



Australian Government

Department of Health and Ageing



BETTER HEALTH THROUGH RESEARCH AND INNOVATION

## Access to Medicines Working Group

### July 2007

The Department of Health and Ageing, and Medicines Australia, have formed an Access to Medicines Working Group (AMWG) to help them work together more effectively. The AMWG will manage the many activities jointly undertaken by the Department and Medicines Australia, and provide advice on access to new medicines to the Minister for Health and Ageing for the consideration of Government.

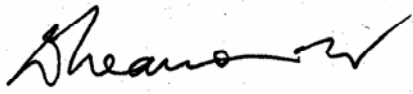
The AMWG is jointly chaired by David Learmonth, Deputy Secretary of the Department, and Will Delaat, Vice Chair of Medicines Australia, and comprises senior representatives of each organisation. The first meeting took place on 24 April 2007.

The terms of reference charge the AMWG with:


1. Providing strategic oversight of ongoing joint activities undertaken by the Department and Medicines Australia to enhance the Pharmaceutical Benefits Scheme (PBS) processes; and
2. As a result of reforms to the PBS announced in 2006, considering issues relating to timely and appropriate access to effective new medicines on the Pharmaceutical Benefits Scheme (PBS), including:
  - the capacity to further streamline and coordinate processes to reduce the time it takes to list a medicine on the PBS;
  - possible impacts on the listing process of mandatory price reductions from 1 August 2008 for medicines on the new F2 formulary;
  - the potential for improving clinical trial, economic and financial data to inform Pharmaceutical Benefits Advisory Committee (PBAC) and Pharmaceutical Benefits Pricing Authority (PBPA) decision making processes;
  - in collaboration with the PBAC, developing and articulating a set of principles for assessing evidence and information relating to new medicines and for improving the transparency of the decision making process;
  - the practical limitations to the evidence available to the PBAC to facilitate decision making around access to new medicines and the development of options to manage uncertainty in such situations; and
  - opportunities for informing and learning from the broader international debate about evidentiary requirements and trends in drug development to support the economic evaluation of new medicines.

The AMWG recognises the importance of drawing appropriately on the expertise and authority of the Pharmaceutical Benefits Advisory Committee and the Therapeutic Goods Administration, and of consulting with a range of other important stakeholders. The group is developing a work plan that will identify priorities consistent with the wide range of work already underway to enhance the operation of the PBS, and will ensure appropriate opportunities for stakeholder input.

The AMWG looks forward to continuing the constructive engagement that began under the Post-PBAC Review and was continued throughout the discussions on the PBS reforms, in order to meet our shared objective of access for the community to cost effective and life-enhancing medicines through the PBS.



David Learmonth  
Deputy Secretary  
Department of Health and Ageing



Will Delaat  
Vice Chair  
Medicines Australia