Senate Community Affairs Committee

INQUIRY INTO NATIONAL HEALTH AMENDMENT (PHARMACEUTICAL AND OTHER BENEFITS – COST RECOVERY) BILL 2008

ANSWER TO QUESTION ON NOTICE

Hearing, 28 July 2008

Question: 1

Topic: COST RECOVERY FOR LISTING MEDICINES ON THE PHARMACEUTICAL BENEFITS SCHEME AND STAKEHOLDER CONSULTATIONS

Mr David Learmonth queried (CA 62):

'Would it help if we provided a bit of an outline of the consultation process?'

Senator Moore responded (CA 62):

'That would be very useful.'

Answer:

Information about the consultations undertaken in preparation for the introduction of cost recovery arrangements for the listing of medicines on the pharmaceutical benefits scheme is attached.

Attachment

Stakeholder Consultations

Background

The policy to recover the costs associated with listing of medicines and vaccines on the Pharmaceutical Benefits Scheme (PBS) was first announced in the 2005-06 Budget and at that time was scheduled to commence on 1 July 2007.

In summary, there have been three rounds of stakeholder consultations since the original announcement and ongoing contact with industry, particularly through Medicines Australia and the Generic Medicines Industry Association.

Round One Consultations

November 2005 – February 2007

The first round of consultations commenced in late 2005 and included an issues paper, subsequent meeting and later, written advice from the Department about the deferral of the policy's implementation until 1 January 2008, sent in December 2006. These consultations primarily involved Medicines Australia and Generic Medicines Industry Association. Later that year, the Department provided written advice to Medicines Australian and Generic Medicines Industry Association that the Government had deferred implementation from 1 July 2007 until 1 January 2008.

Round Two Consultations

April 2007 – August 2007

The second round of consultations also centred on a discussion paper, which was distributed across the sector. See table that follows for further details.

Unlike the 2005 paper, which was necessarily broad, the second (2007) paper concentrated on mechanisms for cost recovery, such as levies, fees and charges.

The wide ranging responses to the discussion paper and the meetings that followed contained a strong and consistent message from the sector that the preference was for a fees only mechanism, structured as simply as possible.

The Department responded by reflecting its costs in a fee schedule that had minimal fee points for administrative ease and efficiency. The time associated with the activities that relate to the listing process, that is, each individual step had been captured in the costing process, which allowed for fees per submission as currently proposed. This accords as closely as possible with industry's stated preference.

Round Three Consultations

May 2008 onwards

The third round of consultations occurred after the recent Budget 2008-09 announcement that cost recovery would be implemented on 1 July 2008. This phase consisted of information sessions for pharmaceutical companies and meetings with Medicines Australia and Generic Medicines Industry Association. The information sessions were held in both Melbourne and Sydney in June 2008 and covered proposed fees and administrative processes if the arrangements take effect.

The Department has also established a consultative mechanism with industry, specifically on cost recovery arrangements and has already had the first of those meetings with Medicines Australia and the Generic Medicines Industry Association on 3 June 2008.

In addition, the Department has set up an email mailbox specifically for industry consultation pbscostrecovery@health.gov.au and has fact sheets, in for the form of questions and answers on its website (at pbs.gov.au) for industry and consumers.

A table summarising the consultation that has taken place and the corresponding dates, follows.

Summary of Stakeholder Consultations on Cost Recovery Arrangements: 2005-2008

Date	Consultation	Type
15 November 2005	Issues Paper - Medicines Australia Generic Medicines Industry Association	Paper
21 November 2005	Generic Medicines Industry Association	Meeting
25 November 2005	Medicines Australia	Meeting
12 May 2006	Generic Medicines Industry Association	Meeting
8 June 2006	Medicines Australia	Meeting
8 December 2006	Medicines Australia Generic Medicines Industry Association	Written advice - deferred implementation
February 2007	Broadcast industry email	Written advice - deferred implementation
April 2007	Discussion Paper – Distributed to Medicines Australia, Generic Medicines Industry Association, Consumer Health Forum, Australian Medical Association, Pharmacy Guild, Pharmaceutical Society of Australia, Society of Hospital Pharmacists of Australia and Australian Self-Medication Industry Association	Paper
24 April 2007	Generic Medicines Industry Association	Presentation
30 April 2007	Consumers Health Forum (CHF)	Teleconference
8 May 2007	Medicines Australia	Presentation
5 August 2007	Medicines Australia	Meeting
28 May 2008	Association for Regulatory and Clinical Scientists	Presentation
3 June 2008	Medicines Australia and Generic Medicines Industry Association	Meeting
10 & 12 June 2008	Melbourne and Sydney	Information sessions

