Community Affairs
Legislation Committee

Examination of Budget Estimates 2003-2004

Additional Information Received

VOLUME 6

Outcomes: whole of portfolio, Outcomes 1 & 2

HEALTH AND AGEING PORTFOLIO

FEBRUARY 2004

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

ADDITIONAL INFORMATION RELATING TO THE EXAMINATION OF BUDGET EXPENDITURE FOR 2003-2004

Included in this volume are answers to written and oral questions taken on notice and tabled papers relating to the SUPPLEMENTARY budget estimates hearing on 5 November 2003

HEALTH AND AGEING PORTFOLIO

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Department of Health and Ageing

Mr Elton Humphrey
Secretary
Senate Community Affairs Legislation Commitee
Parliament House
Canberra ACT 2600

Dear Mr Humphrey

Supplementary Budget Estimates Hearing of 5 November: Whole of Portfolio

On 5 November I appeared before the Senate Community Affairs Legislation Committee and provided answers to questions from Senator McLucas in relation to Departmental arrangements for laptop encryption passwords.

On reading the transcript I now realise that the answer I provided was incomplete with regard to all of the encrypted laptops on issue in the Department.

Senator McLucas asked:
How many people hold that password?
Ms Seittenranta: It is the individual's password.
Senator McLucas: And has to be accessed by that individual?
Ms Seittenranta: Yes

That answer was correct for laptops being allocated to individual users at the time, however for encrypted laptops previously on issue there were two other categories existing at the time of answering the question:

1. Laptops where encryption was subject to a common password. These laptops were being upgraded at the time to ensure that the encryption facility was subject to unique passwords only known to the individual user. This upgrade has since been completed; and
2. Fourteen laptops which were subject to 'pooled' use. For these laptops, the encryption password for each particular laptop was known to all the users of that laptop. This situation, by necessity, still exists.

Eija Seittenranta
Chief Information Officer
Nov 2003

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-095

OUTCOME Whole of Portfolio

Topic: IP RIGHTS AND THE AUSFTA

Written Question on Notice

Senator Carr asked:

There have been reports recently that such IP is an issue on the AUSFTA agenda. In September, the NIH announced that it was working on the development of a specific approach to effect control and handling of IP without impacting on the Bayh-Dole Act.

(a) Can the NHMRC provide an update on this issue?

(b) Has either the Department or NHMRC been asked to provide information or briefings to Australian FTA negotiators on this issue?

(c) What is the formal position of the Department, and the Australian Government on this issue?

(d) What proposals have been received on this issue from the American negotiators?

(e) Has the Department sought or received advice from the NHMRC on this matter?

(f) Can you provide copies of relevant briefing papers on this issue?

(g) What would be the effect on medical and health research in Australia if such rights or control to IP were conceded under an AUSFTA agreement?

Answer:

(a) The NHMRC is not aware of any further developments. The moratorium has been extended indefinitely.

(b) The Department, in collaboration with the NHMRC, has provided background information to Australian FTA negotiators on this issue.

(c) There should be no change to current obligations on Australian researchers under NIH grants. The current grant conditions have served Australia and the US well in the past and will continue to do so.

(d) American negotiators involved in the AUSFTA have not made any proposals in relation to this matter.

(e) As there have been no proposals by US negotiators on this issue, there has been no need to seek advice from the NHMRC on this matter.

(f) Not applicable.

(g) There are no proposals on the table in the AUSFTA negotiations relating to ownership of intellectual property associated with medical and health research.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-026

OUTCOME Whole of Portfolio

Topic: PBS AND AUSTRALIA US FTA

Written Question on Notice

Senator Nettle asked:

(a) Is the Department still monitoring developments in the negotiations for the proposed Australia-US Free Trade Agreement?

(b) Have the US negotiators asked for additional information? If so, what was the subject and nature of that information? When was it requested? Did the Department provide the information? If so, when did it provide the information?

(c) Can the department confirm that the US negotiators have not put forward a proposal about changes to the PBS?

(d) Is the department anticipating that a proposal will be put forward before negotiations conclude?

Answer:

(a) Yes.

(b) There have been several information exchanges between the Department of Health and Ageing and US negotiators in regard to the PBS and its place as an essential component of our health care system and National Medicines Policy. These exchanges took place during negotiation rounds and inter-sessional meetings.

(c) Yes.

(d) Public comments from US officials have indicated that the PBS is an area that may be raised in negotiations. Regardless of whether proposals are tabled by the US, the Government has stated its commitment to access to affordable medicines through a sustainable PBS.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-027

OUTCOME Whole of Portfolio

Topic: PBS AND AUSTRALIA US FTA

Written Question on Notice

Senator Nettle asked:

(a) Can the department confirm that US negotiators have written to Industry Minister Ian McFarlane requesting changes to laws governing generic drugs? (See article Herald Sun 30/10/03)

(b) If yes, what can you tell the committee about this request?

(c) If no, is the department aware of any request from US trade negotiators for changes to laws governing generic drugs and their relationship to patented drugs?

(d) If no, have US negotiators referred to the issue of generic medicines in the course of negotiations? (Or) Have US negotiators requested any information from the department about generic medicines and the PBS? If yes, please provide details.

Answer:

(a) No. This is a question for the Department of Industry, Tourism and Resources.

(b) Not applicable.

(c) Yes. The US has put forward proposals dealing with the situation in which a generic manufacturer seeks marketing approval for a generic drug while a patent is still in place. As with any other proposal the US has made in this negotiation, the Australian Government is examining closely the impact of such proposals for Australia.

(d) US negotiators have not requested any information from the Department of Health and Ageing about generic medicines and the PBS.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-028

OUTCOME Whole of Portfolio

Topic: PBS AND AUSTRALIA US FTA - GENERIC MEDICINES

Written Question on Notice

Senator Nettle asked:

(a) How significant are generic medicines in Australia? What proportion of the PBS budget and volume is spent on generic medicines?

(b) For the benefit of the committee, can the department explain what steps a manufacturer of a generic drug needs to take to have their drug made available in Australia?

(c) Is a company intending to manufacture a generic version of a drug whose patent is soon to expire, required to advise the holder of the patent? If not, why not?

(d) Is it the case that US negotiators are seeking changes to regulations governing the manufacture by generic drug makers of drugs coming out of patent? If so, what are the details of the request? If not, or don't know, what would be the effect of such a change.

(e) Would the department support such a change to Australian regulations? If not, why not? If so, why?

(f) Why should originator companies be notified that someone plans to manufacture a generic version of a drug to which they hold a patent that is about to expire?

(g) Surely a patent is granted as a form of protection, to enable an originator company to obtain a premium price for a specified period, in large part as a means of return on investment in research and development?

(h) Are you aware that there has been a considerable level of legal action overseas by originator companies against generics manufacturers?

(i) Why wouldn't we expect such a situation to arise here if the TGA were required to notify originator companies of an application by a generics manufacturer?

(j) What would be the cost to the Australian Budget of introducing these sorts of changes?

Answer:

(a) Around 1500 drugs are listed on the Pharmaceutical Benefits Scheme (PBS). Of these, 320 drugs have a generic brand available. There is often more than one generic brand available for a drug listed on the PBS.

Around 2,500 different branded items are available on the PBS. Of these, about 800 (32%) are items supplied by generic manufacturers.

For the 12 months ending October 2003, PBS-listed products supplied by generic medicine manufacturers accounted for about 18.1% of the volume of prescriptions subsidised under the PBS and about 10.2% of the Australian Government cost for PBS prescription subsidies.

Notes - These figures include only those PBS prescriptions for which a Government subsidy has been paid. They do not include prescriptions for PBS-listed medicines bought by general patients at prices below the current PBS general patient co-payment of $23.10. As these medicines are not subsidised under the PBS for general patients, data is not captured on them. The total generic medicines market supplied in Australia includes: subsidised PBS generic medicines (included in the data above); PBS-listed generic medicines bought by general patients at prices less than the general patient co-payment; and, non-PBS generic medicines (ie. private scripts).

(b) In Australia, all medicines must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in the market. For a new or innovator medicine, a sponsor is required to submit an application with extensive supporting data to establish the quality, safety and efficacy of the product for its intended use. Intending sponsors of generic products must still make an application to TGA and submit evidence of quality and to show that the generic medicine is bioequivalent to the innovator medicine. This means that the generic must be shown to be absorbed and treated by the body in the same manner as the innovator product. Once this is established, the information on safety and efficacy of the innovator can be extrapolated to the generic and approval is granted.

(c) There is no requirement under the Therapeutic Goods legislation for a company intending to manufacture a generic version of a drug whose patent is soon to expire to advise the holder of the patent. This has not been judged necessary in Australia.

(d) No. However, the US has put forward proposals dealing with the situation in which a generic manufacturer seeks marketing approval for a generic drug while a patent is still in place.

(e) As with any other proposal the US has made in this negotiation, the Australian Government is examining closely the impact of such proposals for Australia. Australia has not agreed to any US proposals in this regard.

(f) An argument that is made by supporters of notification is that the originator company has a right to be informed that a generic manufacturer intends to manufacture a generic version of their product.

(g) Yes.

(h) The Department of Health and Ageing is aware of legal action overseas by originator companies against generic manufacturers.

(i) The Department of Health and Ageing cannot comment on a hypothetical situation.

(j) It is not possible to calculate the cost of hypothetical changes without knowing the exact nature of the change.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-113

OUTCOME WHOLE OF PORTFOLIO

Topic: MANAGEMENT ADVISORY COMMITTEE REPORT - ORGANISATIONAL RENEWAL

Written Question on Notice

Senator Carr asked:

Work-life balance issues have been identified as important for the public service. The March 2003 Management Advisory Committee report Organisational Renewal discussed workforce planning issues, stating:

As the labour market tightens into the future, there will be increased pressure on attracting the skills required and maintaining competitive remuneration packages which support effective recruitment at the base grade and lateral levels.

Employment conditions and the capacity for work/life balance will be an important element of such packages, and may offer APS agencies a competitive edge…

Increased flexibility in working patterns and arrangements will be an important part of the response to the demographic changes, recognising the life stage dynamics influencing workforce participation.

The APS has been a leader in providing family friendly work practices (e.g. part-time work, flexible working hours, home based work, purchased leave) and needs to continue in this role through flexible conditions and supportive management approaches as part of its attraction and retention strategy.

In light of the MAC report, the following questions are asked of each Department:

(a) What has been the department's response to the MAC report to date?

(b) Which issues identified in the MAC report have been identified as priority areas for the department?

(c) What family friendly or work-life balance initiatives:

(i) exist in the department;
(ii) are available to staff through the certified agreement; or
(iii) are contained in the certified agreement, but the granting of them in individual cases is discretionary on the part of the organisation.

(d) What family friendly or work-life balance initiatives has the department introduced in, or since, the implementation of the department's most recent certified agreement?

(e) With respect to certified agreement-based family friendly or work-life balance provisions – what number and proportion of departmental staff are making use of such provisions in areas including:

(i) purchased leave (also known as 48/52 schemes);
(ii) negotiated part-time work arrangements;
(iii) parental leave;
(iv) use of information, advice or counselling services made available by the department;
(v) departmental provisions of facilities (such as family care facilities); and
(vi) home based work.

Answer:

(a) The Department is responding to the MAC report by undertaking the following activities:

- staff surveys and implementation of an exit survey procedure to keep track of the attraction, retention and separation factors and trends relevant to this agency;
- development of a mature-aged workers policy;
- continuation of the Department's formal graduate program;
- continued use of the available employment frameworks to structure workforce strategies (eg certified agreements and Australian Workplace Agreements);
- revision of the learning and development strategy to provide increased and equitable access to all staff;
- development of a knowledge management framework that focuses on efficiently capturing, storing and retrieving knowledge; and
- continued provision of flexible employment conditions that focus on balancing work life commitments with other competing interests or commitments, such as family, community work and lifestyle choices. The Department's current certified agreement includes a wide range of leave provisions and flexible working conditions.

The combination of all of these strategies is intended to positively influence staff attraction and retention.

(b) All of the issues identified in the MAC Report are considered priority areas for the Department. The Department is in the process of reviewing and redeveloping its total people management strategy to ensure better alignment with business needs now and in the future, whilst recognising the current and future labour market pressures.

(c) (i), (ii) and (iii) As part of the previous Certified Agreement 2000 – 2002, the Department made a commitment to incorporate a holistic balanced approach into the existing framework of its organisational culture. This framework consists of principles that underpin valuing staff and lifestyle choices as well as a commitment to building a culture that places emphasis on the health and well being of staff and encourages a balance between work and personal commitments. The current Certified Agreement 2002 – 2004 strengthens this commitment and introduces additional activities designed to support the development of a comprehensive, national, evidence-based health and well being program. Further information about the Department's family friendly and work-life balance initiatives, as outlined in the certified agreement, is readily available through the Internet at www.health.gov.au/pdf/ca2002.pdf. Refer to Part E, Section 1, Clauses 100 to 109 "Health and Life Strategy"; and Part E, Section 3, Clauses 121 to 162 "Balancing work and personal lives".

(d) The Department has introduced a 10K a Day program as a key element of the Health and Life Strategy. The program encourages each participant to walk at least 10,000 steps per day on average. It was developed with the aim of promoting physical activity, wellbeing and balancing work and life. This initiative has proven to be highly valued by staff.

(d) Unless stated otherwise, the following figures include the core Department, the Office of the Gene Technology Regulator (OGTR), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), CRS Australia and the Therapeutic Goods Administration (TGA).

(i) 96 staff (2.3%) accessed purchased leave during the 2002-2003 financial year. Figures exclude CRS Australia.

(ii) As at 30 June 2003 there were 1,228 part time staff (20.5%) in the Department.

(iii) 33 staff (0.8%) accessed parental leave during the 2002/2003 financial year. This provision was established with the introduction of the recent certified agreement. Figures exclude CRS Australia.

(iv) 344 staff (8.4%) accessed the Department's counselling service (Employee Assistance Program) for the first time in the 2002/2003 financial year; the total utilisation rate for 2002/2003 was 19.5%. Figures exclude CRS Australia.

(v) The Staff Amenities Room in Central Office is used on a daily basis. The number and proportion of departmental staff who use this room is not recorded.

Across the Department, approximately 2% of staff accessed their local family care room during the 2002/2003 financial year. This figure includes the core Department only.

(vi) There are two types of home based work provisions: (1) formal ongoing, and (2) informal ad hoc. Approximately 15 staff members accessed the formal ongoing home based work provision during 2002/2003. Informal ad hoc home based work is arranged locally and accurate numbers are not readily available.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-146

OUTCOME Whole of Portfolio

Topic: NON-ONGOING EMPLOYEES

Written Question on Notice

Senator Carr asked:

(a) How many employees are employed as a non-ongoing employee in each year of the previous 6 years?

(b) What percentage of total agency employees are non-ongoing employees for each of these years?

(c) How many of these have been employed for more than 1 year as a non-ongoing employee?

(d) How many of these have been employed for more than 2 years as a non-ongoing employee?

(e) How many of these have been employed for more than 3 years as a non-ongoing employee?

(f) How many employees were employed on fixed-term contracts, in each year of the previous 6 years?

(g) What percentage of the total number of employees is this for each of these years?

(h) What was the percentage of total employees for contract employees, for each year of the previous 6 years?

(i) How many employees were employed on fixed-term contracts at each classification level, for each year of the past six years?

(j) How many employees on a fixed-term contract, for each year of the past six years, have been employed more than once on a fixed-term contract? Please provide details of position classification in each instance.

Answer:

(a) All figures provided are based on headcount as at 30 June 1998, 1999, 2000, 2001, 2002 and 2003.

The figures provided below for 1998 and 1999 are expressed in terms of temporary employees under the previous *Public Service Act 1922.* The figures from 2000 onwards are expressed as non-ongoing employees, under the current *Public Service Act 1999.*

Financial Year	**2002-03^^**	**2001-02^**	**2000-01^**	**1999-00^**	**1998-99^**	**1997-98#**
Non-ongoing headcount at 30 June	838	370	413	404	441	1,091

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

(b) The table below lists the percentage of total agency employees classified as temporary employees for 1998, 1999 and non-ongoing employees from 2000 to 2003.

Financial Year	**2002-03^^**	**2001-02^**	**2000-01^**	**1999-00^**	**1998-99^**	**1997-98#**
Non-ongoing headcount at 30 June	14.01%	9.81%	11.53%	12.00%	13.92%	20.13%

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

(c)(d)(e) The following table lists the results for the number of temporary and non-ongoing employees that have been employed for more than 1 year, more than 2 years and more than 3 years.

Financial Year	**2002-03^^**	**2001-02^**	**2000-01^**	**1999-00^**	**1998-99^**	**1997-98#**
Non-ongoing for more than 1 year	90	67	35	42	30	161
Non-ongoing for more than 2 years	25	17	6	6	7	36
Non-ongoing for more than 3 years	18	4	2	6	11	60

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

(f)(g)(h)(i)(j) All non-ongoing staff are employed under fixed term contracts, and so answers for (f) – (j) are the same as those for (a) – (e).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-142

OUTCOME Whole of Portfolio

Topic: STAFFING LEVELS

Written Question on Notice

Senator McLucas asked:

In June at Senate Estimates hearings, Mr Alan Law (COO) provided an answer to Senator McLucas in response to a question on department staffing levels that he later clarified in a letter dated 25 June.

Given that these figures have now been clarified several times, could we please have again the corrected answers to questions E03-211 and E03-197, updated if necessary?

Answer:

The information provided in response to Question on Notice number E03-211 is correct and up to date at 25 July 2003. The answer corrected the information provided in the answer to E03-197 of February 2003. No further update is necessary.

Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Mr Elton Humphery
Secretary
Senate Standing Committee on Community Affairs
The Senate
Parliament House
Canberra ACT 2600
AUSTRALIA

Dear Mr Humphery Elton

Please find attached a copy of my letter of 2 October 2003 to the Department of Education Science and Training in regard to their application for a licence from the CEO of ARPANSA for the National Radioactive Waste Repository.

You may recall that I undertook to supply a copy of this letter to the Committee at the request of Senator Wong at the Estimates hearings last Wednesday night (Hansard, CA 113 of 5 November refers). I indicated to Senator Wong that I wished to inform the recipient Department of my action before supplying the letter and I have now done so.

Yours sincerely

John Loy
CEO of ARPANSA
10 November 2003

By facsimile: 5 pages

Australian Government

Australian Radiation Protection and Nuclear Safety Agency

2 October 2003

Dr Jeff Harmer
Secretary
Department of Education Science and Training
GPO Box 9880
Canberra ACT 2601

Dear Dr Harmer

DEST Application for a facility licence under the *Australian Radiation Protection and Nuclear Safety Act 1998- Request for further information and clarification of application*

I refer to the facility licence application that you have made on behalf of the Department of Education Science and Training and submitted on 15 August 2003. I refer also to my letter to you dated 28 August 2003 where I indicated that the application was in a form approved by me (under paragraph 35(a) of the *Australian Radiation Protection and Nuclear Safety Act 1998* (ARPANS Act)). In that letter I left open the possibility that I would write to you once my review of the substance of the application had commenced, if I required clarification or further information from you.

I have undertaken an initial review of the application relying on the guide to the application set out in Volume I and the accompanying materials in Volumes II and III. Taking into account that the application is for a licence to site, construct and operate the repository, I have formed a preliminary view that the application in its current form requires further clarification and possibly supplementation.

The text of the application must address all of the matters that I am required to consider having regard to my decision making under section 32 of the Act. In general, the application at present briefly states a proposition and refers to a supporting document in Volume II or III. It would be helpful if an addendum to the application were prepared that referred specifically to the particular parts of the evidence provided and/or relied upon in support of each particular matter.

This initial review has also given rise to the issues set out below. These are brought to your attention so that you have an opportunity to address them and to place before me such further submissions or other material as you see fit. I emphasise that I have not reached any final view, or decision, on any aspect of the application.

Parts 1 and 2 of Volume I set out the scope of the application and general information about the application. There are no particular matters arising at this stage.

PO Box 655
Web: www.arpansa.gov.au
619 Lower Plenty Road

Part 3. Organisational Arrangements

The Roles and Responsibilities of the Repository Operator and its relationship to DEST
Given that you are seeking a licence to operate the repository prior to having engaged a Repository Operator, it is of the utmost importance that I understand fully the relationships between and the respective roles of the DEST and the Repository Operator and how these will be implemented. The same issue arises, to a lesser extent, in regard to the foreshadowed civil and transport contractors.

Part 3 of Volume I refers to the Repository Management System, specifically to the Management and Quality Manual, to describe the responsibilities of the various parties. It is not clear to me what is relied upon in this regard in the Management and Quality Manual, which is a higher level description of the quality system to apply.

The application also refers to the Scope of Work document in Volume III. This document implies that many key decisions in relation to the preparation of the site, design, construction and operation of the facility will be the preserve of the Repository Operator. I would like further submissions in relation to the manner in which the Scope of Work document relates to the other material relied upon in the application. I would like a detailed exposition of these issues. For example, can you detail the documents that comprise the "design brief" mentioned at page 5 of the Scope of Work.

In addition I would like information as to how the relationship between the Repository Operator and the sub contractors, civil and transport, is intended to work and the specific documents if any that will govern their respective scope of work.

Part 4. Selection of site 40a

Part 4 of the application points to the site selection process leading to the preparation of the Environmental Impact Statement and its assessment and the approval of two sites under the EPBDC Act. It makes the broad argument that the three sites assessed in the EIS process were those that best met the siting criteria, within a region that itself had been assessed against these criteria. However, I need to make a full assessment of site 40a under the ARPANS Act. It would be helpful if DEST would draw out the **site-specific** evidence relied upon in relation to site 40a and compare this to the siting criteria included in the *Code of practice for the near-surface disposal of radioactive waste in Australia*.

This assessment should go on to point to how any limitations of the specific site have been addressed through engineered safeguards or waste conditioning and packaging.

Part 5. Physical Works

The matters raised under Part 3 above are also relevant to this part of the application.

Part 5.3 refers to the environmental monitoring to be undertaken between disposal campaigns and refers to the Environmental Management Manual in Volume III. That manual is a detailed description of the environmental monitoring proposed, but does not relate the plan clearly to the radiological protection objectives set for the repository. It would be helpful if there were a description of the basis on which the plan has been devised. In such a

description, you might wish to refer to your position in regard to the protection of non human biota in the environment.

Part 6. Arrangements for Managing Safety

The application states that "the primary tool for control of the repository by DEST is the Repository Management System" which is detailed in Volume II of the application.

The manuals, which comprise the Repository Management System, are high level documents that establish a management framework for the repository and on which the operational procedures are to be based. The working level documents - operational procedures and work instructions - are also shown as part of the Repository Management System (Fig1.1, Vol II) but are yet to be developed.

I note that the Scope of Work (referred to previously) requires the RO to develop detailed operational, safety and environmental procedures that are consistent with the Repository Management System. I note that in relation to these procedures the application has in section 1 of Volume I distinguished between those procedures that are key and those that are so called "non-critical" which are referred to as "not essential to the operation or safety of the repository." It is stated that the Repository Operator will develop these. Given that these procedures will contain the detailed implementation of the management system, could you provide further justification as to the choices that have been made between critical and non-critical procedures so that I may consider whether or not the repository will be effectively controlled and safely operated.

Part 7. Facility Design

Design of the Repository

The design concepts for the disposal structures are based on a multi-barrier approach. Three barriers are proposed:

- First Barrier – waste conditioning and packaging
- Second Barrier – engineered safeguards
- Third Barrier – natural site conditions

The waste conditioning and packaging requirements are described in the 'Waste Acceptance Plan' and the engineered safeguards in the 'Disposal Structure Design Concepts'. The report by Searco 'Activity Limits for the Post-closure Safety of the National Radioactive Waste Repository' does not appear to rely on the first two barriers but on the natural site conditions to determine the risks for various exposure pathways. I would appreciate therefore your advice as to following:

a) What form will the first two barriers take and
b) What is the reliance placed on these barriers, if any, to achieve satisfactory performance of the repository during operations and post-closure?

Safety Analysis Report (SAR)

The SAR in Volume III is a brief summary document that refers to the assessments undertaken and their results. It is presumably relying on detailed analyses in other documents, which need to be referenced and made available.

Waste Acceptance Plan - Waste Acceptance Criteria

As you would be aware Waste Acceptance Criteria are critically important to an evaluation of this application as the design of the facility and the operating procedures are dependant on the waste form and its packaging. In turn the criteria for determining the waste form and packaging are dependant on transport requirements, operational safety at the site and how the waste will behave in disposal structures during operations, the institutional control period and post institutional control.

The activity limits set out in the Waste Acceptance Plan and derived from scenarios adopted in post closure radiological risk assessment for many short-lived nuclides are extremely high. This leads to the following questions

a) How will the post closure criteria be used to produce activity limits for waste packages? Is it intended that the activity limits determined by post closure criteria be modified to take into consideration the generic activity concentration limits derived from the near surface disposal code?
a) Having regard to the transport criteria, how do these transport criteria affect the package limits proposed for the various categories of package types permitted by the transport code for both sealed and unsealed sources?
b) Given that dose rates at the surface of the package will be constrained because of the operational health physics requirements and transport requirements how will these dose rate requirements affect the activity limits for containers?

There are no matters arising from Part 8 at this time.

I look forward to your response in the near future to the issues in this letter. Please note that I propose to publish this letter on the ARPANSA website. I would appreciate your submissions if any if you do not agree with this course of action.

In relation to the review of the application I restate that I have not reached any final view, or decision, on any aspect of the application.

Yours sincerely

John Loy
CEO of ARPANSA

TGA Therapetic Goods Adminstration
PO Box 100 Woden ACT 2606

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

Dear Mr Humphrey

Supplementary Budget Estimates Hearing 5 November 2003: Outcome 1

I am writing to clarify statements made by officers attending the Supplementary Budget Estimates 2003-2004 of the Senate Community Affairs Legislation Committee on 5 November 2003.

During committee hearings, Senator Forshaw sought further details of the contingent liabilities disclosed in the Notes to Therapeutic Goods Administration financial statements for the year ending 30 June 2003 (Health and Aged Care Annual Report 2002-03, p.380). The Secretary of the Department of Health and Ageing, Ms Jane Halton, indicated during the discussion on these items that we would check our records and clarify the information provided if required.

Australian Accounting Standards and the Finance Minister's Orders require the disclosure of contingent liabilities, including the commencement of legal proceedings, where the liability is assessed as have only a remote likelihood of success or is unable to be reliably quantified.

The two items disclosed relate to legal action contemplated or in place that had been notified to the Department prior to 30 June 2003. The first relates to a claim brought by Botani Australia Pty Ltd concerning the disclosure of confidential/proprietary information relating to an acne cream to another company with a very similar name. The second matter related to an action brought by a person against a manufacturer of a herbicide that the safety direction for the use of the herbicide was inadequate. The Commonwealth was joined as a defendant on the basis that it had regulatory functions in relation to safety standards for the product, including adequate labelling requirements. It appears that the manufacturer concerned was able to demonstrate the absence of a link between the chemicals in the herbicide and the injuries sustained by the claimant, so the claim against the Commonwealth was discontinued. Neither matter was connected with the action taken by the Therapeutic Goods Administration to suspend the manufacturing licence of Pan Pharmaceuticals Limited and conduct a consumer level recall of products manufactured by it.

In statements made to the committee, officers noted that there was some probability that legal action could be brought against the Therapeutic Goods Administration as a result of its regulatory decisions regarding Pan Pharmaceuticals Limited and sponsors who were

supplying goods manufactured by Pan Pharmaceutical Ltd. I wish to reiterate that no actions had commenced during the 2002-2003 financial year.

Yours sincerely

Terry Slater
National Manager

November 2003

Department of Health and Ageing

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

Dear Mr Humphrey

Supplementary Budget Estimates Hearing 5 November 2003: Outcome 1

On 5 November 2003 Mr Ross O'Donoughue, the former First Assistant Secretary of the Population Health Division, appeared before the Senate Community Affairs Legislation Committee to answer questions in relation to Outcome 1 Population Health and Safety. I would like to amend statements made by Mr O'Donoughue at that time.

1. When commenting on the implementation of programs in response to the Australian Technical Advisory Group on Immunisation recommendations Mr O'Donoughue stated

The Meningococcal C Vaccination Program which was announced in August of 2002 and will cost $298 million over four years was the highest priority ATAGI recommendation which was dealt with and incorporated in the schedule in January of this year. (see page CA 129 of the Proof Committee Hansard of 5 November 2003).

It is not fully correct to refer to the recommendation made by the Australian Technical Advisory Group on Immunisation on meningococcal C disease as being the "highest" priority. The Australian Technical Advisory Group on Immunisation presented its recommendation on meningococcal C disease to Government for consideration of funding ahead of the other recommendations, which were presented to Government in November 2002.

The National Program was funded in accordance with advice from the ATAGI and in light of the following factors:

- Concerns raised by Federal and State/Territory Governments, through the Australian Health Ministers' Conference in 2001;
- A high degree of community concern;
- The dramatic jump in group C disease reported in some States;
- The higher fatality rate for group C disease;
- The short lead time prior to winter, being the peak meningococcal season; and
- The need to secure vaccine supply given the worldwide shortage at that time.

2. When commenting on the estimated cost of implementing the remaining recommendations of the ATAGI Mr O'Donoughue stated:

Replacement of oral polio vaccine with IPV- inactivated polio vaccine – is $15.8 million in our estimate in year one and $0.3 million ongoing. (see page CA 129 of the Proof Committee Hansard of 5 November 2003).

This is incorrect. The correct figure, based on Departmental estimates is $10.3 million in the first year and $15.8 million ongoing.

3. When commenting of pneumococcal vaccination programs for Australians aged 65 years and over Mr O'Donoughue stated

We would still have the existing program which funds people over 65 with medical risks, but not all people over 65 years of age, as ATAGI has recommended (see page CA 129 of the Proof Committee Hansard of 5 November 2003).

To clarify, polysaccharide pneumococcal vaccine is available to all people aged 65 years and over and to those over the age of 2 years with medical risk factors, through the Pharmaceutical Benefits Scheme. This is a subsidised scheme not a fully funded vaccination program.

Yours sincerely

Andrew Stuart
First Assistant Secretary
Population Health Division

November 2003

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-086

OUTCOME 1: Population Health and Safety

Topic: EAR INFECTIONS

Written Question on Notice

Senator Crossin asked:

Following a study published in the Medical Journal of Australia in August, NACCHO has called for the wider use of ciprofloxacin ear drops to treat runny ear or suppurative otitis media. The drugs now in common use to treat this infection are known to be toxic to hearing.

What action has the Department taken to encourage the regulatory authorities to approve ciprofloxacin eardrops for the treatment of runny ears in Indigenous children? If no action, why not?

Answer:

It is a requirement under the Therapeutic Goods Act 1989 that products to be imported into, supplied in, or exported from Australia be included in the Australian Register of Therapeutic Goods (ARTG). In order for a product to be included in the ARTG, a sponsoring company is required to make an application to have the product included for a particular use (indication). A sponsor cannot be compelled to submit an application to register or supply a product or to vary the particular use (indication) for that product.

The TGA has contacted the sponsor of this product and informed it of the study. The TGA encouraged the sponsor to consider making an application to have the ciprofloxacin product, Ciloxan, registered to treat suppurative otitis media. The application would be used to support a formal extension of use for Ciloxan in the market place.

The NACCHO trial compared two forms of topical treatment for chronic suppurative otitis media. These were the currently recommended (Antibiotic Guidelines) treatment - Sofradex (framycetin/gramicidin/dexamethasone), and a treatment currently used overseas: - ciprofloxacin drops to the ear.

TGA registration of Sofradex ear drops is currently not consistent with treatment of chronic suppurative otitis media, as there is a contraindication to use in the presence of perforation of the tympanic membrane. This was based on data previously provided in support of its other indications, but its usage is a matter for the individual doctor's clinical judgement in practice. Sofradex is currently indicated for inflammatory and allergic conditions of the ear e.g. otitis externa.

The ciprofloxacin treatment used was an eye drop preparation, Ciloxan, because the equivalent ear drop preparation is not currently available in Australia. The only ciprofloxacin ear preparation currently available in Australia is a combination of ciprofloxacin and hydrocortisone, Ciproxin HC ear drops, and is only recommended for use in otitis externa (outer ear infection) in people over the age of 2 years. It also is non sterile. These ear drops are registered in Australia but are contraindicated for use in the presence of perforated tympanic membrane. Use of the eye preparation for chronic suppurative otitis media is not consistent with the registered indications, but again is a matter of clinical judgement by the treating physician.

Recommendations for Clinical Care Guidelines on the management of Otitis Media in Aboriginal and Torres Strait Islander Populations were released in July 2001. These guidelines remain current but may be reviewed to incorporate new evidence and expert advice. OATSIH and the Office of Hearing Services are also participating in a joint workplan which is addressing the recommendations made in the report of the Commonwealth funded review of ear and hearing services. An element of this workplan is to assess the uptake of the guidelines among practitioners to improve the first line management of otitis media.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-109

OUTCOME 1: Population Health and Safety

Topic: PSYCHOSTIMULANTS INITIATIVE

Written Question on Notice

Senator Denman asked:

(a) This question was asked at June 2003 – can we please have an update as question was not answered for parts (a) – (c).

The Portfolio Budget Statements (p.66) allocate additional funding of $2M over two years for the Psychostimulants Initiative. It is indicated that this funding will provide for the evaluation of treatment options and the development of guidelines for frontline workers.

a) Has a decision been made on which treatment options will be evaluated?
b) If not, what will the process of selecting treatment options involve?
c) Who will develop the guidelines for frontline workers?

(b) Have the consultations referred to in the answer now occurred? If not, why not?

Answer:

(a) This information is not available at this time. A detailed implementation strategy for this initiative is currently being finalised.

(b) A consultation process to identify priority areas to be addressed through the Initiative has been conducted with a range of key stakeholders including the Australian National Council on Drugs, the Alcohol and Other Drugs Council of Australia and the National Expert Advisory Committee on Illicit Drugs.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-110

OUTCOME 1: Population Health and Safety

Topic: NATIONAL COMORBIDITY INITIATIVE

Written Question on Notice

Senator Denman asked:

(a) This question was asked at June 2003 – please can we have an update as question was not answered.

In the Portfolio Budget Statements (p.65) $4.4M over two years will be allocated to improve service coordination and treatment outcomes for clients with both illicit drug addiction and mental illness. Could you please provide a further breakdown on how this money will be spent – who it will be distributed to, and what initiatives will it fund?

(b) Have the consultations referred to in the answer now occurred? If not, why not?

Answer:

(a) This information is not available at this time. A detailed implementation strategy for this initiative is currently being finalised.

