Access Consortium
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 Access Consortium - Generic Medicines Working Group (GMWG).

Background

The Access Consortium, formerly known as ACSS Consortium, was formed in 2007 by four regulatory authorities: Australia's Therapeutic Good Administration (TGA), Canada's Health Canada (HC), Singapore's Health Sciences Authority (HSA), Switzerland's Swiss Agency for Therapeutic Products (Swissmedic). The United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) joined the Access Consortium in 2020. Each agency shares similar challenges such as increasing workload, increasing complexity of issues relating to medicinal products and pressure on available resources. The Access Consortium is under the leadership of the Heads of Agencies (HoA) of the participating regulatory authorities.

Objectives

The specific focus of the GMWG is on issues relating to generic medicines. The five 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 faced by regulators and industry. The GMWG 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:

- Create efficient work sharing arrangements for the five participating Access Consortium members;
- Share best practices and lessons learned on issues relating to the regulation of generic medicines amongst the Access Consortium members and with broader, multilateral 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 has implemented the Generics Medicines Work Sharing Initiative (GMWSI), which assesses applications submitted simultaneously in two, or more of the participating regulatory agencies.

The goals of the GMWSI 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 GMWSI also aims to perform robust assessments by providing the appropriate level of regulatory oversight using dedicated resources.

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Meetings/Communications

The GMWG holds regular teleconferences and may meet face to face periodically to advance the priority work initiatives.