (NOT LABELLED AS FOOD)

Written Question on Notice

Senator Cherry asked:

(a) How can consumers know whether a therapeutic product they consume (that is ingested by humans) is irradiated or not?

(b) Why are therapeutic products being irradiated without being labelled?

Answer:

(a) & (b)

The use of irradiation during the manufacture of therapeutic products is an internationally accepted practice. Irradiation may be used for the reduction of microbial contamination and for the decontamination and sterilisation of starting materials, packaging components and products.

All therapeutic goods must be manufactured by licensed manufacturers in accordance with the Code of Good Manufacturing Practice (GMP). If a decontaminating treatment, such as irradiation, has been used in the manufacture of a therapeutic good, the sponsor of the product must be able to demonstrate that the process is effective, that the product is safe for its intended purpose, and that the product has been manufactured in accordance with the Code of GMP to ensure its quality. Consistent with GMP, the minimum amount of irradiation necessary to produce the desired effect must be used.

Therapeutic goods legislation requires that the label on a therapeutic good provides adequate information to enable the safe and effective use of the product, including the name and amount of the active ingredient(s), directions for use and required warning statements. There is no labelling requirement for irradiation steps used in the manufacture of therapeutic goods.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-305

OUTCOME 1: Population Health and Safety

Topic: 'THERAPEUTIC PRODUCTS' (NOT LABELLED AS FOOD)

Written Question on Notice

Senator Cherry asked:

(a) Why are some irradiated herbal teas allowed to be marketed without being labelled "irradiated"? It has been confirmed, by Australian herbal tea manufacturer Hilde Hemmes, that some of their herbal teas which are marketed as "Therapeutic Quality" are irradiated though they are not labelled as irradiated. Other herbal teas from the same company which are marketed as "Superior Quality" are.

(b) How is the consumer to know whether "Therapeutic Quality" herbal teas have been irradiated?

(c) Why does FSANZ not require the labelling of these products - which to the consumers eye are packaged almost identically?

Answer:

(a)-(c)

Herbal teas may be regulated as foods or therapeutic goods, depending on the claims that are made for them. The Therapeutic Goods Administration (TGA) is responsible for the regulation of therapeutic goods, including herbal remedies, pharmaceuticals, and other therapeutic products. Food Standards Australia New Zealand (FSANZ) is responsible for food standards. Unlike foods, therapeutic goods must be manufactured under rigorously controlled conditions and manufacturers must be approved by the TGA for all steps in their manufacture, including irradiation.

The use of irradiation during the manufacture of therapeutic products is an internationally accepted practice. Irradiation may be used for the reduction of microbial contamination and for the decontamination and sterilisation of starting materials, packaging components and products.

All therapeutic goods must be manufactured by licensed manufacturers in accordance with the Code of Good Manufacturing Practice (GMP). If a decontaminating treatment, such as irradiation, has been used in the manufacture of a therapeutic good, the sponsor of the product must be able to demonstrate that the process is effective, that the product is safe for its intended purpose, and that the product has been manufactured in accordance with the Code of GMP to ensure its quality. Consistent with GMP, the minimum amount of irradiation necessary to produce the desired effect must be used.

Therapeutic goods legislation requires that the label of a therapeutic good provides adequate information to ensure the safe and effective use of the product, including the name and amount of the active ingredient(s), directions for use and required warning statements. There is no labelling requirement for irradiation steps used in the manufacture of therapeutic goods.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-306

OUTCOME 1: Population Health and Safety

Topic: 'THERAPEUTIC PRODUCTS' (NOT LABELLED AS FOOD)

Written Question on Notice

Senator Cherry asked:

(a) What herbal remedies, therapeutic products, and pharmaceuticals are currently being irradiated in Australia and New Zealand?

(b) What herbal remedies, therapeutic products, and pharmaceuticals are approved for irradiation in Australia and New Zealand?

Answer:

(a) & (b)

The use of irradiation during the manufacture of therapeutic products is an internationally accepted practice. Irradiation may be used for the reduction of microbial contamination and for the decontamination and sterilisation of starting materials, packaging components and products.

All therapeutic goods must be manufactured by licensed manufacturers in accordance with the Code of Good Manufacturing Practice (GMP). If a decontaminating treatment, such as irradiation, has been used in the manufacture of a therapeutic good, the sponsor of the product must be able to demonstrate that the process is effective, that the product is safe for its intended purpose, and that the product has been manufactured in accordance with the Code of GMP to ensure its quality. Consistent with GMP, the minimum amount of irradiation necessary to produce the desired effect must be used.

For some herbal products, irradiation is the preferred method for reducing microbial contamination, as some other methods, such as moist heat or chemical sterilisation, may reduce or destroy the activity of the product's active ingredients, thereby reducing its effectiveness.

Although the Therapeutic Goods Administration (TGA) is able to provide a consolidated list of sterile products, it is unable to provide a list of products that have been sterilised by irradiation.

The TGA is not in a position to provide information about products being supplied in New Zealand as this falls outside its current jurisdiction.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-307

OUTCOME 1: Population Health and Safety

Topic: 'THERAPEUTIC PRODUCTS' (NOT LABELLED AS FOOD)

Written Question on Notice

Senator Cherry asked:

What has FSANZ done to inform the public that herbal remedies, therapeutic products, and pharmaceuticals are being irradiated?

Answer:

The Therapeutic Goods Administration (TGA) is responsible for the regulation of therapeutic goods, including herbal remedies, pharmaceuticals, and other therapeutic products. Food Standards Australia New Zealand (FSANZ) is responsible for food standards.

The use of irradiation during the manufacture of therapeutic products is an internationally accepted practice. Irradiation may be used for the reduction of microbial contamination and for the decontamination and sterilisation of starting materials, packaging components and products.

For some herbal products, irradiation is the preferred method for reducing microbial contamination, as some other methods, such as moist heat or chemical sterilisation, may reduce or destroy the activity of the product's active ingredients, thereby reducing its effectiveness.

Therapeutic goods legislation requires that the label on a therapeutic good provides adequate information to enable the safe and effective use of the product, including the name and amount of the active ingredient(s), directions for use and required warning statements. There is no labelling requirement for irradiation steps used in the manufacture of therapeutic goods.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-308

OUTCOME 1: Population Health and Safety

Topic: 'THERAPEUTIC PRODUCTS' (NOT LABELLED AS FOOD)

Written question.

Senator Cherry asked:

When did the irradiation of therapeutic products, herbal remedies and pharmaceuticals begin in Australia and New Zealand?

Answer:

Irradiation is a widely used procedure and has been used in the manufacture of certain therapeutic goods since before the introduction of Therapeutic Goods Legislation in 1991. The Therapeutic Goods Administration is not in a position to comment on products supplied in New Zealand as this falls outside its current jurisdiction.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-309

OUTCOME 1: Population Health and Safety

Topic: 'THERAPEUTIC PRODUCTS' (NOT LABELLED AS FOOD)

Written Question on Notice

Senator Cherry asked:

What are the approval or licensing requirements for the irradiation of therapeutic products, herbal remedies and pharmaceuticals in Australia and New Zealand.

Answer:

The use of irradiation during the manufacture of therapeutic products is an internationally accepted practice. Irradiation may be used for the reduction of microbial contamination and for the decontamination and sterilisation of starting materials, packaging components and products.

The Therapeutic Goods Administration (TGA) has adopted European Union Medicinal Guideline 3AQ4a – *The Use of Ionising Radiation in the Manufacture of Medicinal Products*. This document provides detailed information about the requirements for irradiation of medicinal products. A copy of this document has been provided (Attachment 1).

All therapeutic goods must be manufactured by licensed manufacturers in accordance with the Code of Good Manufacturing Practice (GMP). If a decontaminating treatment, such as irradiation, has been used in the manufacture of a therapeutic good, the sponsor of the product must be able to demonstrate that the process is effective, that the product is safe for its intended purpose, and that the product has been manufactured in accordance with the Code of GMP to ensure its quality. Consistent with GMP, the minimum amount of irradiation necessary to produce the desired effect must be used.