(b) A consultation process to identify priority areas to be addressed through the Initiative has been conducted with a range of key stakeholders including the Australian National Council on Drugs, the Alcohol and Other Drugs Council of Australia and other experts in the field.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-112

OUTCOME 1: Population Health and Safety

Topic: COMORBIDITY

Written Question on Notice

Senator Denman asked:

(a) The question E03–110 was asked in June 2003 – can we please have an update.

Of the $4.4m allocated in this Budget to look at the National Comorbidity Initiative, what percentage of that will actually be used for Indigenous communities of Indigenous issues?

(b) Have the consultations referred to in the answer now occurred? If not, why not?

Answer:

(a) This information is not available at this time. A detailed implementation strategy for this initiative is currently being finalised.

(b) A consultation process to identify priority areas to be addressed through the Initiative has been conducted with a range of key stakeholders including the Australian National Council on Drugs, the Alcohol and Other Drugs Council of Australia and other experts in the field.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-111

OUTCOME 1: Population Health and Safety

Topic: RURAL AND REGIONAL INITIATIVE

Written Question on Notice

Senator Denman asked:

(a) This question was asked at June 2003 – can we please have an update as parts (a) – (c) were not answered.

The Portfolio Budget Statements (p.68) allocate $4M over the next four years, to improve access to treatment and referral for illicit drug users in rural and regional Australia.

a. How will rural and regional areas be prioritised for this initiative?
b. How will projects be selected under this initiative?
c. How many projects is this funding expected to provide?

(b) Have the consultations referred to in the answer now occurred? If not, why not?
(c) What did the Department's investigation reveal regarding the extent of the unmet need in rural and regional areas for the treatment and referral of illicit drug users?
(d) What were the key areas of deficiencies in terms of services?

Answer:

(a) This information cannot be provided in advance of the outcomes of a consultation process to further define the implementation of the Initiative.

(b) A consultation process to identify priority areas to be addressed through the Initiative is currently being conducted with a range of key stakeholders including the Australian National Council on Drugs, the Alcohol and Other Drugs Council of Australia and other experts in the field.

(c) Until such time as the consultation process is complete, the extent of unmet need in rural and regional areas for the treatment and referral of illicit drug users is unclear.

(d) Until such time as the consultation process is complete, the key areas of deficiencies in terms of services is unclear.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-015

OUTCOME 1: Population Health and Safety

Topic: REVIEW OF THE TOBACCO ADVERTISING PROHIBITION ACT 1992

Written Question on Notice

Senator Denman asked:

Has a decision now been made on the public release of the issues paper relating to the Review of the Tobacco Advertising Prohibition Act 1992? If so, could a copy be provided?

Answer:

The issues paper relating to the Review of the *Tobacco Advertising Prohibition Act 1992* was released for public consultation on 30 August 2003. Its availability was advertised in all major national newspapers, as well as being published on the Department of Health and Ageing's website. Copies were also distributed to relevant individuals and organisations. Submissions on the issues paper closed on 17 October 2003.

A copy of the issues paper is attached.

This issues paper is published on the internet at www.health.gov.au/tobacco

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03–016

OUTCOME 1: Population Health and Safety

Topic: HOUSE STANDING COMMITTEE REPORT ON THE INQUIRY INTO SUBSTANCE ABUSE, RESPONSE TO TOBACCO ISSUES

Written Question on Notice

Senator Denman asked:

(a) Has the Government taken any steps to implement the recommendations of the House Standing Committee Report on the inquiry into substance abuse in Australian communities in each of the following areas:

(i) including tobacco as a priority in relevant national health strategies;
(ii) making tobacco dependence a national health priority;
(iii) requiring the adoption of tobacco control policies and investment as a condition of health care financing at state, territory and agency levels;
(iv) making free or low cost tobacco smoking cessation services and aids readily available throughout Australia, including for pregnant women and their partners;
(v) investigating the cost benefit analysis of subsidising aids such as nicotine patches under the PBS

(b) If so what are, in each case, such steps?

(c) If not, why not, in each case?

(d) Has the Government initiated or does it have any plans to initiate a study of the price elasticity of tobacco consumption in Australia to determine what is the minimum price increase that would stop large numbers of people smoking as a result of the price alone?

(e) If so, what is the nature of such plans?

(f) If not, why not?

Answer:

The issues raised are the subject of recommendations made by the House of Representatives Standing Committee on Family and Community Affairs Report on the Inquiry into Substance Abuse in Australian communities. Responding to these recommendations is a policy matter for the Government.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-018

OUTCOME 1: Population Health and Safety

Topic: SALE OF TOBACCO PRODUCTS

Written Question on Notice

Senator Denman asked:

(a) Has the Government taken any steps either (i) alone or (ii) in conjunction with State and Territory Governments, to develop and legislate for nationally consistent regulations governing the registration and licensing of the wholesalers and retailers of tobacco products? If so what are they?

(b) If not, why not?

(c) If so, do such steps include plans for heavier penalties for the sale of (i) cigarettes and (ii) other tobacco products to minors than apply at present? If so, what are they?

(d) If not, why not?

Answer:

The issues raised are the subject of recommendations made by the House of Representatives Standing Committee on Family and Community Affairs Report on the Inquiry into Substance Abuse in Australian Communities.

Responding to these recommendations is a policy matter for the Government.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-019

OUTCOME 1: Population Health and Safety

Topic: PROMOTION OF TOBACCO PRODUCTS

Written Question on Notice

Senator Denman asked:

(a) Has the Government taken any steps either (i) alone or (ii) in conjunction with State and Territory Governments, to ensure the banning of all remaining forms of the promotion of tobacco products including advertising , sponsorship, incentives to retailers and public relations activities? If so, what are they?

(b) If not, does the Government plan to take any such steps?

(c) If not, why not?

(d) Is the Government concerned about the continuance of any particular form(s) of such promotion? If so, which?

Answer:

(a,b,c) The Australian Government is currently conducting a review of the *Tobacco Advertising Prohibition Act 1992 (*ACT) and has called for public submissions on a recently released Issues Paper. Submissions received will inform any proposed amendments to the Act.

(d) The results of the review will be analysed to identify any areas of concern that may appropriately be addressed by seeking amendments to the legislation.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-020

OUTCOME 1: Population Health and Safety

Topic: EXEMPTION OF NICOTINE FROM CLASSIFICATION AS A POISON

Written Question on Notice

Senator Denman asked:

(a) Has the Government or is the Government considering removing nicotine's exemption from classification as a poison under the Commonwealth's Standard for the Uniform Scheduling of Drugs and Poisons?

(b) If so, when is it planned that the removal would take effect?

(c) If the Government is not considering such removal, why not?

Answer:

The issues raised are the subject of recommendations made by the House of Representatives Standing Committee on Family and Community Affairs Report on the Inquiry into Substance Abuse in Australian Communities.

Responding to these recommendations is a matter for the Government.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-021

OUTCOME 1: Population Health and Safety

Topic: PHARMACOTHERAPY

Written Question on Notice

Senator Denman asked:

(a) What proportion of (i) Commonwealth and (ii) State and Territory Government funding for drug treatment and rehabilitation is available for treatment services to provide comprehensive support to opioid dependent people who are receiving pharmacotherapy?

(b) What amount does this translate to in dollars terms in 2003-2004 and in future years covered by the forward estimates?

(c) For what period of time is such funding available to each recipient?

(d) Is funding available to fund further research and trials of new medications and techniques?

(e) Is funding available to fund research into pharmacotherapies for opioid dependence?

Answer:

(a)(i)Under the National Illicit Drug Strategy 'Tough on Drugs' Non Government Treatment Grants Programme, (NGOTGP) the Australian Government allocates funding to non government organisations to provide drug treatment services across Australia.

No specific proportion of this funding is allocated to any particular treatment type. The specific treatment provided is determined by the service, based on the client's assessed need.

(a)(ii)This information is not available.

(b) In relation to (a)(i) as part of the 2002-03 Budget, $65.1 million (over four years) was allocated by the Australian Government for the continuation of the NGOTGP. This funding is being implemented through a two-stage process.

$47.6 million (over three years) has been allocated to 113 treatment services nationally under Stage 1 of the NGOTGP to a range of treatment services nationally including outreach support, outpatient counselling, inpatient and outpatient detoxification, and medium to long term rehabilitation.

(c) Current services are funded for the period 2003-2004 – 2005-2006.

(c) Yes.

(e) Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-022

OUTCOME 1: Population Health and Safety

Topic: ABSTINENCE PROGRAMS

Written Question on Notice

Senator Denman asked:

(a) Does the allocation of funding within available programmes give priority to treatments including naltrexone that focus on abstinence as the ultimate outcome?

(b) Is there any provision within (i) currently funded programmes or (ii) the forward estimates for Commonwealth funding of a trial of naltrexone implants?

(c) If so, is funding available for support services to ensure a fully valid trial?

Answer:

(a) Under the National Illicit Drug Strategy 'Tough on Drugs' Non Government Treatment Grants Programme, (NGOTGP) the Australian Government allocates funding to non government organisations to provide drug treatment services across Australia.

No specific proportion of this funding is allocated to any particular treatment type. The specific treatment provided is determined by the service, based on the client's assessed need.

(b) The National Health and Medical Research Council is funding a clinical trial of naltrexone implants as part of its $10.2 million funding boost for health and medical research in Western Australia.

(c) See (b) above.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-011

OUTCOME 1: Population Health and Safety

Topic: TREATMENT OF HEROIN ADDICTS INCLUDING METHADONE MAINTENANCE

Written Question on Notice

Senator Denman asked:

(a) Has the Government considered or does it plan to consider the recommendations of the House Standing Committee Report on the inquiry into substance abuse in Australian communities that as a high priority the Commonwealth, State and Territory Governments:

  (i) increase the proportion of heroin addicts in treatment from 45 per cent to 80 per cent of the total number of heroin dependent people in order to reduce heroin-related harm and deaths; and
  (ii) increase the target to include everyone who requests treatment as resources permit?

(b) If not, why not?

(c) What programmes does the Government have in place or plan to provide comprehensive support services to those in receipt of methadone maintenance treatment, in particular to achieve the objective of enabling them to become abstinent from all opioids?

Answer:

The issues raised are the subject of recommendations made by the House of Representatives Standing Committee on Family and Community Affairs Report on the Inquiry into Substance Abuse in Australian Communities.

Responding to these recommendations is a policy matter for the Government.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-013

OUTCOME 1: Population Health and Safety

Topic: AUSTRALIAN NATIONAL COUNCIL ON DRUGS

Written Question on Notice

Senator Denman asked:

(a) Has the Australian National Council on Drugs done any work to date or does it plan to undertake any work to determine the best practice models of residential rehabilitation?

(b) Is there any provision within (i) currently funded programmes or (ii) the forward estimates for Commonwealth funding to establish these models in urban and rural areas?

(c) If so, in which areas will funding be allocated in each year covered by current and forward estimates?

Answer:

(a) The Australian National Council on Drugs (ANCD) has advised that it has not undertaken any work to determine the best practice models of residential rehabilitation, nor is such work planned for the future at this stage.

(b) See (a) above.

(c) See (a) above.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-014

OUTCOME 1: Population Health and Safety

Topic: RESIDENTIAL REHABILITATION PROGRAMMES

Written Question on Notice

Senator Denman asked:

(a) Is it planned to transfer the responsibility and co-ordination of residential rehabilitation programmes from the Department of Health and Ageing to the Department of Family and Community Services to undertake of same?

(b) If so, from when is it planned for this to take effect?

Answer:

The issues raised are the subject of recommendations made by the House of Representatives Standing Committee on Family and Community Affairs Report on the Inquiry into Substance Abuse in Australian communities.

Responding to these recommendations is a policy matter for the Government.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-004

OUTCOME 1: Population Health and Safety

Topic: TGA COMMITTEE

Written Question on Notice

Senator Denman asked:

I refer to Professor Mathew's advice to me at the June Estimates Committee Hearings. Has the TGA Committee which he indicated had a watching brief on the relationship between women over 65 years, HRT and dementia, since produced any reports or studies on the subject. If so, can these be made available? If not, can an indication be given as to when any reports might be expected?

Answer:

The Australian Drug Evaluation Committee has considered this issue twice (at its August and October meetings) and issued a statement on each occasion. These statements are posted on the TGA website. http://www.tga.gov.au/docs/html/hrtadec2.htm
Copies of the statements are attached [not included electronically].

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-114

OUTCOME 1: Population Health and Safety

Topic: POLIO VACCINATION

Written Question on Notice

Senator McLucas asked:

(a) Quantify and graphically depict any price fluctuations in the Oral Polio Vaccine from 1998-2003.

(b) What is the net effect of price rises on the additional cost of the ATAGI recommendation regarding IPV (currently $20 million)?

(c) Is the Department aware of concerns that the supply of OPV to Australia may not be able to be maintained as supply to developing countries should take preference?

(d) Does the Federal Government contribute to the WHO-Rotary partnership to eradicate polio?

(e) How much money is contributed? What other resources are contributed?

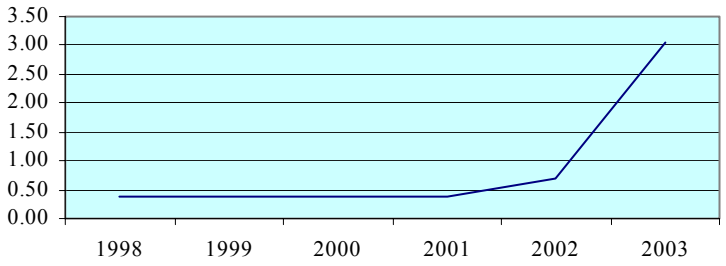
(f) What is the Department's timetable for switching to IPV?

Answer:

(a) The following reflects the price of Oral Poliomyelitis Vaccine (OPV) between 1998 and 2003:

- 1 January 1998 to 31 May 2002, $0.37 per dose
- 1 June 2002 to 30 September 2003, $0.70 per dose
- 1 October 2003 to present, $3.05 per dose.

Price of OPV 1998-99 to 2003-04



(b) The estimated cost of introducing IPV (Inactivated Poliomyelitis Vaccine) to the National Immunisation Program at 2, 4, 6 months and 4 years of age, after offsetting the current price of OPV at $3.05 per dose, is $15.9 million per annum.

(c) The Department is aware of the high demand on OPV due to eradication efforts worldwide. The recent price increase for OPV has provided GlaxoSmithKline Australia with a much more competitive position to ensure supply, and as a result, there are no foreseeable supply issues for Australia.

(d)&(e) Yes. As part of the four-year Global Polio Initiative, the Australian aid program is matching Rotary International's funds for further polio eradication activities, dollar for dollar, up to $10 million over the period 2001-02 to 2004-05. In 2003-04 AusAID will match up to $3.45 million.

AusAID also provides financial assistance through its International Health Program to support poliomyelitis surveillance and routine immunisation activities in the Region. Since 1992, the Australian aid program has contributed over $22 million to surveillance and immunisation campaigns in the region, in China, Cambodia, Indonesia, PNG and the Pacific. In 2002-03, AusAID's International Health Program provided $1.76 million to WHO's Department of Vaccines and Biologicals, which includes funding for polio surveillance and routine immunisation.

The Government is still considering the recommendation from the Australian Technical Advisory Group on Immunisation to replace the OPV currently funded under the National Immunisation Program with the IPV when available in combination. This recommendation will be considered in the context of the 2004-05 Federal Budget.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-115

OUTCOME 1: Population Health and Safety

Topic: IMMUNISATION

Written Question on Notice

Senator McLucas asked:

(a) Manufacturers of vaccines say that it is impossible for them to predict demand when a vaccine is recommended but not funded. There have been reports that parents wanting to purchase NHMRC recommended vaccines have not been able to do so. What, if anything, is the Department doing to assist vaccine manufacturers in ensuring supply?

(b) Doctors' groups such as the RACGP and the AMA said that the two-tiered immunisation scheme is a "nightmare". Specify actions taken by the Department to help doctors in this regard.

Answer:

(a) When a vaccine has been registered for use in Australia by the Therapeutic Goods Administration, a vaccine manufacturer can enter the Australian market. It is a commercial decision of a manufacturer to supply vaccine to Australia depending on their assessment of the market.

(b) The Department of Health and Ageing, in consultation with the National Immunisation Committee, the Australian Technical Advisory Group on Immunisation, and the Minister for Health and Ageing, developed a comprehensive communications strategy to alleviate any potential confusion that may result from the discordance between the technically recommended Australian Standard Vaccination Schedule (ASVS) and the Government funded National Immunisation Program (NIP).

The communications strategy was developed to provide information to parents and immunisation providers including General Practitioners. The following lists the activities undertaken for GPs:

- a mailout with brochure on changes to the ASVS and the NIP;
- updating the Immunise Australia Program website with factsheets, frequently asked questions, the provision of the Handbook, and the NIP summary card;
- provision of advice to the Immunisation Infoline that receives calls from immunisation providers including General Practitioners;
- media releases on changes to the NIP; and

- articles in professional newsletters including:

    - ADGP News (Australian Divisions of General Practice)
    - NGPIC News (a newsletter prepared by the National General Practice Immunisation Coordinator of the Australian Divisions of General Practice)
    - Friday Fax (Royal Australian College of General Practitioners)
    - Immunisation Network Newsletter (Health Insurance Commission)
    - Forum (Health Insurance Commission)
    - GP Review (Royal Australian College of General Practitioners).

The following components of the communication strategy are to be implemented over the next few months:

- direct mailout of the Australian Immunisation Handbook 8th Edition, 2003, a CD-ROM of the Immunisation Handbook, and the National Immunisation Program Summary Card to all immunisation providers and other interested parties;
- technical factsheets for immunisation providers including General Practitioners; and
- updating publications such as 'Understanding Childhood Immunisation', 'Keep It Cool' and 'Immunisation Myths and Realities'.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-144

OUTCOME 1: POPULATION HEALTH AND SAFETY

Topic: IMMUNISATION

Written Question on Notice

Senator McLucas asked:

(c) The process surrounding the recommendations for new vaccines being approved has been extremely long and funding has not been forthcoming for all the vaccines recommended. Can the Government give any justification for the length of time involved?

(d) Are any suggested changes to the process by which vaccines are recommended and funded going forward?

(e) With parents and doctors now facing choices between funded and unfunded vaccines, what are the potential liability issues for doctors if they do not discuss the options with parents?

(f) The Department have previously stressed that all of the recommendations in the draft Handbook were under consideration. Some of these have now been funded. Are the remainder still under consideration or has a decision been reached regarding them?

(g) The recommendations that have had funding announced – the changes to DTPa and the changes to pneumococcal – when will these be implemented?

(h) What cost is associated with each of the recommended vaccines?

(i) Will funding for these recommended vaccines be considered in the context of the 2004-05 Federal budget?

Answer:

(a) In making recommendations to the National Health and Medical Research Council (NHMRC) and the Government, the Australian Technical Advisory Group on Immunisation (ATAGI) follows due process to ensure that the recommendations are based on a scientific review of the evidence, and follows NHMRC procedures and requirements for public consultation and independent review.

The Government has funded several ATAGI vaccine recommendations. The remaining recommendations will be considered in the context of the 2004-05 Federal Budget.

(b) The process for recommending vaccines for inclusion on the Australian Standard Vaccination Schedule is determined by the NHMRC procedures, processes and the *NHMRC Act (1992).* Vaccines provided free under the National Immunisation Program (NIP) are funded through the Special Appropriation for Vaccines. There are no plans to change this funding mechanism.

(c) It is the responsibility of immunisation providers to fully inform themselves and parents of vaccine choices available. The NHMRC approved Australian Standard Vaccination Schedule is a guideline that provides clinical best practice and is to be used by the provider in the context of his or her clinical judgement.

(d) The remaining ATAGI recommendations for funding new vaccine programs under the NIP remain with Government for consideration of future funding.

(e) The removal of the 18 month dose of diphtheria-tetanus-acellular pertussis (DTPa) vaccine became effective on 19 September 2003, following an announcement by the Minister for Health and Ageing.

Replacement of Adult Diphtheria and Tetanus (ADT) vaccine with adult/adolescent formulation diphtheria-tetanus-acellular pertussis (dTpa) vaccine for adolescents aged 15-17 years will occur from 1 January 2004, following discussion with States and Territories. Expansion of the National Childhood Pneumococcal Vaccination Program to include additional groups of children with identified predisposing medical conditions occurred immediately in most jurisdictions. Queensland and the Northern Territory have chosen to implement the expansion from 1 January 2004.

(f) This question was answered at the Supplementary Budget Estimates Hearing of 5 November 2003 by Mr Ross O'Donoughue (see page CA 129 of the Proof Committee Hansard of 5 November 2003) and clarified in a letter to the Senate Community Affairs Legislation Committee from Mr Andrew Stuart dated 27 November 2003.

(g) Yes.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-145

OUTCOME 1: Population Health and Safety

Topic: VACCINES

Written Question on Notice

Senator McLucas asked:

(a) How much does the Government estimate parents would have to spend to immunise their children with the vaccines recommended by the NHMRC but which they refuse to fund?

(b) Does the Government recognise that their decision is likely to mean that vaccine manufacturers will promote approved and recommended vaccines which will compete with funded vaccines?

(c) Does the Government acknowledge that having two schedules - one funded and the other recognised as best practice - will drive reduced credibility and confidence in the immunisation schedule as the funded program is likely to be perceived to include 'second best' vaccines compared to those available privately?

(d) Will this contribute to falling vaccine coverage rates?

(e) Recognising that the burden of pertussis falls more heavily in adolescents than in children, does the Government intend to supplement the adolescent dose of DTPa with a 'catch-up' program aimed at all 12-17 year olds?

Answer:

(a) The Government has not refused to fund the remaining vaccine recommendations and has these under consideration. The private purchase price of vaccines varies between pharmacies.

(b) No. There have always been vaccines available on the private market that have not been recommended on the Australian Standard Vaccination Schedule or funded under the National Immunisation Program. Immunisation providers will continue to provide all relevant information to parents and carers on vaccine choices to ensure informed consent. Parents and carers can choose to immunise their child/ren against any disease with vaccines provided free under the National Immunisation Program or with vaccines purchased privately. Vaccines provided free under the National Immunisation Program

will not be influenced by vaccine companies promoting their products on the private market.

(c) & (d)

No. The Government does not recognise that there are two schedules. Australia has one schedule, a technical best practice schedule approved by the National Health and Medical Research Council, called the Australian Standard Vaccination Schedule, and a Government funded National Immunisation Program that provides free vaccine against a core set of diseases. The Government does not accept the statement that the National Immunisation Program contains "second best" vaccines. All vaccines funded under the National Immunisation Program have been approved by the Therapeutic Goods Administration for use in Australia and are also included on the National Health and Medical Research Council "best practice" Australian Standard Vaccination Schedule.

Clearly articulating the distinction between the Schedule and the Program is imperative to maintaining the excellent coverage Australia enjoys today. The Australian Government has developed and is implementing a comprehensive communication strategy. This Strategy and the continued support of immunisation providers, professional organisations and the community will reassure parents and carers and prevent declining coverage rates.

(e) No. The Australian Standard Vaccination Schedule in the Australian Immunisation Handbook 8th Edition recommends adult/adolescent formulation diphtheria-tetanus-pertussis (dTpa) vaccine at 15 to 17 years of age. The reasons for recommending this vaccine at this age include the need to ensure an adequate interval between vaccines that contain tetanus antigens and to reduce the burden of disease in older adolescents who will soon be moving into child-bearing years. The Australian Technical Advisory Group on Immunisation did not recommend a catch-up component for adolescent dTpa vaccination.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-032

OUTCOME 1: Population Health and Safety

Topic: DSEB - IMPLANON

Written Question on Notice

Senator Harradine asked:

(a) In answer to question EO3-054 (June 2003) at (d) the Department lists a number of options ADRAC can use for obtaining further information about reports. Is ADRAC pursuing any of these options to obtain more information about reasons for pregnancies after insertion of Implanon?

(b) In question (e) I asked "What is the Department doing to ensure this [incorrect insertion/failure of Implanon resulting in subsequent pregnancy] does not happen again?" The answer provided referred to consumer medicine information and physician training - it does not describe any new initiative of the Department to prevent repeat cases. If the Department is not taking any action, please provide reasons as to why not?

Answer:

(a) In answer to question E03-054 (June 2003), the TGA listed a number of options ADRAC can use for obtaining further information about reports. The relevant option in the case of the reports of pregnancy and insertion of Implanon is that if ADRAC receives a report with insufficient information from a sponsor company, then that company may be asked to obtain and provide further details. The TGA has contacted Organon and made such a request on several occasions (most recently in October 2003), but no further information is available at this time.

(b) The TGA does not regulate medical practice, it regulates the pharmaceutical industry through the supply of therapeutic goods, and this is the area in which the TGA can take action. As part of the terms and conditions of product approval, the TGA regulates Product Information (PI) documents and the information in the PI documents is then reflected in the Consumer Medicine Information (CMI) documents.

The TGA reviewed the PI document for Implanon and requested that the CMI document also refer to the palpability of the inserted rod. Organon agreed to do this.

The instructions on insertion and timing of insertion are considered adequate in the light of available information on the cases of failure.

As described in E03-054 (June 2003), the TGA is also aware of the training program provided by the sponsor, Organon, and supports doctors attending this if they are using Implanon.

The PI states:

"The presence of the implant should be verified by palpation directly after insertion. If the implant cannot be palpated or when the presence of the implant is in doubt, other methods must be applied to confirm its presence (see How to insert Implanon, below). Until the presence of Implanon has been verified, a backup contraceptive method must be used.

Implanon should be inserted on day 1 to 5, but at the latest on day 5, of the woman's natural cycle (day 1 being the first day of her menstrual bleeding).

The use of Implanon during pregnancy is contraindicated."

The CMI states:

"Before you have Implanon inserted or removed, confirm that your doctor is familiar with the technique. For uncomplicated removals, it is necessary that Implanon be inserted directly under the skin. Incorrect insertion may lead to complicated removals that may result in scarring.

Make sure your doctor shows you how to gently feel the implant in your arm after insertion. If you cannot feel the implant in your arm after insertion you should tell your doctor and use a back up method of contraception until the presence of the rod is confirmed. Avoid manipulating the rod after insertion to prevent it from moving from its original position."

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-033

OUTCOME 1: Population Health and Safety

Topic: DSEB - IMPLANON

Written Question on Notice

Senator Harradine asked:

(a) In answer to question EO3-055 (June 2003) at (a) Organon (Australia) provided a response through the TGA which stated "the doctor should rule out pregnancy before insertion of the implant". How does the doctor do this without a pregnancy test? Organon also stated "The product information states that the implant is to be inserted on days 1-5 of the menstrual cycle. This precludes the possibility that the user is pregnant at the time of the insertion". How is it possible that in 43 cases doctors could get this wrong? Can the Department provide information as to how much later after 1-5 days of the menstrual cycle Implanon was inserted and why a pre-existing pregnancy was not ruled out? Doesn't the fact that 43 women were pregnant demonstrate that the TGA's assertion that "These precautions should be adequate" is not valid?

(b) In answer to question (b) the TGA refers a number of times to "insufficient information about the outcomes of those pregnancies and the status of the Implanon implant (i.e. removed/not removed)". How can the Department provide information relevant to women's health and the health of their children and to improving medical practice in this area when there is so much missing information? Does this concern the Department and what is the Department going to do about it? The Department states "Organon has assured the TGA that it is monitoring on-going pregnancies and will advise the TGA of any adverse outcomes in infants". Could the TGA please pass on any advice in this regard to the Committee?

Answer:

(a) The product information document does state that the implant is to be inserted on Days 1–5 of the menstrual cycle (Day 1 being the first day of menstrual bleeding). If this instruction is followed, this should mean that the implant is not inserted in someone already pregnant.

It is possible that some if not all of the doctors in the 41 cases inserted implants after Day 5 of the menstrual cycle, or that they may have acted on incomplete or inaccurate information in determining the day of cycle.

While the TGA does not regulate the practice of doctors, individual doctors may choose to supplement the advice on insertion on Days 1–5 with a pregnancy test. However, as indicated in the response to E03-055 (June 2003), the TGA agrees with the sponsor that the precautions around insertion on Days 1–5 of the menstrual cycle should be adequate.

(b) Information from spontaneous, post-marketing adverse event reports is only one component of the information available to the TGA when making decisions regarding medicines. The TGA considers many other sources of information, including clinical trial results (including, but not limited to, those submitted as part of a medicine's initial registration package), published data from the medical literature, reports from international regulatory agencies, and local expert advice. It is also a requirement of registration that the TGA be regularly provided with a report containing details and analysis of all adverse events reported for that medicine internationally. This is called the Periodic Safety Update Report, or PSUR.

The TGA does not have regulatory powers over medical practice. While it actively encourages medical practitioners to report adverse events, and Australia has perhaps the world's highest per capita reporting from practitioners, it does not have any powers to require reporting. Despite this, the TGA has been in contact with Organon on several occasions (most recently in October 2003) to see if further information can be provided, but no further information is available at this time. The TGA will pass on any advice it receives from Organon in relation to any adverse outcomes in infants.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-034

OUTCOME 1: Population Health and Safety

Topic: EXPERT COMMITTEE - REVIEW COMPLEMENTARY MEDICINES INDUSTRY

Written Question on Notice

Senator Harradine asked:

I have received a number of letters from constituents concerned about the Expert Committee appointed to review the Complementary Medicines Industry. How does the Department respond to concerns that:

(a) The committee has no expertise from the important health food retail sector, or herbal manufacturing;

(b) There is no naturopath and no General Practitioner who practices natural healthcare on the committee; and

(c) The committee has representatives from pharmaceutical companies, and the OTC pharmaceutical industry body but the industry association, the Complementary Healthcare Council, is not represented?

Answer:

(a) A complete list of members of the Expert Committee is included as Attachment 1.

Membership of the Expert Committee includes four members with experience in the manufacture and marketing of complementary medicines: Mr Ross Johnston (Vice President of Manufacturing Operations, Asia Pacific, Wyeth), Mr Darin Walters (Chief Executive Officer, Blackmores Ltd), Ms Juliet Seifert (Executive Director, Australian Self-Medication Industry (ASMI)) and Mr Phillip Daffy (Consultant to the complementary medicines industry, including the Complementary Healthcare Council of Australia (CHC)).

(b) Mr David McLeod is a practising naturopath. Dr Stephen Myers has a Bachelor of Medicine and is also qualified as a naturopathic practitioner.

(c) Members of the Expert Committee were selected on the basis of their expertise in relevant areas relating to complementary medicines and the health system, not as representatives of various stakeholder groups.

ASMI also represent the complementary medicines industry and Ms Juliet Seifert, the CEO, was included because of her expertise in the quality use of medicines, including complementary medicines.

Mr Philip Daffy is a consultant to the CHC and Mr Darin Walters, CEO of Blackmores Ltd were also members of the Committee. Blackmores Ltd is a prominent member of the CHC.

Attachment 1

EXPERT COMMITTEE ON COMPLEMENTARY MEDICINES IN THE HEALTH SYSTEM

COMMITTEE MEMBERS

NAME	AFFILIATION	*EXPERTISE*
Dr Michael Bollen (Chair)	Former member of the National Health and Medical Research Council Principal, BMP Healthcare Consulting Pty Ltd	Quality use of medicines, healthcare delivery, consumer medicines information and general medical practice
Dr John Aloizos	Chair, Australian Pharmaceutical Advisory Council	Implementation of all aspects of National Medicines Policy and general medical practice
Associate Professor Alan Bensoussan	Centre for Complementary Medicine Research, University of Western Sydney Member, Expert Advisory Panel on Complementary Medicines	Use and evaluation of complementary medicines and therapies in clinical practice; practitioner education and training
Dr Kerry Breen	Chair, NHMRC Australian Health Ethics Committee	Ethical issues associated with the promotion and use of medicines
Professor Terry Campbell	Head, UNSW Department of Medicine St Vincent's Clinical School, Sydney Member, Pharmaceutical Benefits Advisory Committee	Clinical pharmacology
Mr Philip Daffy	Consultant to the complementary medicines industry including the Complementary Healthcare Council of Australia	Product development complementary medicines
Dr Paul Dugdale	Chief Health Officer, ACT Department of Health	State and Territory issues associated with practitioner regulation, regulation of dispensed and extemporaneously compounded complementary medicines
Associate Professor John Eden	University of New South Wales, School of Women's and Children's Health	Use of complementary medicines and therapies in medical practice, particularly in women's health
Mr Ross Johnston	Vice President Manufacturing Operations Asia Pacific Wyeth	Quality assurance in the manufacture of complementary, OTC and prescription medicines

Professor Alastair MacLennan	Department of Obstetrics and Gynaecology, University of Adelaide	Complementary medicine epidemiology and safety of complementary medicines
Mr David McLeod	Naturopath, Fellow with the Australian acupuncture and Chinese Medicine Association	Use of complementary medicines in complementary medicine practice; practitioner education and training
Professor Stephen Myers	Director, Australian Centre for Complementary Medicine Education and Research, Southern Cross University/ University of Queensland Member, Complementary Medicines Evaluation Committee	Use and evaluation of complementary medicines in medical practice; practitioner education and training
Mr Anthony Nunan	Principal - Parade Pharmacy; Nunan's Watsonia Pharmacy; Heath's Road Medical Clinic Pharmacy Chairman – Australian Medicines Handbook	Small business issues; quality use of medicines; postgraduate pharmacist education and training; pharmacy
Ms Juliet Seifert	Executive Director, Australian Self-Medication Industry	Quality use of medicines and industry issues, including complementary medicines
Associate Professor Anne Tonkin	Department of Clinical and Experimental Pharmacology, University of Adelaide Former Chair, Complementary Medicines Evaluation Committee	Evaluation of efficacy and clinical pharmacology, medical education
Mr Darin Walters	Chief Executive Officer; Blackmores Ltd	Complementary medicines industry
Professor Bill Webster	Head, Department of Anatomy and Histology, University of Sydney Member, Complementary Medicines Evaluation Committee	Toxicology and the safety of complementary medicines
Associate Professor Heather Yeatman	Head, Graduate School of Public Health, University of Wollongong Member, Complementary Medicines Evaluation Committee Member, Food Standards Australia New Zealand Board	Consumer issues associated with the use of complementary medicines, food and nutrition

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-035

OUTCOME 1: Population Health and Safety

Topic: EXPERT COMMITTEE - REVIEW OF COMPLEMENTARY MEDICINES INDUSTRY

Written Question on Notice

Senator Harradine asked:

How far has the committee advanced in its review and when is the report expected to be completed?

Answer:

The Expert Committee presented its recommendations to the Parliamentary Secretary, the Hon Trish Worth MP, on 26 September 2003. Ms Worth publicly released the Committee's report and invited stakeholder comment on 31 October 2003.

