MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

10 June 2010

Naomi Bleeser
Committee Secretary
Senate Community Affairs References Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Ms Bleeser

Thank you for your letter of 2 June 2010 requesting further information from Medicines Australia, in particular, on whether the provisions of the recently announced Memorandum of Understanding (MoU) signed between the Australian Government and Medicines Australia has adequately addressed the issues Medicines Australia raised during the Inquiry into Consumer Access to Pharmaceutical Benefits.

Whilst the MoU has provided the industry with a four-year moratorium on the formation of new Therapeutic Groups along with some "best-endeavour" timelines around the PBS listing of medicines requiring Cabinet consideration, Medicines Australia does not believe that these have fully addressed the issues identified by Medicines Australia in its submissions to the inquiry.

Throughout this inquiry, Medicines Australia has consistently argued that Therapeutic Groups:

(1) are redundant following the introduction of PBS Reform, and in particular the splitting of the PBS into the F1 and F2 formularies underpinned by distinctly different mechanisms of price setting and price maintenance;

(2) undermine industry confidence in the Australian business environment by permitting the Government to intervene at any point in time without consultation in the market, putting ongoing investment at risk; and

(3) do not produce savings for the taxpayer that outweigh the patient risks and business costs described in Medicine Australia's first submission (including costs to consumers).

The MoU has not changed our position on this. On the contrary, we believe that the MoU strengthens our argument for the removal of all legislative and policy provisions governing the formation of Therapeutic Groups, for all the reasons listed above.

The MoU provides the Government with the confidence that the F2 market, through PBS Reform, will deliver savings to the taxpayer over and above what it had estimated. Through strengthened price disclosure arrangements, as well as other adjustments to pricing policy, the Government was able to announce $1.9 billion in PBS savings over the next 5 years.

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More now than ever, the ongoing sustainability of the PBS is not dependent upon the use of the Therapeutic Group policy.

In return, the Government through the MoU acknowledged that a stable pricing environment was important for the continuation of a viable and responsible medicines industry in Australia. To this end, the Australian government has committed to provide the industry with four years of price-related certainty. **Importantly, this includes a moratorium on the formation on new Therapeutic Groups – an explicit acknowledgement that these create considerable and unnecessary uncertainty for business by prematurely causing the transition of on-patent F1 medicines into F2.**

Finally, the MoU does not address concerns that Medicines Australia has about the current $10 million Cabinet threshold. This figure was established in 2001 and has remained at this level ever since. It has not been adjusted to reflect changes in the economy or even indexed to inflation as per a Productivity Commission report a number of years ago.

Whilst Medicines Australia appreciates the commitment in the MoU of a "best-endeavours" six-month timeline for those submissions considered by Cabinet, we continue to argue that resetting the threshold so that it reflects the "real" level of that established in 2001 would further reduce delays in the listing of many life-savings medicines. As such, our recommendation to raise the Cabinet threshold to $20 million and indexed to inflation remains unchanged.

Please do not hesitate to contact me should you require any additional information or clarification of any matter presented in this submission.

Yours sincerely

Dr Brendan Shaw
Chief Executive