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Question: 3

Topic: COST RECOVERY FOR LISTING MEDICINES ON THE PHARMACEUTICAL BENEFITS SCHEME AND THE COMMERCIAL READY PROGRAM

Senator Colbeck asked (CA 67):

'Were you consulted in respect of the removal of the Commercial Ready Program?'

and (CA67):

'Why can't you tell us whether there was any consultation between the two departments?'

Answer:

The Department is not able to identify considerations leading to government decisions or possible government decisions.

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ANSWERS TO QUESTIONS ON NOTICE

Hearing, 28 July 2008

Question: 4

Topic: COST RECOVERY FOR LISTING MEDICINES ON THE PHARMACEUTICAL BENEFITS SCHEME AND THE PERCENTAGE OF UNSUBSIDISED PRESCRIPTIONS

Senator Colbeck asked (CA 68):

'Do you have any percentages here? What percentage of prescriptions in Australia would be private or non-PBS?'

Answers:

Approximately 8 per cent of prescriptions are dispensed on a private basis. That is, 8 per cent of all dispensed prescriptions are either for medicines not listed on the Pharmaceutical Benefits Scheme (PBS), or indications (uses) that are not specified on the PBS.

Prescriptions paid for by general patients at a price less than the co-payment, currently $31.30, are known as under co-payment. Under co-payment prescriptions as a proportion of PBS prescriptions (that is, without including private prescriptions) are approximately 20 per cent, or around 18 per cent of the total of the total number of dispensed prescriptions. The Government does not contribute to the cost of these medicines, until such time as a patient reaches the safety net threshold.

Approximately twenty five percent of all dispensed prescriptions are unsubsidised (that is, are either private or under co-payment).

The total number of prescriptions dispensed in the Australian community in 2007 is summarised in the attached table.

Attachment

Dispensed community prescriptions in Australia in 2007

Prescription classification	*Number dispensed*
Concessional Ordinary	113,299,403
Concessional Safety Net	33,964,419
Doctors Bag	344,612
General Ordinary	19,541,394
General Safety Net	4,522,880
Ostomy	162,629
Private	**18,829,744**
RPBS Ordinary	10,932,197
RPBS Safety Net	3,467,194
Under co-payment	**45,849,943**
Total	*250,914,416*

Source: Drug Utilisation Sub-Committee database

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ANSWER TO QUESTIONS ON NOTICE

Hearing, 28 July 2008

Question: 5

Topic: COST RECOVERY FOR LISTING MEDICINES ON THE PHARMACEUTICAL BENEFITS SCHEME AND THE PALLIATIVE CARE CLINICAL STUDIES COLLABORATIVE

Senator Moore stated (CA48):

'We will ask the department, when they come, to give us a brief on that whole program. So they can take care of that.'

Senator Moore then asked (CA 69):

'Mrs Macdonell, we discussed that process with Palliative Care Australia and we said that we would ask the department for some information on that situation, so can we get some information on that particular process with regard to palliative care drugs? We want to follow up on how that is operating.'

Answer:

The Commonwealth has provided funding of approximately $9.46 million (GST inclusive) over the period 2006-2010 to assist with the establishment and ongoing costs of the Palliative Care Clinical Studies Collaborative (the Collaborative).

Background

This Collaborative forms part of the Australian Government's commitment to improve access to and quality use of palliative care medicines in the community and is a key initiative of the National Palliative Care Program. The Palliative Care Medicines Working Group provides the Department with expert advice on improving access to affordable palliative medicines in the community including guidance and advice to the Collaborative.

The aims of the Collaborative are to:

- develop an efficient and effective method of generating research data that will support the listing of palliative care medicines on the Australian Register of Therapeutic Goods
- build the research capacity of the palliative care sector so that ongoing clinical medication studies can occur
- increase the evidence base to support the ongoing implementation of studies on medicine use and quality practice in palliative care.

It is intended that the clinical studies will evaluate the effectiveness of individual medications

in symptom management for palliative care patients and provide data on the benefit to risk balance for each of those medications.