The Government is consulting widely on the Expert Committee's findings and recommendations to help inform its response to the report. Copies of the report have been sent to more than 80 stakeholder groups, including members of the complementary medicine industry, practitioner and consumer groups, seeking their comments. In addition, a copy of the report is available for downloading from the TGA's web-site and comment has been invited from interested groups or individuals. The closing date for submissions is 31 January 2004.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-100

OUTCOME 1: Population Health and Safety

Topic: EXPERT COMMITTEE ON COMPLEMENTARY MEDICINES IN THE HEALTH SYSTEM

Written Question on Notice

Senator Forshaw asked:

In respect to the Expert Committee on Complementary Medicines in the Health System (the Bollen report) please provide the following information:

(a) Copies of the Committee's Minutes and Meeting papers;

(b) Copies of correspondence between the Committee and the Minister for Health, the Parliamentary Secretary for Health, officials of the Department of Health and the TGA;

(c) Copies of all reports, papers and expert testimony that the Committee received.

Answer:

(a), (b) & (c)
The Expert Committee was established to provide a response on matters related to its Terms of Reference. Members participated on the clear understanding that their views, expressed at the various committee meetings, would remain confidential. Similarly, submissions were made to the Expert Committee in the expectation that the contents would be available only to the Committee. The internal workings of the Committee are therefore considered to be confidential to the Committee itself. Disclosure of the documents sought could have a substantial adverse effect on the ability of the TGA to secure appropriately qualified and experienced persons to serve on committees and provide open and robust advice in the future and on the willingness of external stakeholders to provide input to those deliberations.

The results of the deliberations by the Expert Committee are set out in their report titled *Complementary Medicines in the Australian Health System* released for public consultation in October 2003. A copy of this report is attached (Attachment 1) and is also available on the TGA's web site at http://www.tga.gov.au/docs/pdf/cmreport.pdf

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-036

OUTCOME 1: Population Health and Safety

Topic: IBUPROFEN

Written Question on Notice

Senator Harradine asked:

I refer to a recommendation of the National Drugs and Poisons Schedule Committee to allow the sale of the anti-inflammatory Ibuprofen in supermarkets for the first time.

a) Could the Department provide reasons for this decision?
b) Has the Department considered concerns expressed by the Pharmacy Guild of Australia that it "has grave concerns for the public safety" because of the recommendation?
c) How are consumers to be advised that Ibuprofen is a poor option for people suffering stomach ulcers, asthma, and high blood pressure and for women in either the first or third trimester of pregnancy?
d) Did the NDSPC consider the Guild's argument that selling the drug in supermarkets may lead to up to 20,000 "adverse events" a year?

Answer:

a) Although the National Drugs and Poisons Schedule Committee (the Committee) is constituted under the *Therapeutic Goods Act 1989* and the Department provides the Secretariat, the *Therapeutic Goods Regulations 1990* (Section 42ZCX) requires the Committee and not the Department to make a record of the reasons for its scheduling decisions. The Committee is required to include in a public notice instruction on how the record of reasons for an amendment may be accessed. The record of reasons relating to the decision to reschedule ibuprofen is attached.

b) The Pharmacy Guild of Australia made submissions to both the June 2003 and October 2003 meetings of the Committee. The Committee considered the information submitted by the Guild when reaching its decision.

c) Consumers will be advised through appropriate labelling to be mandated in the entry for ibuprofen in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

d) Yes. The claim was included in the Pharmacy Guild's submission considered by the October 2003 meeting.

Attachment 1.

EXTRACT FROM THE RECORD OF REASONS OF MEETING 39 OCTOBER 2003
IBUPROFEN (Item 12.2)

PURPOSE

The Committee considered further public submissions in relation to June 2003 decision to exempt small packs of ibuprofen from scheduling.

BACKGROUND

2. The June 2003 NDPSC Meeting made an initial decision to exempt from scheduling divided preparations containing 200 mg or less of ibuprofen per dosage unit in packs containing 25 or less dosage units when labelled with a recommended maximum daily dose of 1200 mg of ibuprofen. The decision was based on the Committee's opinion that:

The proposed indication and the product are suitable for self-identification and self-treatment without professional advice;

The safety profile of low dose ibuprofen in the OTC setting is good;

A comparison with similar unscheduled analgesic products (aspirin and paracetamol in small pack sizes) indicated that short term intermittent use of low dose ibuprofen had a relatively good safety profile.

Ibuprofen administered orally has been demonstrated to have a wide therapeutic index and the risk of masking a serious disease is very low.

Ibuprofen has a very low to absent potential for abuse.

There is considerable OTC marketing experience in Australia as well as considerable international marketing experience with prescription, pharmacy and general sales. The spontaneous reporting rates of adverse events in Australia and overseas has also been low.

DISCUSSION

Members noted that a large number of post-meeting submissions were received (Attachment 3). Some submissions were from those who did not make a pre –meeting submission and therefore, did not comply with regulation 42ZCZ of the Therapeutic Goods Regulations 1990. Nonetheless, the Committee agreed to consider all submissions received up to 17 September 2003 for this item.

The consideration commenced with a presentation by an expert member who had reviewed in detail the submitted references. The Committee discussed the following points raised in post-meeting submissions opposing the decision to exempt low dose ibuprofen from scheduling.

Concerns about the PAIN study

The Committee noted that several submissions enclosed or quoted an article recently published in Australian Pharmacist by Professor Gregory Peterson (University of Tasmania) regarding the PAIN study referred to in the sponsor's submission. The PAIN study was a large randomised clinical trial investigating the tolerability of aspirin, ibuprofen and paracetamol for short-term analgesia. XXXXXXXXXX expressed doubt on the methodology and hence the strength of evidence presented in the PAIN study on which he believed the

down-scheduling decision was based. He pointed out that the published paper did not include comprehensive inclusion and, in particular, exclusion criteria for patients included in the study.

A copy of the final clinical trial report for the PAIN study, which contained more details than the published version, had been obtained by the Secretariat and reviewed by an expert member. It was noted that the exclusion criteria in the PAIN study were essentially the contra-indications associated with ibuprofen, aspirin and paracetamol, which included gastrointestinal ulcer, pregnancy or lactation, allergy to NSAIDs and severe asthma. Members were of the view that it seemed probable that the cohorts studied in the PAIN Study were similar to those who would take appropriately ibuprofen purchased on unrestricted sale. It was noted that the contraindications and precautions associated with the use of ibuprofen were to be covered by appropriate labelling of the small packs.

The Committee noted that after excluding patients with a history of upper gastrointestinal ulcer in the PAIN study, the incidence of drug-induced abdominal pain and dyspepsia was lower in the ibuprofen-treated group than with other groups. On this basis, it was reasonable to conclude that based on the findings of the PAIN study, low dose ibuprofen for intermittent and short term use had a better gastrointestinal safety profile compared to aspirin and paracetamol for the same use.

Concerns on gastrointestinal complications

The Committee noted that several submissions expressed concern on the potential gastrointestinal (GI) complications induced by ibuprofen. The FDA report (Memorandum from RA Bonnel et al, 2002) referred to by XXXXXXXXXX, reviewed 197 cases of GI bleeds, ulceration or perforation reported for over-the-counter NSAIDs in the US during 1998-2001, including 105 cases for ibuprofen. FDA reviewers concluded that the patients in the study were at increased risk for GI bleeding in the setting of a past GI event, other significant inter-current illness or past medical history, consumption of alcohol, tobacco use or use of another OTC or prescription medication concomitantly. The expert member noted that the FDA report did not include a reference to the denominator of exposure during the specified time and therefore, a true incidence of GI events could not be determined for this OTC use. Furthermore, another reference provided by XXXXXXXXXX (McCarthy et al 1999) which estimated the risk of adverse events in patients using various classical NSAIDs based on outcome studies of large databases suggested ibuprofen to be considerably safer in terms of upper GI complications compared to other NSAIDs including aspirin, naproxen, diclofenac, piroxicam and ketoprofen.

The Committee agreed that any potential gastrointestinal complications could be covered by an appropriate warning statement.

Concerns about the elderly users and potential risks.

Members noted that although the majority of users of unscheduled analgesics would be healthy individuals aged under 50, based on the sponsor's claim which was accepted by the NDPSC, there would be a population of users at or over 65 years. Several submissions expressed their concerns on the potential risks for ibuprofen use in this sub-population given its side effects and contraindications.

The Committee noted information cited by XXXXXXXXXX and XXXXXXXXXX (from Newspoll survey) that "nearly a quarter of a million Australian could potentially take low-dose aspirin and ibuprofen together". The Committee also noted information cited by XXXXXXXXXX (from survey of pharmacists) that 1% of the total pharmacy response had

reported intervention by the pharmacist in a requested sale of ibuprofen to someone already taking low-dose aspirin. The Committee noted that concern about the possible interference of ibuprofen with the cardioprotective effects of low-dose aspirin was based on a study of the effects of cyclooxygenase inhibitors on antiplatelet effects of aspirin (Catella-Lawson et al, NEJM, 2001) and a study of clinical events using a clinical record database (MacDonald TM, Wei L. Lancet 2003). In this latter study, the patients had had their medication supplied by a hospital system and may have been taking ibuprofen long term. Members indicated that it was not possible to draw firm conclusions relevant to the general sale of ibuprofen from this study as there was a lack of information on doses and duration of treatment with ibuprofen, and no adjustment for severity of diseases and other risk factors (e.g. smoking) was made for each treated group.

Members were of the view that although long term use of ibuprofen might interact with the cardioprotective effects of low-dose aspirin, this effect was unlikely to be a significant concern with short term use of low dose ibuprofen based on available information. The Committee decided that inclusion of a precautionary statement relating to use of ibuprofen in elderly patients, such as "Unless a doctor has told you to, don't use this product if you are taking other medicines containing aspirin or other anti-inflammatory medicines or other medicines you are taking regularly" would reduce possible risks associated with self-administration of ibuprofen in patients taking low dose aspirin.

Concerns on women users and the risk of miscarriage

The Committee noted that several post-meeting submissions mentioned the findings of a cohort study conducted in the US and published in the British Medical Journal (Li et al 2003), which suggested an increase in relative risk for miscarriage in users of NSAIDs. The cohort study was based on interviews of 1055 pregnant women recruited immediately after confirmation of pregnancy, about the use of NSAIDs, aspirin and paracetamol. The paper did not provide an analysis for each of the NSAID used by the subjects in the study except aspirin, and had the limitation of being a *post hoc* analysis of a study originally designed to assess the prenatal exposure to magnetic fields. Whilst it was noted that the cohort study concluded that paracetamol had no effect on the risk of miscarriage, members' attention was drawn to an early finding of a heightened risk of spontaneous abortion or foetal death in paracetamol overdose during pregnancy (Riggs et al, Obstet Gynaecol 1989).

Based on available information, there was no compelling evidence to suggest that ibuprofen was associated with a higher incidence of miscarriage compared to other NSAIDs. However, the Committee agreed that it was appropriate to include a precaution not to use ibuprofen if pregnant on the product label.

Concerns on NSAIDs-related renal failure ("triple whammy")

Members discussed the potential risk of drug-related renal failure associated with the use of NSAIDs together with ACE inhibitors and/or diuretics. Some recent Australian data (ADRAC, 1990-2002) were provided. These indicated that the number of reported cases of renal failure implicated with 1). ibuprofen alone, 2). Ibuprofen and ACE inhibitor or diuretic, or 3). Ibuprofen, ACE inhibitor and diuretics represented only 3-4% of the total reports of renal failure attributed to all NSAIDs, alone or in combination. While great caution was needed to interpret spontaneous reports data it was suggested that ibuprofen showed fewer reported adverse renal effects compared to other NSAIDs.

The XXXXXXXXXX representative expressed concern that the Committee was down-playing the importance of the ADRAC reports of renal failure and was potentially showing a lack of consistency in decision-making. The Committee considered that these concerns would be addressed through appropriate labelling.

NSAIDs-induced asthma
Members were aware of the concerns on NSAIDs-induced asthma by several respondents. Similar to that for aspirin, a warning statement for NSAID-induced asthma was already proposed for ibuprofen products.

Concerns on the pack size of the product
XXXXXXXXXX claimed that 25-dose forms representing a 4-day treatment was an excessive pack size for open sale ibuprofen. However, XXXXXXXXXX did not provide any evidence to support the safety concern raised with the 25-tablet (5 g ibuprofen) pack size, which the Committee noted was equivalent to the pack size of general sale aspirin (7.5 g) and paracetamol (12.5 g). On this basis, the Committee agreed that the pack size limit of 25 tablets (total of 5 g ibuprofen) remained appropriate.

Consultation to doctors / pharmacists
Several pharmacy organisations raised the issue that use of ibuprofen required pharmacist consultation, given the potential side effects. The Committee noted that the current S2 classification did not require intervention by a pharmacist in each sale. The Committee also noted that the potential side effects associated with short-term use of ibuprofen would be dealt with in the warning statements that would be required for general sale products. In addition, the Committee emphasised that a decision to exempt a product from scheduling does not preclude the sale of such a product in pharmacies where access to a pharmacist is available to consumers.

Current availability
Ibuprofen in divided preparations containing 200 mg or less of ibuprofen per dosage unit in a pack containing 50 or less dosage units and labelled with a recommended daily dose of 1200 mg or less of ibuprofen was included in Schedule 2 (S2) in May 1995. S2 means that pharmacist intervention is not mandatory at the point-of-sale, and that the request for advice is initiated by the purchaser. During this period of S2 availability, no significant safety issues were submitted to the Committee. In addition, a member advised that ibuprofen was an S2 product in NSW, which was allowed to be sold in country stores without pharmacists, and this had not given rise to major adverse cases being reported.

Consistency with other NSAIDs in scheduling
The Committee confirmed that ibuprofen was a NSAID with a good safety record that was comparable to paracetamol and better than aspirin, particularly, in relation to gastrointestinal events. Although paracetamol was generally considered as the first line analgesic agent, ibuprofen was safer than paracetamol in overdose, due to the hepatotoxicity associated with paracetamol overdose.

The Committee concluded that there was sufficient evidence to support the exemption from scheduling requirements of intermittent low dose and short-term use of ibuprofen, provided that appropriate warning statements were included on the product label.

DECISION 2003/39 – 19 - Variation of Amendment (Decision 2003/38 – 23)

In accordance with subregulation 42ZCZ(3), the Committee agreed to vary the amendment (Decision 2003/38-23) made at the June 2003 meeting to exempt divided preparations containing 200 mg or less of ibuprofen per dosage unit in packs containing 25 or less dosage units when labelled with a maximum recommended daily dose of 1200 mg of ibuprofen from scheduling, by amending the label Warning

Statements.

The decision was based on the following reasons:

The indications for low dose (≤1200 mg/day) oral administration of ibuprofen are suitable for self-identification and treatment without professional advice.

Ibuprofen has a comparable safety profile to existing unscheduled analgesic products (aspirin and paracetamol in small pack sizes) indicated for the same use.

Ibuprofen products have been available for general sale in the USA since 1984, and in the UK since 1996 with no significant safety issues arising over that time, and there is considerable OTC marketing experience in Australia as an S2 medicine.

Ibuprofen has a wide therapeutic index, and the risk of masking a serious disease is very low.

Appropriate warning statements for GI complications, pregnancy, asthma and use in certain age groups have been included to reduce the risks in sensitive sub-populations.

Ibuprofen has a very low to absent potential for abuse.

Schedule 2 - Amendment

IBUPROFEN - amend entry to read:

IBUPROFEN in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen:

(a) in liquid preparations when sold in the manufacturer's original pack containing 4 grams or less of ibuprofen; or

(b) in divided preparations, each containing 200 mg or less of ibuprofen, in packs of 100 or less dosage units **except** when:

(i) as the only therapeutically active constituent other than an effervescent agent;

(ii) packed in blister or strip packaging or in a container with a child-resistant closure;

(iii) in a primary pack of 25 or less dosage units;

(iv) the primary pack is labelled with a warning statement to the following effect:

WARNING - This medication may be dangerous when used in large amounts or for a long time (period);

CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. Prolonged use without medical supervision could be harmful; or

CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. Prolonged or excessive use without medical supervision could be harmful; and

(v) the primary pack is labelled with warning statements to the following effect:

Don't use [this product / name of the product]:
If you have a stomach ulcer
In the last 3 months of pregnancy [*This statement may be omitted in preparations used exclusively for the treatment of dysmenorrhoea*]
If you are allergic to ibuprofen or other anti-inflammatory medicines; and

Unless a doctor has told you to, don't use [this product / name of the product]:
For more than a few days at a time
With other medicines containing aspirin or other anti-inflammatory medicines or other medicines that you are taking regularly
If you have asthma
In children 6 years of age or less
If you are aged 65 years or over
If you are pregnant [*This statement may be omitted in preparations used exclusively for the treatment of dysmenorrhoea*].

Schedule 4 - Amendment

IBUPROFEN - amend entry to read:

IBUPROFEN **except**:

(a) when included in or expressly excluded from Schedule 2; or

(b) in preparations for dermal use.

ATTACHMENT 3 - IBUPROFEN SUMMARY OF POST-MEETING COMMENTS - ITEM 12.2

XXXXXXXXXXX was satisfied with the decision made in the June 2003 Meeting, and seeks to further clarify: 1) Only one of the three warning statements from Appendix F, 34 and 35 will be required in Schedule 2 – then Amended entry for ibuprofen; 2) Recent approval of the XXXXXXXXXXX label by the TGA/MEC is taken to be compliance with the scheduling requirements. XXXXXXXXXXX also provided remarks on recent media coverage relating to safety issues, including hospital admissions due to improper use of medicines; potential drug-drug interactions; contraindications; and aspirin-sensitive asthmatics. In addition, XXXXXXXXXXX submitted another letter (dated 7/10/2003) to comment on some media coverage, in particular, on a paper recently published in British Medical Journal (2003) regarding NSAIDs and the risk of miscarriage.

- XXXXXXXXXXX expressed their interest on the decision, and further presented a recent press release on the effect of ibuprofen in breast cancer. According to XXXXXXXXXXX, USA, long term use (5 years or longer) of low doses of ibuprofen is associated with a significantly decreased risk of breast cancer among postmenopausal women, probably by inhibiting cyclooxygenase-2 (COX-2). It was more effective than aspirin, and paracetamol was not protective.

- XXXXXXXXXXX did not support the decision. XXXXXXXXXXX submitted that the points listed in the Record of the Reasons in fact indicate that ibuprofen meets the criteria for S2. XXXXXXXXXXX submitted what it claimed was new evidence on the potential risk of ibuprofen.

  - It was claimed that a study in the UK found that the third most frequently implicated class was NSAIDs accounting for 12.5% of all drug-related admissions (76% for cardiovascular and central nervous system drugs).
  - It was claimed that a study in US revealed a relationship between NSAID use and miscarriage.
  - It was claimed that an increased risk of heart/renal failure is associated with the use of NSAIDs together with ACE inhibitors and/or diuretics (“triple whammy”).
  - It was claimed that a US survey showed that there was a high prevalence of analgesic use in the adult population, and a high rate of multiple analgesic use in females and younger age groups.

- XXXXXXXXXXX opposed the decision. XXXXXXXXXXX submitted a Newspoll study on the incidence of concomitant use of blood thinning medication and ibuprofen for pain relief, which included 604 males and females 45 years and over. On this basis, the following points were highlighted by XXXXXXXXXXX from the survey report:

  - 43% of the total 604 patients were identified as being at risk of suffering a heart attack or stroke due to conditions including diabetes, high blood pressure, high cholesterol, previous heart attack or stroke.
  - 26% of the total subjects stated that they took blood-thinning medication to prevent a heart attack or stroke, and from these 71% took aspirin products, and 29% took prescription and other products. 86% of the subjects who took blood-thinning medication also reported taking a pain relief medicine in the last 12 months.

- XXXXXXXXXXX submitted that in the last 12 and 3 months, 17% and 8% respectively of those taking aspirin to prevent a heart attack or stroke also took an ibuprofen product to relieve pain.
- XXXXXXXXXXX submitted that clinical studies have demonstrated that concomitant administration of ibuprofen antagonises the irreversible platelet inhibition induced by aspirin, thereby having a deleterious impact on its cardioprotective effects. XXXXXXXXXXX stated that the adverse event data from UK and USA directly associated with ibuprofen could not be considered satisfactory to substantiate a rescheduling to open sale status.
- XXXXXXXXXXX submitted that paracetamol is considered by specialists and other healthcare practitioners as first line treatment for mild to moderate pain. Paracetamol already has a wide distribution for immediate public access and there is no public health benefit to be gained by improving public access to a second-line medicine, which should be dispensed after professional consultation if paracetamol is considered to be inappropriate.
- XXXXXXXXXXX suggested that the decision be deferred for a period of a further 12 months during which time, more intensive and extensive research could be undertaken on the use of ibuprofen and its associated risks.
- In a letter to XXXXXXXXXXX (copy submitted), XXXXXXXXXXX expressed concerns that de-scheduling and allowing supermarket sales of ibuprofen will pose significant public health risks of side effects and complications.
- In the "Conclusions" section of its submission, XXXXXXXXXXX submitted that "the data contained in this report suggest, when extrapolated, that the deregulation of ibuprofen to an exempt from classification status may give rise to approximately 20,000 adverse events each year". XXXXXXXXXXX submission did not explain how this figure was derived and no details of the distributions of the nature or the severity of the claimed 20,000 adverse events were provided.

- An article recently published in Australian Pharmacist by Professor Gregory Peterson (University of Tasmania) expressed doubt on the strength of evidence presented in the PAIN study on which XXXXXXXXXXX believed the down-scheduling decision was based. The main points are summarised as the following:

- There were considerable methodological deficiencies in the published PAIN study. In particular, the published paper did not include comprehensive inclusion and exclusion criteria for patients included in the research study, there was no objective measurement of compliance with therapy reported and the patients were mainly young (mean average age of 43 years) therefore the results would not be applicable to the elderly. The fact that the PAIN study was funded by XXXXXXXXXXX raised the possibility of bias and doubts about the scientific and ethical integrity of any data produced.
- There was already a large body of literature on the gastrointestinal side effects of NSAIDs consistently showing that groups which had a markedly elevated risk of NSAIDs-induced gastrointestinal events included the elderly, persons with prior history of peptic ulcer disease and its complications, persons receiving anticoagulant or corticosteroid therapy, and persons who required long-term NSAID therapy, especially at high dosages.
- Information on recent (within the past week) use of multiple analgesics, plus data on tobacco, alcohol and other factors, were obtained from 627 patients enrolled in the American College of Gastroenterology (ACG) bleeding registry and from 590 procedure-matched controls. The risk of gastrointestinal bleeding was increased 2-3 fold among

recent users of aspirin, ibuprofen and other NSAIDs at OTC doses, in a dose-related manner, based on these data. In contrast, no excess was found among paracetamol users.

- It had been documented that many pregnant women take ibuprofen at some point during the pregnancy without being aware of the potential risks. Its ready availability in supermarkets would simply reinforce the misguided perception that the drug is innocuous.

- XXXXXXXXXXX opposed the decision. The following points were raised:

- XXXXXXXXXXX agrees with the Commonwealth Government that the use of the right medicine in the right patient for the right condition to achieve the right outcome is extremely important.

- XXXXXXXXXXX survey showed that pharmacists do intervene in the sale of ibuprofen, a finding consistent with the S2/S3 standards. Professional intervention stops potential adverse events, stops drug interactions and is clearly contributing to the quality use of the product.

- XXXXXXXXXXX submitted that not all pain states are the same and not all analgesics are appropriate for every pain state, nor are all analgesics appropriate for every patient (Therapeutic Guidelines, Analgesic, Version 4, 2002). XXXXXXXXXXX believe that without professional advice, the quality use of ibuprofen will be much reduced, and inappropriate uses and adverse consequences may occur.

- XXXXXXXXXXX was concerned that the product label for exempt ibuprofen could have up to seven warning statements on each pack, some of which could be very serious, and if not read and understood by the consumer, could result in potentially fatal outcomes. For example, use in people taking warfarin or methotrexate.

- Responding to some statements in the Record of Reasons of the June 2003 Meeting, the following points were also submitted by XXXXXXXXXXX single doses of ibuprofen do inhibit the anti-platelet effect of low dose aspirin. 2) No solid data in Australia and overseas to rule out its effects on asthma, gastrointestinal and thrombotic events due to antagonism of low dose aspirin. 3) Ibuprofen is contraindicated in many patient groups eg. pregnancy, peptic ulcers, cardiac failure and aspirin sensitive asthma, where paracetamol may be used. There are more contraindications and drug interactions for ibuprofen than paracetamol. 4) The fact that "the safety of low dose ibuprofen in the OTC setting is good" may be due to the intervention of the pharmacist, but may be lost if it was sold in non-pharmacy outlets.

- XXXXXXXXXXX asked the NDPSC to give fully referenced feedback on issues raised in this submission and in its previous letters to the Committee.

- XXXXXXXXXXX was disappointed at the decision, and submitted the following points in response to the reasons for the decision:

- There is no evidence to suggest that greater availability and unsupervised sale of ibuprofen is warranted.

- That the statement "without any increase in the incidence of adverse effects for general sale of ibuprofen in the USA and UK" had not been substantiated by the Committee. It was claimed that a study in USA in 1990-1992 indicated that OTC NSAIDs use may represent a more important cause of peptic ulcer disease and ulcer-related haemorrhage than previously appreciated. Similarly in a UK study, an estimation of 12.5% of drug-related hospital admissions were due to NSAIDs of which ibuprofen and diclofenac were most commonly implicated.

- The fact that significant risks are associated with the indiscriminate use of aspirin and paracetamol should be a basis for stricter scheduling of ibuprofen, rather than for the addition of a third agent of this type, unless the latter shows an apparent superior safety profile.

- Australian OTC marketing experience (S3 and S2) with ibuprofen can not be extrapolated to predict its safety as an unscheduled medicine.

- It was submitted that reliance cannot be placed on package labelling to adequately inform consumers on the use of this medicine. For example, a study in 578 pregnant women in rural USA showed that despite package labelling, 15% of these women took OTC ibuprofen at sometime during the pregnancy, and 5.7% during the third trimester.

- If ibuprofen is unscheduled, there is clearly no personalised, professional advice on the appropriate use of medicines which occurs in the pharmacy setting.

- XXXXXXXXXXX strongly opposed the June 2003 decision relating to ibuprofen. XXXXXXXXXXX supported its submission with one volume of references, which was assessed by the Clinical Pharmacologist, who reported the evaluation outcome to the meeting. The following points were included in the submission:

- It was submitted that 17-26% of purchasers of OTC analgesics are aged 50 years or older who are likely to have other medical conditions. The Prescribing Information for current prescription-only ibuprofen products XXXXXXXXXXX and XXXXXXXXXXX suggests that caution should be taken even when used in the elderly at low prescription doses of 1200-1600 mg.

- 34% of purchasers are women aged between 18 and 39 years. It was submitted that new data published in British Medical Journal (2003) indicates that use of either ibuprofen or naproxen during pregnancy or around the time of conception increased the risk of miscarriage by 80% or higher.

- In addition to headache, primary conditions related to the potential use of ibuprofen include back and neck pain that requires treatment 1.5 days per week on average, migraine, joint pain, muscular pain and dysmenorrhoea with a varied frequency of suffering.

- It was submitted that based on the NDPSC June 2003 meeting decision, there would be seven label warning statements (asthma, stomach ulcers/disorders, allergy to ibuprofen, impaired kidney function, heart failure, pregnancy, concomitant medications) on the packet. Would they be too many for a medicine on supermarket shelves? Would more be required?

- It was submitted that case reports showed that a single OTC dose of ibuprofen can cause a fatal asthma attack. In addition, a group of ~ 20% asthmatics are sensitive to aspirin/ibuprofen, and the average age of appearance of NSAID-induced asthma was in the early 30s.

- It was submitted that the anti-platelet, cardioprotective effect of low-dose aspirin may be blocked by a single OTC dose of ibuprofen, which could lead to increase in both overall and cardiovascular mortality.

- It was submitted that recent USA reports indicate increased incidence (by 20%) of GI bleed, including over 100 hospitalisations (5 deaths and 12 life-threatening GI complications) directly associated with OTC doses of ibuprofen.

- It was submitted that the pack size of 25 dose units (for 4.17 days treatment) is inconsistent with the current warning statement for OCT ibuprofen "if symptoms persist for more than 3 days, consult a doctor", or with packs of unscheduled paracetamol and aspirin (25 tablets for 3 days treatment).
- It was submitted that the anti-inflammatory effects of ibuprofen only appear at >1200 mg/day, but not at OTC doses.

(Submissions from those who did not make a pre –meeting submission and therefore, did not comply with regulation 42ZCZ of the Therapeutic Goods Regulations 1990.)

- XXXXXXXXXXX did not support the rescheduling based on the following concerns:

- The recent Review of Non-prescription Analgesics by the Medicine Evaluation Committee referred to this: "While each of the three main non-prescription analgesics – paracetamol, aspirin and ibuprofen – can be considered individually, the controls on them must not be seen in isolation. Restrictions on one will result in substitution with another and the advantages and disadvantages of the substitution must be contemplated by public health authorities." XXXXXXXXXXX takes the view that the Committee needs to be cognisant of the broader picture, when considering the down-scheduling of ibuprofen.
- XXXXXXXXXXX expressed concern at the possibility of patients doubling up on doses of NSAIDs to produce gastrointestinal disturbance, with ulceration and haemorrhage being more serious complications. Pharmacists frequently find that patients requesting ibuprofen are already taking a prescribed NSAID including ibuprofen itself. Counselling of consumers prior to purchasing ibuprofen should be maintained within the pharmacy setting.
- The issue of drug interactions, including so-called "triple whammy", a combination of diuretics, ACE inhibitors and NSAIDs, has become more pressing. The elderly are more at risk of this complication, since they are naturally more likely to seek a non-prescription medicine for arthritic pain while they are receiving concomitant cardiovascular medication.
- XXXXXXXXXXX advised that it was so concerned with the matter that it would give consideration to approaching the XXXXXXXXXXX with a view to recommending the amendment not taking effect in this State, despite the obvious disadvantages of non-uniformity of scheduling.

- XXXXXXXXXXX expressed concerns on potential drug interactions and inappropriate use of ibuprofen and other NSAIDs. For example, a patient requested for XXXXXXXXXXX for a joint pain, and further asked for some XXXXXXXXXXX for headache, with the intention of taking both concurrently.

- XXXXXXXXXXX did not support the decision, and emphasised the role of pharmacists in ensuring the safe use of XXXXXXXXXXX.

- Some individual pharmacists (XXXXXXXXXXX; XXXXXXXXXXX; XXXXXXXXXXX; XXXXXXXXXXX; XXXXXXXXXXX; XXXXXXXXXXX) submitted comments to express their various views and concerns on the down-scheduling. In summary, it was submitted that on many occasions, pharmacists intervene in the inappropriate use of ibuprofen and other NSAIDs. Product label alone would not provide sufficient information to ensure safe use of ibuprofen, given its potential adverse effects and contraindications, and would not assist consumers in selecting a more suitable medication. XXXXXXXXXXX made the following recommendations: 1) to reschedule

all products containing aspirin to pharmacy/pharmacist only, and 2) to label all products containing paracetamol with the words “containing paracetamol” in font at least equal to the trade name of the pack.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-038

OUTCOME 1: Population Health and Safety

Topic: NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

Written Question on Notice

Senator Harradine asked:

Is the NDPSC aware of comments by Stephen Greenwood, executive director of the Pharmacy Guild, who says that a major flaw in the process of approving drugs for public release is the fact that the Minister has no discretion to overturn decisions? Does the Department consider such a power necessary in the interests of public safety? If not, why not?

Answer:

The NDPSC is currently constituted under amendments made by the Australian Parliament in 1999 to the *Therapeutic Goods Act 1989.* Those amendments did not include a discretion for the Minister to overturn decisions of the Committee because legal effect to the decisions of the Committee is given through State and Territory law.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-039

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

(a) Was the application to allow Postinor-2 to be sold over-the-counter considered at the October meeting of the National Drugs and Poisons Schedule Committee?

(b) Was the Commonwealth's representative present for this meeting? If so, how did the Commonwealth representative vote?

(c) Did the Commonwealth representative have any concerns with providing Postinor-2 over-the-counter? If so, what were those concerns?

(d) Who is the Commonwealth representative and what are the representative's affiliations? How is the representative chosen?

Answer:

(a) The application for levonorgestrel (Postinor-2) to be sold over the counter was initially considered at the June 2003 meeting .It was considered again at the October 2003 meeting as the Committee was required under *Therapeutic Goods Regulation 42ZCZ(3)* to consider the post-June 2003 meeting submissions on the initial decision that met the criteria of *Regulations 42ZCY(1)(c) and 42ZCX(1) and (2).* When it considered these post-meeting submissions on levonorgestrel the Committee was required to either confirm, vary or set aside the decision of the June 2003 Committee meeting.

(b)&(c)
Yes. The Commonwealth member chaired the meeting. When the matter was put to the vote, the Chair was not required to exercise his vote as the recommendation had passed by a clear majority.

(d) Dr John McEwen, Principal Medical Adviser, Therapeutic Goods Agency was appointed by the Parliamentary Secretary to the Minister for Health and Ageing as the Commonwealth's representative.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-040

OUTCOME 1: Population Health and Safety

Topic: POSTINOR-2

Written Question on Notice

Senator Harradine asked:

(a) How many submissions did the NDPSC receive prior to the preliminary and final decisions with respect to Postinor-2? For each meeting, how many submissions were for and how many against the availability of Postinor-2 over the counter?

(b) Isn't the NDPSC's process for public consultation flawed when the drug sponsor's application is not made public so that its claims cannot be considered and addressed by the public and when submissions are not made public? Shouldn't the NDPSC move to a more transparent process?

(c) How does the Department propose to record and monitor adverse health reactions from use of Postinor-2? Does the Department have any record of adverse reactions to date? If so, please provide details.

Answer:

(a) The NDPSC received 71 pre June 2003 meeting submissions and 198 post June 2003 meeting submissions with 53 pre-meeting submissions opposing and 18 pre-meeting submissions supporting the decision. Of the post meeting submissions 166 were opposed to the decision and 32 were supportive.

(b) The Department believes transparency of the functions of the Committee is important, however, the *Therapeutic Goods Regulation 42ZCU*, authorises the Chair of the Committee to only mention in the published public notice in the *Gazette* 'each substance to be considered for scheduling at a meeting'. *Therapeutic Goods Regulation 42ZCY* includes in subregulation (3) that "Nothing in subregulation (1) requires the Committee to disclose in the notice, or to provide access to, information that it properly regards as requiring confidentiality for commercial reasons."

The NDPSC's processes will be reviewed as part of the implementation of the single scheme for the regulation of therapeutic products for Australia and New Zealand.

