

Access to Medicines Working Group (AMWG) Communique – 15 September 2015

AMWG Meeting:

The sixth meeting of the reinvigorated AMWG occurred on 15 September 2015. At the end of March 2015 in the context of the PBS Access and Sustainability negotiations and the 2015-16 Budget process, the AMWG was temporarily suspended.

Attendees:

Attendees included co-Chairs: Mr Andrew Stuart (Deputy Secretary of Department of Health) and Mr Martin Cross (Chairman of Medicines Australia); representatives from Medicines Australia and the Pharmaceutical Benefits Division of the Department of Health.

Purpose:

To reconvene after several months in abeyance and update the AMWG on progress against the three current work-streams:

1. Managed Access Programme (formerly Managed Entry Scheme)
2. Section 99ACB of the *National Health Act 1953*
3. Transparency of PBS processes

Progress:

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

Managed Access Programme

Significant progress had been made on developing a framework for a Managed Access Programme in early 2015. The draft framework was provided for PBAC review and comment at the March 2015 meeting. The PBAC considered, amended, and published a revised draft. The group expects the final version of the framework to be agreed and published in the coming months.

99ACB

There remain fundamental points of disagreement on the interpretation of section 99ACB of the *National Health Act 1953*. There has been limited progress on achieving resolution. However both parties agreed to progress discussions, including

with the Generic and Biosimilars Medicines Association, over the coming months in an effort to seek a resolution.

Transparency

Medicines Australia and Health discussed condensed transparency principles and the development of transparency and efficiency initiatives. Both parties will progress the sub-group work over the coming months.

Next steps:

The AMWG is expected to reconvene in February 2016 with subgroup work progressing in between.

Medicines Australia has communicated its desire for comparator erosion to be the next topic for discussion on the AMWG agenda following the completion of the current work streams.