

# Access to Medicines Working Group

## Communique

### 22 May 2020

The Access to Medicines Working Group (AMWG) met via teleconference on 22 May 2020. Attendees included representatives from Medicines Australia (MA), the pharmaceutical industry and the Department of Health (the department).

Members noted there has been a significant increase in the number of Pharmaceutical Benefits Scheme (PBS)-listed biosimilar brands over the last six months, and also that biosimilars' share of the overall volume of biological medicines dispensed under the PBS has nearly doubled in the last two years.

The COVID-19 pandemic has affected implementation of Stage 2 PBS process improvements and supporting cost recovery arrangements. Improvements will not be implemented from 1 July 2020. Members noted that the draft 2020-21 Cost Recovery Implementation Statement – *'Listing of Medicines on the PBS and designated vaccines on the NIP'* was open for public consultation and included the fees for 2020-21 that had been consulted on in early 2019.

Members discussed MA's concern about not being able to access a pathway for immediate Pharmaceutical Benefits Advisory Committee (PBAC) reconsideration for *positive* recommendations under the proposed Stage 2 PBS process improvements. To inform whether this is a material concern or not, it was agreed that data will be collected to determine the number of positive recommendations received where an applicant confirms they want to return to the immediate next PBAC for reconsideration using existing agreed processes.

In relation to the work of the comparator selection subgroup, MA requested that explanatory information about comparators in PBAC submissions should be conveyed via an information session to be held by the department.

Members noted that the implementation of Public Summary Document (PSD) redaction changes had been delayed in response to MA's requests to allow sponsors time to review the procedure guidance before submission lodgement. Members noted the updated PSD guidelines are now available on the [PBS website](#) and that the standardised redaction criteria will apply to those submissions lodged for the November 2020 PBAC meeting with process improvements to apply to submissions considered at the July 2020 PBAC meeting.

The AMWG subgroups will continue to progress key priorities of the AMWG as outlined within the Strategic Agreement, and there will be further discussion of the AMWG 2020-21 priorities at the next meeting. The next AMWG meeting will be held in October 2020.