(c) The Department proposes to rely on the Adverse Drug Reporting Advisory Scheme which operates under the Adverse Drug Reaction Advisory Committee (ADRAC). In addition to the voluntary reporting by health professionals, the sponsor is required as a

condition of registration to report all serious suspected adverse reactions occurring in Australia as they come to notice and to provide details of other suspected adverse reactions occurring in Australia on request and as part of Periodic Safety Update Reports. In addition, reports of adverse reactions occurring overseas are monitored through review of the Periodic Safety Update Reports received from, and separately through, direct communication with overseas regulatory agencies.

ADRAC has received 10 Australian reports of suspected adverse reactions to levonorgestrel (Postinor-2), including 8 reports of unintended pregnancy (outcomes were 1 miscarriage, 1 termination, 1 tubal ectopic requiring salpingectomy, and 5 unknown), 1 report of vaginal bleeding, and 1 report of nausea and vomiting.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-041

OUTCOME 1: Population Health and Safety

Topic: FAMILY PLANNING PROGRAM

Written Question on Notice

Senator Harradine asked:

I refer to recent press reports about a sex survey given to a Year 9 class at Wodonga High School which included questions such as:

If you have never slept with a person of the same sex, is it possible all you need is a good lesbian-gay lover?
What do women and men do in bed together? How can they truly know how to please each other being so anatomically different?
Why heterosexuals feel compelled to seduce others into their lifestyle?
Since most child molesters were heterosexual do you consider it safe to expose to heterosexual teachers?

According to a report in The Australian (29 October 2003) the survey had originally been given out at a professional development course run by the Federally funded Family Planning Victoria and designed by the Australian Research Centre in Sexual Health and Society at Latrobe University.

Did the Department allocate specific funds to Family Planning Victoria to design, distribute and promote this survey?

Did the Australian Research Centre in Sexual Health and Society receive any Federal funding for the development of the survey?

Has the Department received any complaints about the material?

Is the Department investigating any complaints?

Does the Department consider this is an appropriate use of federal funding?

Does the Department consider this is appropriate material for school children?

Answer:

No.

Yes.

No.

No.

The Professional Development Resource is one of four resources produced by ARCSHS that comprise the *Talking Sexual Health* package. The package was initiated in 1997 in order to respond to a number of research findings, including the following:

that secondary students had a high level of understanding about the transmission and prevention of HIV and other STIs, however still engaged in unsafe behaviours;
approximately 50% of Year 12 students were sexually active;
only 53.6% of young men and 27.7% of young women used condoms every occasion they had sex;
alcohol and drug use were major predictors of unsafe sex;
between eight and eleven per cent of year 10 – 12 students did not identify as exclusively heterosexual; and
students were not as well informed about STIs, hepatitis C and other blood borne viruses as they were about HIV.

The Department does consider that the classroom materials in the *Talking Sexual Health* package is appropriate material for school children.

> The Professional Development Resource of the *Talking Sexual Health* package is a training document. This Resource was developed specifically to provide teachers with the skills necessary to effectively implement the classroom materials.
>
> The sex survey, which forms part of the Professional Development Resource and which was given to a Year 9 class at Wodonga High School, was distributed by a substitute teacher who was unfamiliar with the *Talking Sexual Health* package, and had not participated in professional development training. The Professional Development Resource states that the Resource has been designed for use by education authorities in professional development settings only and is not appropriate for school children.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-048

OUTCOME 1: Population Health and Safety

Topic: SOUTH AUSTRALIAN RED CROSS BLOOD SERVICE

Written Question on Notice

Senator Harradine asked:

I refer to recent action taken by the Therapeutic Goods Administration (TGA) in placing restrictive conditions on the manufacturing licence held by the South Australian Red Cross Blood Service (ARCBS). Please provide a list of the breaches of the good manufacturing practice licence discovered in an unscheduled audit in September 2003.

Answer:

GMP audit reports are commercial-in-confidence and the TGA is unable to release details of the report without approval of the manufacturer. In summary, the TGA had concerns about the safety and quality of 11 donations (involving 21 blood components) that could not be assured because the test results for cytomegalovirus (CMV) screening had been incorrectly manually entered onto the National Blood Management System as negative for CMV.

As a result, a condition was placed on the licence of the South Australia ARCBS, preventing further manual data entry of donor screening test results in South Australia until it can be demonstrated processes are being carried out accurately. South Australia ARCBS must now use only fully automated tests for blood donor screening, interfaced with the National Blood Management System.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-049

OUTCOME 1: Population Health and Safety

Topic: INCORRECT LABELLING OF BLOOD PRODUCTS

Written Question on Notice

Senator Harradine asked:

I refer to the use of 21 blood products labelled negative to a member of the herpes group of viruses, cytomegalovirus (CMV) when these products were CMV positive.

(a) What penalties apply to blood services engaging in such serious and health threatening breaches of standard procedures?

(b) Has the TGA conducted any other unscheduled audits of other blood services in the past five years? If so, what did these audits discover?

(c) How often are audits carried out?

Answer:

(a) Administrative and criminal penalties may apply to manufacturers of therapeutic goods, including blood services, who engage in critical or major breaches of their Good Manufacturing Practice (GMP) licence.

Under the *Therapeutic Goods Act 1989*, the TGA can immediately condition, suspend, or cancel any manufacturing licence if there is an imminent risk of death, serious illness, or serious injury. For less serious breaches where there is no imminent risk of death, serious illness, or serious injury, the TGA can issue a notice of intention to condition, suspend, or cancel licences.

In relation to criminal penalties, companies in breach of their GMP licence may face imprisonment, financial penalties, or both. Imprisonment may be up to 12 months and financial penalties may be up to 1,000 penalty units for an individual, or 5,000 penalty units for a company. A penalty unit is worth $110.

(b) There have been a number of unscheduled audits of the Australian Red Cross Blood Service (ARCBS) undertaken by the TGA. These have been undertaken in response to:

- serious recalls notified to the TGA;
- low level compliance at scheduled GMP audit; and
- verification of audit commitments made to address audit deficiencies.

In the majority of cases these audits have revealed:

- failure of blood services to provide adequate supervision and training;
- failure of staff to follow documented procedure;
- manufacture of therapeutic goods without a manufacturing licence; and
- unacceptable record management and review.

To rectify deficiencies at sites subjected to an unannounced audit, there would be:

- increased surveillance of these sites, through increasing the audit frequency;
- close monitoring of recalls generated from these sites;
- regular updates required with regard to corrective and preventative actions.

(c) Audit frequency for ARCBS sites are based on a risk assessment. Primary sites (high risk) that undertake collection, processing and testing (Sydney, Melbourne, Adelaide, Brisbane, Perth, Darwin, Canberra, and Hobart) are audited 12 monthly.

Depending on the compliance rating, processing, apheresis and Hub sites (medium risk) are audited between 18 and 30 months.

Centres collecting whole blood only (low risk) or are operated as a mobile venue are audited between 24 and 48 months.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-101

OUTCOME 1: Population Health and Safety

Topic: THERAPEUTIC GOODS MANUFACTURERS DETAILS

Written Question on Notice

Senator Forshaw asked:

For each of the companies or individuals that manufacture or sponsor, or have in the past manufactured or sponsored, therapeutic goods, devices or medicines either in Australia or overseas for the past four years please provide details of any on site audit or visit or inspection of any sort by the TGA. Please provide the information in the following way:

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

Answer:

As a result of discussions with Mr Alan Griffin MP to clarify the information required, it was agreed that the following information about GMP audits in relation to medicines for each company audited over the past four years would be provided:

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

(a), (b) & (c)

Refer to Attachment A for the names of Australian manufacturers audited by the TGA over the past four years, and the dates of those audits. Refer to Attachment B for the names of overseas manufacturers audited by the TGA over the past four years, and the dates of those audits.

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

(e) The release of company GMP licence action is generally treated as commercial-in-confidence. In summary, over the past four years, one manufacturer of medicinal products has had its manufacturing licence revoked by the TGA and one manufacturer of medicinal products has had its manufacturing licence suspended for six months by the TGA. These regulatory actions were due to the manufacturers failing to observe the Manufacturing Principles of the Therapeutic Goods Act 1989.

Seventeen manufacturers have voluntarily applied to have their manufacturing licence revoked following discussion of TGA audit findings. An additional four manufacturers have asked for their manufacturing licence to be suspended for a specific period of time. In all twenty one cases, the manufacturer was having difficulty complying with the Manufacturing Principles of the Therapeutic Goods Act 1989 and would have faced regulatory action by the TGA if they had not voluntarily revoked or suspended their manufacturing licence.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-102

OUTCOME 1: Population Health and Safety

Topic: OVERSEAS GMP LICENSED FACILITIES

Written Question on Notice

Senator Forshaw asked:

Can you provide figures on the number of overseas GMP licensed facilities for the past 4 years?

Please provide the information on a six monthly basis for:
(a) When and why did you write to all sponsors of therapeutic goods manufactured internationally requesting information on the status of their current GMP license or pre-clearance certificates?
(b) How many of the international facilities have responded and is there a back log of preclearances to be processed?
(c) How many overseas manufactures of complementary and pharmaceuticals have past their GMP inspection dates?
(d) Have any international companies who make medicines or therapeutic goods not been inspected within the past 2 years?
(e) Has the TGA made special arrangements (or any arrangements) with the overseas manufactures with regards to GMP inspections or pre-clearance status?
(f) What is the time frame an overseas manufacturer could expect a GMP audit in and how does this compare to Australia?

Answer:

Following discussion to clarify the information required, the following answers are provided.

(a) The TGA has in place an overseas GMP assessment program to ensure that overseas manufacturers of therapeutic goods imported into Australia comply with Australian requirements for good manufacturing practice. As part of this program, the TGA writes to Australian sponsors on a regular basis seeking renewal of evidence of GMP compliance for overseas manufacturers they use for supply of therapeutic goods.

Following the agreement of the therapeutic goods industry peak bodies to the Corcoran Review recommendation to introduce fees for GMP pre-clearance assessments for overseas manufacturers, the TGA wrote to 497 Australian sponsors in May and June 2003 where the GMP status of their overseas manufacturers was due for reassessment. The letter noted that the TGA could, for a fee, seek on the sponsor's behalf, evidence for pre-clearance from overseas regulatory authorities.

(b) The TGA has received replies covering 1376 overseas manufacturers. There is no backlog of pre-clearance applications arising from these responses.

(c) The TGA classifies GMP reassessment status as being overdue if more than 6 months past the nominal renewal date. TGA inspections are undertaken where GMP certification is not available from a recognised overseas regulatory authority. The TGA's inspection program is therefore heavily weighted to countries in Asia and the subcontinent. The audit program over the past 2 years has been severely impacted by the curtailment of travel to these countries due to heightened security concerns and increased public health risks such as SARS. Notwithstanding this, at the end of 2003 there were 21 overseas manufacturers passed their inspection date of which 5 were overdue. These all have a low risk index for GMP compliance and have been scheduled for inspection by the TGA in the first half of 2004.

(d) & (f) Depending on the product risk category and the compliance level assigned at the previous audit, both Australian and overseas manufacturers can routinely expect a GMP audit approximately every 12-36 months. These frequencies may be modified if other risk factors become known and could result in a special audit being conducted at any time.

As at 31 December 2003, fifty-one (51) overseas manufacturers of medicines previously audited by the TGA have not been audited within the past 2 years. Those due for audit have been included in the 2004 audit schedule.

(e) The TGA does not have any special arrangements with any overseas manufacturers with regard to GMP inspections or preclearances.

The TGA has special arrangements with recognised overseas regulators that enable their GMP inspections of manufacturers to be recognised by the TGA as evidence of GMP compliance. Where necessary, the TGA can request these authorities to carry out a special inspection in order to enable the TGA to obtain this evidence. These arrangements reduce the need for the TGA to carry out overseas inspections itself and reduce the cost of regulatory compliance for Australian sponsors.

The TGA recognises GMP certificates issued by regulatory authorities that have a system of GMP auditing and licensing equivalent to that of the TGA, eg. European Union (EU) countries, European Free Trade Association (EFTA) countries, Canada, USA, Singapore and New Zealand.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-103

OUTCOME 1: Population Health and Safety

Topic: ADVERSE DRUG REACTION REPORTING

Written Question on Notice

Senator Forshaw asked:

In respect to the answer provided to Senator McLucas, number E03-155, regarding adverse drug reaction reports made about Pan Pharmaceutical products, were any of these products tested by either the TGA, or by another body on behalf of the TGA? If yes please provide details of:

(a) the name of the product
(b) the name of the sponsor
(c) who tested the product and where was it tested
(d) the date of the testing
(e) why the product was tested
(f) the result of testing
(g) any follow up the TGA has made in respect to the testing of the product.

Answer:

(a) – (g) A report from the Adverse Drug Reactions Advisory Committee (ADRAC), dated August 2003 and covering a reporting period of 28 April to 30 June 2003, was provided as an attachment to the response to E03-155 (June 2003). This report covered 68 adverse reactions (ADRs) associated with at least one product putatively manufactured by Pan Pharmaceuticals.

Between 30 June and 31 October 2003, a further 12 ADR reports associated with products which were possibly manufactured by Pan were received.

The TGA attempted to recover for testing, the products actually used by the complainants. In some cases, where the specific batch or offending sample was not available for testing, an alternative batch was obtained.

In all, only 11 samples (10 distinct products) from batches which had been recalled were received for testing. All testing was done by the TGA Laboratories.

In view of the nature and extent of contamination that was possible in Pan's products, the only testing that was feasible was targeted at possible causes of the reported adverse reaction (see answer to question E03-104 – November 2003). In some cases this involved screening

for the presence of pharmaceutical drugs while in others it involved testing for the correct identity and level of the declared active ingredient.

The results of the testing are set out in the attached table.

Aust. L	Description	Sponsor	Batch #	ADRAC reference	Reason for Testing	Date tested	Outcome
16436	MINERALS; VITAMINS TABLET METAGENICS CROTICO B5 B6	Health World P/L	5060	186123	Hallucination	06/2003	No pharmaceuticals detected
28403	PYRIDOXINE HYDROCHLORIDE TABLET 100MG NATURES OWN VITAMIN B6	Bullivants Natural Health Products P/L	205166	186731	Lack of efficacy against hyperoxaluria	09/2003	Correct amount of Vit B6. Different amount of an excipient (Ca Phosphate) to that stated on ARTG
33613	COD-LIVER OIL CAPSULE 275MG CENOVIS	Faulding Healthcare P/L	205376	186041	Seizure	06/2003	No pharmaceuticals detected
55445	FISH OIL CAPSULE 1GF MICROGENICS NATURAL FISH OIL	Optimum Healthcare P/L	78288	186154	Palpitations	06/2003, 09/2003	No pharmaceuticals detected. No heavy metals.
57562	SERENOA SERRULATA CAPSULE 167MG GOLDEN GLOW PROSTA-GUARD	Queensland Biochemics P/L	206327	188101	Nausea, vomiting, fatigue	10/2003	No pharmaceuticals detected
57562	SERENOA SERRULATA CAPSULE 167MG GOLDEN GLOW PROSTA-GUARD	Queensland Biochemics P/L	206327 (based on information from reporter)	188101	Nausea, vomiting, fatigue	10/2003	No pharmaceuticals detected

67964	ZINGIBER OFFICINALE GINGER TABLET 500MG TRAVACALM NATURAL	Key Pharmaceuticals P/L	82249 (based on information from reporter)	185445	Hypertension, Migraine, Nausea, Vomiting	05/2003	Hyoscine not detected
69421	CHROMIUM PICOLINATE; HERBS TABLET WYLD FOR WOMEN	NYDA P/L	80558	186073, 186074 (and possibly 185336, 185763)	Acute renal failure, Interstitial nephritis; Hepatitis, Polyarthropathy. Elevated serum chromium	06/2003	Chromium levels consistent with label
72975	BACOPA MONNIERI; GINKGO BILOBA; LECITHIN CAPSULE BRAHMI	Bullivants Natural Health Products P/L	254	186041	Seizure	06/2003	No pharmaceuticals detected
60277	FISH OIL CAPSULE 1.2G NATURE'S OWN OMEGA-3 (No packaging - information from reporter)	Bullivants Natural Health Products P/L	205273 (based on information from reporter)	186244	Pulmonary embolus	09/2003 10/2003	No heavy metals. No pharmaceuticals detected.
67706	BIO ORGANICSGLUCOSAMINE SULPHATE CAPSULES (No packaging - information from reporter)	Bullivants Natural Health Products P/L	205142 (based on information from reporter)	186244	Pulmonary embolus	no testing	Capsules badly degraded on receipt. No testing done.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-104

OUTCOME 1: Population Health and Safety

Topic: TESTING OF PAN PHARMACEUTICALS PRODUCTS

Written Question on Notice

Senator Forshaw asked:

Is the TGA aware of any overseas companies, Australian companies or other international regulators or Australian regulators, or individuals having tested any of the products manufactured by Pan Pharmaceuticals since 28 April 2003 for safety. If yes please provide the following details for each product that was tested:

(a) the name of the product
(b) the name of the sponsor
(c) who tested the product and where was it tested
(d) the date of the testing
(e) why the product was tested
(f) the result of testing
(g) any follow up the TGA has made in respect to the testing of the product.

Answer:

The TGA is only aware of one instance of testing of Pan products undertaken by a company in the period since 28 April 2003. An article in the Financial Review of 11 July 2003 reported that independent tests had found that Pan had blended poor quality sunflower oil with tuna oil in the manufacture of a trial batch of capsules. According to the newspaper, the sponsor of the capsules was Clover Corporation who had intended to use the capsules in a clinical trial. The TGA-initiated recall of Pan products prevented the capsules from being released. The TGA does not have any details relating to the testing of these capsules.

Laboratory testing is generally directed at determining whether selected attributes of a product meet relevant quality standards. These attributes may, or may not, have any relevance to product **safety**, which is more generally assured through a rigorous process of pre-market evaluation or approval of substances used in product manufacture. Furthermore, such testing is only a part of a total quality assurance program. Quality can only be assured if it is built into the entire process of manufacture, from receipt and quality assurance of raw ingredients to proper controls over manufacturing processes, to final quality control testing.

Widespread and serious deficiencies and failures in the company's manufacturing and quality control procedures of Pan Pharmaceuticals Ltd, including systematic and deliberate manipulation of quality control test data, meant that the TGA could have no confidence in the quality or safety of any products manufactured since May 2002. Where the quality of a medicine can not be assured, neither can the safety or the effectiveness of that medicine.

An independent Expert Advisory Group (EAG) informed TGA that, because of the nature and extent of the manufacturing breaches, the quality of the products could not be guaranteed and therefore neither could their safety or effectiveness be assured. The EAG also advised that the products posed a risk to public health and safety. The EAG further advised the risks would increase with time and could be realised at any time. These risks included severe organ damage, severe allergic reactions and infections. Acting on the advice of the EAG, the TGA initiated a recall of all products manufactured by Pan Pharmaceuticals since May 2002.

It is not a practicable option to use testing to decide whether any of the products could be considered safe enough to return to the market. The only testing undertaken by the TGA has been in relation to investigations of adverse reactions (see answer to question E03-103).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-105

OUTCOME 1: Population Health and Safety

Topic: API PRODUCTS

Written Question on Notice

Senator Forshaw asked:

With respect to the manufacturer API which asked the TGA to suspend their license on 9 September 2003 please provide the following information on the API products that were tested by TGA.

(a) The name of the products and batch.
(b) The name of the sponsor.
(c) Who tested the product and where it was tested.
(d) The date of testing.
(e) Why the product was tested.
(f) What they were tested for.
(g) The results of testing.
(h) Any follow up the TGA has made in respect to the testing of the product.

Answer:

(a), (b), (d), (f), (g) This information is provided at Attachment 1.

(c) All testing was conducted by staff in the Therapeutic Goods Administration Laboratories.

(e) All products were tested to monitor compliance with quality standards following an audit of the manufacturing site by TGA on 28 – 30 July 2003.

(h) Follow up action facilitated by the TGA included:
- A recall of API manufactured promethazine elixirs from the Australian market following the identification of a fault with these products. Details are provided in the Table. Please note that API manufactured two different promethazine formulations. Samples of one of these formulations were found to be unacceptable with respect to the amount of a promethazine degradation product present in the samples and these products were recalled. The recalled promethazine formulation was manufactured for several sponsors: Chemists Own; Fauldings Healthcare; Soul Pattinson; AMCAL; ICN Pharmaceuticals. The second promethazine formulation was manufactured by API for Pharm-a-care Laboratories Pty Ltd. This formulation was found to comply with quality standards and no follow up action was warranted.

- Cessation of market supply of PHOLCODINE ORAL LIQUID; DRY TICKLY COUGH following a finding that one excipient in the formulation differed in content from that originally approved by TGA. Details are provided in the Table.

The name of the products and batch	The name of the sponsor	The date of testing	What they were tested for	The results of testing
RAPIDEINE CLEAR TABLETS [BATCHES 73716, 72984, 72482, 72502]	SOUL PATTINSON (MANUFACTURING) PTY LTD	13/08/03	Sample packaging Uniformity of Content of Codeine Phosphate Sample appearance Identification codeine	Sample found acceptable with respect to applied tests
PARACETAMOL ORAL SUSPENSION CHILDREN'S 5-12 YEARS [BATCH 77617B]	SOUL PATTINSON (MANUFACTURING) PTY LTD	7/08/03	Label compliance Microbiological Examination	Sample found acceptable with respect to applied tests
CREAM 5% BLISTEX ANTIVIRAL COLD SORE CREAM [BATCH 75832]	KEY PHARMACEUTICALS PTY LTD	7/08/03	Label compliance Microbiological Examination	Sample found acceptable with respect to applied tests
GUAIPHENESIN; PSEUDOEPHEDRINE ORAL LIQUID CONGESTED COUGH [BATCH 73902]	SOUL PATTINSON (MANUFACTURING) PTY LTD	7/08/03	Label compliance Microbiological Examination	Sample found acceptable with respect to applied tests
PROMETHAZINE HYDROCHLORIDE	SOUL PATTINSON (MANUFACTURING) PTY	7/8/03 (Batches	Sample appearance Label compliance	Samples found unacceptable with respect to level of a degradation

ORAL LIQUID 1MG/ML ALLERGY RELIEF [BATCHES 76619 , 77121, 73028, 71173, 72906A]	LTD	76619 & 77121) 8/8/03 (Batch 73028) 26/8/03 (Batches 71173 & 72906A)	Degradation products Identification Promethazine Assay of Promethazine Hydrochloride Microbiological Examination	product. Recall of product was undertaken.
CLOTRIMAZOLE CREAM 10MG/G PHARMACIST [BATCH 77064]	PHARM-A-CARE LABORATORIES P/L	11/09/03	Sample appearance Related Substance Identification of Clotrimazole Assay of Clotrimazole Homogeneity assay of Cream	Sample found acceptable with respect to applied tests
CODEINE PHOSPHATE ORAL LIQUID 5MG/ML LINCTUS [BATCH 76580]	MCGLOINS CLASSIC BRANDS PTY LIMITED	10/09/03	Sample appearance Identification of Codeine Assay of Codeine Phosphate Identification of Propyl hydroxybenzoate Identification of Methyl hydroxybenzoate Assay of Methyl hydroxybenzoate Assay of Propyl hydroxybenzoate	Sample found acceptable with respect to applied tests
BROMPHENIRAMINE; DEXTROMETHORPHAN; PHENYLEPHRINE ORAL LIQUID [BATCH 75247]	SOUL PATTINSON (MANUFACTURING) PTY LTD	7/08/03	Label compliance Sample appearance Identification of Brompheniramine maleate Assay of Brompheniramine maleate Microbiological Examination	Sample found acceptable with respect to applied tests

IBUPROFEN ORAL SUSPENSION 20MG/ML SOUL PATTINSON [BATCHES 76416, 75855]	SOUL PATTINSON (MANUFACTURING) PTY LTD	7/08/03	Label compliance Microbiological Examination Preservative efficacy	Samples found acceptable with respect to applied tests
ACICLOVIR CREAM 5% ANTIVIRAL COLD SORE TREATMENT [BATCH 75830]	SOUL PATTINSON (MANUFACTURING) PTY LTD	7/08/03	Label compliance Microbiological Examination	Sample found acceptable with respect to applied tests
POVIDONE-IODINE TOPICAL LIQUID [BATCH 77208]	SOUL PATTINSON (MANUFACTURING) PTY LTD	7/08/03	Label compliance Microbiological Examination	Sample found acceptable with respect to applied tests
ETHYLMORPHINE HYDROCHLORIDE; CODEINE PHOSPHATE ORAL LIQUID [BATCH 76768]	SOUL PATTINSON (MANUFACTURING) PTY LTD	7/08/03	Label compliance Microbiological Examination	Sample found acceptable with respect to applied tests
OXYMETAZOLINE HYDROCHLORIDE NASAL SPRAY 0.5MG/ML [BATCH 77191A]	SOUL PATTINSON (MANUFACTURING) PTY LTD	13/08/03	Label compliance Microbiological Examination	Sample found acceptable with respect to applied tests
CODEINE PHOSPHATE 8MG; PARACETAMOL 500MG TABLET RAPIDEINE	SOUL PATTINSON (MANUFACTURING) PTY LTD	13/08/03	Sample appearance Identification of Codeine Uniformity of Content of Codeine Phosphate	Sample found acceptable with respect to applied tests

[BATCH 74834]				
CHLORPHENIRAMINE; PARACETAMOL; PSEUDOEPHEDRINE TABLET SINUS [BATCH 76779]	SOUL PATTINSON (MANUFACTURING) PTY LTD	13/08/03	Sample appearance Identification of Chlorpheniramine Maleate Uniformity of Content of Chlorpheniramine Maleate	Sample found acceptable with respect to applied tests
PROMETHAZINE HYDROCHLORIDE ORAL LIQUID 1MG/ML CHEMISTS' OWN [BATCHES 74939, 75757, 76284]	CHEMISTS' OWN PTY LTD	26/08/03	Sample appearance Identification of Promethazine Assay of Promethazine Hydrochloride Degradation products	Samples found unacceptable with respect to level of a degradation product. Recall of product was undertaken.
PROMETHAZINE HYDROCHLORIDE ORAL LIQUID 1MG/ML CHEM MART [BATCH 75031, 73028A, 72906, 74217]	FAULDING HEALTHCARE PTY LTD	26/08/03	Sample appearance Identification of Promethazine Assay of Promethazine Hydrochloride Degradation products	Samples found unacceptable with respect to level of a degradation product. Recall of product was undertaken.
PROMETHAZINE HYDROCHLORIDE ORAL LIQUID 1MG/ML TERRY	FAULDING HEALTHCARE PTY LTD	26/08/03	Sample appearance Identification of Promethazine Assay of Promethazine Hydrochloride	Sample found unacceptable with respect to level of a degradation product.

WHITE [BATCH 75573]			Degradation products	Recall of product was undertaken.
PROMETHAZINE HYDROCHLORIDE ORAL LIQUID 1MG/ML AMCAL [BATCHES 75763, 77587, 72612, 76914]	ALLIED MASTER CHEMISTS OF AUSTRALIA LTD	26/08/03	Sample appearance Identification of Promethazine Assay of Promethazine Hydrochloride Degradation products	Samples found unacceptable with respect to level of a degradation product. Recall of product was undertaken.
PROMETHAZINE HYDROCHLORIDE ORAL LIQUID 1MG/ML NYAL [BATCHES 73812 , 73813, 75267]	ICN PHARMACEUTICALS AUSTRALASIA P/L	26/08/03	Sample appearance Identification of Promethazine Assay of Promethazine Hydrochloride Degradation products	Samples found unacceptable with respect to level of a degradation product. Recall of product was undertaken.
PROMETHAZINE HYDROCHLORIDE ORAL LIQUID 1MG/ML PROGAN [AUST R 18891] [BATCHES 77344, 76909, 76910, 76701, 77416]	PHARM-A-CARE LABORATORIES P/L	22/09/03	Sample appearance Identification of Promethazine Assay of Promethazine Hydrochloride Degradation products	Samples found acceptable with respect to applied tests

IBUPROFEN ORAL SUSPENSION 20MG/ML SOUL PATTINSON [BATCH 75855]	SOUL PATTINSON (MANUFACTURING) PTY LTD	11/09/03	Sample appearance Identification of Ibuprofen Assay of Ibuprofen Identification of Propyl hydroxybenzoate Identification of Methyl hydroxybenzoate Assay of Methyl hydroxybenzoate	Sample found acceptable with respect to applied tests
CLOTRIMAZOLE CREAM 20MG/G CLOFEME 3 DAY CREAM [BATCH 7775A]	HEXAL AUSTRALIA PTY LTD	25/09/03	Sample appearance Identification of Clotrimazole Assay of Clotrimazole Related Substance by HPLC	Sample found acceptable with respect to applied tests
PHOLCODINE ORAL LIQUID 1MG/ML SOUL PATTINSON DRY TICKLY COUGH [BATCHES 76804]	SOUL PATTINSON (MANUFACTURING) PTY LTD	11/09/03	Sample appearance Identification of Pholcodine Assay of Pholcodine Assay of Citric acid	Sample found unacceptable. Level of Citric acid [excipient] significantly below approved amount. No safety issue. Sponsor ceased supply.
SALICYLIC ACID; PODOPHYLLUM RESIN TOPICAL LIQUID POSALFILIN [BATCH 76446]	NORGINE PTY LTD	11/09/03	Sample appearance Identification of Salicylic acid Assay of Salicylic acid	Sample found acceptable with respect to applied tests
ASPIRIN; DIHYDROCODEINE TARTRATE TABLET SOLUBLE CODOX [BATCH 76763]	BOOTS HEALTHCARE AUSTRALIA PTY LTD	11/09/03	Sample appearance Identification of Dihydrocodeine Uniformity of Content of Dihydrocodeine	Sample found acceptable with respect to applied tests

NAPROXEN SODIUM TABLET 275MG NUROLASTS [BATCH 75839]	BOOTS HEALTHCARE AUSTRALIA PTY LTD	11/09/03	Sample appearance Identification of Naproxen Assay of Naproxen Uniformity of Content of Naproxen Dissolution	Sample found acceptable with respect to applied tests
LOPERAMIDE HYDROCHLORIDE TABLET 2.15MG GUARDIAN [BATCH 71888]	GUARDIAN PHARMACIES AUSTRALIA PTY LTD	12/09/03	Sample appearance Uniformity of weight Identification of Loperamide Assay of Loperamide	Sample found acceptable with respect to applied tests
LOPERAMIDE HYDROCHLORIDE TABLET 2.15MG AMCAL ANTI-DIARRHOEA [BATCH 71472]	ALLIED MASTER CHEMISTS OF AUSTRALIA LTD	12/09/03	Sample appearance Uniformity of weight Identification of Loperamide Assay of Loperamide	Sample found acceptable with respect to applied tests
DIMENHYDRINATE TABLET 50MG SOUL PATTINSON TRAVEL TABLETS [BATCH 640]	SOUL PATTINSON (MANUFACTURING) PTY LTD	17/09/03	Sample appearance Identification of Dimenhydrinate Uniformity of weight Assay of Dimenhydrinate	Sample found acceptable with respect to applied tests
MINERALS; VITAMINS CAPSULE SOUL PATTINSON [BATCH 76831]	SOUL PATTINSON (MANUFACTURING) PTY LTD	11/09/03	Sample appearance Identification of Thiamine Identification of Riboflavine Assay of Thiamine Assay of Riboflavine	Sample found acceptable with respect to applied tests

BENZYL BENZOATE LOTION 250MG/ML BENZEMUL APPLICATION [BATCH 74458]	MCGLOINS CLASSIC BRANDS PTY LIMITED	11/09/03	Sample appearance Identification Benzyl benzoate Assay benzyl benzoate	Sample found acceptable with respect to applied tests
CLINDAMYCIN ORAL SOLUTION 10MG/ML CLINDATECH [BATCH 73922, 74459A]	DERMATECH	25/08/03	Label compliance Microbiological examination	Samples found acceptable with respect to applied tests
TRETINOIN CREAM 0.5MG/G RETRIEVE [BATCHES 75624, 76552, 74892, 73127, 77013, 77249, 74893, 72852A, 75853, 75620, 77250, 72343, 76553, 77012A, 73128, 73129]	DERMATECH LABORATORIES	25/08/03	Label compliance Microbiological examination	Samples found acceptable with respect to applied tests
THIORIDAZINE ORAL SUSPENSION 10MG/ML MELLERIL [BATCH A0206]	NOVARTIS PHARMACEUTICALS	25/08/03	Identification of thioridazine Content of thioridazine pH Label compliance Microbiological examination Impurities related to thioridazine	Sample found acceptable with respect to applied tests

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-106

OUTCOME 1: Population Health and Safety

Topic: TGA COMPLAINT DETAILS

Written Question on Notice

Senator Forshaw asked:

In respect to all complaints or queries received by the TGA regarding Therapeutic goods, devices or medicines for the past 4 years please provide the following information:

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

Answer:

As a result of discussions with Mr Alan Griffin MP to clarify the information required, it was agreed that the following information in relation to complaints about non-prescription medicines received over the last two years relating to the supply of registered or unregistered products should be provided:

(a) Details of the nature of the complaint
(b) The date the complaint was received
(c) The description of the product (with any confidential information identifying the company removed)
(d) The outcome of follow-up action for the complaint
(e) The date the complaint was finalised

All complaints received by or referred to the TGA Surveillance Unit are investigated. Consideration is given to the seriousness of the alleged offence to determine whether a criminal prosecution may be appropriate or, in the case of a relatively less serious offence, whether some other administrative action is more appropriate to ensure compliance with legislative requirements

Priority is given to activities that:
(a) involve the risk or actual occurrence of death, serious illness or serious injury
(b) pose a significant public health risk
(c) involve counterfeit therapeutic products
(d) involve unapproved therapeutic products, and/or unapproved manufacturers
(e) involve a significant degree of criminality, or repeated and persistent alleged offenders

In the period 1 January 2002 to and including 2 December 2003, the TGA Surveillance Unit received 409 complaints relating to the supply of registered or unregistered non-prescription medicines of which investigation into 137 complaints are not yet completed. The details are summarised in the attached papers.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-107

OUTCOME 1: Population Health and Safety

Topic: TGA OUTSTANDING COMPLAINTS

Written Question on Notice

Senator Forshaw asked:

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

Answer:

The answer to this question has been included in the response to E03-106.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-108

OUTCOME 1: Population Health and Safety

Topic: STAFF EMPLOYED BY TGA

Written Question on Notice

Senator Forshaw asked:

(a) How many staff are employed by the TGA? Please provide figures for each employment category of permanent, non-ongoing, casual, etc.