For some herbal products, irradiation is the preferred method for reducing microbial contamination, as some other methods, such as moist heat or chemical sterilisation, may reduce or destroy the activity of the product's active ingredients, thereby reducing its effectiveness.

The TGA is not in a position to provide advice as to the approval or licensing requirements for the irradiation of therapeutic products, herbal remedies and pharmaceuticals in New Zealand, as this falls outside of its current jurisdiction.

**Guideline Title The use of Ionising Radiation in the Manufacture of Medicinal Products**
**Legislative basis Directive 75/318/EEC as amended**
**Date of first adoption December 1991**
**Date of entry into force July 1992**
**Status Last revised December 1991**
**Previous titles/other references None/III/9109/90**
**Additional Notes This note for guidance deals with the use of ionising radiation in the manufacture of medicinal products. It should be read in conjunction with Volume IV of "The Rules Governing Medicinal Products in the European Union", particularly the annex on ionising radiation.**





## 1. INTRODUCTION

This note for guidance is intended for applicants wishing to use ionising radiation in the manufacture of medicinal products. Irradiation may be used for microbial decontamination, sterilisation or other treatments. Different materials or products may be irradiated: starting materials, packaging materials, intermediate products, bulk products and finished products. Information should be given in sufficient detail to enable the competent authority to evaluate whether or not the manufacturing subprocess is effective and the product is safe for the patient.

Manufacturers using ionising radiation in the manufacture of medicinal products should refer to the Guide to Good Manufacturing Practice (Volume IV of "*The Rules Governing Medicinal Products in the European Union*") and in particular to the annex on ionising radiation used in the manufacture of medicinal products and, where relevant, to the annex on manufacture of sterile medicinal products.

## 2. ADMINISTRATIVE DATA

a) The name and description of the product (including its packaging material) to be irradiated should be given. Its shape, size and composition (type and quantity of substances) should be described in detail. Furthermore, it should be made clear whether starting materials, packaging materials, intermediate products, bulk products or the finished product are irradiated. Sizes of production batches and of irradiation batches should be defined. In the case of a continuous process, a batch comprises all the units processed in a given period of time.

b) The purpose of the irradiation should be stated. Both the minimum dose to achieve this purpose and the maximum permissible dose should be stated.

c ) In addition to the names and addresses of all manufacturers involved in the manufacture of the product, the name and address of the irradiation plant should be

given, making clear which operations are to be conducted at which site.
d) A copy of the authorisation referred to in Directive 75/319/EEC as amended and covering the irradiation plant should be attached to the application.

## 3. MANUFACTURING PROCESS

Irradiation of a medicinal product is part of its manufacturing process and the description of that part of processing should be sufficiently detailed. The application should include the following information:



### 3.1 Description of the irradiation plant

a) Type (radionuclide source, electron generator) and builder of the plant;
b) working mode (batch- or continuous mode);
c ) authorised and actual activity of the radionuclide in the radiation source (GBq), or the maximum and minimum electron energy (MeV) of the generator as appropriate;
d) concise description of the plant including drawings, showing clearly the course of the product within the plant, the position and geometry of the irradiation source and the conveyor system including the source pass mechanism.

### 3.2 Description of the irradiation process

a) a description of the material to be irradiated should be given, including limits (if any) on bioburden and any process aimed to limit or control the bioburden. Action to be taken when particular bioburden limits are exceeded should be stated;
b) the number and positions of the irradiation containers in relation to the position of the source during the whole dwelling time, and the method of moving them through the chamber, should be described;
c ) the material and dimensions of the irradiation container should be described;
d) the maximum total irradiation time and the maximum dwelling time of the product i n the irradiation chamber should be stated;
e) results of dose mapping studies using a “dummy product” are required;
f ) the loading pattern of the product must be stated for each irradiation container. If the load consists of mixed products, the composition of the load must be described including their stated position in the irradiation container. The mean density of the load and the acceptable maximum density should be given. A modification of the loading pattern may be acceptable provided a new dose mapping is performed, showing that the stated minimum and maximum doses are not exceeded;
g) when the loading pattern of the product within the irradiation container has been defined, dose mapping should be performed with a sufficient number of appropriate dosimeters to show the distribution of the absorbed dose within the loaded irradiation container and to show the places of minimum and maximum doses. This dose mapping should be carried out for a representative number of irradiation containers to determine the variability of the absorbed dose in the load of one container and the differences between several containers.
Note: Separate dose mapping exercises should be carried out for each product or distinct category of products and each pathway to be used for processing products.
h) a written standard operating procedure should be established including the following minimum items:
– the loading pattern of product(s) within the irradiation container;
– the type, number and location of routine dosimeters within one irradiation batch or within a stated period of time in the case of a continuous process;

– any adjustments to be applied to the routine dosimeter measurements to convert them into the absorbed dose at both minimum and maximum positions;
– the stated minimum and maximum absorbed dose including experimentally determined errors of dosimeters;
– whether or not repeated treatment is acceptable; for the product concerned, the circumstances in which such repeated treatment is allowed, and the number of occasions on which it is allowed for a particular batch;
– in the case of electron beam irradiators electron energy, average beam current, beam width and conveyor speed should be stated with acceptable limits.
Note: The stated minimum dose is that required for the intended purpose, the stated maximum dose is limited by unacceptable changes induced by irradiation in the product and/or the packaging, or imposed by official restrictions.
A minimum absorbed dose of 25 kGy may be regarded as adequate for the purpose of sterilising pharmaceutical components or products which have a low initial bioburden and no radioresistant spores. Other doses may be used provided that a biological validation has been performed.

## 4. VALIDATION OF THE IRRADIATION PROCEDURE

### 4.1 Validation with regard to the irradiation procedure and dose

a) with electron irradiation, if the maximum electron energy exceeds 10 MeV, it should be demonstrated that no radionuclides develop in the product;
b) information derived from experimental investigations into the acceptable variation i n the loading pattern should be given;
c ) information should be included on the errors due to the type of dosimeters used and on the influence of their position;
d) information on the relationship between the absorbed doses in the extreme positions within the load and the positions of routine dosimeters should be given.

### 4.2 Validation with regard to the purpose of irradiation (see section 2.b)

For reduction of bioburden and/or sterilisation:
a) Where appropriate, information on the bioburden of the product before irradiation should be given with data from several batches to show the usual bioburden levels and types of organisms usually present;
b) data on the reduction of bioburden during the irradiation with different doses, including the minimum dose, should be given for at least 2 batches;
c ) an inactivation curve derived from the above data should be submitted. If the test specimen itself has a low bioburden, it should be artificially contaminated with > 107 cfu/single unit preferably with a microorganism originally occurring in the product and with a minimum D-Value of 3 kGy;



d) the bioburden limit on the product prior to irradiation should be based on data derived from a) – c).
In other cases, experimental results should show that the purpose of irradiation has been achieved.

### 4.3 Validation with regard to the quality of the product

a) Information should be given about any qualitative and quantitative changes in the product, including its packaging, as a result of irradiation;
Note: Methods used for quantitative determinations should be validated i n accordance with the note for guidance *Validation of Analytical Procedures: Methodology*.

b) Information should be given about the formation of radiolysis products or other

degradation or interaction products. Whenever possible, the radiolysis products should be identified;
c ) the results of the studies carried out with high doses of radiation to determine the maximum dose should be given;
d) as assessment of the significance of any observed changes should be included;
e) information should be given about the effect of irradiation on the stability of the product and therefore stability studies should be performed on products which have received the maximum absorbed dose.
Note: The relevance of any changes in the product induced by irradiation as regards quality of the product as well as health and safety of the patient should be discussed. The toxicological risks caused by products of irradiation (see section 3.3.b) should be evaluated. Safety of the irradiated product for the patient should be discussed in the expert report.

