

**ACSS Generic Medicines Working Group
Public Statement
Face-to-face Meeting
(29-30 October 2018, Canberra, Australia)**

On 29-30 October 2018 the ACSS Consortium Generic Medicines Working Group (GMWG) met in Canberra, Australia, to advance information and work sharing in the field of generic drug applications.

The focal point of the discussion was to review the response from industry to the ACSS Generic Medicines Work Sharing Trial (GMWST).

To this end the Working Group (via TGA International) sent an invitation letter to the global heads of generic companies to solicit participation. The Working Group also agreed:

- That the GMWST should remain open to new applicants;
- To look into extending the GMWST to 'generic like' submissions such as new dosage forms, additional strength products and reformulations;
- To seek further feedback from industry and peak organizations on the current response rate to the GMWST.

On Quality topics, the GMWG members discussed the draft versions of the *Guidance for Quality Assessors - Drug Product* and a common *Quality Assessment Report (QAR)* template for Drug Products and agreed to finalization once they had been revised.

During the meeting, the *Guidance for Bioequivalence Assessors* was discussed and moved towards completion.

Specific technical issues of interest and mutual areas of concern, such as the use of foreign assessment reports, were discussed with the aim to facilitate work sharing arrangements in the assessment of generic drug applications among the ACSS Consortium members.

The next face-to-face meeting of the ACSS Consortium GMWG is expected to take place in May 2019.