ACSS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND

ACSS Generic Medicines Working Group

Mandate

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Purpose

The purpose of this document is to share a common understanding of the objectives and the operations of the Australia, Canada, Singapore and Switzerland (ACSS) Consortium - Generic Medicines Working Group (GMWG).

Background

The ACSS Consortium was formed in 2007 by four regulatory authorities of Australia, Canada, Singapore, and Switzerland that share very similar challenges such as increasing workload, increasing complexity and pressure on available resources. The ACSS Consortium is under the leadership of the Heads of Agencies (HoA) of the participating regulatory authorities.

The Generic Medicines Working Group (GMWG) was established in 2012. There are also a number of working groups with specific responsibility for different projects, including the New Chemical Entities Working Group, Information Technology Working Group, Complementary Herbal Products Working Group, and the Generic Medicines Working Group. The four regulatory agencies share responsibility of leading these working groups.

Objectives

The specific focus of the GMWG is on issues relating to generic medicines. The four regulatory agencies share the same desire to work with trusted, like-minded regulators, enable regulatory convergence of technical requirements, adopt harmonised standards and share successes of existing models for collaboration in order to meet the challenges of global issues. It aims to:

- create opportunities and benefits for regulatory programmes through:
    - greater alignment of regulatory approaches and technical requirements
    - more efficient use of resources through information and work sharing
    - establishment of an effective network among trusted, like-minded regulatory authorities;
- produce immediate and ongoing results in priority work areas; and
- serve as a “proof of concept” for other international regulatory cooperation initiatives.

Scope of work

The GMWG is mandated to undertake a range of activities including, but not limited to the following:

- Develop and implement true information and work sharing arrangements for the four participating ACSS Consortium members;
- Share best practices and lessons learned on issues relating to the regulation of generic medicines amongst the ACSS Consortium members and with broader, multi-lateral collaborative initiatives;
- Demonstrate a model for other collaborations among regulatory authorities;
- Support and inform the efforts of the International Coalition of Medicines Regulatory Authorities (ICMRA) to develop global information and work sharing approaches; and
- Support the development of secure IT platforms and solutions to enable effective mechanisms for information and work sharing initiatives.

In addition, the GMWG is undertaking a Generics Medicines Work Sharing Trial (GMWST), which assesses applications submitted simultaneously in two, or more of the participating agencies.

The goals of the GMWST are to:

- harness efficiencies in the registration process;
- promote regulatory convergence and harmonisation of technical data requirements;
- build confidence between agencies; and
- provide data to be used for the development of a 'business as usual' work sharing arrangement.

The GMWST also aims to perform quality assessments by providing the appropriate level of regulatory oversight using dedicated resources.

Australia's TGA is facilitating communications on this work sharing trial. Any queries relating to the GMWST can be directed to tga.international@health.gov.au.

Meetings/Communications

The GMWG meets semi-annually and also holds regular teleconferences to advance the work.