

## Access to Medicines Working Group – Terms of Reference

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1. Providing strategic oversight of 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 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;
  - 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.