AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793
T | 61 2 6270 5400
F | 61 2 6270 5499
E | info@ama.com.au
W | www.ama.com.au
42 Macquarie St Barton ACT 2600
PO Box 6090 Kingston ACT 2604

16 September 2008

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 Elton

Please find attached the AMA's submission to the Committee's inquiry into the National Health (Pharmaceutical Benefits – Charges) Regulations 2008.

The AMA's comments are made on the updated version sent to us by the Department of Health and Ageing on 12 September 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 5400.

Yours sincerely

Francis Sullivan
Secretary General

fs:bh

D08/7293

AMA Submission to the
Senate Standing Committee on Community Affairs inquiry into the National Health (Pharmaceutical Benefits – Charges) Regulations 2008

Introduction

The Pharmaceutical Benefits Scheme (PBS) is a significant health policy that provides Australians with affordable access to high quality medicines that have been assessed by the Pharmaceutical Benefits Advisory Committee (PBAC) to be clinically and cost effective.

The draft National Health (Pharmaceutical Benefits – Charges) Regulations 2008 (the regulations) provide for cost recovery by the Department of Health and Ageing for the costs of the process for listing drugs on the PBS. The regulations set the fees for lodging applications to the PBAC and provide the circumstances for exemption or waiver of those fees.

The AMA has already outlined its policy concerns about the introduction of cost recovery arrangements for the PBS listing process in its submission to the Committee dated 11 July 2008.

At a practicable level, the AMA is concerned that, particularly for low volume and/or low price products, pharmaceutical companies may decide that there is no business case to bring a new product to the Australian market. We are concerned that this may impact on Australians' access to some medicines that will improve their health outcomes. These might be products that would be listed with indications for small patient groups such as palliative care, oncology, paediatric preparations and medications for Indigenous Australians. With scientific and technological advances there may be other circumstances in the future that we cannot predict now.

It is in that context that the AMA makes its comments on the draft regulations.

Draft regulations

The AMA does not believe that the draft regulations adequately address our overarching concern about access and affordability of high quality medicines.

The draft regulations, particularly the waiver provision, could be improved to provide a better process to allow pharmaceutical companies to weigh up the business case to bring low volume and/or low priced products to the Australian market.

Waiver provision

Regulation 15 provides that the Department can waiver all or part of a lodgement fee, a pricing fee and an independent review fee. The AMA is heartened to see that situations sited in the consultation draft Explanatory Statement where waiver might be appropriate, are similar to those that the AMA is concerned about.

The waiver decision is twofold: there is a public interest test; and an assessment that payment of the fee would make the application financially unviable.

With these two factors in mind, the AMA believes the draft regulations provide for the waiver decision to be made:

- at a time when the information that is needed to properly make the decision is not available; and
- by the wrong entity.

The public interest test

The public interest test will depend upon the indications (or patient groups) for which the product is approved for listing: the people that would benefit from the listing; the alternative treatments the health care system would need to deliver to these people because the product is not available and/or affordable because it is not subsidised.

Therefore the decision maker will need to consider the extent to which there is a public interest in the application being assessed by PBAC.

Financial viability of the application

The extent to which the payment of the fee would make the application financially unviable would depend upon the final listing of the product on the PBS: the listed indications; and the listed price. The final listing will have a bearing on the sales the company could expect.

Clinical indications and the listing price are at the heart of PBAC consideration of the clinical and cost effectiveness of PBS medicines.

The waiver decision

The AMA is of the view that in effect, the full information (i.e. the material facts) needed to make a waiver decision will not be available until after the PBAC has assessed the application and made its recommendations on listing. However, we realise deferring the waiver decision until the information is available will not be practical. Therefore, the waiver decision will have to be based on expected outcomes if the PBAC were to consider and approve the listing as set out in the company's application.

In that context and in light of the policy objectives of the PBS, the AMA believes it is appropriate for the Minister, not the Department, to make the waiver decision. It should not be an administrative decision made by Departmental officials. To ensure transparency, the AMA recommends that the regulations include a requirement for the Minister's decision that a fee is or is not payable to be tabled in the Parliament.

Example of waiver

On a minor matter, the AMA considers the example provided in regulation 15 of a circumstance in which a fee could be waived should in fact be an exemption under regulation 14. Pharmaceutical companies should not be required to pay fees where PBAC has asked them to make an application to change a listing.

Decisions about the amount of fee that is payable

Regulation 5 essentially provides for the Department to make a decision about the category the application falls into and therefore the amount of the fee that is payable. The AMA does not have any concerns with these decisions being made by the Department, but believes the relevant provisions could be clearer and processes could be streamlined.

Minor applications
It appears that paragraph 3(3)(a) will mean that applications to list medicines in a different form, for example, a paediatric preparation of a medicine that is already listed on the PBS in adult form will only attract an lodgement fee of $12,500. This should significantly improve the business case for pharmaceutical companies to bring different forms or preparations of medication to the Australian market.

For clarity, and to avoid unnecessary reviews of decisions, the AMA believes the regulations should be amended to include specific circumstances that would render applications in the minor category.

Major applications
In respect of paragraphs 3(2)(b) and 3(2)(e), the AMA notes that the PBAC must make a judgement on whether the application is for substantial change to the current listing or is a substantive change to a previous application. It appears from the draft regulations that this would have to occur before the Department could determine the application was in the major category and attract the highest fee.

This appears to the AMA to be a protracted process that could delay PBAC consideration of the application itself. The requirement for the PBAC to consider the specific situations in paragraphs 3(2)(b) and 3(2)(e) should be removed, leaving the Department to make decisions about the category of applications without reference to the PBAC. As with minor applications, the regulations should include specific circumstances that would render applications in the major category.

Summary

As previously stated, 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. If cost recovery is introduced, these principles should be at the heart of any process designed to assess fee waiver applications.

In respect of the draft regulations, the AMA believes:

- the Minister, not the Department, should make waiver decisions about the payment of lodgement and listing fees;
- the Minister's decisions about waiver applications should be tabled in Parliament;
- the regulations should include specific circumstances that would render applications in the minor category; and
- the requirement for the PBAC to consider the specific situations in relation to applications in the major category should be removed from paragraphs 3(2)(b) and 3(2)(e) and the specific circumstances included in the regulations.