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# GLOSSARY

***Absorbed Dose***
The quantity of radiation energy imparted per unit mass of material. The unit of absorbed dose is the Gray (Gy) where 1 Gray is equivalent to absorption of 1 Joule per kilogram (J.kg-1).

***Batch***
A defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.
Note: To complete certain stages of manufacture, it may be necessary to divide a batch into a number of subbatches, which are later brought together to form a final homogeneous batch. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterised by its intended homogeneity.
For control of the finished product, the following definition has been given in Directive 75/318/EEC as amended: 'For the control of the finished product, a batch of a proprietary medicinal product comprises all the units of a pharmaceutical form which are made from the same initial mass of material and have undergone a single series of manufacturing operations or a single sterilisation operation or, in the case of a continuous production process, all the units manufactured in a given period of time'.

***Bioburden***
The total number of all viable aerobic bacteria, yeasts and moulds expressed as colony forming units (cfu) per unit or gram of product.

***Bulk Product***
Any product which has completed all processing stages up to, but not including, final packaging.

***Dose Mapping***
An exercise conducted within the irradiation equipment to determine the distribution of absorbed dose throughout a load of product or simulated product of specified density ("dummy product") arranged in the irradiation container in a defined configuration.

***Dosimeter***
A device or system having a reproducible measurable response to radiation, which can be used to measure the absorbed dose in a given material.

***Dummy Product***
Homogeneous material of known density for filling the irradiation container for the purpose of carrying out dose distribution experiments with ionising radiation.

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***Finished Product***
A medicinal product which has undergone all stages of production including packaging.

***Intermediate Product***
Partly processed material which must undergo further manufacturing steps before it becomes

a bulk product.

***Irradiation Container***

The outermost container in which the products are irradiated.

***Packaging Material***

Any material employed in the packaging of a product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

***Starting Material***

Any substance used in the production of a product, but excluding packaging materials.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-310

OUTCOME 1: Population Health and Safety

Topic: 'THERAPEUTIC PRODUCTS' (NOT LABELLED AS FOOD)

Written question.

Senator Cherry asked:

What, if any, herbal remedies, therapeutic products, and pharmaceuticals have been irradiated in the past but are no longer irradiated (or approved for irradiation)? If any, what has lead [sic] to the change in these products status or approval?

Answer:

The Therapeutic Goods Administration is unable to provide a consolidated list of products that have been irradiated in the past but which are no longer irradiated, as it does not hold this information in its records.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-311

OUTCOME 1: Population Health and Safety

Topic: IRRADIATED MEAT ANIMALS

Written Question on Notice

Senator Cherry asked:

(a) Steritech, Australia's only commercial irradiation company, markets itself as a place to irradiate cereals and grains. What cereals, grains and animal feed are currently being irradiated in Australia? Why are they being irradiated? What are these cereals and grains used for? Who consumes these cereals and grains?

(b) How can Food Standards Australia New Zealand (FSANZ) assure Australian and New Zealand consumers that irradiated grain fed to meat animals does not change the quality and safety of the meat?

(c) What studies have been done on the effects of eating meat from animals that have been fed irradiated grain? If any, what were the results and conclusions of these studies?

(d) What effect does eating irradiated food have on the health of the animal eating it?

Answer:

(a) There is no approval in the Code to irradiate cereals or grains for human consumption.

(b)-(d)
FSANZ does not regulate animal feed and cannot comment on animal health effects.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-312

OUTCOME 1: Population Health and Safety

Topic: BEE HIVES

Written Question on Notice

Senator Cherry asked:

Bee hives for honey are also being irradiated in Australia. What studies have been done to show the effects of irradiation on honey produced in irradiated beehives?

Answer:

Food Standards Australia New Zealand (FSANZ) is unaware that beehives are being irradiated. Honey is not approved in the Code to be irradiated. Therefore, the safety and technological need to irradiate honey has not been assessed by FSANZ.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-313

OUTCOME 1: Population Health and Safety

Topic: PET FOOD

Written Question on Notice

Senator Cherry asked:

(a) Steritech is currently promoting itself as a place to irradiate Pet Food. The scientific studies proving irradiation's negative health impacts were mostly carried out on animals. Does Food Standards Australia New Zealand (FSANZ) consider it ethical to feed irradiated food to non-human animals?

(b) Which government department/s is/are responsible for approving the irradiation of pet food?

(c) What are the labelling requirements for irradiated pet food?

(d) What are the justifications for the irradiation of pet food? If any, what are the alternatives.

(e) Does FSANZ believe that pet owners/carers have the right to know whether their pet's food has been irradiated or not?

(f) How can pet owners know if their pet food has been irradiated?

Answer:

(a) FSANZ does not regulate pet food and cannot comment on this point.
(b) FSANZ is not aware of any Department that approves irradiation of pet foods.
(c) FSANZ does not regulate pet food and cannot comment on this point.
(d) FSANZ does not regulate pet food and cannot comment on this point.
(e) FSANZ does not regulate pet food and cannot comment on this point.
(f) FSANZ does not regulate pet food and cannot comment on this point.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-314

OUTCOME 1: Population Health and Safety

Topic: FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ) APPROVAL PROCEDURE

Written Question on Notice

Senator Cherry asked:

Why did you approve the irradiation of breadfruit, carambola, custard apple, lychee, longan, mangosteen, paw paw and rambutan when the only scientific study on the effects of irradiation reviewed by FSANZ in the assessment report (A443) was on mangoes?

Answer:

The safety of irradiated food has been examined through numerous animal and human feeding studies performed over a number of years. Various expert committees have assessed the results of these studies in order to examine whether there are any toxicological concerns following consumption of irradiated foods. These studies have provided no evidence that irradiated foods, in particular, irradiated tropical fruits in the diet leads to toxicological concerns.

Animal and human feeding studies have not been conducted on every possible food. However, studies on a wide range of foods have established that foods of similar class and composition react similarly following irradiation. Therefore, the results of studies on a particular class of food can be extrapolated to others. This concept is termed chemiclearance. Therefore, foods that are similar in their chemical makeup to others which have already previously undergone an extensive safety evaluation can be approved for food use without the necessity to undertake a further safety evaluation. Therefore, the results from other fruits that have been irradiated (eg oranges, strawberries, and peaches) in addition to mangoes supported the safety of any fruit as a class. The concept of chemiclearance and the full FSANZ safety assessment was thoroughly detailed in the Final Assessment Report for Application A443-Irradiation of tropical Fruits.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-315

OUTCOME 1: Population Health and Safety

Topic: FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ) APPROVAL PROCEDURE

Written Question on Notice

Senator Cherry asked:

All of the studies referenced in FSANZ's latest assessment report are derived from the World Health Organisation (WHO) reports, and 21 out of the 22 studies cited were conducted BEFORE 1982, and only one in 1990. Given that the moratorium on food irradiation in 1989 was the direct result of this Parliamentary Committee investigation, how does FSANZ explain that it has effectively used out of date and inadequate information to approve irradiation?

Answer:

FSANZ does not feel that because past safety studies were conducted before a specific date (eg 1982) that this negates the conclusions, as they conformed to general toxicological testing requirements. Overall, FSANZ concluded that there were no toxicological concerns following irradiation of tropical fruits. By virtue of the concept of chemiclearance and the past safety studies performed on fruits (including tropical fruits) irradiated food was considered equivalent to non-irradiated food or fruits that have been treated with more conventional treatment protocols (eg heating for quarantine purposes) with respect to safety, nutritional properties and wholesomeness. FSANZ also noted that previous Expert Committees had examined the issue of the safety of irradiated foods (which included all the studies before 1982) on numerous occasions including the most recent report from the World Health Organisation (WHO) in 1999, which verified the safety of irradiated foods at high doses. The WHO considered these studies appropriate to ascertain the safety of irradiated foods.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-316

OUTCOME 1: Population Health and Safety

Topic: FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ) APPROVAL PROCEDURE

Written Question on Notice

Senator Cherry asked:

Why aren't FSANZ conducting or commissioning independent studies of the effects of consuming irradiated food?