(b) How many staff are employed in the Office of the Gene Technology Regulator? Please provide figures for each employment category of permanent, non-ongoing, casual, etc.

(c) How many staff are employed in the Office of Chemical Safety? Please provide figures for each employment category of permanent, non-ongoing, casual, etc.

(d) What is the current timetable for the proposed merger between the TGA and NZ agency? Please outline all current merger milestones.

(e) Regarding the proposed merger between the TGA and the NZ agency, what consultations have occurred between the TGA and employees and employee representatives? Please provide dates of consultations, and copies of any materials given to employees.

(f) What will be the anticipated changes to terms and conditions of employment for current TGA employees under the current merger plan?

(g) Has the TGA done any survey of TGA employees to ascertain their preferences regarding any of the terms and conditions of their future employment in a merged agency? Please provide full details and results of investigations.

(h) What are the main areas of concern that have been raised with the TGA by TGA employees regarding the merged agency?

(i) Have any TGA employees sought guarantees or made representations about their continued employment as part of the Australian Public Service? Please provide details of all representations.

(j) Does the TGA anticipate any significant staff turnover/resignations as a result of the merger? What inquiries has the TGA made on this and what are the results of these TGA inquiries.

Answer:

In accordance with discussions to clarify the removal of confidential material, the following answers are provided:

(a) As at 7 November 2003 TGA employed 438 full time equivalent staff in the following employment categories:

Ongoing (permanent)	400
Non-ongoing	36
Casual	2

(b) As at 7 November 2003 the Office of the Gene Technology Regulator employed 56 staff in the following employment categories:

Ongoing (permanent)	40
Non-ongoing	16
Casual	0

(c) As at 7 November 2003 the Office of Chemical Safety employed 75 staff in the following employment categories:

Ongoing (permanent)	67
Non-ongoing	8
Casual	0

(d) The joint Agency is expected to commence operations on 1 July 2005. Major milestones are the signing of the Treaty in December 2003 between Australia and New Zealand to establish the joint scheme for the regulation of therapeutic products with the introduction of the enabling legislation into the Australian Parliament in the first half of 2004.

(e) Consultation with employees and employee representatives occurred on the following dates:

- TGA Staff Consultative Forum

28 March 2003
27 June 2003
25 July 2003
21 August 2003
2 October 2003
26 November 2003
18 December 2003
It is proposed to meet at least monthly commencing February 2004

- Department of Health and Ageing National Staff Participation Forum

29 July 2003
9 December 2003

- Consultation with employee representatives

3 June 2003

- Staff briefings

26, 27, 28, 29 and 30 May 2003; 5 June 2003
22, 23 and 24 October 2003
8 and 9 December 2003

Employees and their representatives were briefed on and discussed employment related issues at each forum. Information has been made available to employees via the TGA Intranet and copies are attached (Attachment A).

(f) It is too early to identify any specific changes in employment conditions. Changes from the conditions that currently apply will ultimately require consideration by the proposed Board and the Ministerial Council.

(g) No.

(h) The main areas of concern relate to:

- Mobility from the Agency back to Australian Public Service (APS) agencies
- Portability of accrued leave entitlements
- Retention of current superannuation entitlements
- Preservation of APS type conditions in Agency legislation such as a Code of Conduct, Statement of values and retention of the merit principle for recruitment and selection
- Ability to recruit and retain suitably qualified and experienced staff
- Recognition of all prior Commonwealth and Trans Tasman Agency employment for the purposes of calculating early retirement benefits in the event of becoming excess to requirements following a return to an APS agency.

(i) Yes. See attached letters from unions (Attachment B).

(j) The TGA does not expect significant turnover/resignations as a result of the merger. The TGA has traditionally had a lower separation rate than the Department of Health and Ageing as a whole particularly amongst the professional/technical staff. The current 2003 separation rate for TGA is lower than for the 2002 year.

It is not possible to provide any definitive assessment of the possibility of staff losses until a final decision is made by the Australian and New Zealand Governments on the employment framework to apply to the new agency.

Attachment A

MATERIALS PROVIDED TO STAFF

Folio

1. HR Policy Options for the "Proposed Trans Tasman Joint Therapeutic Products Agency" – Alan Doolan and Ian Miller – 20 May 2003

2. HR Policy Options for a Trans Tasman Agency on

    (a) Model/Options – 18 June 2003
    (b) Issues of general interest – 23 July 2003
    (c) Funding and Finance – 23 July 2003
    (d) Terms and Conditions of Employment – 4 July 2003
    (e) Mobility to and from the New Agency – 3 July 2003
    (f) Summary of Employment Provisions for Option 3 (Option C)

3. Presentation: Terry Slater, National Manager, TGA – "Proposed Trans Tasman Joint Therapeutic Products Agency"

ATTACHMENT B

CORRESPONDENCE FROM STAFF REPRESENTATIVES

1. Letter to National Manager TGA dated 16 July 2003
2. Letter to Parliamentary Secretary (undated)
3. Letter to Parliamentary Secretary 8 September 2003

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-164

OUTCOME 1: Population Health and Safety

Topic: LEGAL COSTS

Hansard Page: CA 97

Senator Forshaw asked:

(a) How much has the TGA spent on legal costs in the last financial year?

Answer:

(a) In the last financial year (2002/03) the TGA paid $245,408 for legal advice and professional fees.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-165

OUTCOME 1: Population Health and Safety

Topic: GMP LICENCE SUSPENSIONS

Hansard Page: CA 98,99

Senator Forshaw asked:

How many manufacturers of complementary therapeutic goods or medicines had their good manufacturing practice licence suspended, either voluntarily or at the request of the TGA, between January 2001 and January 2003?
Please give:
(a) the names of the manufacturers,
(b) the circumstances which led them to the loss of the licence,
(c) whether it was at the request of the TGA or voluntarily,
(d) an indication of the products they manufacture,
(e) any remedial action that has been taken since the suspension or the cancellation.

Answer:

(a) – (e) No manufacturers of complementary therapeutic goods or medicines have had their good manufacturing practice licence suspended, either voluntarily or at the request of the TGA, between January 2001 and January 2003.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-166

OUTCOME 1: Population Health and Safety

Topic: GMP REASSESSMENT DATES

Hansard Page: CA 100

Senator Forshaw asked:

(a) Give details of any companies where there has been a lapse of time from the due date for GMP reassessment to when pre-clearance was re-issued, including the length of time lapsed.
(b) Do you know whether the pre-clearance certificate for Banner (India) had expired?

Answer:

Following discussion to clarify the information required, the following answers are provided.

(a) The TGA has special arrangements with recognised overseas regulators that enable their GMP inspections of manufacturers to be recognised by the TGA as evidence of GMP compliance. Where necessary, the TGA can request these authorities to carry out a special inspection in order to enable the TGA to obtain this evidence. These arrangements reduce the need for the TGA to carry out overseas inspections itself and reduce the cost of regulatory compliance for Australian sponsors.

    It is the responsibility of Australian sponsors to maintain the currency of GMP evidence for overseas manufacturers they use and to provide updated evidence in a timely manner to the TGA. The TGA classifies GMP reassessment status as being overdue if it is 6 months past the nominal renewal date. For those overseas manufacturers of medicines whose GMP evidence was due for reassessment before 1 January 2004, 143 had passed their nominal due date and have not been reassessed. Of these 2 were overdue as follows (according to month and year of expiry):

    Less than 6 months overdue: 2 – January 2003, February 2003.

(b) The GMP pre-clearance evidence held by the TGA for Banner Pharmacaps, Bangalore, India has not expired. The pre-clearance evidence is based on a GMP inspection undertaken by the Medicines & Health Products Regulatory Authority (MHRA), United Kingdom on 13-14 December 2001. This evidence is current

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-099

OUTCOME 1: Population Health and Safety

Topic: ECHINACEA PRODUCTS

Written Question on Notice

Senator Forshaw asked:

The November issue of Choice magazine includes a report and results of a product test of 10 Echinacea products that are popular with Australian consumers.

The Choice article refers to numerous international and domestic studies done into Echinacea products, including the Counsumerlab product testing in 2000, the 2003 American Medical Association study entitled Echinacea and truth in labelling, and the 1998 Australian study mentioned in the choice article.

(a) Has the TGA looked into any of this research and done any work to verify studies in depth and considered such issues as the truth in labelling claims, efficacy, safety or stability? If yes please provide details as to what the TGA determined from this research and any action the TGA have taken as a result of the research.

(b) Has the TGA done any testing of Australian manufactured Echinacea products? If so what were the results of any testing?

(c) Is the TGA investigating, or has it investigated, the product labelling or advertising of Echinacea products in respect to whether the labelling or advertising is potentially misleading or inaccurate? If yes please provide details of the investigation and the outcomes of the investigation?

Answer:

(a) The Choice article on Echinacea indicates that the scientific evidence to support claims that Echinacea may help boost the immune system or fight the common cold is, at best, equivocal. The article also questions the long-term safety of Echinacea use, especially by people with chronic illness such as certain immune disorders eg multiple sclerosis, HIV/AIDS.

The article also reports on the results of a study of 10 Australian Echinacea products commissioned by Choice, which measured two of the chemical components of

Echinacea. The study found varying levels of these two chemical elements in the products analyzed, and inferred from these results that there is a poor basis to assist consumers to compare Echinacea products against each other, and questioned the lack of standardization of such products against marker or active components.

Echinacea, like most other plant/herbal materials, is chemically complex. Any therapeutic effect from Echinacea products may be due to any one, or a combination, of its chemical constituents. There is no consensus as to which constituents are the active ingredient(s) in Echinacea products. The analysis of products to determine cichoric acid or alkylamide content is misleading if this were to be equated with the therapeutic activity of a particular Echinacea product. For example, a recent report suggested that certain glycoproteins may be the active principles of Echinacea species.

While cichoric acid or alkylamides may be useful as 'marker' compounds to indicate product consistency, there is not sufficient evidence to indicate that they are responsible for the therapeutic activity of the herbal medicine or its extract. Subsequent to the publication of the Choice article, TGA has been informed by the senior investigator at the University of Sydney who conducted the analyses on behalf of Choice, that the interpretation placed on the findings by the publishers was not one which they themselves had endorsed, given the uncertain link between levels of certain marker compounds and efficacy as described above.

The TGA maintains a watching brief on issues that arise in relation to complementary medicines in the international and the national arenas. The results of testing of Echinacea products in America have been reviewed. However, it must be noted that most herbal (including Echinacea) products in the USA are not regulated as medicines, and are not therefore subject to the quality and safety controls that are applied to complementary medicines in Australia. As a consequence, problems with product ranges in the USA do not usually mean that the same problems will arise with Australia's regulated products containing similar ingredients.

When the therapeutic goods legislation was enacted in 1991, most herbal products were defined as low-risk medicines, and evidence of their efficacy was not required to be produced by the sponsor for the Therapeutic Goods Administration (TGA) to assess. When a sponsor makes an application to include a medicine on the Australia Register of Therapeutic Goods (ARTG), the applicant must certify that they hold information to support any claim that they make relating to the medicine. This information may be requested by TGA if the need arises. The recent Expert Committee report, *Complementary Medicines in the Australian Health System*, has recommended that this aspect of the current regulations be strengthened.

In 1999 the Complementary Medicines Evaluation Committee (CMEC) conducted a safety review of Echinacea. The CMEC recommended to the TGA that Echinacea be maintained as a substance suitable for use in Listed (low risk) medicines. CMEC considered that there was insufficient evidence to require a warning statement on Echinacea products and recommended to the TGA that they maintain vigilance on adverse reactions to Echinacea products.

(b) There are three species of Echinacea that are generally recognised as having therapeutic value: *Echinacea angustifolia, Echinacea purpurea, and Echinacea pallida*. The TGA does include Echinacea products in its routine testing program and has sampled a significant number of Echinacea products. The focus of testing has been to ensure the correct species of the herb is in the product or to monitor compliance with TGA's microbiological quality standards.

In the period 1992/93/94, 27 Echinacea products were analysed for the presence of the correct species of the herb. One product was found to contain the herb *Parthenium integrifolium* in place of Echinacea and this product was recalled by TGA. A number of other issues relating to confusion over the exact species of Echinacea used in the products were taken up with the respective manufacturers. Since 1997, as a follow up to this work, a later survey of 25 Echinacea products found that all products tested contained the species of Echinacea that was stated on the product label. In the absence of evidence linking the efficacy of Echinacea products to particular components, the survey did not attempt to analyse the products for purported active or other components. In addition to these two surveys, a further 25 products containing Echinacea as an ingredient have been tested. Seventeen of these 25 were tested for levels of microbiological contamination. Of these 17 products, one failed to comply with microbiological quality standards and it was recalled. The remaining products were submitted for TGA analysis for reasons related to other ingredients or issues with the products not related to Echinacea.

(c) The Echinacea article in Choice was included in the agenda for the recent meeting of the Complementary Medicines Evaluation Committee (CMEC) held on 28 November 2003. The CMEC recommended to the TGA that it conduct a review of the current scientific literature relating to the immunomodulatory effects of Echinacea with a view to identifying the optimal marker compounds for herbal quality and efficacy. The CMEC also recommended that the TGA incorporate into its post-market monitoring program the testing of the quality of a sample of Echinacea products based on those accepted markers. The TGA is now in the process of responding to these recommendations.

None of the products included in the Choice survey make claims on the Australian Register of Therapeutic Goods for their cichoric acid or alkylamide content. Should claims for a particular component of Echinacea be made and found not to be true, the TGA would undertake regulatory action.

Also, it is noteworthy that the recent Expert Committee report, *Complementary Medicines in the Australian Health System*, recently released to enable a wide input of views to be considered in formulating the Government response, suggested that a greater level of accountability by sponsors was called for in the way products are presented in the market place. In particular, the Expert Committee suggested that where ingredients are highlighted to consumers in terms of conferring a certain efficacy on the product, sponsors must not only hold relevant evidence as currently required, but must submit this evidence in summary form to the TGA. The TGA would then be in a stronger position to be able to confirm the veracity of labelling and advertising claims.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-023

OUTCOME 1: Population Health and Safety

Topic: NATIONAL NUTRITION SURVEY

Written Question on Notice

Senator Nettle asked:

(a) When was the last time that the Commonwealth Department of Health and Ageing conducted a national nutrition survey?

(b) How was the information used? What benefits were derived from it?

(c) Does the department consider such a survey beneficial?

(d) Is it correct that the department was scheduled to undertake a national nutrition survey this year?

Answer:

(a) The last National Nutrition Survey was administered in 1995-6. The survey was undertaken by the Australian Bureau of Statistics and the Australian Government Department of Health and Ageing with financial contributions from Australia New Zealand Food Standards Authority (ANZFA), Australian Institute of Health and Welfare (AIHW), New Zealand Ministry of Health, all Australian states and territories except the Northern Territory, Australian Government Department of Veterans' Affairs and the National Heart Foundation.

(b) The National Nutrition Survey provided representative national information on food and nutrient intake, eating habits and consumption patterns, and physical measurements of height and weight of Australians aged two years or over.

This information was used by the Australian Government to monitor progress towards Australia's dietary and health recommendations; inform decisions relating to food fortification, and nutrition and toxicological safety policies; assess the relationship between diet, nutritional status and health outcomes; and glean information relating to trend data from previous monitoring activities undertaken in 1983 and 1985.

(c) This is a policy matter for Government.

(d) No.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-024

OUTCOME 1: Population Health and Safety

Topic: NATIONAL NUTRITION SURVEY

Written Question on Notice

Senator Nettle asked:

(a) Is it correct that the department was scheduled to undertake a national nutrition survey this year?

(b) If yes:

(i) Why has this not happened?

(ii) Has the survey been rescheduled - if so, what is the new timeline?

(iii) Was an amount of funds set aside to conduct the survey? How much? What has happened to this funding?

If no:

(i) When does the department intend conducting the next national nutrition survey?

(ii) Have funds been set aside this financial year to conduct the survey?

(iii) If the department does not intend to conduct a national nutrition survey, how does it propose to obtain the information it would otherwise obtain by this process?

Answer:

(a) No.

(b) If yes: N/A

If no:

(i) There are no current plans for another National Nutrition Survey.

(ii) No.

(iii) The Australian Government Department of Health and Ageing is continuing to utilise the data provided by the 1995 National Nutrition Survey and other relevant monitoring activities such as the National Health Survey, the Women's Health Australia longitudinal study, the Longitudinal Study of Australian Children, the Australian Secondary Schools Alcohol and Drug Survey, and the Australian Diabetes, Obesity and Lifestyle Study (AUSDIAB).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-025

OUTCOME 1: Population Health and Safety

Topic: NATIONAL NUTRITION SURVEY- OBESITY

Written Question on Notice

Senator Nettle asked:

The Government has identified obesity as a significant health issue for Australia and has highlighted the importance of behavioural and diet change to prevent illness. Why then is the government opposed to conducting a national nutrition survey to provide the data required to develop policy approaches to improving nutrition?

Answer:

The Australian Government recognises the importance of monitoring and surveillance for behavioural risk factors including nutrition. The Australian Government obtains this information from a range of sources including the National Health Survey, the Women's Health Australia longitudinal study, the Longitudinal Study of Australian Children, the Australian Secondary Schools Alcohol and Drug Survey, and the Australian Diabetes, Obesity and Lifestyle Study (AUSDIAB).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-098

OUTCOME 1: Population Health and Safety

Topic: BREACH OF CONSTRUCTION LICENCE FOR THE REPLACEMENT RESEARCH REACTOR

Written Question on Notice

Senator Carr asked:

During the last twelve months ARPANSA has found INVAP in breach of the conditions of the licence to construct the new research reactor at Lucas Heights. The stated reason in the 2002-03 Annual Report for not imposing any sanction on INVAP was, first, that this was the first breach and, secondly, you were satisfied with commitments made that such a breach would not be repeated.

(a) What was the nature of those commitments?

(b) What are the 'improvements to their process that they [INVAP] will institute' that you accepted?

(c) Have you completed your additional investigations into the incorrect excisions to the reactor pool liner?

(d) What determination have you reached?

(e) Why did INVAP's improvements to their process not prevent these major mistakes?

(f) While you have now approved the restorative work to the reactor pool liner, what sanctions are under consideration for this further breach of the licence to construct?

Answer:

(a) INVAP gave Dr Loy, CEO of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), a commitment to institute improvements in its work process to ensure that the situation would not reoccur.

(b) Dr Loy accepted the following improvements in INVAP's work process:
- establishment of a group within INVAP's project management structure to ensure observance of ARPANSA's requirements by all parties;

- amendment of INVAP's procedures to explicitly include ARPANSA's requirements in the requirements for manufacturing documentation and drawings;
- modification of the project management plan to implement these changes; and
- communication of these actions by INVAP to the complete sub contractor chain.

(c) Yes. Dr Loy's decision and reasons for that decision, dated 29 August 2003, were made available on the ARPANSA website on that date.

(d) After undertaking an assessment of the information provided to Dr Loy by the Australian Nuclear Science and Technology Organisation (ANSTO) and the advice received on that information from ARPANSA staff, welding experts from the Commonwealth Scientific and Industrial Research Organisation and Toshiba Corporation of Japan as well as members of the Nuclear Safety Committee of ARPANSA, the CEO decided that:

(i) The error made by the fabricator in rolling the plate inside out for the construction of the reactor pool liner was the result of the fabricator applying a mental model of how the convention of drawing a circular vessel applied, rather than examining the drawing sufficiently closely or asking for additional information.

(ii) Subsequent to the error being made, the fabricator then made errors of judgement in carrying out unauthorised repairs and in not immediately raising a "non conformance report", as was required by his own Quality Assurance system, to be resolved by the designer (INVAP)

(iii) The deficiencies in implementation of the fabricator's QA system arose from a lack of resources devoted to QA and a lack of an independent QA decision-maker. That these deficiencies existed in the fabricator also reflects on the construction contractor (John Holland Evans Deakin Industries).

Dr Loy then made the following regulatory decisions:

(i) The unauthorised repairs to the three small holes in the lowest plate in the reactor pool liner and the repairs in strake two and eight that required only additional plate and longitudinal welds have been undertaken consistent with the Code that originally formed the basis of my approval of the reactor pool liner for construction. Therefore I accepted the repairs as being in conformity with my original approval to construct.

(ii) The repair strategy for the remainder of the reactor pool liner set out by INVAP (and accepted by ANSTO) together with the revised welding procedure recommended by the Welding Technology Institute of Australia and the revised organisation of the fabricator's workshop gave me confidence that the repaired vessel would be in conformity with my original approval.

In addition, Dr Loy imposed a number of additional licence conditions on the licence that had the effect of ensuring that ARPANSA would finally approve the reactor pool liner

before it could be accepted by INVAP or ANSTO and that certain additional information of the quality of the welded structure would be made available to substantiate the quality and safety of the vessel. Further, the CEO also imposed additional licence conditions requiring ANSTO to report to him on the implementation of the quality system in key sub contractors who were undertaking the construction of items important for safety.

(e) The improvements were identified as a result of the unauthorised cut-outs for which INVAP was found in breach of the facility licence. The errors in fabrication of the reactor pool liner occurred at about the same time as the unauthorised cut-outs were made. Consequently, it would not be possible for the improvements to have prevented the errors in fabrication.

(f) The reactor pool liner fabrication and subsequent repairs were undertaken by a company that is not subject to the conditions of the facility licence issued by Dr Loy authorising construction of the replacement research reactor – this is due to the jurisdictional provisions of the *Australian Radiation Protection and Nuclear Safety Act 1998*. At the time of the misalignment of the holes, neither ANSTO nor INVAP had accepted the vessel, therefore it had not been "constructed" for the purposes of the licence. ANSTO and INVAP are subject to the facility licence and must comply with all relevant licence conditions. As the errors were not made by either ANSTO or INVAP and they had not accepted the liner as having been constructed in conformity with my approval there was no breach of licence.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-167

OUTCOME 1: Population Health and Safety

Topic: INTERACTION WITH APVMA

Hansard Page: CA105

Senator Cherry asked:

For both the Bayer and Monsanto applications, what interactions have you had with the APVMA in terms of dealing with the issue of the crop management system?

Answer:

On 19 September 2002 the Gene Technology Regulator (the Regulator) advised the Australian Pesticides and Veterinary Medicine Authority (APVMA) of the receipt of applications DIR20 (from Monsanto Australia) and DIR21 (from Bayer CropScience) for commercial release of genetically modified canola, provided copies of the applications and asked for advice on any issues that should be taken into account in the preparation of the risk assessment and risk management plans (RARMPs).

On 7 February 2003 APVMA provided advice to Regulator on preparation of the RARMPs for DIR20 and DIR21.

On 1 April 2003 the Regulator provided the APVMA with, and sought comments on, a copy of the consultation RARMP for DIR21.

On 30 May 2003 the APVMA provided advice to the Regulator to assist the finalisation of the DIR21 RARMP.

On 29 July 2003 the Regulator advised the APVMA of the licence decision on DIR21.

On 2 October 2003 the Regulator provided the APVMA with, and sought comments on, a copy of the consultation RARMP for DIR20. The comment period for the consultation RARMP for DIR20 closes on 28 November 2003.

In addition to these consultations, required under the *Gene Technology Act 2000* and *Gene Technology Regulations 2001,* staff from the Office of the Gene Technology Regulator liaise extensively with staff from the APVMA on scientific and administrative matters relating to complementary regulatory responsibilities.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-168

OUTCOME 1: Population Health and Safety

Topic: STUDIES ON AUSTRALIAN BIODIVERSITY

Hansard Page: CA106

Senator Cherry asked:

Are you aware of any peer-reviewed studies in Australia that have examined the impact of GM canola and the associated herbicide regime on Australian biodiversity?

Answer:

No. To the knowledge of the Office of the Gene Technology Regulator, there have been no peer-reviewed Australian studies on the impact of weed control on biodiversity in genetically modified canola crops.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-169

OUTCOME 1: Population Health and Safety

Topic: CSIRO Report

Hansard Page: CA112

Senator McLucas asked:

Please provide the Committee with details of how to access the report prepared by the CSIRO in response to the British study (UK Farm Scale Evaluations).

Answer:

A copy of the CSIRO report is attached.

Findings from the UK Farm Scale Evaluation of Genetically Modified Herbicide Tolerant crops – an appraisal of their implications for Australia

October 2003

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Purpose of this report

The Farm Scale Evaluation of genetically modified herbicidal tolerant crops is a significant scientific endeavour by the UK Government. CSIRO has followed the research work with interest, including a study tour in 2002 to see first hand the scale and conduct of the experiment and talking with the scientists involved. The broader environmental and agricultural context in which the Farm Scale Evaluation has been conducted needs to be taken into account in order to determine the relevance of the result for Australia. In this report, CSIRO presents its own independent scientific opinion of the results as they may apply to the Australian context.

Summary

1. **The UK government agreed in 1998 to provide nearly £5M over five years to test if the on-farm management of genetically modified herbicide tolerant (GMHT) crops could have any impact on farmland biodiversity compared with conventional agriculture.**

2. **This included three years of extensive field trials, involving four crops, winter and spring canola, sugar beet, and fodder maize, with extensive biodiversity assessments on each farm.**

3. **The experiment found that for spring canola and sugar beet, weed populations were lower in the GM crop than in the conventional crop, and that some invertebrate populations were lower.**

4. **In the UK this has potential risks for their national conservation of biodiversity. Many native bird species in the UK are in decline and depend on farmland weed seeds and invertebrates for survival.**

5. **Weeds in the UK are mostly native species, and maintaining them on farms is therefore critical to nature conservation.**

6. **In Australia, by contrast, our weeds are largely exotic noxious species. Wilderness areas and remnant vegetation are the focus of biodiversity conservation. It is unlikely that improved weed control in Australian field crops would harm the ecology of our conservation areas; it may instead reduce threats to our biodiversity.**

7. **Consequently, while the UK experiment can inform our future research in this area, its findings cannot be extrapolated directly to Australia and are therefore of quite limited applicability to Australian farming systems.**

8. **CSIRO could nevertheless consider developing a research plan to test whether managing non-crop species in Australian field crops has any impact on biodiversity conservation on and off-farm.**

Introduction

The UK government agreed in 1998 to provide nearly £5M over five years to test if the on-farm management of commercial-scale genetically modified herbicide tolerant (GM HT) crops could have any additional impact on farmland biodiversity compared with conventional agriculture. This included three years of extensive field trials, involving four crops, winter and spring canola, sugar beet, and fodder maize; each crop being grown at a commercial scale across 25 farms over three years while undertaking extensive biodiversity assessments on each farm.

The results from spring sown crops of canola, beet and maize was released on Thursday, 16 October at an event hosted by the British Royal Society, and concurrent publishing of eight scientific papers and a public summary on the Royal Society's web pages. The study of the fourth crop, winter canola, will be released at a later date.

The Scientific Steering Committee overseeing the project put significant effort into ensuring that the findings were appropriately peer reviewed when submitted for publication. In addition to the normal process of review of scientific papers, a special advisory board, including broadcaster Sir David Attenborough and other distinguished scientist and experts in the field, was established to ensure the data met the highest standards of scientific excellence.

Following the publication of the data, the UK government's Advisory Committee for Releases to the Environment will hold a series of public meetings and consider the wider environmental and agricultural implications before they formulate a more detailed policy advice to the Government later in the year.

The experiment is unique, both because of its scale and because it is measuring changes to specific biodiversity indicators within the intensive production systems in the UK. Representatives from CSIRO and the Office of the Gene Technology Regulator visited the UK in May 2002 to gain a better understanding of the experiment itself to speak with the scientists involved. It was clear that whilst it is an excellent piece of research work and would make a major contribution to ecological science, the intensive farming practices in the UK, and the relationships between field crops and biodiversity conservation, are vastly different to those in Australia.

In order to assess whether or not the findings from the FSE could be applicable to Australia, CSIRO established a team of ecological experts to form an independent opinion on the findings from the FSE as it may apply to the Australian environment.

Rationale and interpretation of the FSE

Herbicide tolerance is a fairly recent new farming technology. By introducing new genes into existing crop plants, new management strategies become available to control major weed problems through timing and nature of chemicals being used. At present there is significant interest in introducing these genes by genetic modification (GM), but conventionally bred HT canola varieties have been available in Australia since 1993.

The objective of the FSE was to determine whether **management** of GMHT crops affects farmland biodiversity relative to the **management** of non-GMHT varieties of the same crops under normal agricultural practice, and to assess the implications for farmland biodiversity if GMHT crops were grown in UK on a commercial scale. [1]

This comparison between the effect of management regimes on crop weeds and invertebrates is an appropriate topic for an ecological study of this nature. In contrast, much research into environmental risks of GMOs has focussed on the potential for direct toxicity of plants to insects (e.g. the several studies on indirect impact on GM maize on Monarch butterflies). This interest on direct effects naturally has its place in risk assessments, but the wider effect, as in this study, of the changed management regime that may be used for GMHT crops is potentially more far-reaching, and may be positive or negative. Indeed, it is at present not possible to adopt a GM HT crop without taking on the entire management package – the farmer signs up with the company for the crop, the herbicides, and the management regime.

At the time the study was set up, there were claims and counterclaims that the use of GMHT crops could lead to increased biodiversity. Various mechanisms were proposed e.g. GMHT would allow farmers more options for weed management using more benign herbicides; there would be less need for tillage and thus a greater functional seedbank. A significant element of the debate in the UK concerned the decline in the skylark population, which recently was attributed to adoption of more intensive agricultural practices, and it was feared that GMHT would further intensify British farming to the point of measurable impact on farmland birds. [2]

Context of the FSE

Biodiversity trends in the UK

Bird abundance and species richness in the UK are in long-term decline as a consequence of an increase in farming intensity (see Figure 1). A major chain of interactions contributing to this is the reduction in in-field weed populations leading to a decline in the populations of invertebrates and weed seeds, and a consequent decline in bird biodiversity.

[1] Firbank *et al.* (2003): An introduction to the Farm Scale Evaluations (FSE) of genetically modified herbicide-tolerant crops. J. Appl. Ecol. 2003 - 40, 2-16.

[2] Watkinson *et al*. (2000) Predictions of biodiversity response to genetically modified herbicide tolerant crops. Science 289 (5484): 1554 – 1557.

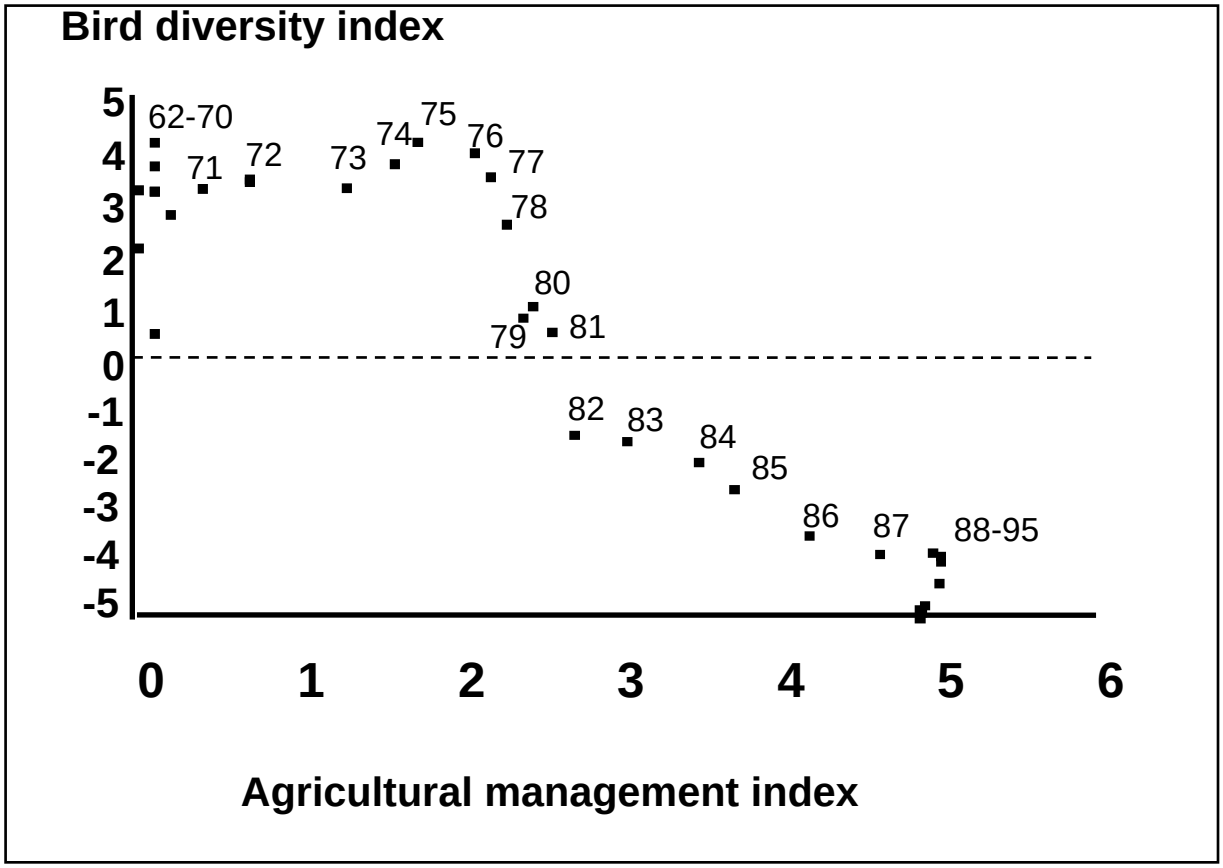


Figure 1: Trends in bird biodiversity in relation to agricultural intensification in England and Wales 1962-1995. Adapted from Chanberlain DE, Fuller RJ, Bunce RGH, Duckworth JC, Shrubb M (2000) *Journal of Applied Ecology* ***37*** *(5): 771-788.*

Broad sustainability and economical issues not covered

The aim of the FSE was to look at the impact of weed management regimes on biodiversity *at the farm scale, not the regional scale*. For example, it did not look at the broad sustainability question of whether GMHT crops would give sufficient yield gain to allow land to be taken out of production and returned to conservation, which already happens in other areas of European agriculture. In fact, there were no measurements of the yield of the four crops, and so they made no comparison of GM vs. conventional yields, or on economic costs and benefits of using GMHT cropping systems. Neither did the research aim to look at gene flow and development of HT in the native weed population per se (But see Appendix 2).

Comparison of on-farm biodiversity in the UK and Australia

A central difference in context between the UK and Australia is in the importance of cropping areas on farms for biodiversity conservation. In Australia, we rely particularly on wilderness and remnant vegetation for conservation of biodiversity. Farming systems should be sustainable, but we do not rely on weeds within our agricultural crop fields to support our wildlife. This is in stark contrast to the UK, where 76% of the land is farmed and in consequence the national conservation effort depends on farms.