Anticipated Outcomes

The anticipated outcomes for the Collaborative are:

- Four completed Phase 3 clinical medication studies with at least one other Phase 3 study developed to full protocol
- Three Phase 4 clinical medication studies
- A separate pharmacovigilance study on the prescribing of benzodiazepines in the palliative care population
- Research into utilisation of medicines on the Pharmaceutical Benefits Scheme with a dual listing (that is, with a palliative indication and general listing)
- Data analysis that will support submissions to the Therapeutic Goods Administration and the Pharmaceutical Benefits Advisory Committee
- Evidence to support the clinical usage of medicines in palliative care
- Increased investigator capacity within the palliative care research community to undertake multi-site clinical medication studies in palliative care
- Greater awareness in the pharmaceutical industry of community needs for palliative care medicines and recognition of the importance of registering palliative care indications on the Australian Register of Therapeutic Goods.

Phase 3 clinical studies will verify the effectiveness of individual medications in symptom management for palliative care patients, and Phase 4 (or pharmacovigilance studies) will provide additional data on the benefit to risk balance for individual medication including the use of medication in a normal clinical setting and in comparison with current practice.

These studies may support the registration of a number of medicines used in palliative care on the Australian Register of Therapeutic Goods, which is a prerequisite for the listing of these medicines on the Pharmaceutical Benefits Scheme.

Current Situation

The last 6 months have been an intense period for the Collaborative with a number of significant milestones reached, including:

- Completion of Standard Operating Protocols and policy documents
- Development of collaboration agreements between Flinders University and participating Phase 3 and Phase 4 sites
- Commencement of recruitment for the Ketamine, Octreotide and Risperidone studies
- Submission of the protocol for Megesterol acetate for ethics approval
- Development of the phase 4 audit protocol
- Conclusion of Octreotide and Megestrol acetate training workshops for all Phase 3 site staff
- Phase 4 audit training workshop for all Phase 4 site staff
- Continued discussions and support from the pharmaceutical companies producing the medicines under study by the Collaborative.

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Question: 6

Topic: COST RECOVERY FOR LISTING MEDICINES ON THE PHARMACEUTICAL BENEFITS SCHEME AND CLARIFICATION OF THE DEPARTMENT OF HEALTH AND AGEING SUBMISSION

Senator Colbeck asked (CA 72):

'So what do you mean by *the making of declaration, determinations, agreements and arrangements* in your submission?

Answer:

The paragraph in the Department's submission that contained this sentence was intended to reflect the wording in the Explanatory Memorandum accompanying the Bill. The actual wording in the Explanatory Memorandum (paragraph 2, under Outline) reads:

> *The Bill provides that the regulations may include prescription of fees payable in relation to <u>those</u> services provided by the Commonwealth such as the making of declarations, determinations, agreements and arrangements.*

In paraphrasing the paragraph for the Department's submission to the Inquiry, it appears the word 'those'; (as contained in the Explanatory Memorandum) has been transposed to read 'other'.

The above reference to 'those services provided by the Commonwealth' refers to the services described in the first paragraph of the Explanatory Memorandum (and also the opening paragraph in the Department's submission).

To read the paragraph in context, the paragraphs preceding it and following it in the Explanatory Memorandum also need to be read.

> *The purpose of the Bill is to amend the National Health Act 1953 (the Act) to enable regulations to be made with respect to services provided by the Commonwealth associated with the exercise of powers by the Minister for the Pharmaceutical Benefits Scheme (PBS) (under Part VII of the Act) and the National Immunisation Program (NIP) (under section 9B of the Act).*
>
> *The Bill provides that the regulations may include prescription of fees payable in relation to <u>those</u> services provided by the Commonwealth such as the making of declarations, determinations, agreements and arrangements.*

Services provided by the Commonwealth in relation to the exercise of those powers by the Minister include the performance of functions by the Pharmaceutical Benefits Advisory Committee (PBAC) and its subcommittees, the Pharmaceutical Benefits Pricing Authority, and related services performed by Departmental officers, contractors and sub-contractors.

The third paragraph provides further examples of those services covered by the Bill.

The Department regrets any confusion that may have arisen from the wording, which appeared in the Department's submission to the Inquiry

Nonetheless, although the Bill allows for specific fees for the activities referred to in the Senator's question, for administrative ease and efficiency the Department intends to minimise the number of fee points. The time associated with undertaking these activities has already been captured in the costing process and is therefore reflected and accounted for in the fee structure currently proposed.