Answer:

Past Expert Committees previously evaluated independent studies performed to assess the safety of irradiated foods at different doses. In addition, FSANZ evaluated recent available studies on the safety of irradiated foods, which were detailed in the Final Assessment reports for Applications A413 and A443. A large number of toxicological studies did not demonstrate any short-term or long-term toxicity related to the irradiation process.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-317

OUTCOME 1: Population Health and Safety

Topic: FSANZ APPROVAL PROCEDURE

Written Question on Notice

Senator Cherry asked:

Why did FSANZ give approval for Steritech to irradiate herbs and spices up to 30kGy when at the time the Codex limit was 10kGy? Application A413 approved September 2001. Codex Case-by-Case Diamond modelling Submissions opposing – vast majority – industry based.

Answer:

Based on the scientific evidence, the use of 30kGy to decontaminate herbs and spices is safe. Some countries currently permit the irradiation of herbs and spices for microbial control up to a maximum dose of 30kGy, including the US, Argentina and Croatia.

The reason for approving a maximum dose of 30kGy for herbs and spices is that some herbs and spices can be so heavily contaminated with micro-organisms that a dose of between 3kGy to 30kGy is required to ensure food safety. Previously, there have been concerns that the maximum dose of 10kGy may not be efficacious in reducing microbial numbers

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-318

OUTCOME 1: Population Health and Safety

Topic: FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ) APPROVAL PROCEDURE

Written Question on Notice

Senator Cherry asked:

What are FSANZ's reasons for approving the irradiation of tropical fruit, almost immediately after the European Union placed a halt on any further irradiation approvals?

Answer:

FSANZ undertook a rigorous independent assessment of Application A443 (Irradiation of Tropical Fruits) to ensure the safety and technological need for the use of irradiation on specific tropical fruits. FSANZ was satisfied from the scientific data and assessment that there were no public health and safety concerns and that an appropriate technological reason existed to irradiate tropical fruits. FSANZ is an independent organisation and makes its assessment based on the available evidence under its statutory requirements (noting and considering other international regulations) but is not bound to incorporate or emulate the regulations of any particular regulatory Authority. It is notable that many countries approve the irradiation of tropical fruits.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-319

OUTCOME 1: Population Health and Safety

Topic: FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ) APPROVAL PROCEDURE

Written Question on Notice

Senator Cherry asked:

What is FSANZ's response to European Union recent independent research finding irradiation to lead to health risks?

Answer:

The European concerns relate to the production of possibly unique chemical products produced following irradiation of specific foods at high doses (eg irradiation of high fat-containing foods may lead to the formation of chemicals referred to as cyclobutanones). However, FSANZ thoroughly investigated these studies in Applications A413 and A443 and concluded that there are no toxicological concerns resulting from the possible formation of new chemical products following irradiation of herbs, spices, herbal infusions and tropical fruits.

FSANZ has not received any applications seeking permission to irradiate foods that may contain high fat levels. The risk from dietary exposure to cyclobutanoes is not present in the currently approved foods, as tropical fruits, herbs, spices and herbal infusions contain virtually no fat.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-320

OUTCOME 1: Population Health and Safety

Topic: FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ) APPROVAL PROCEDURE

Written Question on Notice

Senator Cherry asked:

What products are likely to be considered for approval in Australia and New Zealand in the near future?

Answer:

FSANZ is not aware of any new applications seeking permission to irradiate foods.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-321

OUTCOME 1: Population Health and Safety

Topic: FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ) APPROVAL PROCEDURE

Written Question on Notice

Senator Cherry asked:

How did Australian state and territory ministers vote on the amendments to Standard A17, and irradiation applications A413 and A443?

Answer:

Australian State & Territory Ministers were in support of approval of Standard A17 (now Standard 1.5.3) and both irradiation Applications (A413 and A443) and no amendments were made or requested.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-322

OUTCOME 1: Population Health and Safety

Topic: FSANZ APPROVAL PROCEDURE

Senator Cherry asked:

How did the New Zealand minister vote on the amendments to Standard A17, and irradiation applications A413 and A443?

Answer:

Food Standards Australia New Zealand cannot give out advice on how individual members of the Ministerial Council vote.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-323

OUTCOME 1: Population Health and Safety

Topic: FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ) APPROVAL PROCEDURE

Written Question on Notice

Senator Cherry asked:

The Federal Senate has passed a motion calling for no further approvals without further research. Has FSANZ conducted any further research on food irradiation? If so, what are the findings?

Answer:

FSANZ has conducted no further research on food irradiation as no new applications have been received requesting permission to irradiate other foods.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-324

OUTCOME 1: Population Health and Safety

Topic: HEALTH EFFECTS OF CONSUMING IRRADIATED FOOD

Written Question on Notice

Senator Cherry asked:

(a) Why does Food Standards Australia New Zealand (FSANZ) support food irradiation when numerous studies since the 1950s clearly show negative health effects such as premature death, mutations and other genetic abnormalities, foetal death and other reproductive problems, immune system disorder, fatal internal bleeding, organ damage, tumours, stunted growth and nutritional deficiencies. (Refer to attached Atomic Café document for details on scientific studies)

(b) What evidence shows that the food is never radioactive once irradiated?

Answer:

(a) FSANZ was aware that there were previous adverse findings in some animal studies. These studies were addressed in the World Health Organisation (WHO) (1994) and more recently the WHO (1999) evaluations of the safety of irradiated foods. Toxicological studies have been carried out on a large number of individual foods and although there were studies that purported to show adverse effects, they were not considered scientifically sound for various reasons (such as lack of repeatability, design flaws etc).

The available studies assessed by FSANZ on the currently approved foods, indicated that there were no toxicological concerns and no compounds formed following irradiation that are likely to cause public health and safety concerns.

(b) No measurable radioactivity is induced in foods as the sources of radiation and their energy levels are regulated and controlled and the food itself never comes into direct contact with the radiation source (WHO, 1994). Standard 1.5.3 sets maximum 'energy' limits of 5 megaelectronvolts for X rays and 10 megaelectronvolts for electron beam technology to comply with these international standards. No radioactivity has been induced in foods treated with doses up to 50 kGy (absorbed dose).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-325

OUTCOME 1: Population Health and Safety

Topic: LABELLING

Written Question on Notice

Senator Cherry asked:

(a) How will loose fruit be labelled? The final assessment of Application A443 leaves the labelling requirement, if any, unclear.

(b) How can Food Standards Australia New Zealand (FSANZ) guarantee that producers of loose fruit and other products will label their irradiated products?

(c) How can FSANZ guarantee that retailers will inform the public that loosely irradiated products have been irradiated?

Answer:

(a) Food not required to bear a label eg unpackaged food, must have displayed with it a statement that the food ingredient or component has been treated with ionising radiation.

(b) & (c)
Under the labelling provisions of Standard 1.5.3-Food Irradiation, loose fruit is required to have displayed in close proximity to the fruit that it has been irradiated. This is a mandatory requirement in Standard 1.5.3 and is an enforcement issue for State/Territory/NZ Health Departments and the Australian Quarantine and Inspection Service.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-326

OUTCOME 1: Population Health and Safety

Topic: LABELLING

Written Question on Notice

Senator Cherry asked:

What penalties will be put in place for producers, importer, and retailers who do not adequately label or place signage by irradiated products?

Answer:

Labelling of irradiated foods is a mandatory requirement in Standard 1.5.3 and is an enforcement issue for State/Territory/NZ Health Departments and the Australian Quarantine and Inspection Service. Those regulatory agencies would decide the penalties.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-327

OUTCOME 1: Population Health and Safety

Topic: LABELLING

Written Question on Notice

Senator Cherry asked:

Is FSANZ aware that Surebeam has a filed complaint regarding labelling in the United States?