Nowhere is this clearer than in considering the weed flora that the GMHT technology is designed to suppress in the UK, compared with that in Australia. In the UK, of the dozen

key arable weed species studied in the FSE, eleven are native species. Contrast this with Australia, where the weeds of canola, for example, are all exotic species (see Table 1).

Table 1 Native and exotic status of the top weeds in the UK FSE and the top weeds in Canola in Australia. The two species common to the two systems are shaded.

Key weeds in the UK Farmscale trial[1]		Key weeds of Australian canola crops[2]	
Species	Status (native to UK or exotic)[3]	Species	Status (native to Australia or exotic)
		Arctotheca calendula	Exotic
		Avena spp.	Exotic
		Brassica tournefortii	Exotic
Capsella bursa-pastoris	Native	*Capsella bursa-pastoris*	Exotic
Chenopodium album	Native	*Echium plantagineum*	Exotic
		Emex australis	Exotic
		Fumaria spp.	Exotic
Fallopia convolvulus	Native	*Hirschfeldia incana*	Exotic
Lamium purpureum	Native	*Juncus bufonius*	Exotic
Persicaria maculosa	Native	*Lolium rigidum*	Exotic
Poa annua	Native	*Myagrum perfoliatum*	Exotic
Polygonum aviculare	Native	*Polygonum aviculare*	Exotic
Senecio vulgaris	Native	*Raphanus raphanistrum*	Exotic
Sonchus spp.	Native (all four spp.)	*Rapistrum rugosum*	Exotic
Stellaria media	Native	*Sinapis arvensis*	Exotic
Veronica persica	Exotic	*Sisymbrium orientale*	Exotic
Viola arvensis	Native	*Volunteer cereals*	Exotic
		Vulpia spp.	Exotic

[1] *See Paper 4 in the FSE Royal Society series of papers.*
[2] *See "Canola in Australia: the first thirty years"; P.A. Salisbury et al. (eds) 1999. Organising Committee of the 10th International Rapeseed Congress.*
[3] *See "New Flora of the British Isles"; C. Stace, 1991. Cambridge University Press.*

In Australia, therefore, both farmers and conservationists agree on the need to control weeds. Australian farmers are also active in conservation of remnant vegetation for biodiversity. Moreover, it may be that in-field weed populations in Australia harbour beneficial organisms and may need to be managed carefully to maintain the farming system health. It seems unlikely, though, that the exotic weed populations in our crops are a critical part of our biodiversity conservation effort, except as a source of potential threats. In the UK, there is strong intersectoral disagreement over the benefits and costs of the weeds, because as native plant species, they sustain native populations of herbivores. As an analogy, one would have to imagine the scenario in which Australian farms were also the last havens for Sturt's desert pea, waratahs, and telopeas – the effect of more efficient control of non-canola species would be a major consideration.

Key findings of the FSE and related papers

Overview (All papers, but especially Paper 8)

Refer to Appendix 1 for titles of the papers referred to as Papers 1-8 below and hyperlinks to the papers

In summary, the effect on the weed populations of the management regime for GM crops relative to the conventional crop drove the resulting differences in impact on invertebrates.

- In canola and beet, the GM management resulted in a higher density of weeds shortly after sowing compared to the conventional crop. Following application of the broad spectrum herbicide to the GM crop, the effect was reversed. In maize, by contrast, weed populations were higher throughout the season. The continuing effects of GM management on invertebrates were largely explained by these impacts on week populations.
- The FSE found that for spring canola and sugar beet, weed populations were lower in the GM crop than the conventional, and that some invertebrate populations were consequently lower.
- GMHT crops allowed use of herbicides later in the season, which shifted food resources for invertebrates. The number of species feeding on dead matter increased, a result the FSE authors attributed to the greater availability of dead, decomposing weeds, though a number of other groups remained unchanged.
- Maize contrasted with beet and canola. The GM variety had a higher biodiversity than its conventional counterpart. This the authors attributed to the use of more benign herbicides in the GM crop than that in the conventional crop All the main weeds in the FSE were native species except one.
- Far the largest effect on biodiversity was the effect of crop species, presumably because of differences in the competitive impact of the different species, and in their associated fauna.
- More kinds of herbicides were used in the conventional crops than in the GM varieties.
- It is reasonable to assume that the observed effects were due to the management regime rather than a direct toxicity effect by the GM crop plants.
- In retrospect, it may not seem surprising that GMHT technology would affect weed numbers, as this is the very aim of the technology, and that this would have a direct effect on any invertebrates that feed on them.

Table 2: Impact of GMHT treatment in various trophic groups in the FSE (Paper 8)

Trophic group	Beet	Maize	Canola
Weed biomass	down	up	down
Herbivore abundance	down	up	down
Pollinator abundance	down	up	down
Natural enemy abundance.	Down	up	down
Detritivores	up	up	up

Impacts on weeds (Papers 2, 3 and 4)

- The key finding in the experiment is that the effects on weed populations of growing GM herbicide tolerant (GMHT) crops varies from crop to crop and that there is no overall consistent effect on weed density, biomass and diversity between GM versus non-GM maize, beet and oilseed rape crops.
- Initially, plant densities were higher in GMHT oilseed rape and beet, but following herbicide application this effect was reversed and by the late season weed densities were lower in the GMHT crops. Weed biomass and weed seed rain was also much lower in the GMHT crops which as expected, being the main purpose of the HT technology.
- In contrast, in maize crops weed density was higher in the GMHT treatment, as was late-season biomass and seed rain. Weed species richness was little different in GMHT and conventional treatments of all three crops.
- The reason for these differences appears to be associated with the herbicide regimes used in each crop.

Impacts on invertebrates (Papers 5, 6, 7)

Pitfall trapping of soil surface active invertebrates (Paper 5)

- Many significant differences were detected between catches of invertebrate organisms in GMHT crops and conventional crops – in particular where data were specific to the species level, in other cases the data were aggregated for several species which may mask finer variations. Most higher captures in GMHT treatments involved maize, most smaller captures in GMHT treatments were in beet and canola. The authors argue that effects are indirect (relative to GM traits) and related to differences that can be expected by the particular herbicide management regime.
- In some instances, the data show averaging across broad groups of species, which could overshadow or counter differences between treatments. This was, however, not particularly noticeable in Collembola (detritivores) and their predators.
- Because the data showed little variability between years, environmental zones, initial seed-banks and between different types of crop plants, the authors suggest the results are widely applicable throughout the UK – i.e. not site specific.

Suction trapping of Epigeal and Aerial invertebrates (Paper 6)

- The effects are different in the different crops, but stable across environmental zones.
- In general, most ground and aerial invertebrates were insensitive, but there were some treatment effects.
- Detritivores – animals that feed on decaying matter (Collembola) had more individuals under the changed management strategy in all crops. This was because of more weed biomass being unavailable for decomposition in the treatments.
- Active flower foragers (butterflies, bees) did worse in beets. The treatment had fewer weed flowers available, and the crop was not allowed to flower.
- Predators and groups with "mixed" feeding strategies did about the same. Presumably they rely less on weed flowers or biomass than the other guilds.

Field margins (Paper 7)

Table 3 Responses to GMHT treatment

	Maize	Beet	Canola
Cover	Up	Same	Down
Flowering	Up	Down	Down
Seeding	Down	Down	Down
Butterflies	Same	Same (down in July)	Down
Collembola	Same (up in August)	Same	Same (up in August)
Herbivores	Same	Same (down in August)	Same
Parasitoids	Same	Same (down in August)	Same
Predators	Same	Same	Same

- There were no significant treatment effects on bees, gastropods or other invertebrates in all crops.
- The tilled crop margin receives the same herbicides and nutrition as the crop, and treatment differences in butterfly numbers were due to changes in weed flowering in crop margin, not necessarily direct changes in overall numbers.
- GMHT Maize showed increases in weed cover and flowering. Atrazine used in conventional maize but replaced by another herbicide int GMHT maize probably caused increases in weed cover and flowering.
- The authors argue the consistency of the results across environmental regions and with varying weed densities suggest applicability in general across the UK, but that care is needed to interpret changes on a landscape scale because of different crop effects.

Notes on the invertebrates studied

Bees – The majority occurring in the study were bumble bees and honey bees. In Australia these are exotic invasive species. Forage in crop for short periods and breed elsewhere.

Butterflies – The most abundant species (about half) was also *Pieris rapae*, an exotic pest of brassicas in Australia. These species generally breed elsewhere, and adults forage for nectar and pollen in crops.

Spiders – The Aracneae families in the study are present in Australia, and ecologically equivalent species probably present here. They are present in crop for long periods, breed and feed there.

Collembola, Heteroptera and Carabidae families – also present in Australia, with ecological equivalents here. Present in crop for long periods, breed and feed there.

Related reports published by DEFRA

Four reports from research commissioned by the Department for Environment, Food and Rural Affairs were released on the Department's website on 13 October. These reports are from additional work done in connection with the FSE trial sites and are therefore relevant for the interpretation of the results and the recommendations the UK government may receive for the Advisory Committee for releases to the environment.

A summary of the papers, as prepared by DEFRA, has been released on their website (see http://www.defra.gov.uk/news/2003/031013b.htm) and is included in Appendix 2.

It is important to note that these four reports have not passed through the similar extensive peer review process as the papers from the FSE itself. Furthermore, two of the reports are only summaries of ecological modelling and without details of the methodology or the research data.

CSIRO has included these papers and their findings in this report, as they are relevant to the overall conclusions that we have made.

Implications of the FSE for Australia

The FSE is a robust and rigorous study of great relevance to farming and biodiversity in the UK. Are the results of the FSE relevant to Australia?

Yes, they are relevant to Australian science because:

1. The FSE confirms unequivocally that significant changes in farming systems are likely to change the biota associated with farms;
2. The FSE clearly shows the interdependence of different groups of organisms within farm-land ecosystems; and
3. The FSE shows that the impacts on biodiversity of GM crops relative to conventional crops are dependent on the relative effects of the two management regimes.

No, they are not relevant to Australian farming because

1. Maintenance of crop weeds on Australian farms is not the main focus of our national biodiversity conservation efforts;
2. Weeds in Australia are exotic invaders and are generally regarded as undesirable by farmers (with the exception of those weeds that may harbour insects beneficial to crop management) and conservationists alike; and
3. The precise effects on Australian in-field biodiversity of GMHT crops relative to conventional crops will depend on the choice of crop species itself, the particular gene and the conventional management strategies already employed nwithin an Australian farming context.

An appropriate research agenda for CSIRO to respond to these findings could be developed. It could focus on measuring impacts of conventional HT canola on in-field biodiversity and remnant vegetation. CSIRO could adapt the methodology and experimental design of the FSE but maintain the multi disciplinary approach and the vigorous standards of analysis and data handling.

Acknowledgments

We thank Julie Carter, Joanne Daly, Gary Fitt, Allan Green, Jane Kahler, James Ridsdill-Smith, Gupta Vadakattu, Mary Whitehouse, and Rob Woolaston, for helpful comments on the document.

Appendix 1

List of papers released by the Royal Society

The papers were published in a special volume of the Royal Society's *Philosophical Transactions: Biological Sciences Series B* Volume **358** Issue 1439 29 November 2003.

http://www.pubs.royalsoc.ac.uk/phil_bio/phil_bio.html

A summary paper was also published on DEFRA's website (see http://www.defra.gov.uk/environment/gm/fse)

Paper 1

On the rationale and interpretation of the Farm Scale Evaluations of genetically modified herbicide-tolerant crops (pg. 1779) G. R. Squire; D. R. Brooks; D. A. Bohan; G. T. Champion; R. E. Daniels; A. J. Haughton; C. Hawes; M. S. Heard; M. O. Hill; M. J. May; J. L. Osborne; J. N. Perry; D. B. Roy; I. P. Woiwod; L. G. Firbank

Paper 2

Crop management and agronomic context of the Farm Scale Evaluations of genetically modified herbicide-tolerant crops (pg. 1801) G. T. Champion; M. J. May; S. Bennett; D. R. Brooks; S. J. Clark; R. E. Daniels; L. G. Firbank; A. J. Haughton; C. Hawes; M. S. Heard; J. N. Perry; Z. Randle; M. J. Rossall; P. Rothery; M. P. Skellern; R. J. Scott; G. R. Squire; M. R. Thomas

Paper 3

Weeds in fields with contrasting conventional and genetically modified herbicide-tolerant crops. I. Effects on abundance and diversity (pg. 1819) M. S. Heard; C. Hawes; G. T. Champion; S. J. Clark; L. G. Firbank; A. J. Haughton; A. M. Parish; J. N. Perry; P. Rothery; R. J. Scott; M. P. Skellern; G. R. Squire; M. O. Hill

Paper 4

Weeds in fields with contrasting conventional and genetically modified herbicide-tolerant crops. II. Effects on individual species (pg. 1833) M. S. Heard; C. Hawes; G. T. Champion; S. J. Clark; L. G. Firbank; A. J. Haughton; A. M. Parish; J. N. Perry; P. Rothery; D. B. Roy; R. J. Scott; M. P. Skellern; G. R. Squire; M. O. Hill

Paper 5

Invertebrate responses to the management of genetically modified herbicide-tolerant and conventional spring crops. I. Soil-surface-active invertebrates (pg. 1847) D. R. Brooks; D. A. Bohan; G. T. Champion; A. J. Haughton; C. Hawes; M. S. Heard; S. J. Clark; A. M. Dewar; L. G. Firbank; J. N. Perry; P. Rothery; R. J. Scott; I. P. Woiwod; C. Birchall; M. P. Skellern; J. H. Walker; P. Baker; D. Bell; E. L. Browne; A. J. G. Dewar; C. M. Fairfax; B. H. Garner; L. A. Haylock; S. L. Horne; S. E. Hulmes; N. S. Mason; L. R. Norton; P. Nuttall; Z. Randle; M. J. Rossall; R. J. N. Sands; E. J. Singer; M. J. Walker

Paper 6

Invertebrate responses to the management of genetically modified herbicide-tolerant and conventional spring crops. II. Within-field epigeal and aerial arthropods (pg. 1863) A. J. Haughton; G. T. Champion; C. Hawes; M. S. Heard; D. R. Brooks; D. A. Bohan; S. J. Clark; A. M. Dewar; L. G. Firbank; J. L. Osborne; J. N. Perry; P. Rothery; D. B. Roy; R. J. Scott; I. P. Woiwod; C. Birchall; M. P. Skellern; J. H. Walker; P. Baker; E. L. Browne; A. J. G. Dewar; B. H. Garner; L. A. Haylock; S. L. Horne; N. S. Mason; R. J. N. Sands; M. J. Walker

Paper 7

Invertebrates and vegetation of field margins adjacent to crops subject to contrasting herbicide regimes in the Farm Scale Evaluations of genetically modified herbicide-tolerant crops (pg. 1879) D. B. Roy; D. A. Bohan; A. J. Haughton; M. O. Hill; J. L. Osborne; S. J. Clark; J. N. Perry; P. Rothery; R. J. Scott; D. R. Brooks; G. T. Champion; C. Hawes; M. S. Heard; L. G. Firbank

Paper 8

Responses of plants and invertebrate trophic groups to contrasting herbicide regimes in the Farm Scale Evaluations of genetically modified herbicide-tolerant crops (pg. 1899) C. Hawes; A. J. Haughton; J. L. Osborne; D. B. Roy; S. J. Clark; J. N. Perry; P. Rothery; D. A. Bohan; D. R. Brooks; G. T. Champion; A. M. Dewar; M. S. Heard; I. P. Woiwod; R. E. Daniels; M. W. Young; A. M. Parish; R. J. Scott; L. G. Firbank; G. R. Squire

Appendix 2

DEFRA Information Bulletin, dated 13 October 2003:

From four Defra-funded research studies (three concerning gene flow from GM crops and the fourth into the effect of farm management on wildlife) are now available on the Defra website at www.defra.gov.uk/environment/gm/research (these reports are not the results of the farm-scale evaluations of GM crops).

All of these are being forwarded to the Government's statutory advisers on GM crop releases - the Advisory Committee on Releases to the Environment - so that they can advise on their implications for current, pending and future releases of GM crops.

They will also be passed to the reconvened GM Science Review Panel for their consideration (for more details see www.gmsciencedebate.org.uk).

The four research reports published today are:

1. "Quantifying landscape-scale gene flow in oilseed rape (RG0216)"

This project was commissioned from the Scottish Crops Research Institute to examine the regional nature of gene flow in oilseed rape and its implications for crop purity. The main results of this project have already been published separately (see www.defra.gov.uk/environment/gm/research/epg-rg0216.htm for a full list). This study suggests that for oilseed rape:

(i) The amount of pollen-mediated gene flow rapidly declines over tens of metres from the pollen source,

(ii) Gene flow from a large area of plants to a neighbouring field of fully fertile plants is of the order of 0.1% (one seed in a thousand contains DNA from both crops) and

(iii) Long distance pollen-mediated gene transfer can occur, but that this is rare. This means that relatively small separation distances can reduce impurity through cross-pollination in fields of fully fertile oilseed rape to low levels (around 0.1%, or below), but that complete (100%) purity cannot be maintained by geographical separation.

The study provides evidence of some pollen-mediated gene flow to 'bait plants' over a distance of 26 km. Non-GM, male-sterile oilseed rape plants (so-called bait plants) were predominantly used in this study to help detect gene flow (as these plants rely on pollen from a male fertile oilseed rape variety for fertilisation). This study provides evidence that insects are predominately responsible for cross-pollination in oilseed rape. It also suggests that bee-to-bee contact in the hive is an effective means of dispersing pollen through the foraging area of a bee colony.

2. "The potential for oilseed rape feral (volunteer) weeds to cause impurities in later oilseed rape crops (RG0114)"

This study was carried out by the Central Science Laboratory and the Scottish Crops Research Institute. It examines whether oilseed rape (*Brassica napus*) could persist in the environment as feral (volunteer) weeds, for long enough, and in high enough numbers, to cause impurities in later crops.

Particular attention was given to the possibility of GM ferals affecting the purity of subsequent non-GM crops. The study uses information on the life-cycle biology of oilseed rape (mostly from non-GM oilseed rape crop plants) that has already been published to model how long feral populations from an oilseed rape crop would persist under different management practices.

The model considers a typical rotation of winter oilseed rape followed by two years of winter wheat over a period of 18 years. The rates of decline in feral oilseed rape population densities predicted by the modelling were consistent with the results of field studies. The model indicates that an impurity threshold of 1% could be met within reasonable timescales (e.g. five years) but only if feral oilseed rape plants are rigorously controlled i.e. they are destroyed before they set seed. If no attempt to control feral oilseed rape plants is made, the model predicts that the presence of the original variety in subsequent crops would not fall below 1% for16 years.

The predictions made in this project will be compared to the persistence of feral oilseed rape populations left by GM herbicide tolerant varieties in the Farm-scale Evaluations.

Early indication of the results of this project led to Defra, in July, advising farmers involved in FSEs to avoid growing non-GM oilseed rape on the same sites owing to the risk of contamination by persistent volunteers (See Defra press notice 311/03).

The project does not indicate that GM varieties persist longer than non-GM varieties of oilseed rape. The GM trait however, allows the persistence to be accurately measured for the first time.

3. "Monitoring gene flow from GM crops to non-GM equivalent crops in the vicinity (EPG 1/5/138). Part 1: Forage Maize"

This study, carried out by the Central Science Laboratory and the Centre for Ecology and Hydrology, monitored gene flow from genetically modified (GM) crops to adjacent non-GM equivalent crops. It was undertaken to validate assumptions made in the original risk assessments concerning gene flow from GM plants. Gene flow was monitored at the farm-scale evaluation (FSE) sites of fodder maize crops.

Overall, results showed that there was a rapid decrease in the rate of cross-pollination within the first 20m from the donor crop and beyond this distance the rate of decrease was much slower. There was significant variation in levels of GM/ non-GM cross-pollination between sites in each year, although the variation between years across all sites was not significant.

Results from individual fields was related both to wind direction during the flowering period, synchrony of flowering between the two (GM and conventional) crops and to separation distances between the crops.

Evidence of low level gene flow was detected, beyond both the 80m and 200m separation distances recommended for forage maize and sweetcorn respectively. However the report concludes that a separation distance of only 24.5m would be required to meet the 0.9% threshold recommended by the EU, and that the 80m seperartion distance recommended by SCIMAC would be sufficient to ensure that cross-pollination levels were below 0.3%. These findings are in-line with expectations based on previous work.

4. "Modelling the effects on farmland food webs of herbicide and insecticide management in the agricultural ecosystem"

This project is a review of information relating to the effect of crop management on farmland birds. It attempts to gather information to predict how changes in crop management might affect birds. The project was commissioned from the University of East Anglia by Defra with a specific view to assisting the interpretation of the GM crop farm-scale evaluation results. The FSEs did not study birds directly, but they did study bird food resources. This project develops the methods for predicting how changes in bird food resources will affect birds themselves.

It is equally applicable to changes in crop management associated with any farming system - not just GM. It will therefore be of wider interest to conservationists.

The study will be made available to ACRE when they are asked to advise government on the implications of the farm-scale evaluation results, following publication on 16 October.

Appendix 3

Notes on methodology

Scale and replication

Scale is a critical factor in ecological research. Ecological phenomena may be absent or undetectable at anything other than large spatial scales. Examples include (i) bush-fires, where experimental fire plots that are too small will never allow fires to reach the highest intensity achieved in nature and (ii) the large foraging ranges of grazing mammals, necessitating very large grazing trials. The FSE was carried out at an extremely large scale. There is no precedent research undertaken world-wide in terms of replicate size and number for a study of the effects of cropping on biodiversity. Because the study was of the effects of on-farm crop management, it had to be at the scale of working farms.

Treatments

The effects measured were four crop species (winter and spring canola; maize, sugar beet) X two crop types (GMHT and conventional) X three years X 20 – 25 sites (replicates).

A range of seasonal conditions were sampled by comparing the GMHT and conventional crops in three years, 2000, 2001, 2002, with each site compared during the subsequent two years of other crops, mainly cereals.

The crops were managed in the customary way by farmers on their own working farms and in accordance with their license in the case of the GM crops.

Measurements taken in the FSE

Sensitivity

Prior to the main study, the FSE team examined a large body of information on cropping environments and crop management throughout Great Britain, to select and characterise the FSE fields relative to commercial fields. They selected sites on the basis of physical characteristics and management to represent current agriculture, and the background variation that would be encountered, if the GMHT crops were grown commercially.

A difference of 50% change in the selected biota was identified as a large impact relative to effects of earlier changes due to changes in agrochemical treatments last century. The most appropriate design, split-plot, over 60-75 sites was found to provide sufficient discriminatory statistical power to discern such an impact.

Herbicide usage

Farmers recorded their herbicide usage in field notebooks. (See Paper 2). Usage was audited to determine if there were biases relative to the expected inputs. No systematic bias was found.

Indicator species

Taxonomic and functional groups sensitive to changes in field management or crop variety were identified for specific monitoring. Responses in the biota to changes in management were found likely to be observed within a single season. These were

- seed bank, which is especially rapidly responsive,
- emerged weed flora,
- aerial or surface-dwelling herbivores; and
- detritivores and their more specific predators and parasites.

Wider foraging species, bees, butterflies, carabid beetles were included with appropriate monitoring methods.

Sampling was carried out in the field and in the field margins. The latter are regarded as key habitats for conservation in the UK.

Measurements not taken

It is relevant to note that these measurements of the trials were not taken:

- most soil-dwelling organisms because of their loose association with weed management over one season;
- birds and mammals, because the large spatial scale (even larger than the scale of the FSE) over which they forage meant that impacts would be impossible to detect.
- No measurement on the persistence in the environment of the herbicides used.

Furthermore there were no measurements of crop production to allow a comparison of economic benefits of the different species and type.

Extrapolation from the FSE

The selection of appropriate variation in the FSE sites was considered to enable extrapolation of results to predict outcomes of broader application of GMHT crops in Great Britain using appropriate modelling, especially for relatively sedentary or slow-moving biota and less so for wider-ranging species. Nevertheless, predictions at wider scales were seen as complicated by management decisions of farmers in response to various economic factors and available choices.

Models were used to extrapolate from measured effects on the weeds and invertebrates to effects on birds. (See Appendix 2)

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-192

OUTCOME 1: Population Health and Safety

Topic: CORRESPONDENCE WITH COMMITTEES

Hansard Page: CA 114

Senator Wong asked:

Can you provide us with copies of the correspondence to the two committees

(a) Nuclear Safety Committee
(b) Radiation Health Committee

for which issues were referred in relation to DEST's licence application.

Answer:
The terms of reference concerning advice to be provided to the CEO of the Australian Radiation Protection and Nuclear Safety Agency by the Nuclear Safety Committee and the Radiation Health Committee are available from ARPANSA's website at http://www.arpansa.gov.au/pubs/reposit/nscadvice.pdf and http://www.arpansa.gov.au/pubs/reposit/rhcadvice.pdf

Panel of Providers of Health Economics Services

1	ACIL Tasman Pty Ltd
2	Adhealth Pty Ltd
3	Allen Consulting Group
4	Applied Economics Pty Ltd
5	Australian Healthcare Associates
6	Bainbridge Consultants Pty Ltd
7	Centre for health Economics Research and Evaluation (CHERE)
8	Fresbout Consulting
9	Global Health Economics and Outcomes Research Pty Ltd
10	Health Outcomes International Pty Ltd
11	Health Technology Analysts
12	Healthcare Management Advisors
13	Latrobe University
14	Melbourne University, Health Economics Group
15	Monash University, Health Economics Unit
16	M-TAG
17	Dr Nicholas Graves
18	NATSEM (University of Canberra)
19	Network Economics Consulting Group
20	O.R. Systems
21	Price Waterhouse Coopers

Statement of Requirement for CHERE consultancy for Department of Health & Ageing

In relation to identified health policies on Medicare, the consultant is required to provide advice to the Department on methodological considerations in economic modelling. The work will focus on a model commissioned by the Senate Select Committee on Medicare to estimate the inflationary effects, if any, of elements of *A Fairer Medicare* and alternative policies under consideration by the Committee.

The work is expected to identify and examine influences on the reliability and robustness of economic models and provide advice as to the sensitivity of economic modelling to underlying assumptions.

The consultant will be required to:

(a) provide comment in a time period agreed between the consultant and the Commonwealth on the methodology used in the report to the Senate Select Committee, and
(b) if required, provide a written report summarising their advice.

The Department, at the conclusion of (a), will determine the need for (b).

TABLED BY SEN McLUCAS

THE AUSTRALIAN

Fri 30 Aug 2002

Surprise pathology lab checks in tests crackdown

Misha Schubert

HEALTH authorities will spring surprise checks on pathology laboratories and repeat patients on any lapse in testing standards to avoid a repeat of the inaccurate pap smear results uncovered earlier this year.

Federal Health Minister Kay Patterson announced the reforms yesterday.

They were developed after she earned three laboratories in parliament in March for failing accreditation checks over the non-detection of abnormal cell changes. Such tests are essential in the early diagnosis of cervical cancer, which can develop rapidly and fatally if untreated.

"These reforms will make it much tougher for the small number of laboratories which fail to meet high standards to continue to operate," she said.

There was a bit of an imbalance between natural justice for the laboratories and natural justice for patients and doctors

Senator Kay Patterson
Federal Health Minister

Laboratories that fail accreditation in future will have 14 days to explain to the Health Insurance Commission why they should stay in business, but can then appeal a decision through the Administrative Appeals Tribunal.

For the first time, they will be named on a website, and forced to retest any results given during a period of uncertainty about their performance.

All new laboratories will be inspected before they qualify for Medicare payments — and checked again six months later.

Senator Patterson said the changes would ensure the interests of patients were given greater priority.

"There was a bit of an imbalance between natural justice for the laboratories and natural justice for patients and doctors," she said. "We've skewed it back to what is appropriate and acceptable."

The majority of Australia's 800 pathology laboratories were of "gold standard", the minister said.

"There are only a handful [of failing laboratories] and those were discovered through the normal processes of testing. It wasn't that somebody died, it wasn't a tragedy like that, its because we had systems in place," she said.

THE AGE

Fri 30 Aug 2002

Errant labs face public shaming

David Wroe
Health Reporter

Pathology laboratories that risk public safety face public shaming, spot checks and a curtailed appeals process after the Pap smear scandal earlier this year.

Under new regulations, announced by federal Health Minister Kay Patterson yesterday, poorly performing labs will have just 14 days to explain themselves before they are stripped of their Medicare accreditation.

Senator Patterson said she had been extremely concerned that suspect labs were avoiding sanctions through the "extended and protracted series of legal processes". "(This has) frustrated the public's and doctors' legitimate right to know when a laboratory has failed," she said.

"The process has been too slow and it has focused on the needs of pathology services and not enough on the health interests of users of pathology laboratory services.

"Natural justice for laboratories is important; however the public interest and patients' health and safety must be the main concern."

In March, Melbourne pathology firm General Diagnostic Laboratories became the centre of a cervical cancer screening maelstrom when it emerged that the Health Insurance Commission had taken away its Medicare accreditation.

GDL had failed to spot four times as many pre-cancerous cervical cells as the national average in 2000.

About 34,000 Victorian women GDL screened between 1999 and March this year were urged to be retested.

Senator Patterson named two more laboratories deemed dangerous, both in NSW. They were Medtest Laboratories and the now defunct Wiedebinda Pathology Laboratory.

David Weedon, president of the Royal College of Pathologists of Australasia, expected a small number of poorly performing labs would be picked up immediately in the crackdown.

"The number would be no more than four or five," Professor Weedon said. "There have been laboratories ... that have spun out the accreditation process. They use every step along the way ... they can go on for months and months."

About 500 accredited laboratories operate in Australia. Under the new regulations, to be introduced on Sunday, suspect laboratories will be named on websites if the commission believes it is in the public interest.

Presently they cannot be identified during the lengthy appeals process.

The commission will also be able to move more quickly to suspend a suspect lab's Medicare accreditation without waiting for the pathology watchdog, the National Association of Testing Authorities, to finish investigating.

The review by law firm Corrs Chambers Westgarth, which began long before the GDL scandal erupted in March, emphasised Australia's pathology accreditation system was fundamentally sound but needed some finetuning.

A commission spokeswoman welcomed the new standards, saying they would give greater clarity to the roles of the three organisations that police laboratories.

The Australian Association Pathology Practices also welcomed the changes, which it said would ensure the public can continue to have confidence the results provided by the pathologists.

Association president Ilia Haagsma said: "The measures announced today will ensure that the tiny proportion of laboratories which do not meet appropriate standards are identified and dealt with in a more timely manner." with AAP

Media Release

Senator the Hon Kay Patterson
Minister for Health and Ageing

ENHANCED PATHOLOGY LABORATORY TESTING STANDARDS TO PROTECT PUBLIC HEALTH AND SAFETY

August 29, 2002

The Federal Minister for Health and Ageing, Senator Kay Patterson, today announced measures to enhance standards of pathology laboratory testing and identify laboratories that pose a risk to public health and safety.

Spot checks of pathology laboratories, public notification of laboratories which fail to meet standards, and greater sanctions for the Health Insurance Commission to act against non-performing laboratories, are parts of the package to strengthen laboratory accreditation procedures.

Senator Patterson was announcing the Government's response to a comprehensive review of the accreditation arrangements for pathology laboratories.

The report, undertaken by Corrs Chambers Westgarth, found that although accreditation arrangements are fundamentally sound, there are key areas where improvements should be made.

Senator Patterson earlier this year named three pathology laboratories that had failed to perform pap smear testing to the required standard.

She said reforms of pathology laboratory testing, which would be implemented next month, would minimise delays in enforcing sanctions against laboratories that failed to meet the required standard.

The major reforms include:

- Safety and Quality: The Health Insurance Commission (HIC) will be able to undertake spot checks of laboratories.
- Early Warning System: The National Association of Testing Authorities (NATA), which assesses laboratories, will get earlier information on poorly performing laboratories. NATA will provide early warning of possible concerns to the HIC.
- Public Notification System: Up-to-date information about the laboratories' accreditation status on websites letting people know about their performances.
- Streamlining of Appeals Process: Speeding up the review, action and appeal processes. Quicker and more streamlined appeals process by NATA. HIC can act independently of the NATA appeals process if it has concerns and believes it is in the public interest.
- Tougher Sanctions: If laboratories fail to meet standards, access to Medicare benefits will be cut.

Senator Patterson said under current arrangements, laboratories which failed testing standards could continue to be eligible for Medicare benefits while they appealed an adverse decision by the National Association of Testing Authorities.

"I have been extremely concerned that when a laboratory has been found to be performing below standard, a convoluted and protracted series of legal and administrative processes has frustrated the public's and doctors' legitimate right to know when a laboratory has failed," she said.

"The Government's ability to remove Medicare funding from these poorly performing laboratories had been impeded.

"The process has been too slow and it has focused on the needs of the pathology services and not enough on the health interests of users of pathology laboratory services.

"Natural justice for laboratories is important, however, the public interest and patients' health and safety must be the main concern. I have moved with these reforms to restore the balance.

"Laboratories that fail will be given 14 days to show cause - if they don't, they will lose their access to Medicare benefits."

Senator Patterson said Medicare provided $1 billion a year for pathology services performed at more than 500 accredited pathology laboratories.

"The vast majority of laboratories perform an excellent job in providing high-quality testing for the Australian public," she said.

"These changes are directed at the small number of laboratories which are not performing to the required standard. These measures will ensure that these laboratories cannot beat the system and they will not survive."

Senator Patterson said the initiatives would ensure that Australia maintained its place as a world leader in pathology testing. In particular, Australia had one of the best early detection programs for cervical screening in the world.

The Federal Government spends $100 million a year through Medicare to support the National Cervical Screening program. Deaths from cervical cancer have fallen by 40% between 1986 and 1998 as the result of the screening program.

Senator Patterson said: "An effective and safe pathology accreditation system is at the very heart for our national screening programs for breast and cervical cancer.

"We are about to run pilot programs to test for bowel cancer to find out if we can introduce a national screening program for the early detection of bowel cancer, which kills about 90 people a week.

"The public can be confident that the reforms I have announced today will make a good system even better and ensure the highest of standards and safety of pathology laboratory accreditation in this country."

Media Contact:
Randal Markey, Media Adviser, 0417 694 520

Department of Health and Ageing

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

Dear Mr Humphrey

Supplementary Budget Estimates Hearing 5 November 2003: Outcome 2

On 5 November 2003 I appeared before the Senate Community Affairs Legislation Committee to answer questions in relation to Outcome 2: Access to Medicare.

