Subject:

Request for Expressions of Interest (EOI) to Participate in the Australia, Canada, Singapore, and Switzerland (ACSS) Consortium - Generic Medicines Work Sharing Trial (GMWST)

To: Generic Drug Associations and Applicants,

The *ACSS Consortium* is a collaborative initiative of like-minded, medium-sized regulatory authorities between Australia's Therapeutic Goods Administration (TGA), Health Canada (HC), Singapore's Health Sciences Authority (HSA) and the Swiss Agency for Therapeutic Products (Swissmedic) of Switzerland. Regulatory authorities face very similar challenges, such as increasing workload and increasing complexities in the medicinal products and applications that are being regulated, thus contributing to increasing pressure on available resources. The purpose of this international information sharing and work sharing consortium is to build synergies and share knowledge amongst the regulatory authorities with the goal of improved health and safety benefits as a consequence of enhanced effectiveness and efficiency of regulatory systems. The ACSS Consortium has been and continues to serve as a "testing ground" for new and innovative collaborative approaches and can act as a pilot forum for larger international initiatives.

The *Generic Medicines Working Group (GMWG)* within the ACSS Consortium has focussed its efforts on topics associated with marketing authorisation applications for generic medicines. Significant progress has been made on information sharing and regulatory convergence in the areas of Quality and Bioequivalence. The next stage in its work programme is to explore opportunities for greater work sharing within the ACSS Consortium.

To enable these mutual interests, the ACSS Consortium has launched the ***Generic Medicines Work Sharing Trial (GMWST)***, an innovative work sharing model for the coordinated assessment of a generic application that has been filed with multiple ACSS Consortium agencies. The trial will work through the practicalities of undertaking a coordinated assessment that will complement the regulatory decision-making within each jurisdiction. Very short timelines for the assessment of applications have been suggested for this pilot in order to rapidly gain experience on the potential opportunities associated with the work sharing trial and to encourage participation by applicants.

This is an opportunity for a truly unique global collaboration between regulatory authorities and the pharmaceutical industry. The trial has the potential to provide a model that could be adopted on an even larger scale. The valuable knowledge and experience obtained through this pilot exercise will inform internal procedures on the effective use of foreign assessment reports as well as collaborative work with international regulatory partners.

Further benefits for the pharmaceutical industry could include a reduction in regulatory burden (e.g., with the filing of common dossiers), more timely regulatory decisions, concurrent marketing authorisations to multiple markets, and the opportunity to contribute to advancing regulatory innovation.

The applications for this trial should be submitted simultaneously to at least two, but preferably more, of the ACSS Consortium members. The lead agency, designated as the "Reference Regulatory Agency (RRA)", will prepare the assessment reports following the full review of the dossier. The other participating agencies, acting as the "Concerned Regulatory Agencies (CRAs)", will perform a peer review of the assessment reports and the application and provide supplementary comments (as needed).

It is preferable that Modules 2-5 of the application contain common information. However, any differences in Modules 2-5 should be clearly identified by the applicant (e.g., using the template provided within the Expression of Interest form for summarising any differences). In addition, the application submitted to each of the identified regulatory authorities would include the country-specific Module 1 for the respective agency.

The ACSS Consortium - Generic Medicines Working Group has developed the following series of documents to provide details on and guide the operational elements of this trial:

1. *GMWST Expression of Interest (EOI) form (including the Summary of Differences table)* - to be completed by the applicant to signal interest in participating in the GMWST and to summarise key information related to the generic application;
2. *GMWST Operational Procedures* - outlines operational steps, target milestones and recommendations for the planning and the filing of an application with the trial;
3. *GMWST Questions and Answers* - provides further details in a Q&A format to give specific guidance on elements of the trial.

At this stage, we are soliciting interest from applicants for participating in this innovative work sharing trial. Australia's TGA is facilitating communications on this work sharing trial. Applicants who are interested in participating in the trial should signal their interest by forwarding the completed Expression of Interest (EOI) form to tga.international@health.gov.au.

Any queries relating to the GMWST should also be directed to tga.international@health.gov.au. Any queries for the local regulatory authority relating to this trial can be directed to:

- Australia: tga.international@health.gov.au,
- Canada: bps_enquiries@canada.ca,
- Singapore: HSA_TP_Enquiry@hsa.gov.sg, or
- Switzerland: Networking@swissmedic.ch

Communications via e-mail should include "ACSS Consortium - GMWST" in the subject line.