Answer:

Food Standards Australia New Zealand (FSANZ) is aware that a lobby group named Public Citizen and the Centre for Food Safety filed a false advertising complaint with the Federal Trade Commission against Surebeam. Surebeam had requested permission from the United States Food and Drug Administration to label irradiated foods as 'treated by electronic pasteurisation' or 'cold pasteurised' but permission was not granted.

A declaration that a food had been subject to 'electronic pasteurisation' would not comply with the requirements of Standard 1.5.3 of the Australia New Zealand Food Standards Code.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-328

OUTCOME 1: Population Health and Safety

Topic: LABELLING

Written Question on Notice

Senator Cherry asked:

Is Food Standards Australia New Zealand (FSANZ) concerned that Steritech opposes the labelling of irradiated food?

Answer:

As an independent regulatory agency, it is not the role of FSANZ to engage in a subjective judgement of attitudes of specific applicants when an application is made to amend the Food Standards Code.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-329

OUTCOME 1: Population Health and Safety

Topic: LABELLING

Written Question on Notice

Senator Cherry asked:

How can Food Standards Australia New Zealand (FSANZ) ensure the labelling will not be removed or just the Radura symbol used?

Answer:

This is an enforcement issue for the State/Territory/New Zealand Health Departments and the Australian Quarantine Inspection Service.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-330

OUTCOME 1: Population Health and Safety

Topic: LABELLING

Written Question on Notice

Senator Cherry asked:

What are the labelling requirements for meat that is fed irradiated grain? If none, why are there not labelling requirements for meat that is fed irradiated grain?

Answer:

There are no labelling requirements for meat that is fed irradiated grain. Food Standards Australia New Zealand, through the Australia New Zealand Food Standards Code regulates food for human consumption. This does not extend to conducting food safety assessments of stock feed.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-331

OUTCOME 1: Population Health and Safety

Topic: FEEDING IRRADIATED FOOD TO CHILDREN

Written Question on Notice

Senator Cherry asked:

Currently in the USA, irradiated food does not have to be labelled when served in schools. If irradiated food is going to be served in Australian schools, how will Food Standards Australia New Zealand (FSANZ) ensure that:

1) balanced information on irradiation be made available to parents, guardians and students. That information should include the effects of irradiation on nutrition and any adverse health effects from consuming irradiated foods;

2) clear labelling for menu items that have been irradiated is provided– labelling must say either "treated with irradiation" or "treated by radiation" (euphemisms, such as "cold pasteurization" or "electronic pasteurization" could not be used)?

And will FSANZ:

1) require the display of prominent signs in cafeterias when irradiated food is being served;

2) prohibit the mixing of irradiated with non-irradiated food;

3) require that traditional non-irradiated meals always be served?

Answer:

(1) and (2)
Standard 1.5.3 requires that irradiated food or food containing irradiated ingredients or components that are exempt in Standard 1.2.2 - Application of Labelling and Other Information Requirements from bearing a label and which is displayed for sale must have a written statement that the food, or an ingredient of a food or a component of the food has been treated with ionizing radiation. This would mean that irradiated food sold unpackaged and displayed for sale, including ready to eat foods, would need to be accompanied by a written statement advising consumers of the treatment of food with ionizing radiation.

A package of food sold other than at retail must also include:

(a) a statement that the food has been irradiated;
(b) the minimum and maximum dose of the irradiation;
(c) the identity of the facility where the food was irradiated; and
(d) the date or dates of irradiation.

However, this is an enforcement issue for State/Territory/NZ Health Departments.

FSANZ agrees that the term 'electronic pasteurisation' should not be used to indicate that a food or an ingredient of a food had been irradiated. Irradiated food must be labelled in accordance with the general provisions in food law and fair trading law as they relate to false, misleading or deceptive conduct. A declaration that a food had been subject to 'electronic pasteurisation' would not comply with the requirements of the standard.

(1) (2) and (3)
In relation to FSANZ's position on: (1) the display of prominent signs in cafeterias when irradiated food is being served; 2) prohibition on the mixing of irradiated with non-irradiated food; and 3) requirements that traditional non-irradiated meals always be served:

> All food that was being served would need to meet all the requirements of the Food Standards Code, for both irradiated and non-irradiated foods, in particular, the mandatory labelling requirements for foods currently permitted to be irradiated.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-332OUTCOME 1: Population Health and Safety

Topic: PUBLIC AWARENESS AND EDUCATION

Written Question on Notice

Senator Cherry asked:

(a) What steps have Food Standards Australia New Zealand (FSANZ) taken to "provide sufficient information to enable consumers to make informed judgements against what they value and understand"?

(b) What has FSANZ done to inform the public about food irradiation?

Answer:

The development of Standard 1.5.3 followed an extensive and detailed process of public consultation and commissioning of reports and inquiries from a period beginning in the mid 1980s and culminating in the decision by Health Ministers on the final Standard in 1999.

The stages of development were as follows:

- a draft National Health and Medical Research Council Draft Standard (1986);
- consultation, which demonstrated consumer concerns;
- a Health Minister's Report in 1987;
- report to the House of Representatives in 1988;
- a moratorium on the sale of irradiated foods imposed 1988 to 1999;
- an initial FSANZ[5] proposal to develop the Standard and initial community consultation in 1992;
- World Health Organization Review of the Safety and Nutritional Adequacy of Irradiated Food in 1994;
- a Draft Standard was released for public consultation (Australia 1995 and NZ 1999); and
- approval of the Standard in 1999.

Therefore, at every stage public consultation was sought, and the views considered by FSANZ and its predecessors (National Food Authority and Australia and New Zealand Food Authority).

In addition, both Applications that FSANZ has assessed have involved extensive public consultation. FSANZ has always provided factual information in relation to the Applications, the process for assessing them, issues in relation to the Applications including fact sheets on the assessment process and food irradiation in general to facilitate transparency of the process.

[5] At that stage the Authority was known as the National Food Authority (NFA)

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2-4 June 2004

Question: E04-333

OUTCOME 1: Population Health and Safety

Topic: PUBLIC AWARENESS AND EDUCATION

Written Question on Notice

Senator Cherry asked:

(a) According to Food Standards Australia New Zealand (FSANZ), whose role is it to inform the public about food irradiation?

(b) How has FSANZ worked to inform the public of both the pros and cons of food irradiation?

(c) Does FSANZ consider consumer concern about food irradiation to be legitimate?

(d) What will FSANZ do to improve community access to information about changes to food standards and food irradiation approvals?

Answer:

(a) FSANZ has a role in informing the public about food irradiation. However, other bodies have roles to play. For example, industry has a role to play, to say whether or not food is irradiated (facilitated by the labelling requirement in the Standard 1.5.3) and to specify the purpose of the irradiation process, for example, 'disinfestation to control critical quarantine pests'.

(b) FSANZ has always made available its assessment reports on food irradiation Applications and up-to-date fact sheets on food irradiation.

(c) FSANZ has always acknowledged their concerns and has undertaken a rigorous safety assessment to address specific consumer concerns in relation to safety of food irradiation and also concerns in relation to the need for this technology.

(d) FSANZ will maintain its open and transparent processes in assessing any future Application to irradiate specific foods. All assessment reports would be available, and consultation with stakeholders is always undertaken where necessary.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-334

OUTCOME 1: Population Health and Safety

Topic: TRADE

Written Question on Notice

Senator Cherry asked:

Have any studies been done to address the issue of negative impacts on Australian farmers due to increased imports of irradiated food?