I would like to clarify a statement made by me at this time. When asked to give the figures for the elements of the development of the PBS Community Awareness Campaign, I stated:

*The media buy is $8.84 million. For the advertising tools – the actual production of the advertising – it is $2.2 million. For public relations, it is $0.7 million. For the non-English speaking background campaign, it is $0.3 million. For the indigenous campaign, it is $0.25 million. For market research, it is $0.5 million. For printing, it is $0.4 million. Distribution of campaign materials is also $0.4 million and production of some visual media – video and audio news and satellite – is $0.1 million. The total is $13.77 million (*see page CA8 of the Proof Committee Hansard of 5 November 2003).

These amounts are the amounts spent on those elements of the Campaign development I identified in my previous response. Additional expenses incurred for the campaign include $100,000 allocated for the PBS Call centre, $46,900 in pitch fees, $36,900 to produce the brochure stand and $15,000 in incidentals bringing the total cost for the campaign in terms of development work to $13.97 million.

Rob Wooding
First Assistant Secretary
Information and Communications Division
November 2003

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-04, 5 November 2003

Question: E03-154

OUTCOME 2: ACCESS TO MEDICARE

Topic: NON-ONGOING EMPLOYEES

Written Question on Notice

Senator Carr asked:

(a) How many employees are employed as a non-ongoing employee in each year of the previous 6 years?

(b) What percentage of total agency employees are non-ongoing employees for each of these years?

(c) How many of these have been employed for more than 1 year as a non-ongoing employee?

(d) How many of these have been employed for more than 2 years as a non-ongoing employee?

(e) How many of these have been employed for more than 3 years as a non-ongoing employee?

(f) How many employees were employed on fixed-term contracts, in each year of the previous 6 years?

(g) What percentage of the total number of employees is this for each of these years?

(h) What was the percentage of total employees for contract employees, for each year of the previous 6 years?

(i) How many employees were employed on fixed term contracts at each classification level, for each year of the past six years?

(j) How many employees were employed on a fixed term contract, for each year of the past six years, have been employed more than once on a fixed term contract? Please provide details of position classification in each instance.

Answer:

(a)
1998 -	176
1999 -	136
2000 -	162
2001 -	189
2002 -	282
2003 -	269

(b)
1998 -	4.10%
1999 -	3.07%
2000 -	3.64%
2001 -	4.24%
2002 -	6.30%
2003 -	5.68%

(c)
1998 -	11
1999 -	21
2000 -	47
2001 -	57
2002 -	100
2003 -	67

(d)
1998 -	1
1999 -	4
2000 -	10
2001 -	17
2002 -	43
2003 -	33

(e)
1998 -	1
1999 -	0
2000 -	1
2001 -	3
2002 -	20
2003 -	20

(f) The definition of "employees engaged on a fixed term contract" is the same as that for non-ongoing employees; that is, non-ongoing employees are, by definition, employed for a fixed term. These questions are answered at (a) to (e) above. For questions (f) to (i), it is assumed that the questions refer to consultants/contractors.

Information on actual consultant/contractor numbers engaged by HIC were not obtainable until 2003 and therefore data for years prior to 2003 is not available. Annually, HIC also reports on consultant/contractor expenditure for individual companies exceeding $10,000 for the financial year, however, this does not incorporate the actual numbers of consultants/contractors engaged.

2003 - 238

(g) 2003 - 5.02%

(h) This question is the same as (g).

(i) Contractor/consultants are paid an hourly or daily rate and do not have a classification.

(j) No data is obtainable by HIC to answer this question.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-087

OUTCOME 2: Access to Medicare

Topic: IMPACT OF A FAIRER MEDICARE ON INDIGENOUS COMMUNITIES

Written Question on Notice

Senator Crossin asked:

There has been very little discussion or analysis of the impact of the Government's Fairer Medicare package on Indigenous people, especially the more remote communities.

(a) As the Minister works to improve the Government's Medicare package, what specific initiatives are you working on to help Indigenous people?

(b) What is being done to ensure that Indigenous people have access to a bulk billing doctor?

(c) What is being done to get more doctors into AMS clinics? For example, what assistance is being provided to help with medical indemnity costs?

Answer:

(a) **MedicarePlus** invests $2.4 billion to 2006/07 to protect and strengthen Medicare. A number of measures will benefit the Aboriginal and Torres Strait Islander population:

- A $5 MBS item for bulk billed services to concession card holders and children under 16 will make it easier for doctors to bulk bill these patients. About 75% of Indigenous Australians are eligible for a Commonwealth Concession Card.

- The MedicarePlus safety net reimburses 80% of out of pocket costs for medical services provided outside hospital once an annual threshold is reached. For concession card holders and families who receive Family Tax Benefit (A), the safety net will apply once annual costs reach $500 per individual or family. For all other Australians, an annual threshold of $1,000 per individual or family applies.

- The availability of a doctor is key to accessing affordable medical services. MedicarePlus invests over $1 billion in increasing and supporting the medical workforce, with a focus on areas with the greatest need for a doctor or nurse. Areas of need often align with rural and remote localities and the outskirts of major cities. These are areas where the majority of the Indigenous population reside. Workforce measures of particular note include:

- Grants to support employment of practice nurses and allied health professionals (including Aboriginal health workers) in general practice. 457 full time positions will be supported focussed on urban areas of workforce shortage; and
- Measures that will see more overseas trained doctors practising in areas of need. All Aboriginal Community Controlled Health Organisations are considered to be areas of workforce shortage.

(b) **MedicarePlus** provides a new $5 MBS item for each bulk billed service that a GP provides to people covered by a Commonwealth Concession Card and children under 16. As noted at (a) above, measures that increase the supply of the medical workforce are also an important factor in the provision of accessible, affordable health services.

(c) As described at (a) above, certain workforce measures in **MedicarePlus** will be of particular benefit to Aboriginal Community Controlled Health Organisations. In addition, GPs working in Aboriginal Community Controlled Health Organisations will receive the new $5 MBS item in respect of each bulk-billed service they provide to a patient covered by a Commonwealth Concession Card or to a child under 16.

Medical indemnity is subject to a separate review process, being conducted in collaboration with the medical profession.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-137

OUTCOME 2: Access to Medicare

Topic: IT EXPENDITURE FOR GPS

Written Question on Notice

Senator McLucas asked:

In a media release dated 20 May 2003, the former Minister for Health, Senator The Hon Kay Patterson, stated that "the Government has already spent $400 million on information technology initiatives and programs in general practice."

Please provide information about how this $400 million was allocated.

Answer:

The $400 million expenditure mentioned was paid through the Practice Incentives Program (PIP) Information Management/Information Technology (IM/IT) incentives and initiatives as shown in the table below.

Payment description	Total expenditure
IM/IT tier 1	$164,095,288
IM/IT tier 2	$103,818,432
IM/IT tier 3	$98,609,105
Total of IM/IT incentive payments	$366,522,824
Transition payment	$33,946,872
IM/IT + transition payments	$400,469,696

The IM/IT element was a core component of the initial PIP incentive items introduced in August 1999. The element consists of the three tiers as follows:

IM/IT tier 1 – Provision of data to the Commonwealth
IM/IT tier 2 – Use of bona fide electronic prescribing software to generate the majority of scripts
IM/IT tier 3 – Use of a computer connected to a modem to send and/or receive clinical data

In order to ease the transition from the Better Practice Program and facilitate the introduction of the PIP, the Commonwealth made a one-off 'transition payment' available to practices wishing to participate in the new program.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-029

OUTCOME 2: Access to Medicare

Topic: MEDICAL INDEMNITY - COMPOSITION OF REVIEW

Written Question on Notice

Senator Nettle asked:

(a) Can the Department explain the process by which the review committee's composition was determined?

(b) How were the members of the committee selected? By whom?

(c) Why is there no representative of consumers on the committee?

(d) Did the Department provide any advice to the Minister about the review and the review committee? When did it provide that advice?

Answer:

(a)&(b) The Minister for Health and Ageing appointed the members of the Medical Indemnity Policy Review Panel.

(c) The Panel is not intended to be a representative group.

(d) Yes. The Department provided advice to the Minister on a number of occasions before the Panel was announced.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-030

OUTCOME 2: Access to Medicare

Topic: MEDICAL INDEMNITY - TIMEFRAME AND PUBLIC INPUT FOR REVIEW COMMITTEE

Written Question on Notice

Senator Nettle asked:

(a) Who set the reporting date for the review committee?

(b) Given the complexity of the issue and the long-term social and budgetary implications of any changes to existing arrangements, why was the committee given such a short timeframe in which to undertake its work?

(c) Why is this process closed off from the public?

(d) Did the Department provide any advice to the Minister about the timeframe of the review process and whether it should be open to the public.

Answer:

(a)&(b) The Minister for Health and Ageing set the reporting date for the Medical Indemnity Review Panel.

(c) The process is not closed off from the public. Submissions from members of the public have been made to the Panel.

(d) Yes. The Department provided advice to the Minister on a number of occasions before the Panel and terms of reference were announced.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-031

OUTCOME 2: Access to Medicare

Topic: MEDICAL NEGLIGENCE MEETING

Written Question on Notice

Senator Nettle asked:

(a) Are you aware of an article by Richard Ackland, published in the Sydney Morning Herald on 31 October 2003?

(b) The author describes a meeting between the Minister Tony Abbott and five NSW plaintiff lawyers on 21 October about the medical negligence issue. What can you tell the committee about that meeting?

Answer:

(a) Yes.

(b) The Department did not attend the meeting.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-042

OUTCOME 2: Access to Medicare

Topic: CONSUMER MEDICINE INFORMATION DOCUMENTS

Written Question on Notice

Senator Harradine asked:

(a) Has the Department done any work to find out whether there is any effective distribution of consumer medicine information (CMI) documents to people purchasing prescription medicine? If so, please provide a copy of the latest research.

(b) (i) What is the proportion of pharmacists in Australia who provide CMI documents to consumers?
(ii) What is the proportion of pharmacists in Australia who are paid to provide CMI documents to consumers?

(c) (i) How much is paid to pharmacists to provide CMI documents to consumers purchasing prescription medication?
(ii) What was paid to pharmacists across Australia for each of the past three financial years?

(d) (i) How many pharmacists received payments for printing and distributing CMI documents to consumers in each of the last three financial years?
(ii) What is this number as a proportion of the total number of pharmacists?

(e) Is the Department paying pharmacists for providing CMI documents when they do not always perform this task? If so, what compliance work is the Department undertaking to ensure that payments are only made to pharmacists who are providing this service to consumers?

Answer:

(a) Pharmacists have always been required to provide advice to consumers about the use of their medicines. Provision of this information is part of their professional obligations. The State and Territory governments regulate the pharmacy profession.

The Australian Government's Medicines Information to Consumers (MIC) Program which has been established under the third Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia, recognises that pharmacists face additional costs in providing written CMI to consumers.

An evaluation of the MIC Program has been commissioned and is currently underway. As well as assessing the overall impact of the Program, the evaluation will assess the extent to which community pharmacies are providing written CMI to consumers purchasing prescription medicines.

The evaluation of the MIC Program is scheduled to be completed in the second half of 2004.

(b) (i) Of the 4,921 pharmacies approved to supply pharmaceutical benefits in 2002-03, 73% submitted written verification that they provided written CMI to consumers during September and October 2003.

(ii) During September and October 2003, 3,587 community pharmacies registered under the MIC Program verified that they were providing written CMI, and therefore received the ongoing MIC Participation Allowance.

(c) (i) The MIC Program provides financial incentives to offset some of the costs associated with the provision of written CMI. These incentives have been designed to assist pharmacists to meet their professional obligation to advise and counsel consumers about the use of their medicines.

In the initial phase of the MIC Program, a $3,000 one-off MIC Readiness Payment provided funds to 4,873 pharmacies to assist with the set-up costs associated with the provision of written CMI during counselling sessions with consumers. The payment, which was available during August 2001, was designed to assist with start-up costs for printers, software and renovations to the pharmacy to create a consumer counselling area.

In the second phase of the MIC Program, pharmacies were encouraged to register for the Program through the provision of a one-off $1,000 MIC Registration Incentive payment. Pharmacies registering in the Program by 31 December 2002 were eligible to receive the payment.

The MIC Participation Allowance is an ongoing payment of 10c per PBS or Repatriation Pharmaceutical Benefits Scheme (RPBS) prescription dispensed by pharmacies participating in the MIC Program. The Allowance is payable every two months on submission of a written declaration from the pharmacy verifying that it is providing written CMI to consumers purchasing prescription medicines.

(ii) The amount paid to pharmacies under the MIC Program for each of the last three financial years is outlined below:

Total expenditure

MIC payments (date of effect)	**2000-01 ($ million)**	**2001-02 ($ million)**	**2002-03 ($ million)**
Readiness Payment (Aug 2001)	nil	14.619	nil
Registration Incentive (Dec 2002)	nil	nil	4.301
Participation Allowance (from Jan 2003)	nil	nil	4.178

(d) (i) The one-off MIC Readiness Payment was made available to pharmacies during August 2001 to assist with start-up costs incurred by pharmacies preparing to provide written CMI to consumers. The payment was available during the 2001-02 financial year. 4,873 pharmacies received the payment during the 2001-02.

The one-off MIC Registration Incentive Allowance was made available to pharmacies who registered in the MIC Program by 31 December 2002. The payment was available during the 2002-03 financial year. 4,301 pharmacies received the payment during 2002-03.

The MIC Participation Allowance which provides ongoing financial assistance to help pharmacies to provide written CMI, was introduced on 1 January 2003. The allowance is payable every two months on submission of a written declaration that the pharmacy is providing written CMI to consumers purchasing prescription medicines.

The number of approved pharmacies which have received the Allowance since its introduction are outlined below.

Number of pharmacies

Jan - Feb 2003	Mar - April 2003	May - June 2003	July – Aug 2003	Sept – Oct 2003
439	2,531	3,332	3,764	3,587

(ii) Of the 4,972 pharmacies approved to supply pharmaceutical benefits during 2000-01, 98% received the MIC Readiness Payment.

Of the 4,924 pharmacies approved to supply pharmaceutical benefits during 2001-02, 87% received the MIC Registration Incentive Allowance.

The number of approved pharmacies, which have received the MIC Participation Allowance as a proportion of the total number of pharmacies approved to supply pharmaceutical benefits is outlined below:

Proportion of approved pharmacies

Jan - Feb 2003	Mar - April 2003	May - June 2003	July – Aug 2003	Sept – Oct 2003
9%	51%	68%	76%	73%

(e) Pharmacists registered to participate in the MIC Program are required to verify that they are providing consumers with written CMI in line with the professional practice standards developed by the Pharmaceutical Society of Australia. Submission of written verification is required every two months. Monitoring compliance with these arrangements is the responsibility of the Health Insurance Commission, as part of their ongoing audit program.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-158

OUTCOME 2: Access to Medicare

Topic: POSITRON EMISSION TOMOGRAPHY (PET)

Hansard Page: CA 31

Senator Denman asked:

Other than those who received assistance through the Patient Travel Assistance Scheme, are statistics available on the number of Tasmanians who travelled to Victoria and to other states and territories for a PET scan in 2002-03, up until now, for the separate states?

Answer:

In 2002-03, 210 Tasmanian patients received assistance through the Patient Travel Assistance Scheme to travel interstate to receive PET scans. The number of Medicare-eligible PET scans performed on Tasmanian patients in this period was 194. All of these 194 scans were performed in Victoria with the exception of one performed in New South Wales.

In the July-September 2003 quarter, 64 Tasmanian patients received assistance through the Patient Travel Assistance Scheme to travel interstate to receive PET scans. The number of Medicare-eligible PET scans performed on Tasmanian patients in this period was 61. All of these 61 scans were performed in Victoria with the exception of one performed in New South Wales.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-043

OUTCOME 2: Access to Medicare

Topic: POSITRON EMISSION TOMOGRAPHY (PET) SCANNER FOR TASMANIA.

Written Question on Notice

Senator Harradine asked:

(a) Could the Department provide reasons for the decision of the Government to not make available a Positron Emission Tomographer (PET) Scanner for Tasmania?

(b) Does the Department acknowledge the difficulties for Tasmanian patients who must be sent to Melbourne at significant inconvenience and Government expense for scanning as well as the difficulties for those who are too sick or face other difficulties with travel?

Answer:

(a) The National Review of Positron Emission Tomography, completed in 2000, recommended a moderate expansion of PET services to enable the evaluation of the technology. The Review's report is available on the Department's website at www.health.gov.au/haf/pet/petfinal.htm.

The Review recommended a distribution of two Medicare-funded facilities each in New South Wales and Victoria, and one funded facility each in Queensland, Western Australia and South Australia. The Review noted: 'This distribution model is primarily dependent on State populations, but also recognises the realities of the geographically dispersed population of Australia'. The Review did not consider that the population of Tasmania (or the Northern Territory or the Australian Capital Territory) warranted a PET scanner.

(b) The current distribution of Medicare-funded PET scanners recognises PET's status as a promising technology requiring further evidence-based evaluation before wider diffusion and increased funding is contemplated.

It is unfortunate but inevitable that access to expensive medical technology requiring extensive infrastructure and professional support will entail varying amounts of travel for patients. This is currently the case for PET services–including within States which have a PET scanner.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-044

OUTCOME 2: Access to Medicare

Topic: POSITRON EMISSION TOMOGRAPHY (PET) SCANNING

Written Question on Notice

Senator Harradine asked:

(a) Does the Department acknowledge that PET scanning is one of the most important advances in the management of cancer patients for some time in that it is a simple straight forward test which clearly shows areas of hidden cancer?

(b) Does the Department agree that results of PET scanning can have an important influence on treatment recommendations?

Answer:

(a) The Department has acted on the findings of the Medical Services Advisory Committee (MSAC) that PET is potentially an effective technology, and that further data collection is necessary to establish whether or not it affects patient outcomes.

(b) The aim of the current PET evaluation program is to develop an evidence base sufficient to enable MSAC to reach conclusions about PET's clinical and cost effectiveness. This will include careful consideration of whether PET has a significant impact on patient management decisions.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-045

OUTCOME 2: Access to Medicare

Topic: Scientific Supporting Committee.

Written Question on Notice

Senator Harradine asked:

(a) Did the Scientific Supporting Committee in its report find that PET scanning was clinically effective and possibly cost effective?

(b) Why were the expert opinions ignored in the final decision?

(c) Is it correct that a specialist from the Peter MacCallum Clinic wrote to the Chair of the Scientific Supporting Committee and the chair of the Medical Services Advisory Committee (MSAC) requesting that his name be removed from any connection with MSAC's downgrading of the Scientific Supporting Committee's report?

Answer:

(a) No. Supporting Committees of the Medical Services Advisory Committee (MSAC) do not make findings. Neither do Supporting Committees make reports, this being the responsibility of MSAC. Some members of the Supporting Committee did provide separate written advice to MSAC and this advice made stronger claims about the effectiveness and cost-effectiveness of PET than those of MSAC's findings.

(b) Expert opinions were not ignored in the final decision. However, MSAC's recommendations in relation to PET were primarily based on analysis of the evidence from the international scientific literature, not individual clinical opinion.

(c) A specialist from the Peter MacCallum Cancer Institute (also a member of the MSAC PET Supporting Committee) wrote to the Secretary for the Department of Health and Ageing on 5 December 2003, referring to his letter dated 2 April 2003, which he noted had not been sent at that time due to an administrative error within his office. In the April letter, he requested that, in the absence of specific changes to the 2000 report of the Review of positron emission tomography, and the associated MSAC report, his name be removed from those documents.

This specialist was one of seven clinicians on the PET supporting committee, which also included representatives of MSAC and the Department. As is typical of an MSAC review process, the supporting committee's members expressed a range of views in the course of the committee's deliberations. However, no committee member other than the specialist in question made a formal statement of dissent in relation to the PET review's findings.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-046

OUTCOME 2: Access to Medicare

Topic: PBS – THE EUREKA PROJECT

Written Question on Notice

Senator Harradine asked:

I refer to a formal complaint by the Melbourne Forum and Consulting Group, The Eureka Project, made to the Medical Practitioners Board of Victoria over its failure to enforce conflict of interest guidelines between high profile medical researchers and drug companies which support their activities. The complaint named prominent HRT advocate Dr Susan Davis, Director of Research at Melbourne's Jean Hailes Foundation, for failing to declare potential conflicts of interest which arise because of funding which the foundation received from the manufacturers of HRT medicines. Does the Department agree that with HRT revenue being about $1.1 billion a year in Australia with $700 million of this coming from the PBS, the relationship between practitioners, researchers and drug companies needs to be declared?

Answer:

The Department agrees that material relationships between health care professionals, medical researchers and pharmaceutical companies should be declared if there are potential conflicts of interest.

The National Health and Medical Research Council (NHMRC), the independent statutory body within the Health and Ageing Portfolio, administers Australian Government funds specifically appropriated for health and medical research and training. The NHMRC has formulated comprehensive guidelines concerning disclosure of potential conflicts of interest.

Medical research institutions receiving Australian Government funding must comply with the *Joint NHMRC/Australian Vice Chancellors Committee (AVCC) Statement and Guidelines on Research Practice*. These Guidelines provide for high standards of ethical conduct, including requiring funded institutions to have clearly formulated policies for potential conflict of interest.

The drugs most commonly prescribed for Hormone Replacement Therapy (HRT) in Australia are oestrogen and progestogen. These drugs are either prescribed individually or in combination products (ie, oestrogen and progestogen in one formulation).

The majority of oestrogen and progestogen products available in Australia are listed on the Pharmaceutical Benefits Scheme (PBS). There is a relatively small number of other HRT drugs available in Australia that are not listed on the PBS.

The total Government cost of PBS HRT listed drugs for the 2002-03 was $35,801,705. The total number of scripts for this period was 2,913,657.

Cost data for drugs not listed on the PBS are not available. However, the total number of scripts for 2002-03 for HRT drugs not listed on the PBS was 12,687.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-047

OUTCOME 2: Access to Medicare

Topic: PBS – MEDICAL RESEARCHERS AND DRUG COMPANIES

Written Question on Notice

Senator Harradine asked:

Does the Department have any role or responsibility in enforcing conflict of interest guidelines between medical researchers and drug companies?

Answer:

Medical research institutions receiving Australian Government funding must comply with the *Joint NHMRC/Australian Vice Chancellors Committee (AVCC) Statement and Guidelines on Research Practice*. These Guidelines provide for high standards of ethical conduct, including requiring funded institutions to have clearly formulated policies for potential conflict of interest.

In addition, under clause 22 of the Deed of Agreement between the Commonwealth and National Health and Medical Research Council (NHMRC) Administering Institutions in receipt of funding to conduct medical research, the Institution warrants that, at the date of signing the Deed, no conflict of interest exists or is likely to arise in the performance of its obligations under the Deed. Specifically under clause 22.4, if the Institution fails to notify the NHMRC, or is unable or unwilling to resolve or deal with the conflict as required, the Commonwealth may terminate the Deed in accordance with clause 15 (Termination and Suspension).

The pharmaceutical industry's Code of Conduct provides that relationships between the industry and healthcare professionals, including sponsorship activities, should be able to withstand both public and professional scrutiny and enhance the quality use of medicines. Sanctions can be imposed if provisions of the Code of Conduct have been breached.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-116

OUTCOME 2: Access to Medicare

Topic: MEDICAL AND PHARMACEUTICAL SERVICES

Written Question on Notice

Senator McLucas asked:

On what date are the thresholds and co-payments indexed?

Answer:

The Consumer Price Index (CPI) is released by the Australian Bureau of Statistics (ABS) in late October each year. Pharmaceutical Benefits Scheme (PBS) co-payments and safety safety net thresholds are adjusted annually in light of changes to the CPI. These changes apply from 1 January each year.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-117

OUTCOME 2: Access to Medicare

Topic: PIP - PAYMENTS FOR AFTER HOURS CARE

Written Question on Notice

Senator McLucas asked:

(a) Has the Department found any evidence of practices claiming PIP payments for the provision of after hours care who are not actually doing so in accordance with the requirements of the program?

(b) If so, how many?

(c) What action will be taken against them?

(d) Is the Department able to put a dollar figure on the cost of non-compliance?

Answer:

(a) Yes.

(b) The HIC has identified 181 practices through regular audit processes over the period 1 July 2000 to 30 June 2003.

(c) The HIC has taken a range of actions in relation to the 181 practices. These have included advising practices of the non-compliance, stopping payments, undertaking recoveries and where appropriate providing information to practices to assist them in understanding the requirements.

(d) For those practices audited the cost of non-compliance in relation to after hours PIP payments from the period 1 July 2000 to 30 June 2003 totals $1,129,040.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-118

OUTCOME 2: Access to Medicare

Topic: PIP PROGRAMS - NON-COMPLIANCE AND POSSIBLE FRAUD

Written Question on Notice

Senator McLucas asked:

(a) For practice audits conducted each year since 2000-2001 please provide the following data:

(i) practices receiving payments for using electronic data but were not meeting the requirements for that payment

(ii) practices receiving payments for the provision of after-hours care but not meeting the requirements for that payment

(iii) practices registered with PIP as two distinct practices but were found during the audit process to only be entitles to register as one practice

(b) How many instances of recovery action have there been?

(c) Why was recovery action only taken in some instances?

(d) Can the Department indicate how much money has inappropriately obtained – either deliberately or inadvertently – across all elements of the PIP?

(e) Is the Department/HIC taking action against those found to be fraudulently obtained PIP payments?

(f) It the Department/HIC has found evidence of flaws in systems contributing to fraudulent PIP claiming, will these systems be re-designed to minimise the risk?

Answer:

(a) Of the 765 practices audited between 1 July 2000 and 30 June 2003 HIC found:

(i) 18 practices received payments for using electronic data but did not meet the requirements for these payments.

(ii) 181 practices received payments for providing after-hours care but did not meet the requirements for these payments.

(iii) 3 instances where two practices registered with PIP were only entitled to register as one practice.

(b) There have been 127 instances where recovery action has been undertaken over the three-year period 1 July 2000 to 30 June 2003.

(c) In the majority of instances HIC undertake recoveries. There have been occasions when a recovery was not undertaken as a practice was found to be compliant after further review or appeal. In addition, where the non-compliance has been widespread indicating a systemic misunderstanding, recovery action has been waived in preference for providing information to assist practices to understand the requirements.

(d) The HIC audit program has identified that the following amounts have been inappropriately paid to practices across all elements of the PIP:

2000-01	$94,984.40
2000-02	$1,186,742.06
2002-03	$1,036,244.40

(e) The HIC have not identified any cases of fraud to obtain PIP payments.

(f) The system has checks and balances to minimise risks. However, where difficulties with interpretation of incentive requirements are identified the HIC provides practices with information to assist them in understanding the requirements. In addition, requirements are changed to ensure that they are clear and consistent with industry practice.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-119

OUTCOME 2: Access to Medicare

Topic: IMMUNISATION INCENTIVES

Written Question on Notice

Senator McLucas asked:

It has been reported that more than 1500 practices missed out on incentive payments for immunisation in the August quarter, after the government increased the minimum threshold to qualify from 85% immunisation coverage to 90%.

(a) Why did so many practices miss out on payments in this quarter?

(b) Of these practices which missed the incentive, how many were paid/will be paid the incentive in the November quarter?

Answer:

(a) In the August 2003 Outcomes quarter there were 1,326 practices that did not receive a General Practice Immunisation Incentives (GPII) Outcomes payment. This number reduced to 580 following the August re-calculation in November 2003.

Practices missed a payment because they did not meet the requirements of the program. These requirements have recently changed, and practices need to submit their immunisation data earlier than they did previously. If it was only slow submission of immunisation data that dropped practice coverage below 90% then the Outcomes payment was not missed, just delayed until the re-calculation in November 2003.

(b) The routine re-calculation in November 2003 of the August 2003 Outcomes calculation resulted in 746 of the 1,326 practices receiving a payment.

More recent data from the November 2003 Outcomes calculation show that 961 practices missed out on a payment because their coverage was between 85% and 90%. This number reduced to 537 practices in the re-calculation in February 2004 when 424 practices received a payment.

The number of practices missing out on a payment is decreasing.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-120

OUTCOME 2: Access to Medicare

Topic: PIP PROGRAMS - CERVICAL SCREENING

Written Question on Notice

Senator McLucas asked:

Only 16% of eligible general practices received the first cervical screening outcomes payment in March 2003. 3470 eligible practices missed out.

(a) Why were the figures so low?

(b) What has been done to address this?

(c) How will eligible practices which missed the March 2003 payments be able to meet the August 2004 screening target of 70% of female patients?

Answer:

(a) The cervical screening outcomes payment was introduced in August 2003 and will be paid with each PIP quarterly payment. The percentage of practices receiving the first outcomes payment is low. This was expected as the target has been set at a level designed to encourage practices to increase their rate of cervical screening rather than simply rewarding the status-quo. It is expected that more practices will achieve the target and receive payments as they begin to focus on increasing their cervical screening rates.

In addition, limited information was available on cervical screening rates in Victoria resulting in only 46 practices or around 4% of eligible practices receiving payments in Victoria.

(b) Since the August 2003 payment quarter, information has been provided to practices in the November 2003 PIP newsletter drawing attention to the outcomes payment and encouraging practices to focus on increasing their cervical screening rates. Nationally, over 19% of eligible practices received an outcomes payment in the November 2003 PIP quarterly payment.

In addition, the HIC has resolved the issues around access to patient level data for Victoria resulting in a further 199 practices in Victoria receiving the outcomes payment in the November 2003 payment quarter. The proportion of eligible practices in Victoria receiving the outcomes payment has risen to around 24%.

(c) The target for the cervical screening outcomes payment was set at 35% of a practice's female patients aged 20 to 69 years being screened over a one-year period. In August 2004 the target will be set at an equivalent rate of 70% over a two-year period.

Practices that did not reach the 35% target for payment in August 2003 could achieve the target for payment in August 2004 by increasing their cervical screening rates in the next 12 months of this two-year period.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-121

OUTCOME 2: Access to Medicare

Topic: ENHANCED PRIMARY CARE

Written Question on Notice

Senator McLucas asked:

A study by the University of Sydney and the Australian Institute of Health and Welfare has found a low uptake of EPC items for older patients. While patients over 65 comprise 25% of GP consultations and 93.2% had chronic and complex conditions, only 0.6% of older patients encounters were recorded as EPC items.

(a) Why is the rate of EPC uptake so low?

(b) Are the high administration and compliance costs a factor?

Of 310 EPC items examined, only 7 were for case conferences – and 176 were for health assessments.

(c) Does this indicate that GPs are only doing the easy items?

(d) What is being done to encourage GPs to do more than health assessments?

A recent Government evaluation of the EPC package revealed that only 6% of GPs make 50% of all EPC claims.

(e) Why are so few GPs involved? What is the Department doing to expand this program?

(f) What is the Department doing to make the EPC program work better?

(g) How much money has been spent on EPC incentives since the programs inception? Please provide this information by year.

Answer:

(a) In 2002-03 the estimated rate of uptake for EPC annual voluntary health assessments was 17% of the total eligible population. The eligible population is people in the general population aged 75 years and over, and Aboriginal and Torres Strait Islander people aged 55 years and over, excluding hospital in-patients and people living in residential aged care facilities. This is approximately 2% higher than the estimated rate of uptake in 2001-02. Over 560,000 health assessment services have been provided between November 1999, when they were introduced, and September 2003.

EPC care planning and case conferencing services are available to people with chronic conditions and complex needs requiring care from a multidisciplinary team. The study by the University of Sydney and the Australian Institute of Health and Welfare (AIHW) reported that at least one chronic condition was present in 93.2% of general practice patients aged 65 or more. This does not mean that this percentage of older patients also had complex needs and required EPC multidisciplinary care. The number of care planning services provided between November 1999 and September 2003 was approximately 619,000 services. Approximately 32,000 case conferencing services were provided over the same period.

As with other new programs, there is scope for increased and more uniform uptake of the EPC items. However, the evaluation of the EPC items and the associated GP Education, Support and Community Linkages (GPESCL) program found that the EPC items and the GPESCL program had made a significant contribution to improving the management of patients with chronic illness and complex needs in general practice. The evaluation also found that most GPs had used the EPC items at least once, and that while health assessment items were used most in the first two years of implementation, use of care plans was high.

(b) The independent evaluation of the EPC items reported that some GPs regarded the care planning and case conferencing items as complex. In May 2003 the Prime Minister and the former Minister for Health and Ageing, Senator the Hon Kay Patterson, established the Red Tape Taskforce to review Commonwealth arrangements that impact on GP administrative costs. This includes a thorough review of the EPC items.

(c) The figures quoted from the AIHW study do not indicate that GPs are only doing the easy items. They reflect the fact that the study was focused on older patients attending general practice. EPC health assessments are targeted at older Australians and were more prevalent in the survey group. EPC case conferences, which are available to people of any age with chronic conditions and complex needs, tend to be used in specific clinical settings.

(d) Under the GPESCL program, Divisions of General Practice were funded to facilitate uptake of the items. The Royal Australian College of General Practitioners was funded to prepare an EPC Standards and Guidelines publication explaining the use of the items for GPs. Information brochures on the EPC services have been widely distributed. An EPC information kit for workers involved in Indigenous health was widely distributed from April 2003.

(e) During 2002-03, 8% of GPs who provided EPC services were responsible for 50% of EPC claims, while 26% of GPs who provided EPC services were responsible for 80% of EPC claims. While most GPs have claimed at least one EPC service, fewer GPs have

structured their practices to make ongoing use of the items. The reasons for this are likely to be varied, including factors such as the demands of providing standard consultation items, reluctance to take on new services, perceived complexities of requirements and challenges of working in multidisciplinary teams.

The Red Tape Taskforce is considering feedback on the EPC items by GPs and other stakeholders in its current review of the EPC items. Future directions for the EPC items, including any options to increase their use, will be considered when the current review is completed.

(f) The independent evaluation of the EPC items and GPESCL found that the EPC items were a success and should be continued but noted that patience and persistence would be required to embed the EPC items into everyday practice. The evaluation's findings are being considered in the Red Tape Taskforce's review of the EPC items. Future directions for the EPC items will be determined once the Taskforce has reported.

(g) The only incentive that has been paid for use of the EPC items was an incentive payable from February 2002 to November 2002 under the Practice Incentives Program (PIP). During this period PIP included a Care Planning Incentive payment linked to practice uptake of EPC care planning and case conferencing services. This incentive was announced in February 2001 with the first payments commencing in February 2002. $5,982,559 was spent on care planning incentive payments during the period February 2002 to November 2002, when the incentive ceased.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-122

OUTCOME 2: Access to Medicare

Topic: MEDICAL AND PHARMACEUTICAL SERVICES

Written Question on Notice

Senator McLucas asked:

(a) What is the cost to the PBS of drugs used by private hospital patients?
(b) What are the procedures for ensuring that drugs prescribed for patients in private hospitals are used appropriately?

