



Government of **Western Australia**
Department of **Health**

Office of the Chief Medical Officer



Enquiries to:

Phone:

Senator Mitch Fifield
Chair, Standing Committee
on Finance and Public Administration,
P.O.Box 6100
Parliament House
Canberra ACT 2600

Dear Senator Fifield

Re: Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme

In relation to the above, I wish to take the opportunity to submit responses on behalf of WA Health. I have had the opportunity to canvass the Chief Pharmacist and the WA Therapeutics Advisory Group whose sub-committees include the WA Drug Evaluation Panel.

Prefacing my response, I wish to acknowledge the expertise and the work of the PBAC. I would also note that there are already alternatives to the drugs which were favourably reviewed by PBAC but not listed on the PBS by the Commonwealth Government.

Comments in response to the deferral of listing medicines on the PBS that have been recommended by PBAC:

The deferral of PBS listing was both unprecedented and unexpected by WA Health. It is understood that the Commonwealth Government does have the prerogative in considering PBAC recommendations on the grounds of affordability and that it has therefore historically considered all recommendations with an estimated budget cost exceeding \$10 million. None of the medicines recently deferred would be considered in this category.

Therefore, the lack of transparency regarding the reasons for this decision and future plans regarding the implementation of PBAC decisions is a matter of concern. WA Health and indeed other governments will need to address the uncertainties arising from this and thus increased transparency would be of great value.

Comments re consequences for patients: Deferred listing reduces patient access to medications the TGA judges to be safe and PBAC considers efficacious and

cost-effective. As previously stated, one must note that there are alternatives available and therefore impact upon clinical outcomes is mitigated.

In recent years, PBAC has made considerable effort to improve the transparency and timeliness of its processes for both patients and consumers. The Commonwealth decision has undermined these efforts and generated confusion amongst both patients and healthcare providers.

Comments re consequences for pharmaceutical sector: No comment

Comments on future availability of medicines in the Australian market: It is well recognised that as a consequence of its small market size and distance from major markets; drugs and technologies are adopted in Australia at a later stage compared to the US or EU. Until recently, regulatory hurdles have also resulted in late entry to Australian markets. The issues highlighted above are known and predictable. In contrast, the decision by the Commonwealth to defer PBS listing is contrary to current practice and given the lack of transparency, unpredictable in its nature. Therefore, one anticipates that this will negatively impact upon the perception amongst pharmaceutical (and technology) manufacturers as to the hurdles and rewards for entry into the Australian market.

Comments re the criteria and advice used to determine deferrals: The criteria and advice used by the Commonwealth in their decision are not known to WA Health. Additionally, whilst high cost drugs are subject to further review following a favourable response by PBAC, the drugs deferred in this instance do not fit this description. The lack of transparency regarding this decision and also any future change to the administration of the PBS should be made clear to at least key stakeholders (including state health departments) if not publicly.

Comments re financial impact on the Commonwealth Budget: The following response needs to be interpreted with the caveat that PBAC, in reaching its decisions, is privy to data which are not available to State Governments or Departments of Health. Nevertheless, the drugs deferred do not fall into the high cost drug category. Additionally, some of the drugs deferred were recommended by PBAC on the basis of price minimisation and therefore any new expenditure incurred by these drugs would have been offset by reduced expenditure on their alternatives. Finally, in its decision making process, PBAC does take into account, the net costs and benefits of a new medicine and adopts a principle of cost-effectiveness or value for money. For these reasons, it would be reasonable to expect that the cost impact of introducing these drugs onto the PBS would be marginal.

Comments re consultation process prior to a deferral: WA Health is not aware of any consultation prior to the Commonwealth decision to defer listing.

Comments re compliance with the Memorandum of Understanding with Medicines Australia: No comment

In responding to the above Inquiry, it has been interesting to juxtapose the Commonwealth's decision in this instance with its stance over Herceptin. Between 2000 and 2001, PBAC rejected three applications by the manufacturer to list Herceptin on the basis of unacceptably high cost effectiveness ratios. At this point, PBAC sought price reductions from the manufacturer but were unsuccessful in these attempts. Nevertheless, in December 2001, the Commonwealth Government established the Herceptin programme.

Subsequent applications led to the PBAC recommendation in 2006 that Herceptin be available to patients with early stage breast cancer and positive HER-2 status. It is listed on the PBS for this indication. Nevertheless, the Commonwealth continues a separate funding programme which makes Herceptin available to patients with late stage metastatic breast cancer.

In closing, there is a need for greater transparency in:

1. The process for PBS listing and deferral of PBAC recommendations,
2. Any future plans for the role and implementation of PBAC decisions.

It is my hope that through this Inquiry, clarity regarding the above is obtained and dialogue established with stakeholders such as State Governments, prescribers and patients and consumers.

Yours sincerely

Dr Simon Towler
CHIEF MEDICAL OFFICER
/ August 2011