Answer:

Food Standards Australia New Zealand (FSANZ) is not aware of any studies to address negative impacts on Australian farmers. However, during the assessment of Application A443, FSANZ received letters of support from a range of organisations and fruit growers, who argued that granting approval to irradiate tropical fruits would provide an expanded market for Australian growers.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-335

OUTCOME 1: Population Health and Safety

Topic: TRADE

Written Question on Notice

Senator Cherry asked:

Do you think that it should be Australian consumers, and not international trade related agreements (such as the Technical Barriers to Trade, Sanitary and Phytosanitary Measures, and the International Plant Protection Convention) that dictate whether or not irradiated foods should be accepted in Australia? And if not, why are trade interests more important to our food regulatory agency than ensuring the highest level of independent assessment to protect consumer health?

Answer:

Food Standards Australia New Zealand is unable to comment on issues of Government policy.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-336

OUTCOME 1: Population Health and Safety

Topic: TRADE

Written Question on Notice

Senator Cherry asked:

Despite the European Union decision against further irradiation approvals, the following foods are approved or pending approval for irradiation in the USA. How will the Australia United States Free Trade Agreement (AUSFTA) impact on irradiation approvals in Australia and New Zealand? (Following list taken from http://www.sustainabletable.org/issues/irradiation/)

**Foods approved for irradiation in the USA:**

Beef (and beef by-products)
Eggs
Enzymes (dry and hydrated)
Fruit (domestic and imported)
Fruit juice
Garlic powder
Herbs (dried)
Horsemeat (and horsemeat by-products)
Lamb (and lamb by-products)
Onion powder
Pork (and pork by-products such as bacon)
Potatoes
Poultry
Sprouting seeds
Spices (dried)
Vegetables (domestic and imported)
Vegetable juice
Vegetable seasoning (dried)
Wheat flour

**Foods currently being irradiated and sold (2004) in the USA:**

Apples Beef Chicken Eggs Garlic Grapefruit Herbs Mangoes Onions Oranges Papayas Potatoes Spices Strawberries Tomatoes

**Foods pending approval for irradiation in the USA:**

Beef (unrefrigerated)
Clams
Crabs
Crustacean shellfish
Deli meats
Frozen foods
Lamb (unrefrigerated)
Lobster
Oysters
Molluskan shellfish
Mussels
Pork (unrefrigerated)
Ready-to-eat foods
Salads (packaged)
Shrimp

Answer:

Food Standards Australia New Zealand (FSANZ) currently considers applications for irradiated foods on a case-by-case basis. The arrangements in the AUSFTA will not affect the existing FSANZ approvals process.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 22004-2005, 2 & 3 June 2004

Question: E04-337

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: Trade

Senator Cherry asked:

What American irradiated products are likely to be imported to Australia and New Zealand?

Answer:

Currently there are permissions to irradiate herbs, spices, herbal infusions and a range of tropical fruits (carambola, custard apple, longan, litchi, mango, mangosteen, papaya (paw paw) and rambutan. These are the likely foods that could be irradiated in America and imported into Australia and New Zealand.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-338

OUTCOME 1: Population Health and Safety

Topic: TRADE

Written Question on Notice

Senator Cherry asked:

Irradiation approvals in Australia and New Zealand are currently done on a case-by-case basis, will the Australia United States Free Trade Agreement (AUSFTA) impact on the approval process?

Answer:

No. The case-by-case approval under Standard 1.5.3 will continue.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-339

OUTCOME 1: Population Health and Safety

Topic: TRADE

Written Question on Notice

Senator Cherry asked:

Will Food Standards Australia New Zealand (FSANZ) continue to follow the process of calling for public submissions and case-by-case applications for irradiated food from the USA?

Answer:

Yes, that process will continue under FSANZ's statutory obligations.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-340

OUTCOME 1: Population Health and Safety

Topic: TRADE

Written Question on Notice

Senator Cherry asked:

(a) Does Australia require some products to be irradiated before being imported into the country? If so, which products?

(b) Does New Zealand require some products to be irradiated before being imported into the country? If so, which products?

Answer:

(a) Irradiated foods imported into Australia must meet the requirements of the Australia New Zealand Food Standards Code or an Application must be made to Food Standards Australia New Zealand (FSANZ) requesting permission to irradiate a food that is not currently permitted in the Food Standards Code.

(b) Irradiated foods imported into New Zealand must meet the requirements of the Australia New Zealand Food Standards Code or an Application must be made to FSANZ requesting permission to irradiate a food that is not currently permitted in the Food Standards Code.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-341

OUTCOME 1: Population Health and Safety

Topic: ALTERNATIVES

Written Question on Notice

Senator Cherry asked:

Is Food Standards Australia New Zealand (FSANZ) aware that Steritech own and operate ethylene oxide facilities? A method of decontaminating herbs and spices was to use ethylene oxide (EO). EO was only ever a temporary permit with the National Registration Authority (NRA). Since irradiation is seen as the 'viable alternative' to EO, is it the case that the permits will not be renewed by the NRA.

Answer:

FSANZ is not aware of the current status of Steritech's business operations and this question should be directed to Steritech. The Australian Pesticides and Veterinary Medicines Authority (APVMA) (formerly the NRA) has withdrawn the registration of ethylene oxide and whether this is renewed is a matter for the APVMA.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-342

OUTCOME 1: Population Health and Safety

Topic: ALTERNATIVES

Written Question on Notice

Senator Cherry asked:

(a) How does irradiation compare to cold storage in effectiveness for eliminating fruit fly?

(b) How does irradiation compare to heat treatment in effectiveness for eliminating fruit fly?

Answer:

During the assessment of Application A443, Food Standards Australia New Zealand sought advice from Biosecurity Australia on these issues.

(a) Cold treatment is not a viable measure for tropical fruit with product damage and high costs under Australian conditions making it economically unsustainable. Unbroken skin is not a reliable indicator of fruit fly infestation and may not meet stringent quarantine requirements of importing countries.

(b) Heat treatment (hot air or hot water at specified temperature for specified period of time) is currently approved for mango and papaya for interstate trade. Heat treatments are not widely adopted by tropical fruit growers, as product losses tend to be unacceptably high. Research undertaken in Australia has shown, whilst heat treatment is efficacious for most fruit fly species at 47°C, it is not effective for all species at specified time/temperature periods. Beyond this temperature range tropical fruit can become irreparably damaged.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-343

OUTCOME 1: Population Health and Safety

Topic: ALTERNATIVES

Senator Cherry asked:

How does the impact of irradiation on consumer's health compare than traditional disinfestation methods or alternative or natural treatments?

Answer:

By virtue of the past safety studies performed on fruits (including tropical fruits) irradiated fruit is considered equivalent to non-irradiated fruits that have been treated with more conventional treatment protocols (eg heating for quarantine purposes) with respect to safety, nutritional properties and wholesomeness.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2-4 June 2004

Question: E04-344

OUTCOME 1: Population Health and Safety

Topic: ALTERNATIVES

Written Question on Notice

Senator Cherry asked:

(a) Are certified organic products allowed to be irradiated?

(b) There are currently organic products imported into and produced in Australia. How is it that certified organic products, which use neither irradiation, chemical or gas treatments, can be safely imported and exported throughout the world?

Answer:

(a) Food Standards Australia New Zealand (FSANZ) is unaware of certified organic products being irradiated; however, if they were herbs, spices, herbal infusions or selected tropical fruits as detailed in Standard 1.5.3 there would be permissions to irradiate them and they would be required to be labelled.

(b) FSANZ is not aware of specific alternative treatments in relation to certified organic products.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2-4 June 2004

Question: E04-345

OUTCOME 1: Population Health and Safety

Topic: ALTERNATIVES

Written Question on Notice

Senator Cherry asked:

Are Food Standards Australia New Zealand (FSANZ) aware that black tea industry actively lobbied against having their products irradiated?

