

**ACSS Consortium - Generic Medicines Working Group
Public Statement
Face-to-face Meeting
(June 2-3, 2017, Ottawa, Canada)**

(28 October 2017)

Drug Regulatory Agencies from the Australia, Canada, Singapore and Switzerland (ACSS) Consortium Generic Medicines Working Group met on 2-3 June 2017 in Ottawa, Canada, with a focus on a review of the work sharing trial for the coordinated assessment of generic drug applications.

The ACSS Consortium Generic Medicines Working Group (GMWG) met in Ottawa, Canada, ahead of the 5th meeting of the International Generic Drug Regulators Programme (IGDRP). The purpose of this ACSS GMWG meeting was to advance information and work sharing arrangements in the assessment of generic drug applications.

The main focus of the meeting was the *Generic Medicines Work Sharing Trial (GMWST)*, which is modelled on the European Decentralised Procedure (DCP). The discussion focused on the experiences gained with the first application having been assessed within the trial and recommendations for future applications.

The Working Group members:

- Discussed the continuation and expansion of the scope for applications to be considered for the work sharing trial;
- Reviewed and updated the current operational procedures and tools used to guide the work sharing trial;
- Discussed initiatives for raising industry awareness of the trial and to encourage additional candidate applications;
- Agreed to draft and publish an article on experiences and lessons learned from the first application.

The ACSS GMWG members finalised the *Guidance for Bioequivalence Assessors*, the *Guidance for Quality Assessors - Drug Substance* and an updated version of the *Quality Assessment Report (QAR) template for Active Substance Master Files* and progressed work on both the *Guidance for Quality Assessors - Drug Product* and the *Bioequivalence Assessment Report template*. The working group members also discussed specific technical issues of interest and mutual areas of concern, such as data integrity in bioequivalence studies.

Together these guidance documents, templates and discussions will advance work sharing arrangements in the assessment of generic drug applications between the ACSS Consortium members.

The ACSS Consortium GMWG meeting concluded with preparations for the 5th meeting of the IGDRP, which was held from 5-6 June 2017, also in Ottawa.

The next face-to-face meeting of the ACSS Consortium GMWG is scheduled to take place on 27-28 October 2017 in Brasilia, Brazil, in the margins of the 6th IGDRP meeting.