

**ACSS Generic Medicines Working Group
Public Statement
Face-to-face Meeting
(14-15 May 2018, Bern, Switzerland)**

On May 14-15 2018 the ACSS Consortium Generic Medicines Working Group (GMWG) met in Bern, Switzerland, to advance information and work sharing in the field of generic drug applications.

The focal point of the discussion was to further promote the *ACSS Generic Medicines Work Sharing Trial (GMWST)* to raise industry awareness and to encourage future applications.

To this end the Working Group:

- published the Notice to Applicants, Operational Procedures, Questions and Answers and the Expression of Interest (EOI) documents on each agency's website;
- published the article "Sharing the Regulatory Workload" in the DIA Global Forum March 2018¹;
- drafted an invitation letter to be sent directly to generic companies to solicit participation; and
- discussed other potential options to increase candidate applications for the work sharing model.

On Quality topics, the GMWG members reviewed and updated draft versions of the *Guidance for Quality Assessors - Drug Product* and a common *Quality Assessment Report (QAR) template* for Drug Products.

During the meeting, the *Guidance for Bioequivalence Assessors* was revised and discussions on comparator products were initiated to better support information and work-sharing initiatives and to lower the regulatory burden for potential applicants.

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 autumn 2018.

¹https://globalforum.diaglobal.org/issue/march-2018/?_ga=2.222796059.1252234196.1525971362-558706832.1520610024%20-%20sharingtheregulatoryissue