



Australian Government

Department of Health and Ageing



Access to Medicines Working Group

10 December 2010

The Access to Medicines Working Group (AMWG) had its eleventh meeting on 10 December 2010, the first after relevant legislation had passed through Parliament on 22 November 2010.

Given the passage of legislation through Parliament, the AMWG reviewed and agreed on the monitoring framework for implementation of MoU provisions. The AMWG considered progress of these provisions related to stable pricing policy, access and system predictability to ensure they were on target with expectations.

The AMWG agreed on frameworks, commencing 1 January 2011, to improve prompt patient access to new medicines via Managed Entry Scheme and parallel regulatory and reimbursement processes. The Managed Entry Scheme would allow sponsors to seek earlier listing for products in areas of high unmet clinical need while continuing to generate further information regarding the product's potential value. By removing the need to have a positive TGA delegate's overview prior to PBAC lodgement, sponsors would be able to progress regulatory and reimbursement pathways in parallel, potentially reducing time to PBS listing.

The AMWG noted progress on activities related to the MoU designed to observe and predict trends in the PBS market in Australia. From 1 January, activities to monitor trends and drivers of PBS growth, horizon scanning to smooth expectations over workflow and government expenditure over forward years, a mechanism to capture information regarding the effect of reductions in price of F2 medicines on the entry of new medicines, and tracking of Cabinet considerations of new PBS listings would all commence.

The AMWG noted the stakeholder engagement activities in order to ensure the smoothest possible introduction of statutory price reductions and Expanded and Accelerated Price Disclosure requirements. The Department of Health and Ageing had commenced comprehensive education activities regarding the new process including the revised data collection and calculation timeframes.

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