



The PHARMACY GUILD of AUSTRALIA
NATIONAL SECRETARIAT

14 July 2008

Mr Elton Humphery
The Secretary
Senate Community Affairs Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Mr Humphery

National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008

The Pharmacy Guild of Australia welcomes this opportunity to provide a submission to the Senate Community Affairs Committee Inquiry concerning the National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008.

The Guild is the national peak body representing community pharmacy in Australia. It seeks to serve the interests of 5,000 pharmacy proprietors and to support community pharmacy in its role of delivering quality health outcomes to all Australians, through optimum therapeutic use of drugs, drug management and related professional services.

Approximately 70% of product sales through pharmacies are for prescription drugs. 80% of these are for prescription items subsidised through the Pharmaceutical Benefits Scheme (PBS). A total of over 180 million subsidised PBS and Repatriation PBS prescriptions were dispensed in community pharmacies in the 12 months to June 2008.

Australia's PBS is recognised around the world as one of the most efficient and effective universal drug subsidy schemes. Its aim is 'to provide timely, reliable and affordable access for the Australian community to necessary and cost effective medicines'.

The PBS is currently undergoing one of the most significant changes in its history. On 1 August, mandatory 25% price reductions will be implemented on a large range of patent-expired medicines. Also, a system of price disclosure is being implemented to ensure that the price the government pays for PBS drugs closely reflects the price of the drugs in the market. The Guild supports these reforms, which ensure the long-term sustainability and cost-effectiveness of the PBS. Innovator pharmaceutical manufacturers will be most affected by these changes. They will also be the group most impacted by the proposed cost recovery arrangements.

The Guild notes that the estimated additional annual cost of the proposed cost recovery arrangements to the pharmaceutical industry, based on the first full year of operation, will be \$14

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million. Most of this cost will relate to applications from innovator manufacturers. It is important to note that manufacturers will also continue to be required to pay approximately \$170,000 for registering each new product with the Therapeutic Goods Administration (TGA).

Under the proposed arrangements, the total administrative fees payable to have a product registered with the TGA and then listed on the PBS could exceed \$300,000, excluding the significant cost of preparing the applications and submissions.

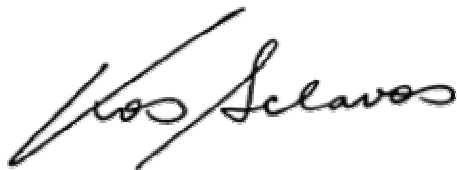
The Guild believes that the aim of the PBS to provide timely, affordable access to cost-effective medicines should be paramount. We are therefore concerned that, in some cases, the introduction of the proposed cost recovery fees may deter, or delay, innovator companies from applying for the listing of important new drugs on the PBS. This may deny access for patients to important new, cost-effective medicines.

The Guild is particularly concerned about the impact of imposing cost recovery in relation to applications for the PBS listing of new drugs that target a small to medium patient population. A high proportion of drugs on the PBS yield a low level of sales revenue each year. Of the 2,800 items currently listed on the PBS, approximately 900 – or 32% - have a total annual sales value of less than \$100,000 nationally. This is based on Guild calculations using Medicare Australia statistics on PBS subsidised prescriptions up to May 2008. While these drugs are for small patient groups, when combined they represent approximately 1.5 million subsidised prescriptions per year across Australia. Should cost recovery fees be imposed in relation to applications for such low volume items, innovator manufacturers may choose not to apply for PBS listing for these types of drugs in future.

This would have one of two consequences. Either the drug would not be made available in the Australian market or it would only be made available as a private prescription item. If the drug was made available only as a private prescription, it would mean that patients requiring the drug would not receive any subsidy and would be subject to significantly higher out-of-pocket costs than would otherwise be the case. As a result, some may choose not to have their prescription filled. This has cost ramifications for other parts of the health system.

The Guild understands that the cost of reviewing and considering applications for PBS listings (and changes to listings) are very significant. However, should cost recovery be structured in a way which acts as a disincentive to innovator pharmaceutical manufacturers – of any size – to apply for PBS listing for any drug, the Guild would not support the imposition of fees.

Yours sincerely

A handwritten signature in black ink, appearing to read "Kos Sclavos". The signature is fluid and cursive, with a long horizontal stroke at the beginning.

KOS SCLAVOS
NATIONAL PRESIDENT