

# ACSS Consortium

Australia-Canada-Singapore-Switzerland Consortium



## Public Statement

***Drug Regulatory Agencies from Australia-Canada-Singapore-Switzerland (ACSS) Consortium Generic Medicines Working Group met on 6-7 May 2016 in Strasbourg, France, to progress the work sharing trial for the joint assessment of generic drug applications***

The ACSS Consortium Generic Medicines Working Group (GMWG), comprising representatives from the drug regulatory agencies of Australia, Canada, Singapore and Switzerland, met in Strasbourg, France, ahead of the 3rd meeting of the International Generic Drug Regulators Programme (IGDRP). The purpose of this meeting was to advance information and work sharing arrangements in the assessment of generic drug applications.

ACSS Consortium members held focused discussions on the Generic Medicines Work Sharing Trial (GMWST) which is modelled on the European Union Decentralised Procedure (DCP). Working Group members also finalised the following GMWST documents:

- Operational Procedures;
- Expression of Interest Form;
- Question and Answer Sheet; and
- Project Plan.

The Working Group received one formal Expression of Interest (EOI) to participate in the GMWST. Consortium members also explored the future possibility of promoting GMWST to Industry by ongoing communications in workshops, industry meetings and events, and publication of GMWST trial results in a journal.

Consortium members finalised the *Guidance for Bioequivalence Assessors* and *Guidance for Quality Assessors for Drug Substance*. The Guidance documents will advance work sharing arrangements in the assessment of generic drug applications between consortium members.

The ACSS Consortium GMWG meeting concluded with preparations for the third meeting of the IGDRP, held on 11-12 May 2016.

The next face-to-face meeting of the ACSS Consortium GMWG is scheduled to take place on 14-15 October 2016 in Mexico City, Mexico and in the margins of the 4th IGDRP meeting.