Answer:

FSANZ did receive submissions from the tea industry under Application A 413 and addressed the issues raised in accordance with its statutory requirements.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 2-3 June 2004

Question: E04-163

OUTCOME 1: Population Health and Safety

Topic: STAFFING LEVELS LICENCE OBLIGATIONS

Written Question on Notice

Senator Carr asked:

Did ANSTO's Director of Nuclear Technology, Mr Jack Dillich, move to change reactor operator staffing levels from 4 to 3 person shifts at the recent resumption of HIFAR operations?

(a) On whose authority did this take place?

(b) Was Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) approval sought?

(c) Was ARPANSA consulted, advised or informed of this development?

(d) Does ARPANSA consider that this was an unapproved activity with significant implications and an action inconsistent with ANSTO's licence obligations?

(e) Did or will ARPANSA take formal action against ANSTO as a result of this event?

If not, why not?

(f) What action has ARPANSA subsequently take to ensure senior management are aware of and comply with these licence obligations?

Answer:

Yes

(a) ARPANSA understands that the basis for the decision was that the Operational Limits and Conditions (OLC) approved by the Chief Executive Officer (CEO) of ARPANSA under a licence condition permits a 'minimum staffing level of three operators'.

(b) The Director, Nuclear Technology indicated in a letter to the CEO of ARPANSA that HIFAR was intended to be operated with three accredited operators in accordance with the 'minimum staffing' OLC after start-up following the recent major shutdown.

(c) See (b) above.

(d) The CEO of ARPANSA views the 'normal' staffing level as being different to the 'minimum' staffing level taking the view that the normal staffing level of four was part of the licensing basis for HIFAR. Further, the CEO of ARPANSA viewed the change to the 'normal' level as a 'relevant change' having 'significant implications for safety' and, therefore, requiring prior approval of the CEO under Regulation 51.

(e) The CEO of ARPANSA wrote to the Acting Executive Director, ANSTO, advising:

- his view that prior approval should have been sought under Regulation 51;
- his expectation that HIFAR return to a normal shift complement of four at the next change of shift;
- that he had directed ARPANSA inspectors to ascertain whether further shifts operated with a shift complement of four operators; and
- if evidence of a breach was provided by ARPANSA inspectors, actions available to him are a direction under section 41 of the *ARPANS Act 1998* (the Act) and suspension or cancellation of licence under section 38.

Subsequent advice from ANSTO was that the normal four (4) person shift was resumed. ARPANSA inspections are being carried out to review compliance.

(f) The CEO of ARPANSA, Director Regulatory Branch and Legal Counsel met with ANSTO senior management to advise them of his interpretations of the Act, Regulation and Licence.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2 & 3 June 2004

Question: E04-164

OUTCOME 1: Population Health and Safety

Topic: AUSTRALIAN RADIATION PROTECTION AND NUCLEAR SAFETY AGENCY (ARPANSA) APPROVAL FOR AUSTRALIAN NUCLEAR SCIENCE TECHNOLOGY ORGANISATION (ANSTO)

Written Question on Notice

Senator Carr asked:

(g) Did ANSTO have ARPANSA approval before it commenced to power up the High Flux Australian Reactor (HIFAR) to 10KW capacity in order to do a balance prior to the resumption of normal operations?

(h) If not, what action has ARPANSA taken to address this non-compliance?

Answer:

(g) Procedures under the HIFAR licence require ANSTO to obtain agreement of the Chief Executive Officer (CEO) of ARPANSA prior to HIFAR returning to full power (10 MW) following a four-yearly 'major shutdown'. Such approval was granted on 2 April 2004. Routine checks, including reactivity balance at 10 KW, are permitted in preparation for returning to full power and do not require prior approval.

(h) This was not a non-compliance and required no action by the CEO of ARPANSA.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2 & 3 June 2004

Question: E04-165

OUTCOME 1: Population Health and Safety

Topic: RADIATION CONSEQUENCES ANALYSIS RELEASE

Written Question on Notice

Senator Carr asked:

Will the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) support the release of the Radiation Consequences analysis, as previously agreed, to help inform community and agency response to the draft Intervention Levels process?

Answer:

No. As indicated previously, because of the national security sensitivity of the information contained in the Radiation Consequences report, it would not be appropriate to release the report. To facilitate emergency planning, the Chief Executive Officer of ARPANSA has provided information about the radiological consequences of various scenarios to emergency agencies.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2 & 3 June 2004

Question: E04-166

OUTCOME 1: Population Health and Safety

Topic: AUSTRALIAN RADIATION PROTECTION AND NUCLEAR SAFETY AGENCY (ARPANSA) INTERVENTION LEVEL

Written Question on Notice

Senator Carr asked:

Can you confirm that ARPANSA is advocating an intervention level that affords less community protection than that currently accepted by both the World Health Organisation and NSW Department of Health?

Answer:

The Radiation Health Committee that advises the Chief Executive Officer of ARPANSA is developing guidelines for intervention in radiological emergencies. The current draft of these guidelines, at present available for public submissions, proposes that the intervention level for stable iodine prophylaxis be an averted dose of 30 mGy for children. An accompanying technical report issued by ARPANSA describes that for Australian radiation emergency scenarios there is minimal benefit in using a 10 mGy averted dose intervention level over 30 mGy (a difference of 0.4 radiation-induced cancer cases). The intervention recommendations seek to optimise the benefit of intervention for all radionuclides that might be involved. This matter remains under consideration by the Radiation Health Committee.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 2-3 June 2004

Question: E04-167

OUTCOME 1: Population Health and Safety

Topic: Waste repository in South Australia

Written Question on Notice

Senator Carr asked:

Concerns expressed by an ARPANSA advisory committee addressing issues relating to the proposed waste repository in South Australia were recently reported in the press (Australian, 13 May 2004, for example).

(a) What steps has ARPANSA taken to address these concerns?

(b) What is the revised timetable for the production and public release of the required fracture, groundwater and other studies?

At that time the CEO of ARPANSA spoke to ABC radio, and noted that ARPANSA would not be making hasty decisions, and would need to be convinced that in all aspects the repository would be safe.

(c) Can ARPANSA provide more precise details of these deliberations, and on possible timetables for approvals and construction stemming from these decisions?

Answer:

(i) Following the Prime Minister's announcement on 14 July 2004 that the Government has decided to abandon the establishment of a national low level waste repository at site 40a, ARPANSA has ceased all assessment of the licence application by the Department of Education, Science and Training.

(j) See (a) above.

(k) See (a) above.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2003-2004, 2-3 June 2004

Question: E04-168

OUTCOME 1: Population Health and Safety

Topic: IAEA peer review team recommendations

Written Question on Notice

Senator Carr asked:

(a) How does ARPANSA intend to address the recommendation from the peer review team that the current licensing process is not consistent with international best practice and should be replaced by step by step or staged licensing process?

(b) Has ARPANSA made a formal response to the remaining IAEA recommendations and how does the Agency intend to ensure that these are adopted in its consideration of this point of the repository project?

Answer:

(a) Following the Prime Minister's announcement on 14 July 2004 that the Government has decided to abandon the establishment of a national low level waste repository at site 40a, ARPANSA has ceased all assessment of the licence application by the Department of Education, Science and Training.

(b) See (a) above.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2 & 3 June 2004

Question: E04-169

OUTCOME 1: Population Health and Safety

Topic: AUSTRALIAN RADIATION PROTECTION AND NUCLEAR SAFETY AUTHORITY (ARPANSA) RELOCATION

Written Question on Notice

Senator Carr asked:

When ARPANSA recently changed premises to a new location 500 metres from its previous offices, what was the rationale and financial cost?

Answer:

Prior to the recent move, the Sydney office of ARPANSA was located in two separate buildings. Over time, these accommodations arrangements became operationally inefficient and administratively more expensive. In addition, the security and access control arrangements became sub-optimal and costly to maintain.

The leases for the two premises expired in February and March 2004. The renewal cost for the leases was expected to increase significantly.