Answer:

(a) It is not possible to accurately determine the Government cost of Pharmaceutical Benefits Scheme (PBS) drugs used by private hospital patients. It is possible to identify the pharmacy that supplied the script, but many private hospitals do not have a pharmacy on the premises, and obtain their drugs from a community pharmacy. In these cases the PBS can not distinguish between drugs supplied for private hospital patients or patients from the general community. However, the Government cost of PBS listed drugs prescribed in private hospital pharmacies for 2002-03 was $46,687,582.

(b) Current provisions governing the operations of the PBS are embodied in Part VII of the *National Health Act 1953* together with the *National Health (Pharmaceutical Benefits) Regulations 1960* made under the Act. Pharmaceutical benefits are prescribed by registered doctors and by dentists who are approved to work within the PBS. Prescribers must heed both Commonwealth and State/Territory laws when prescribing drugs listed on the PBS. In addition, hospitals also have drug safety and medication management protocols.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-124

OUTCOME 2: Access to Medicare

Topic: FORECASTS FOR NON-REFERRED ATTENDANCES

Written Question on Notice

Senator McLucas asked:

In response to a QoN from Senator Lees at the last SE (E03-186) it was stated that expenditure for non-referred attendances (GP visits) in 2002-03 was $130 million less than predicted due to fewer attendances, and that there will consequently be reduced expenditure forecasts for 2003-04 when the MBS model is updated.

(a) What is the expected MBS expenditure for 2003-04 for non-referred attendances?

(b) What will happen to these savings?

(c) How many fewer attendances are expected in 2003-04?

(d) Will declining rate of bulk billing continue to save the Government money in this area?

Answer:

(a) The expected expenditure for 2003-04 for non-referred attendances is $2,831.4 million.

(b) Lower than expected expenditure or a downward revision in estimated expenditure does not represent a saving. The Medicare Benefits Scheme (MBS) is a special appropriation, any expenditure forecasts are purely predictions by the Department of Health and Ageing of Commonwealth outlays for the MBS. The predictions do not represent a specific commitment of, or limit to, Commonwealth expenditure on the program.

(c) Current trends indicate that for 2003-04 there will be around the same level of non-referred attendances as for the 2002-03 financial year.

(d) The patient rebate for a medical service that is covered by the MBS is the same regardless of whether a consultation is bulk billed or not. A change in the proportion of services that is bulk billed will not affect Commonwealth outlays under Medicare.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-125

OUTCOME 2: Access to Medicare

Topic: RURAL AND REMOTE RETENTION PROGRAMS

Written Question on Notice

Senator McLucas asked:

The Health Minister has recently stated (Hansard 13 October) that this Government has been able to attract 2400 doctors to rural and remote areas.

(a) Could you please confirm these figures?

(b) Over what time frame?

(c) Is this individual doctors or FTEs?

(d) How many of these doctors are GPs? How many are specialists?

(e) Please provide the locations where these doctors went.

(f) Do we know how many of the GPs attracted to rural and remote areas are bulk billing their patients?

(g) How many GPs (total) are now practicing in rural and remote ares?
Do these numbers include doctors working for the AMS? (If yes) When were AMS doctors first counted in these numbers?

(h) In the same time frame as above, how many doctors have left rural and remote areas? Can these numbers be provided for GPs and specialists.

(i) In answer to QON E02-075 (November 2002) a table was provided that showed the expenditure of $111.2 million from 1996-97 to 2000-01. Could you please update this table and expenditure?

(j) Can you provide figures for GP numbers in RRMAs 3-7 that show the trend over time? (ie total numbers)

A report from the NSW Rural Doctors Network has projected, using extensive modelling, that NSW alone will be short 410 GPs by 2012. The report has predicted that Government policies will succeed in attracting more doctors to rural areas, but these doctors will work fewer hours.

(k) What is the Department doing to address this particular issue?

Answer:

(a) The Hansard dated 13 October 2003 documents that the Health Minister stated that so far some 2,400 doctors have received $54 million under the **Rural Retention Program**. Yes, these figures are correct.

(b) July 1999 until June 2003.

(c) These are individual doctors.

(d) Only doctors providing primary medical services are eligible for payments. Of the 2,400 doctors, 647 have the capacity to offer specialist services. These are specialists who have become eligible for the Rural Retention Program through the provision of general medical services.

(e) The doctors have been providing medical services mainly in rural and remote communities in Australia.

(f) Over the 2002 Calendar year, 97.3% of doctors in RRMA categories 3-7 bulk billed some or all of their services.

(g) 6,739 GPs provided services in rural and remote areas during 2002-03. This equates to 4,101 full-time workload equivalents (FWE). This includes AMS doctors that bill Medicare. AMS doctors have been approved to bill Medicare since 1997.

(h) It is difficult to obtain accurate and reliable figures on the number of doctors who have left rural and remote areas. Doctors can take leave for extensive periods, at which times they will not be counted as providing services and we cannot be certain that they will or will not return to active duty in a rural or remote location at some time in the future.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-139

OUTCOME 2: Access to Medicare

Topic: MEDICAL INDEMNITY

Written Question on Notice

Senator McLucas asked:

(a) When will the Minister plan to notify doctors of the new date for payment of the IBNR levy?

(b) Is the date for payment of the levy contingent on agreement on issues being reached with the review panel and agreement on the costs being reached with the UMP accountants?

(c) When the levy is finally collected, which Government agency will manage it?

(d) Will this agency collect for itself the interest that this money earns, or will it be accumulated by the IBNR fund?

(e) If the IBNR levy collected turns out, in the years ahead, to have been greater than needed, what provisions are in place to return this to the doctors who paid it?

Answer:

(a) Any announcement that may be made in relation to the IBNR scheme will occur after the current review process is completed.

(b) No. The payment date has already been moved to 1 June 2004 by regulation gazetted on 22 October 2003.

(c) The Health Insurance Commission (HIC) will continue in its role of administration of the IBNR levy as the *Medical Indemnity Act 2002* already provides.

(d) Monies collected from the IBNR levy by the HIC are immediately returned to the consolidated revenue fund, not a separate IBNR fund.

(e) Overpayments of annual payments will be refunded. I announced on 10 October 2003 that the current IBNR levy notices will be withdrawn and existing payments refunded.

In terms of payments over the life of the scheme, at this stage it is expected that contributions will be made over the ten years 2003-04 to 2012-13, while payments may be made for as much as fifteen years after 2012-13. The amount of contribution to be collected over the next ten years will be based on annual actuarial assessments. However, contributions may be reduced in the future. If, after the annual reassessment, the unfunded liability is reduced, doctors' annual contributions may decrease.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-140

OUTCOME 2: Access to Medicare

Topic: MEDICAL INDEMNITY

Written Question on Notice

Senator McLucas asked:

(a) What are the total funds committed by the Government to the medical indemnity cover?

(b) Please provide a breakout of how these funds are allocated.

(c) What funds have already been paid out?

(d) Specifically, have any funds been paid to the ACCC to monitor medical indemnity premiums?

(e) If not, why not?

Answer:

(a) Estimated expenditure for the medical indemnity package for 2003-04 is $67.379m. This covers those elements of the package for which the Government has published budget figures. Costings for more policy developments announced since the Budget will be published shortly in the Mid Year Economic Financial Outlook 2003-04.

(b) Funds allocated to medical indemnity for 2003-04:

Medical Indemnity Subsidy Scheme:	
Neurosurgeons, Obstetricians and GP Proceduralists	$37.682m
Rural Obstetricians	$3.864m
IBNR Levy collection (HIC Departmental costs)	$6.278m
High Cost Claims Scheme	$19.055m
Premium monitoring by ACCC	$0.500m

(c) $4.381m has been spent to date under the Medical Indemnity Subsidy Scheme. There has been no expenditure under other elements of the package.

(d) Yes. $1.5m has been allocated, over three years, to the ACCC to ensure that the premiums insurers charge doctors are actuarially and commercially justified.

$0.5m has already been paid for 2002-03 and a further $0.5m has been allocated for 2003-04 and 2004-05, respectively.

(e) Not applicable

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-141

OUTCOME 2: Access to Medicare

Topic: TRANSOESOPHAGEAL ECHOCARDIOGRAPHY (TOE).

Written Question on Notice

Senator McLucas asked:

MSAC has advised that MBS reimbursement for use of TOE in cardiac surgery should be limited to "intra-operative assessment of cardiac valve competence following valve replacement or repair" because "there is limited evidence of the safety, effectiveness and cost effectiveness of intraoperative trans-oesophageal echocardiography. A number of specialists, mostly anaesthesiologists, have protested this.

(a) What was the incentive for MSAC to look at this procedure?

(b) In considering this issue, which experts did MSAC consult?

(c) Did MSAC consult with the Australian Society of Anaesthetists?

(d) What is the evidence about the cost-effectiveness of the routine use of TOE in cardiac surgery?

(e) Is there any mechanism in place to collect Australian data on the safety and effectiveness of this clinical tool?

Answer:

(a) Intraoperative TOE was referred by the Department to MSAC due to concerns about rapid growth in utilisation of the service and changes in the pattern of specialties which were providing the service.

(b) As part of the MSAC process, Supporting Committees are established to provide expert advice on new and existing technologies. Members are appointed to the Supporting Committees in their capacity as individual experts and not as representatives of professional groups. The following experts were appointed to the Supporting Committee evaluating TOE:

Professor Bryant Stokes, neurological surgery – Chair and member of MSAC
Dr David Barton, Medical Adviser to MSAC
Dr Leeanne Grigg, nominee of the Cardiac Society of Australia and New Zealand

Associate Professor Peter Klineberg, nominee of the Royal Australian and New Zealand College of Anaesthetists
Professor Thomas Marwick, nominee of the Royal Australian College of Physicians
Mr Richard McCluskey, nominee of the Consumers Health Forum
Mr Hugh Wolfenden, nominee of the Royal Australasian College of Surgeons

(c) Consultation took place following the release of the MSAC report to address concerns raised by sections of the medical profession about the review.

The following representatives met with representatives of MSAC, the Department and technical evaluators.

Dr John O'Shea (Cardiac Society of Australia and New Zealand (CSANZ))
Dr Leeanne Grigg (CSANZ)
Associate Professor Peter Klineberg (Australian and New Zealand College of Anaesthetists (ANZCA))
Dr Roman Kluger (ANZCA)
Dr Andrew Mulcahy (Australian Society of Anaesthetists (ASA))

(d) There are a number of published studies providing economic evaluations of TOE, some of which suggest that the technology may lead to savings to the health system. These are referenced and analysed in the MSAC review of TOE which can be viewed at the Committee's website, www.msac.gov.au. MSAC was of the view that it is not clear that these studies would reflect Australian practice. MSAC also concluded that there is limited evidence that TOE improves patient outcomes. Economic findings are of limited value where clinical effectiveness of a technology cannot be demonstrated.

(e) No. However, the Department has had discussions with the Australian Society of Anaesthetists on this matter and the ASA is currently considering establishing a data collection system.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-149

OUTCOME 2: Access to Medicare

Topic: PBS COMMUNITY AWARENESS CAMPAIGN

Hansard Page: CA 13

Senator McLucas asked:

So you had a number of advertising agencies that came to pitch the message.
Can I have the names of those agencies.

Answer:

The names of the advertising agencies who pitched for the campaign (identified through the Ministerial Committee on Government Communications) were as follows:

- Whybin TBWA
- Clemenger BBDO
- Batey Kazoo
- DDB
- Young and Rubicam Mattingly.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-183

OUTCOME 2: Access to Medicare

Topic: PHARMACEUTICAL BENEFITS SCHEME (PBS) COMMUNITY AWARENESS CAMPAIGN

Hansard Page: CA 10

Senator McLucas asked:

Can we get a precis of the evaluation report, the broad outcomes?

Answer:

Preliminary results from an evaluation of the PBS campaign indicate it has performed well. The community's level of awareness of the PBS has increased as well as understanding of the campaign messages. These messages include the fact that the PBS subsidises a large number of medicines and the scheme brings real benefit to prescription medicine users. Uptake of Quality Use of Medicines messages such as "talk to your doctor" was also high.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-150

OUTCOME 2: Access to Medicare

Topic: PHARMACEUTICAL BENEFITS SCHEME (PBS) COMMUNITY AWARENESS CAMPAIGN

Hansard Page: CA 10

Senator McLucas asked:

Please ascertain whether there has been correspondence, particularly from organisations, about the intent of the program?

Answer:

The Department has received correspondence from four organisations about the Campaign:

1 The Pharmacy Guild of Australia
2 Medicines Partnership of Australia
3 Medicines Australia
4 National Asthma Council Australia

None of the organisations questioned the overall intent of the campaign to better inform consumers about the PBS and promote Quality Use of Medicines.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-157

OUTCOME 2: Access to Medicare

Topic: PHARMACEUTICAL BENEFITS SCHEME (PBS) COMMUNITY AWARENESS CAMPAIGN

Hansard Page: CA 25

Senator Allison asked:

What evidence is there that people are stockpiling, which is one of the behaviours which is problematic for the cost of the PBS? Who was this research conducted by?

Answer:

Evidence of consumers stockpiling PBS prescription medicines has been found in research commissioned by the Department in February 2002 and in November 2002, and by the Health Insurance Commission in May 2003.

The February 2002 research conducted by Wendy Bloom and Associates found that more than half the people surveyed believed that some people received PBS subsidised prescriptions they did not really need. A similar number thought that people should ask their doctor if they could do without medication by perhaps changing their lifestyle.

The November 2002 research conducted by Woolcott Research found that many people stocked up on prescription medicines for convenience but did not always use them. People also admitted that they often went to their doctor expecting to receive a prescription, which they then filled just in case it was required. This kind of behaviour, while inadvertent, does constitute waste.

The research undertaken on the Department's behalf was supported by specific research into stockpiling of medicines, which was commissioned by the Health Insurance Commission and conducted by Wendy Bloom and Associates in May 2003. This study found that 25 per cent of people believed that stockpiling was an acceptable form of behaviour and that they had little awareness of the consequences of this to the overall cost of the PBS.

The research found that there were three groups of people who access more medication than they currently need and do so with varying motivation. The groups are:

- those who ensure they have at least one additional packet of medicine on hand to use after their current packet runs out. Respondents did not consider this to be stockpiling, merely a sensible way to manage their medications;

- those that routinely have a number of different packets, or other pharmaceutical products such as inhalers, active at the one time in different locations. This was particularly common in families with children on medication where it was considered necessary to have medication available in a variety of locations; and

- those who admit getting extra medicines to take advantage of them being cheap, or free – if they have reached the safety net. These people consciously build up supply to take advantage of the safety net, acknowledging that they are stockpiling. They defend the practice by claiming that everyone does it, or it is commonplace.

A breakdown of the proportions of people in each of the three categories is not available.

The survey also did not consider the effect of the fact that the safety net relates to a calendar year and whether it has an influence on stockpiling behaviour.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-155

OUTCOME 2: Access to Medicare

Topic: BETTER PRESCRIBING

Hansard Page: CA 14

Senator Lees asked:

(a) Provide a full list of measures in the Department that deal with better prescribing (eg National Prescribing Service, Full cost on labels, etc)

(b) How is the Department evaluating the effectiveness of these measures?

(c) What are the results of any evaluations that have taken place to date?

(d) How often are each of the measures evaluated?

Answer:
(a) – (d) See attached table.

Better Prescribing Measure	Evaluation of Effectiveness	Results of Evaluations	Frequency of Evaluations
National Prescribing Service (NPS) The Department provides funding to the NPS to undertake a range of activities aimed at better prescribing. These include the: • Education and Quality Assurance Program where health professionals are given opportunities to participate in education activities and use quality assurance tools to reflect on their own practice and explore and apply evidence-based therapeutic guidelines; • Independent Information Program where independent, balanced, evidence-based information about medicines is provided to health professionals through *Australian Prescriber*, *NPS News*, *Pharmacy Letter*, *Radar* (providing information on new and revised listings to the PBS) and *the NPS Therapeutic Advice and Information Service;* • Pharmaceutical Decision Support Program which coordinates access to independent Quality Use of Medicines information for prescribers and pharmacists via their computers; and Curriculum and Training Program providing, in partnership with medical, pharmacy and nursing schools, education materials for undergraduate and postgraduate students	NPS conducts ongoing evaluation to measure the process, scope and reach of its activities as well as changes in awareness, skills and behaviours that support Quality Use of Medicines, changes in prescribing behaviour and health outcomes. As well as having specialist staff employed in this area, the NPS has established an evaluation working group. The working group provides evaluation support and feedback to individual NPS programs during their development, implementation and review. As part of the commitment to evidence-based practice in prescription behaviour, the fourth in a series of national surveys commissioned by the NPS was conducted in June 2003. This survey also collected information to assist in measuring the efficiency of National Awareness Campaigns.	In 2002-03, the NPS: - provided feedback of prescribing data to 18,000 GPs through prescribing practice reviews; - completed 8 029 case studies for GPs and pharmacists to help refine decision-making skills; - conducted 3 651 clinical audits and self-audits allowing GPs and pharmacists to assess their own practice against evidence-based guidelines; - conducted 7 133 educational visits and divisional case study group discussions (attended by 2 681 health professionals) coordinated through 110 Divisions of General Practice throughout Australia; - distributed *Australian Prescriber* and *NPS News* six times a year to 55,000 health professionals, including medical practitioners, pharmacists, dentists and students; - provided a web-based curriculum and training program which was used by nine of the eleven medical faculties in Australia; - distributed *Pharmacy Letter* to all pharmacists five times; and - received 6,190 calls to the *NPS Therapeutic Advice and Information Service* mostly from GPs and Community Pharmacists.	The NPS provides ongoing evaluation of its programs. It provides formal reports to the Department each year of the progress of its measures.

Better Prescribing Measure	Evaluation of Effectiveness	Results of Evaluations	Frequency of Evaluations
		In 2002-03 nearly 78% of GPs and 95% of pharmacists surveyed as part of the NPS's ongoing evaluation rated the NPS as being of great or moderate value to health professionals. 91 % of participating pharmacists surveyed reported that NPS services help improve over-the-counter prescribing. *Australian Prescriber* and *NPS News* were evaluated during 2002-03. Of those surveyed, 87% said *Australian Prescriber* provides guidance for appropriate prescribing. There was 74% agreement among GPS that *Australian Prescriber* had influenced prescribing/recommendations. Agreement that *NPS News* helps making therapeutic choices was 74% while 66% agreed the issues raised in *NPS News* influenced prescribing/recommendations	
Enhanced Divisional Quality Use of Medicines Program This program aims at improving prescribing of antibiotics, peptic ulcer drugs and cardiovascular drugs.	A tender process is currently taking place to engage a consultant to evaluate the pilot phase of this program.	An evaluation of the program will be conducted in 2003-04.	After the currently planned evaluations, it is anticipated that a further evaluation of this measure will take place in 2006.
Full Cost on Labels The PBS 'Full cost' on labels initiative informs consumers of the 'full cost' of PBS medicines where a Commonwealth subsidy is paid.	A tender is being developed to undertake an evaluation of this program.	An evaluation of the initiative will be conducted in 2004. All dispensing software providers have incorporated the capacity to print the 'full cost' on labels where a PBS subsidy is paid.	After the currently planned evaluations, it is anticipated that a further evaluation of this measure will take place in 2005.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-156

OUTCOME 2: Access to Medicare

Topic: PUBLIC HOSPITAL PHARMACEUTICAL REFORMS

Hansard Page: CA 15

Senator Lees asked:

(a) Do you have a figure on the impact? There would be an impact in that it has now come off the hospital budgets and gone over to the PBS budgets. What would that impact be - 100 million, 10 million?

(b) What was Victoria's experience compared with other states over a period of time?

(c) What was the impact of the states giving medication for only a day or so to patients on discharge, rather than the full courses that use to be given?

Answer:

(a) The pharmaceutical reforms have been negotiated on the basis that it is cost neutral to the Australian Government. The level of payment by the Australian Government for supply of PBS drugs through public hospital pharmacies is lower than through community pharmacies. The reimbursement rate for hospitals does not include any mark up or dispensing fees, which are paid to community pharmacies.

One of the major benefits for the Australian Government in the negotiation of the pharmaceutical reforms with the States /Territories has been the introduction of funding ceilings on PBS drug items. Risk sharing arrangements have been introduced whereby any costs in excess of the proposed funding ceilings are shared on a 50:50 basis between the Australian Government and the participating State.

Pharmaceutical benefits paid in respect of PBS medicines supplied by public hospital dispensaries to non-admitted patients, patients upon discharge and non-admitted and day only patients receiving cancer chemotherapy were $2,605,559 in 2001/2002 and $14,424,451 in 2002/2003.

(b) The following table sets out total PBS processing by State for the financial years 1999/2000, 2000/2001, 2001/2002 and 2002/2003.

State	Year ending June 2000	Year ending June 2001	Year ending June 2002	Year ending June 2003
NSW	$1,153,852,034 36.32%	$1,365,870,440 35.85%	$1,485,653,078 35.48%	$1,609,125,755 35.17%
VIC	$799,352,573 25.16%	$956,420,847 25.10%	$1,052,915,237 25.14%	$1,160,185,362 25.36%
QLD	$554,614,095 17.46%	$676,312,051 17.75%	$748,374,097 17.87%	$822,234,052 17.97%
SA	$267,003,329 8.41%	$320,533,966 8.41%	$355,662,450 8.49%	$387,713,533 8.47%
WA	$263,387,341 8.29%	$325,983,953 8.56%	$362,377,500 8.65%	$398,027,296 8.70%
TAS	$86,995,748 2.74%	$103,446,508 2.71%	$114,292,507 2.73%	$123,185,125 2.69%
NT	$11,263,997 0.35%	$13,221,364 0.35%	$14,731,374 0.35%	$15,832,581 0.35%
ACT	$40,028,192 1.32%	$48,437,942 1.27%	$53,664,345 1.28%	$58,899,558 1.29%

[The percentage figures are representative of total PBS processing by State for the 12 months ending 30 June 2000, 2001, 2002 & 2003.]

(c) The impact of the States providing patients with two to five days of medication on discharge is that patients would need to visit their community GP immediately after being discharged from hospital to obtain an additional PBS prescription for further medication. Apart from patient inconvenience, this can be an inappropriate use of a GP's time.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-04, 5 November 2003

Question: E03-163

OUTCOME 2: ACCESS TO MEDICARE

Topic: PATHOLOGY LABORATORY CHECKING

Hansard Page: CA 21

Senator McLucas asked:

Please comment on the media release 'Enhanced Pathology Laboratory Testing Standards to Protect Public Health and Safety', August 29 2002, in relation to spot checks on pathology labs, and whether or not what is being described is occurring.

Answer:

The media release of August 29 2002 accurately details current arrangements.

An independent evaluation (Corrs, Chambers Westgarth report commissioned by the Department of Health and Ageing in 2002) of pathology accreditation arrangements concluded that the National Association of Testing Authorities (NATA) assessment process is capable of reliably identifying laboratories that pose a significant threat to public health.

The independent evaluation also concluded that the NATA assessment process should continue to be the preferred mechanism by which laboratories are identified for the purposes of the Health Insurance Commission (HIC) initiating compliance measures.

HIC initiated compliance measures might include an inspection without notice – also referred to as a 'spot check'.

Since the conclusion of the independent evaluation in July 2002, HIC has not received information from the NATA accreditation assessment process nor any other source, requiring the power of inspection without notice to be exercised.

HIC remains in a position to authorise a person or persons to inspect premises without notice.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-04, 5 November 2003

Question: E03-162

OUTCOME 2: ACCESS TO MEDICARE

Topic: MEDICARE SAFETY NET

Hansard Page: CA 27

Senator McLucas asked:

(a) How many individuals reached the Medicare Safety Net threshold for the calendar years (i) 1996 (ii) 1997 (iii) 1998 (iv) 1999 (v) 2000 (vi) 2001 and (vii) 2001?

(b) How many families reached the Medicare Safety Net threshold for the calendar years (i) 1996 (ii) 1997 (iii) 1998 (iv) 1999 (v) 2000 (vi) 2001 and (vii) 2001?

(c) How many individuals and families register for the Medicare Safety Net after they have reached the Safety Net threshold?

(d) How many families register for the Medicare Safety Net, but do not reach the Safety Net threshold?

(e) How much money could a family, who registers late in a calendar year, miss out on?

(f) In which months do families generally tend to reach the Safety Net threshold and how many families do so in each month?

(g) What percentage of costs, involved with the Medicare Safety Net, are (i) GP related (ii) specialist related and (iii) out-of-hospital related?

(h) How many people register for the Medicare Safety Net each year?

Answer:

(a) The number of individuals that reached the Medicare Safety net threshold for the calendar years (i) 1996 (ii) 1997 (iii) 1998 (iv) 1999 (v) 2000 (vi) 2001 and (vii) 2002 is as follows:

1999	9,775
2000	10,372
2001	10,224
2002	10,723

Note: Data for calendar years 1996, 1997 and 1998 is not available due to legislative restraints that only allows the Health Insurance Commission (HIC) to retain unit record data for the past five years.

(b) The number of families that reached the Medicare Safety Net threshold for the calendar years (i) 1996 (ii) 1997 (iii) 1998 (iv) 1999 (v) 2000 (vi) 2001 and (vii) 2002 is as follows:

1999	16,400
2000	17,643
2001	17,931
2002	20,100

Note: Data for calendar years 1996, 1997 and 1998 is not available due to legislative restraints that only allows the HIC to retain unit record data for the past five years.

(c) Individuals are not required to register for the Medicare Safety Net.

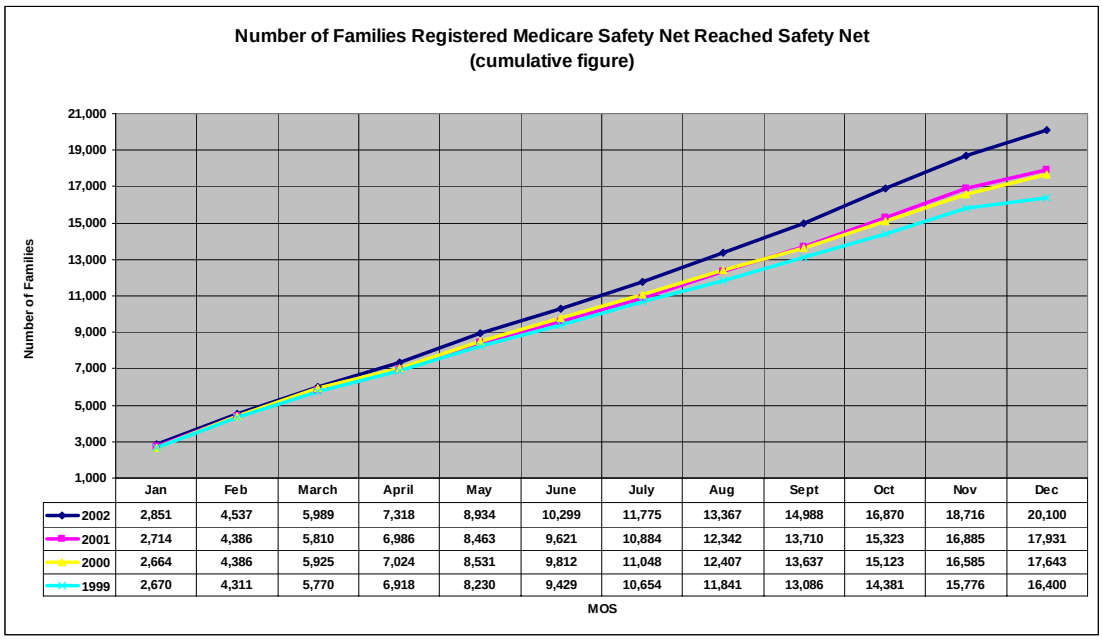
HIC does not maintain data on the number of families who register after they have reached the Safety Net threshold.

(d) Registration for the Medicare Safety Net by a family is only required once. The number of registered families in each year that did not reach the Safety Net threshold is as follows:

1999	1,219,066
2000	1,283,190
2001	1,358,630
2002	1,487,174

(e) It is not possible to answer this question because in any such case the circumstances of the family and their medical expenses history would determine the extent of any such financial gap.

(f) The following graph shows in which months families tend to reach the Safety Net threshold and how many do so in each month:



	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
2002	2,851	4,537	5,989	7,318	8,934	10,299	11,775	13,367	14,988	16,870	18,716	20,100
2001	2,714	4,386	5,810	6,986	8,463	9,621	10,884	12,342	13,710	15,323	16,885	17,931
2000	2,664	4,386	5,925	7,024	8,531	9,812	11,048	12,407	13,637	15,123	16,585	17,643
1999	2,670	4,311	5,770	6,918	8,230	9,429	10,654	11,841	13,086	14,381	15,776	16,400

(g) All Safety Net related services are out-of-hospital, however HIC does not maintain a breakdown of services that are GP or specialist related.

(h) Individuals do not have to register for the Safety Net and families are only required to register once.

The number of individuals covered by family safety net registrations in the last four completed calendar years are:

1999	4,186,098	Number registered since safety net inception.
2000	203,959	Number registered for the year
2001	237,156	Number registered for the year
2002	425,094	Number registered for the year

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-000188

OUTCOME 2: Access to Medicare

Topic: CHERE REQUEST

Hansard Page: CA 34

Senator Forshaw asked:

Could we please be provided with a copy of the actual request or commission that was given to CHERE, precisely telling them what they were to do?

Answer:

A copy of the letter commissioning CHERE to undertake the work and an extract from the contract between the Department and CHERE are attached. These documents together constitute the formal request to CHERE telling them what they were to do.

Australian Government

Department of Health and Ageing

Professor Jane Hall
Director
Centre for Health Economics Research & Evaluation
University of Technology, Sydney
PO Box 123 Broadway NSW 2007

Dear Professor Hall

Acceptance of Proposal

I refer to your proposal of 12 September 2003 to provide an analysis of methological issues associated with the construction of an economic model that has been commissioned by the Senate Select Committee on Medicare.

I agree to the terms of your proposal and the amount of $4,620 (GST inclusive) for part (a) of this work. I agree that, should part (b) of the work proceed, a separate costing will be undertaken and a quote provided before commencement of the work.

Please find enclosed two signed copies of the official order for your signature. Please sign and return one copy to the Department.

Yours sincerely,

A Stuart

Andrew Stuart
First Assistant Secretary
Primary Care Division

17 September 2003

Extract from the contract between the Department of Health and Ageing and the Centre for Health Economics Research and Evaluation (CHERE)

ITEM B. DESCRIPTION OF CONSULTANCY

In relation to identified health policies on Medicare, the consultant is required to provide advice to the Department on methodological considerations in economic modelling. The work will focus on a model commissioned by the Senate Select Committee on Medicare to estimate the inflationary effects, if any, of elements of *A Fairer Medicare* and alternative policies under consideration by the Committee.

The work is expected to identify and examine influences on the reliability and robustness of economic models and provide advice as to the sensitivity of economic modelling to underlying assumptions.

The consultant will be required to:

(c) provide comment in a time period agreed between the consultant and the Commonwealth on the methodology used in the report to the Senate Select Committee, and
(d) if required, provide a written report summarising their advice.

The Department, at the conclusion of (a), will determine the need for (b).

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-189

OUTCOME 2: Access to Medicare

Topic: DEPARTMENT RESPONSE TO COMMITTEE'S RECOMMENDATIONS (SENATE SELECT COMMITTEE ON MEDICARE)

Hansard Page: CA 37

Senator Forshaw asked:

Can we expect a copy of the Department's response for the Government, to the Committee's recommendations shortly?

Answer:

The Government will respond to the Committee's report shortly.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-151

OUTCOME 2 : Access to Medicare

Topic: GPET

Written Question on Notice

Senator McLucas asked:

GPET State by State breakdown of 150 new places. I would like to see a separation between the new 150 and the current 450.

Answer:

The allocation for 2004 is yet to be finalised. A breakdown will be provided when it is available.

Senate Community Affairs Legislation Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2003-2004, 5 November 2003

Question: E03-151
(Supplementary)

OUTCOME 2: Access to Medicare

Topic: STATE BY STATE BREAKDOWN OF 150 PLACES

Written Question on Notice

Senator McLucas asked:

GPET State by State breakdown of 150 new places. I would like to see a separation between the new 150 and the current 450.

Answer:

Further to the response provided on 19 January 2004, a State by State breakdown of the 600 training places available on the Australian General Practice Training Program is at Attachment A.

Attachment A

2004 Training Place Allocation by State and Regional Training Provider

Regional Training Provider	Original Allocation (450)			Revised Allocation (600)		
	Rural	**General**	**Total**	**Rural**	**General**	**Total**
NSW						
Central West Consortium	8	3	11	9	5	14
Coast City Country Training	15	9	24	18	16	34
Institute of General Practice Education	0	21	21	0	28	28
New England Area Training Service	9	1	10	11	3	14
North Coast NSW	8	2	10	11		17
Rhedwest	9	1	10	12	2	14
Sydney Institute of GPET	0	21	21	0	26	26
Valley to Coast	3	20	23	5	27	32
Wentwest	0	21	21	0	28	28
NSW Total	**52**	**99**	**151**	**66**	**141**	**207**
Victoria						
Bogong Regional Training Network	10	2	12	14	3	17
Gippsland	12	0	12	16	0	16
Greater Green Triangle	12	0	12	16	0	16
Victoria Felix	16	4	20	20	7	27
Victorian Metro Alliance	0	59	59	0	79	79
Victoria Total	**50**	**65**	**115**	**66**	**89**	**155**
Queensland						
Central Southern Qld Training	20	35	55	25	48	73
Rural and Regional Qld	18	4	22	22	6	28
Tropical Medical Training	10	10	20	12	14	26
Queensland Total	**48**	**49**	**97**	**59**	**68**	**127**
South Australia						
Adelaide to Outback	10	7	17	14	13	27
Sturt-Fleurieu	10	7	17	12	10	22
SA Total	**20**	**14**	**34**	**26**	**23**	**49**
Western Australia						
WAGPET	25	28	53	25	28	53
WA Total	**25**	**28**	**53**	**25**	**28**	**53+**
Tasmania						
GPT Tasmania	7	5	12	9	7	16
Tas. Total	**7**	**5**	**12**	**9**	**7**	**16**
Northern Territory						
Northern Territory GPE	9	3	12	12	5	17
NT Total	**9**	**3**	**12**	**12**	**5**	**17**
	211	**263**	**474**	**263**	**361**	**624***

*GPET's normal recruitment and selection processes over-allocate places available on the

basis of an assumed attrition rate of applicants prior to the commencement of any training year. For the 600 training places in 2004, 624 represents the allocation target, not the available places.

+ The Western Australian regional training provider (WAGPET) was unable to take any additional places in 2004 because there were insufficient applicants for the increase in the number of training places.