

**SENATE STANDING COMMITTEE ON
COMMUNITY AFFAIRS**

LEGISLATION COMMITTEE

**Inquiry into the National Health
Amendment (Pharmaceutical Benefits
Scheme) Bill 2010**

SUBMISSION

SUBMISSION NUMBER: 22

SUBMITTER

Merck Serono Australia Pty Ltd

20 October 2010
Committee Secretary
Community Affairs Legislation Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Committee Secretary

Re: Senate Community Affairs Legislation Committee Inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

Thank you for the opportunity to make a submission to this timely inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010.

Merck Serono is internationally recognised as a biotechnology leader. We are actively committed to transforming lives through medical science and specialise in the treatment of cancer, neurodegenerative diseases, infertility, endocrine and metabolic disorders and other serious, life-altering diseases.

Merck Serono supports the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 and the submission made by Medicines Australia to the Senate Community Affairs Legislation Committee.

The most important reason for this is that as company positioned in the innovative biotech sector committed to future innovations through research and development, Merck Serono considers stability and certainty in the regulatory and pricing environment to be essential. The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 gives effect to parts of a Memorandum of Understanding (MoU) between the Commonwealth of Australia and Medicines Australia, signed on 6 May 2010, and announced on Budget night 2010.

The Bill enables changes in legislated pricing arrangements for medicines listed on the Pharmaceutical Benefits Scheme (PBS) and through the MoU the Commonwealth has acknowledged that a stable and predictable pricing environment is important for a viable and responsible medicines industry in Australia. We strongly support this objective.

The Commonwealth has committed to provide the Australian pharmaceuticals industry with four years of price-related certainty, including a moratorium on the formation of new Therapeutic Groups. The MoU also contains important policy improvements to the PBS listing process including permitting the TGA and PBAC evaluation processes to be conducted in parallel, a managed entry scheme for some effective and safe medicines for which there is a high, unmet clinical need and includes a commitment from the Government to improve the "timely access to medicines that Australians need" by setting a "best-endeavours" 6 month time limit on those PBAC recommended medicines requiring Cabinet approval.

Merck Serono believes that the MoU and the associated National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 is a significant step forward ensuring the sustainability of the Pharmaceutical Benefits Scheme and we believe the legislation should be supported by the Senate.

Yours sincerely,

David Garmon-Jones
Managing Director