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08/20

Mr Elton Humphrey
Committee Secretary
Community Affairs Committee
Department of the Senate
PO Box 6100
Parliament House
CANBERRA ACT 2600

Sent by email to community.affairs.sen@aph.gov.au

Dear Mr Humphrey

Please find attached the AMA's submission to the Committee's inquiry into the National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008.

The AMA would be pleased to attend a public hearing in Canberra if the Committee wishes to take further evidence.

If you require further information please contact me on (02) 6270 5463.

Yours sincerely

John O'Dea
Deputy Secretary General, Policy

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AMA Submission to the
Senate Standing Committee on Community Affairs inquiry into the
National Health Amendment
(Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008

1. Introduction

The Pharmaceutical Benefits Scheme (PBS) provides Australians with affordable access to high quality medicines. Access to high quality medicines is maintained by Government subsidy of the cost of PBS medicines and limiting the amount that people pay at the point of sale[1]. Vaccines are also subsidised through the National Immunisation Program (NIP).

Medicines that are listed on the PBS are assessed by the Pharmaceutical Benefits Advisory Committee (PBAC) to be clinically safe and cost-effective.

The National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008 (the bill) seeks to recover the costs of listing medicines on the PBS by imposing fees on pharmaceutical companies for the various PBAC processes.

In introducing the bill, the Minister for Health and Ageing said "Australians accessing the PBS and NIP will not be required to pay any extra for PBS listed medicines or vaccines as a result of this measure." The AMA is not convinced that this will be the case, and there is no provision in the bill to guarantee the Minister's statement.

The medical profession sees on a daily basis the significant improvements that PBS listed medicines make to the health of their patients. Medicines play a vital role in improving patient health outcomes and in the fight against disease. For example, better medicines to manage heart disease have avoided the need for operations and allow people to have a better quality of life. Improvements to asthma medications have lead to better health outcomes for children. Diabetes medications are assisting in the management of the disease.

Doctors make prescribing decisions in the best interests of their patients. Doctors know that for some people, an increase in the co-payment for the prescribed medicine, however small, can make the difference as to whether or not they fill their script. If a patient does not fill a script, then his or her health outcome will be compromised.

The AMA considers that pharmaceutical companies will (legitimately) pass the fees they pay for PBAC processes on to the Australian people, either through higher listing prices or at the point of sale.

The AMA also considers that pharmaceutical companies may decide, particularly for low volume products, that there is no business case to bring a new product to the Australian market. This could mean that Australians will not have access to some medicines that will improve their health outcomes.

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[1] The Hon Nicola Roxon MP, Minister for Health and Ageing, Second Reading Speech. Hansard. House of Representatives. 29 May 2008. Page 3844.

The second key principle set out in the *Australian Government Cost Recovery Guidelines*[2] states that "Cost recovery should not be applied where it is not cost effective, where it is inconsistent with government policy objectives or where it would unduly stifle competition or industry innovation".

The AMA believes that the bill is not cost effective and is inconsistent with government policy objectives. The AMA does not support the introduction of cost recovery for PBAC processes, as there will be no net benefit to the Australian people.

2. Cost recovery is not cost effective

Cost recovery for all submissions lodged to the PBAC on or after 1 July 2008, is expected to generate additional revenue of $7 million over four years, with a net cost of $2.2 million[3]. This is an estimated saving only. Even if the saving is realised, it is unlikely to have a significant impact on overall government outlays in the context of the $7 billion PBS program.

The PBS differs from many other areas of regulation in the economy (such as food) because the Government plays a very significant role as a proxy buyer of pharmaceuticals on behalf of patients. The dynamics bear examination:

- The new fees to be imposed on pharmaceutical companies will be a legitimate cost of business and will be tax deductible.
- It is reasonable to assume that pharmaceutical companies will seek higher prices through Pharmaceutical Benefits Pricing Authority processes to recoup these additional costs.
- The taxpayer will then be left funding the resultant additional costs through the purchase of medicines, rather than as a budget allocation to the Department of Health and Ageing.

The effect of cost recovery may simply be a futile churning effect with little or no net benefit. It may even have a negative net outcome taking account of all relevant revenue and expenditure effects such as the costs of administering the cost recovery arrangements. This represents an inefficient use of resources.

3. Cost recovery is inconsistent with government health policy objectives

As previously stated, the health policy objective of the PBS is to provide all Australians with affordable access to high quality medicines.

There is a risk that introducing cost recovery for the PBS listing processes will diminish the affordability of medicines as pharmaceutical companies seek to recoup their listing fees through higher prices.

