

AMWG COMMUNIQUE – DECEMBER 2014

AMWG Meeting:

The fourth meeting of the reinvigorated AMWG occurred on 10 December 2014.

Attendees:

Attendees included co-Chairs: Mr Andrew Stuart (Deputy Secretary of Department of Health) and Mr Tim James (CEO of Medicines Australia – acting co-chair of AMWG); representatives from the Medicines Australia secretariat; industry and the Pharmaceutical Benefits Division of the Department of Health.

Purpose:

The purpose of the meeting was to update the AMWG on progress against the work-streams.

1. Post-market reviews
2. Managed Access Programme (formerly Managed Entry Scheme)
3. Section 99ACB of the National Health Act
4. Transparency of PBS processes

Progress:

Mr James and Ms McNeill updated the AMWG on the meeting with the then Minister for Health, the Hon. Peter Dutton MP on 25 November 2014. The AMWG progress for each topic was reported to the Minister, including the significant progress made on the framework for the initiation and conduct of Post Market Reviews and other policy priorities. The Minister agreed to extend the deadline for the resolution of Managed Access Programme, 99ACB and Transparency to March 2015.

The AMWG sub-groups then provided verbal reports to the AMWG on the progress and achievements to date.

Post Market reviews:

Work on an agreed post-market review framework is nearing completion. Medicines Australia and the Department anticipate an announcement of the agreement and publication of the new framework in the near future.

Managed Access Programme

Substantive progress has been made on developing a workable framework for a Managed Access Programme. The AMWG anticipate broader review of this framework early in 2015 with the aim to provide a final proposed framework to the PBAC for consideration at the March PBAC meeting in 2015.

99ACB

Tripartite meetings between the Generic Medicines Industry Association, Medicines Australia and Health took place on 14 November and 1 December. The sub group identified that there needs to be agreement on the legislative intent before progress can be made on the interpretation of that part of the legislation and that substantial progress will be required in early 2015 if the revised deadline for resolution can be met. The sub group will continue to work offline on these issues.

Transparency

Medicines Australia and Health are developing a road map of transparency activities and projects. The scope of each project is being discussed for commencement in 2015.

Communication:

The AMWG will continue to publish regular communiques to provide updates on progress following each AMWG meeting.