

**ACSS Generic Medicines Working Group
Public Statement
Face-to-face Meeting
(27-28 October 2017, Brasilia, Brazil)**

The ACSS Consortium Generic Medicines Working Group (GMWG) met in Brasilia, Brazil, on 27-28 October 2017. The purpose of this meeting was to advance information and work sharing arrangements in the assessment of generic drug applications.

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

The Working Group members:

- Discussed the continuation of the work-sharing trial according to the updated operational procedures;
- Reviewed the draft article on experiences and lessons learned from the first application; and
- Discussed the publication of the GMWST documents on all of the ACSS agency websites to raise industry awareness of the trial and to encourage candidate applications.
- The GMWST documents were updated and consist of the Notice to Applicants, Operational Procedures, Questions and Answers and the Expression of Interest (EOI) form.

The GMWG members finalised the *Bioequivalence Assessment Report Template* and reviewed milestones for the development of the *Guidance for Quality Assessors - Drug Product* and the *Quality Assessment Report (QAR)* template for Drug Products. The members also discussed specific technical issues of interest and mutual areas of concern, such as the use of foreign assessment reports to support the evaluation of generic medicines applications. These guidance documents, templates and discussions will facilitate work sharing arrangements in the assessment of generic drug applications among the ACSS Consortium members.

The ACSS Consortium GMWG also prepared a summary of its work for presentation at the 6th meeting of the IGDRP, which was held directly after the GMWG meeting, from 30 October to 2 November 2017 in Brasilia.

The next face-to-face meeting of the ACSS Consortium GMWG is scheduled to take place on 14-15 May 2018 in Bern, Switzerland.