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[2] Financial Management Guidance No. 4 July 2005

[3] Australian Government, 'Part 1: Revenue Measures', Budget Paper No. 2: Budget Measures 2008-09, Commonwealth of Australia, Canberra. 2007. Page 9.

Secondly, pharmaceutical companies will carefully consider the business case for bringing new products to the Australian market, taking account of Therapeutic Goods Administration (TGA) approval and PBS listing fees. This will be particularly so for low-volume products. Access to new medicines may be diminished as a result of cost recovery for the PBS.

(a) Risk to affordability of PBS medicines

It will be a legitimate action of pharmaceutical companies to seek to recoup their PBS listing fees through product sales. Inevitably, the listed PBS price of medicines will increase and the cost will be borne in two ways:

- for medicines that are listed above the co-payment amount, the taxpayer will pay more; and
- for medicines that are listed at less than the co-payment amount, the consumer will pay more.

This submission has already discussed the churning effect of PBS listing fees being absorbed by PBS expenditure and the impact on the taxpayer.

As reported in Australia's health 2008, of the 168 million PBS prescriptions issued in 2006, 35 million prescriptions were below the co-payment threshold[4]. Recent research shows that rising co-payments have had a negative impact on the number of PBS medicines dispensed. Changes in dispensing associated with an increase in the co-payment differed depending on medication type and patient beneficiary status, with the greatest decreases observed for concessional beneficiaries[5].

If medicines become more expensive because of cost recovery, and patients are unable to afford to fill scripts, this will lead to poorer health outcomes. It will increase the risk of hospital admissions ultimately leading to increased expenditure on the health system. The cost to the health system could be more than the projected savings of this measure. The Minister for Health and Ageing has said that "the point I think we often miss with the PBS is that we are saving money by often spending money on medications"[6]. Research indicates that $1 spent on medicines saves over $3 in hospital spending or over $6 in broader health spending, including hospitals[7].

(b) Risk to access to PBS medicines

There is a risk that PBS listing fees may reduce the number of products brought to market in Australia. Pharmaceutical companies will assess the business case for bringing a product into Australia based on the costs of TGA approval and PBS listing and the likely sales volumes. The AMA is concerned that, particularly for low

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[4] Australian Institute of Health and Welfare. Page 384

[5] Hynd A et al. Increased patient co-payments and changes in PBS-subsidised medicines dispensed in Western Australia. National Medicines Symposium. 2008.

[6] Breusch, J. PBS surgery not needed: Roxon, Australian Financial Review. 16 May 2008.

[7] Lichtenberg, F. "Do (More and Better) Drugs Keep People Out of Hospitals?" American Economic Review 86. May 1996. 384-388; Lichtenberg, F. Benefits and Costs of Newer Drugs: An Update. Cambridge, MA: National Bureau of Economics Research. June 2002.

volume products, pharmaceutical companies may decide the Australian market is not viable for particular medicines.

4. Cost recovery is inconsistent with government cost recovery guidelines

The Australian Government Cost Recovery Guidelines present a simple decision tree for determining if cost recovery is appropriate (page 31). Where regulation assists a narrow identifiable group of beneficiaries, cost recovery is appropriate. Where regulation has a widespread public good, taxpayer funding is appropriate.

All markets need to be protected so that products are safe and the claims made by the manufacturer are honest. In relation to medicines, the TGA makes this assessment before a product can be sold in Australia. It is a necessary step to market access and cost recovery is appropriate because there is a narrow identifiable group of beneficiaries – pharmaceutical companies are able to market their products in Australia once they have been approved by the TGA.

This is not true of the PBAC process. It is a due diligence process enacted by the purchaser, in this case the Federal Government. By choosing to provide subsidies for pharmaceuticals for all eligible Australians, the Government has created the need to protect taxpayers by ensuring that the subsidies are applied wisely. The Government (purchaser) wants to ensure it is buying a product (already deemed safe for market by the TGA) that is cost effective for the taxpayer. To this end the service provided by the PBAC is a service to Government and the Australian public in the first instance and it is rendered globally to Australian patients and taxpayers for the public good. It is not a service to industry.

In these circumstances, the AMA doubts that cost recovery of PBAC processes meets the criteria in the Government's cost recovery guidelines.

Summary

The AMA does not support the introduction of cost recovery for PBAC processes. The AMA believes the significant public good that the PBS delivers to the Australian public, both in terms of individual health outcomes and overall health expenditure justifies continued Government funding of the PBS listing arrangements.