



14 July 2011

The Secretary
Senate Committee on Finance & Public Administration
References Committee
Parliament House
CANBERRA ACT 2600

Dear Secretary

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

Sanofi welcomes this opportunity to submit to the Senate Committee on Finance and Public Administration's Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme (PBS).

Australia's PBS is intended to provide universal access for patients to treatments that have undergone a rigorous and independent clinical and cost-effectiveness expert assessment.

Given the widespread recognition of the rigour of Australia's PBS system, Sanofi is deeply concerned by the government's unexpected changes to the process for listing medicines on the PBS. This includes the introduction of the requirement that all new PBS listings be approved by Cabinet (rather than only those costing more than \$10 million per year) and the seemingly arbitrary approval of some medicines for listing, but not others, despite them having gone through the rigorous PBAC process.

The sudden introduction of changes to the medicines listing process, lack of consultation and information about the criteria used to determine which medicines will be PBS listed or deferred, and lack of certainty around what future PBS processes will apply to medicines listings, can only lead to increased uncertainty for Australian patients, prescribers and medicines suppliers.

Such unexpected changes to the long-term established PBS listing process also fail to recognise the long timelines, intensive planning, significant investment and global approval processes involved in bringing innovative medicines to Australia. These latest changes can only raise questions about the viability and certainty of Australia as a market for innovative medicines.



The Australian Medicines Industry has worked with the Australian Government to ensure the sustainability of the PBS, including the 2010 Memorandum of Understanding in which industry agreed to \$1.9 billion in savings from the PBS in exchange for a period of stability and certainty. Our industry has been unambiguous about the need for a stable and predictable policy and operating environment in which to continue to make new medicines available for Australian patients.

It is therefore disappointing that the government has made such sudden changes to the PBS listing process that will inevitably lead to further delays in patient access to medicines and create ongoing uncertainty about the Australian medicines policy environment.

Sanofi would urge the Committee on Finance and Public Administration to recommend the government restore certainty to Australia's access to medicines by reversing the current PBS deferrals decision and restoring the \$10 million Cabinet threshold for PBS listings.

If you have any questions or require further information about this submission, please contact me at Sanofi on (02) 8666 2000.

Yours sincerely

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