



Australian Government

Department of Health and Ageing

**MEDICINES**  
*Australia*

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

## Access to Medicines Working Group - 8 April 2009

The Access to Medicines Working Group (AMWG) met on 8 April 2009.

AMWG recommended the implementation of two pilot programs aimed at streamlining the Pharmaceutical Benefits Scheme (PBS) processes. The pilots will consist of:

- 1. Early and extended evaluations of complex submissions** – where an applicant will have the opportunity for two phases of evaluation of a submission by the Pharmaceutical Evaluation Section (PES) and Economic Sub Committee (ESC) prior to it being considered by the Pharmaceutical Benefits Advisory Committee (PBAC). The aim of this pilot is to consider if resubmissions to the PBAC would be reduced by granting the sponsor an extended period, and re-evaluation, to address areas of uncertainty in utilisation and cost effectiveness. The first, or initial, evaluation could be conducted earlier in the Therapeutic Goods Administration process for assessment of the medicine for regulatory approval.
- 2. Enhanced pre-PBAC submission meetings** – where the Department, sponsor and third party stakeholders have the opportunity to meet and discuss submissions to the PBAC in a structured forum. The aim of this pilot is to consider if earlier identification of uncertainty in utilisation and cost effectiveness would reduce the number of re-submissions to the PBAC.

AMWG recommended that the Department of Health and Ageing and Medicines Australia develop a system of workflow planning for submissions to PBAC to assist effective management when running these pilots and in informing consumers.

AMWG agreed that a third Joint Policy Conference on Medicines should be held in 2011. An organising committee for the conference will be established including representation from the Department, Medicines Australia and other interested parties including consumer groups. AMWG will finalise the report outlining the outcomes of the Second Joint Medicines Policy Conference for consideration by the minister prior to publication.

AMWG agreed that the Department should explore providing education for the pharmaceutical industry and consumers on the impact of social values on the PBAC when considering medicines for inclusion on the PBS. In addition, further education options to better equip consumers in providing quality input into the PBAC decision making process will be explored.

AMWG continues to examine the use of post marketing data and the contributions of innovation on the drug development process and objectives of the PBS.

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