

## **ACSS Generic Medicines Working Group Public Statement Mexico meeting (Oct. 2016)**

### ***Drug Regulatory Agencies from Australia-Canada-Singapore-Switzerland (ACSS) Consortium Generic Medicines Working Group met on 14-15 October 2016 in Mexico City, Mexico, 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 Mexico City, Mexico, ahead of the 4th 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 discussions on the Generic Medicines Work Sharing Trial (GMWST) which is modelled on the European Decentralised Procedure (DCP). This discussion focused on the first application currently being assessed as part of the trial. The trial was at the stage after the first round assessment and waiting for the Applicant to respond to the deficiency questions.

The Working Group members:

- Talked about how the trial procedures could be implemented within the local procedures.
- Drafted an Experiences document which is to be added to as this trial progresses.
- To encourage the receipt of further applications for the trial, it was decided to:
  - widen the scope of the dosage forms to be considered for the trial
  - allow for an application to be filed with 2 of the 4 members (rather than 3).

Consortium members agreed a work plan for the development of a *Guidance for Quality Assessors for Drug Product* (to complement the *Guidance for Bioequivalence Assessors* and the *Guidance for Quality Assessors for Drug Substance*) and a *Bioequivalence Assessment Report Template*. Together these guidance documents and templates 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 4th meeting of the IGDRP, to be held on 17-20 October 2016.

The next face-to-face meeting of the ACSS Consortium GMWG is scheduled to take place on 2-3 June 2017 in Ottawa, Canada, in the margins of the 5th IGDRP meeting.