The cost of moving to the new premises, including a substantial capital component, was $641,000.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2 & 3 June 2004

Question: E04-170

OUTCOME 1: Population Health and Safety

Topic: EGYPTIAN REACTOR

Written Question on Notice

Senator Carr asked:

In a press release from the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) following discussions with Egyptian authorities in 2001, the organisation spoke about the need for continuing discussions.

(a) What follow up has taken place between ARPANSA and Egyptian operators since then?

(b) Have their difficulties in operating their reactor been solved?

(c) What is the process of approving an operating licence for the new reactor? Does the reactor have to be fully assembled first?

(d) At what stage is the Final Safety Analysis Report undertaken?

(e) Will this been carried out before the Australian Nuclear Science and Technology Organisation (ANSTO) is granted an operating license?

Answer:

(a) A follow-up visit by an ARPANSA officer to Egypt for discussions on the operation of the ETRR2 reactor is planned for late 2004.

(b) ARPANSA understands that the major issues have been resolved; but see the answer to (a) above.

(l) ANSTO will make a submission seeking approval for an operating licence on the basis of the expected performance of the "as built" reactor. "Cold" commissioning results confirmatory of that expected performance would be required before a licence could be issued. ANSTO cannot load nuclear fuel until an operating licence is issued.

(m) ANSTO's submission to ARPANSA seeking an operating licence would be expected to include a Safety Analysis Report (SAR). This SAR can be characterised as a Final Safety Analysis Report, but will be modified in the light of commissioning results and during the life of the reactor should it be approved to operate.

(n) See (d) above.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2003-2004, 2 & 3 June 2004

Question: E04-291

OUTCOME 1: Population Health and Safety

Topic: DR HARMER CORRESPONDENCE

Hansard Page: CA 32-3.6

Senator Wong asked:

On notice, could you get me the correspondence from you to Dr Harmer on the issues that I previously iterated? I can go through them again, if you want but it is, essentially, the reports that we have been discussing and also his responses to that.

Answer:

Copies of correspondence from the Chief Executive Officer of Australian Radiation Protection and Nuclear Safety Agency to the applicant for a Facility Licence at site 40a at Woomera are enclosed. Also attached are copies of the letters of reply from the Department of Education, Science and Training (DEST), with the exception of two attachments to the letter of 2 June 2004 which were marked 'confidential'. DEST advise that the release of these letters would require permission from the signatories to those attachments.

[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

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-188

OUTCOME 1: Population Health and Safety

Topic: COMMERCIAL RELEASE OF GENETICALLY MODIFIED CANOLA - STATE GOVERNMENT SUBMISSIONS

Hansard Page: CA 11-3.6

Senator Cherry asked:

Would you be able to check with state governments whether they are happy for the actual submissions to be released as well as let the Committee know?

Answer:

Yes. The Gene Technology Regulator will write to State and Territory Governments asking whether their submissions can be released, and will advise the Committee of their response.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-189

OUTCOME 1: Population Health and Safety

Topic: INVESTIGATION INTO PAN PHARMACEUTICALS - PERSONNEL

Hansard Page: CA 20-3.6

Senator Forshaw asked:

Are you able to say how many personnel – how many officers within the Therapeutic Goods Administration (TGA) – are dedicated to this task?

Answer:

As at 22 June 2004, five (5) TGA staff are dedicated to this investigation.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-190

OUTCOME 1: Population Health and Safety

Topic: INVESTIGATION INTO PAN PHARMACEUTICALS – TOTAL COSTS

Hansard Page: CA 20-3.6

Senator Forshaw asked:

I would like to get an idea of the total costs that have been expended on this investigation, including the resources from any other agencies or departments?

Answer:

The total cost incurred by the Therapeutic Goods Administration attributable to investigations of Pan Pharmaceuticals as at 31 May 2004 was $1,165,339 inclusive of disbursements made to other agencies. Because the activity falls within their normal statutory responsibilities, the cost of resources applied to this investigation by those agencies is not separately identified.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-192

OUTCOME 1: Population Health and Safety

Topic: PAN PHARMACEUTICALS – RECOUPED FUNDS

Hansard Page: CA 21-3.6

Senator Forshaw asked:

Why was the TGA only able to recoup a dividend of $8,144 from a total claim of approximately $17,288,000?

Answer:

The total claim lodged by the TGA against the Liquidator of Pan Pharmaceuticals Ltd (Pan) was $17,288,179. This amount included $17,206,739 representing the TGA's estimated cost of administering the national recall of products manufactured by Pan and associated audit, legal and investigation costs (invoiced on 14 May 2003), and $81,440 relating to unpaid audit inspection fees as at 22 May 2003 (the date of voluntary administration).

On 15 March 2004, Pan's Liquidator issued a notice under sub regulation 5.6.54(1) of the *Corporations Act 2001* advising that the formal proof of debt lodged by the TGA had been partially disallowed. The only portion of the claim admitted by the Liquidator was the $81,440 relating to unpaid audit inspection fees. The Liquidator concluded that there was no statutory basis under Commonwealth legislation or common law to support the remaining claim.

The Australian Government Solicitor (AGS) subsequently advised that a person or body invested with statutory functions, or powers, cannot charge for the performance of those functions, or exercise of powers, unless legislation expressly enables them to. The TGA recovers its operating costs from industry through evaluation fees and annual charges prescribed in the Therapeutic Goods Regulations, the Therapeutic Goods (Medical Devices) Regulations and the Therapeutic Goods (Charges) Regulations. As there was no specific power under these Regulations to charge for the costs associated with the product recall, the AGS concluded that the TGA was unable to recover the relevant costs from Pan.

On 27 April 2004 the Liquidator declared a first interim dividend of ten cents in the dollar on the amount of debt admitted by the Liquidator, and $8,144 was subsequently received.

In recent circulars to creditors, the Liquidator has highlighted the complex task of adjudicating the more than $190 million of claims made against Pan's assets.
Although a second dividend is proposed to be declared later in the year, any further dividend will be dependent upon legal proceedings that commenced on 7 April 2004 against a former Director for breaches of duty under section 180 of the *Corporations Act 2001*.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-191

OUTCOME 1: Population Health and Safety

Topic: PAN PHARMACEUTICALS – MANUFACTURING LICENCES TO PREVIOUS DIRECTORS OR OWNERS

Hansard Page: CA 21-3.6

Senator Forshaw asked:

Subsequent to the Pan licence suspension, have any previous directors or owners of Pan applied for or obtained licences to manufacture or import therapeutic goods?

Answer:

Based on information sourced from the Australian Securities and Investments Commission and a review of new manufacturing licence applications submitted to the Therapeutic Goods Administration, there is no record of the previous directors of Pan Pharmaceuticals applying for a new manufacturing licence subsequent to the Pan licence suspension.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2004-2005, 2 & 3 June 2004

Question: E04-187

OUTCOME 1: Population Health and Safety

Topic: EXPERT COMMITTEE ON COMPLEMENTARY MEDICINES IN THE HEALTH SYSTEM - COSTS

Hansard Page: CA 24-3.6

Senator Forshaw asked:

Are you able to give me a breakdown of all the costs? I would like it broken down into where it has been attributed to, and what is able to be recovered and what is not.

Answer:

Total costs for the Expert Committee on Complementary Medicines in the Health System including preparation, publication and distribution of the Expert Committee's report was $315,483.

| | |
|---|---|
| *Members Sitting Fees* | ***= $113,135.26*** |
| **Venue Costs** | = $10,409.70 |
| **Courier Costs** | = $1,760.84 |
| **Stationery Costs** | = $1,204.10 |
| **TGA Staff Salaries** | = $107,926.00 |
| **TGA Staff Costs** | = $12,553.94 |
| **Consultant Fees** | = $56,137.59 |
| **Report Copy Costs** | = $12,356.00 |
| *TOTAL COSTS* | *= $315,483.43* |

The costs associated with the Expert Committee's review were met by the Government in response to the concerns raised by the recall of products manufactured by Pan Pharmaceuticals Limited.