

Questions and Answers (Q&A) Document

ACSS Consortium Generic Medicines Work Sharing Trial (GMWST)

Version	Description of Change	Author	Effective Date
v 1.0	Original publication	ACSS Generic Medicines WG	2016-05-20
v 2.0	Updated following the first application with the GMWST	ACSS Generic Medicines WG	2017-10-05

Background

The *ACSS Consortium* is a collaborative initiative of like-minded, medium-sized regulatory authorities between the 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. 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 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.

Below is a set of questions and answers about the processes for submission and assessment of applications under the ACSS Consortium Generic Medicines Work Sharing Trial (GMWST). This Q&A document compliments and should be read in conjunction with the *ACSS Consortium GMWST Operating Procedures* document.

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. 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.

Questions and Answers

1. Does an application need to be submitted to all four of the ACSS Consortium agencies?

No. It is preferable that the application is submitted in three or four of the ACSS Consortium agencies. However, an application to two agencies will be accepted as well. The application submitted needs to fulfil the specific requirements of the participating agencies to which it is submitted.

2. What are the responsibilities of the applicant prior to filing the application?

The applicant must inform the ACSS Consortium agencies about their intent to participate in the GMWST by submitting the completed EOI form. In this form the applicant will propose their preferred Reference Regulatory Agency (RRA) and identify the other participating agencies with which they intend to file an application. A pre-submission teleconference will be held at least two months prior to the filing of the application between the applicant and the participating agencies to confirm the requirements and process for the submission and assessment of their application. The

applicant will be requested to provide a list of queries at least one week in advance of the pre-submission teleconference.

3. Will each agency conduct a full assessment of the application?

No. One agency will be assigned as the Reference Regulatory Agency (RRA) and will evaluate Modules 2-5. Each of the other participating agencies will act as Concerned Regulatory Agencies (CRAs). The CRAs will conduct a peer review of the Assessment Report provided by the RRA on Modules 2-5 and consult the modules, as needed. The CRAs may raise questions in addition to those of the RRA. All participating agencies (RRA and CRAs) will each evaluate the respective Module 1s in parallel to the other modules.

4. How is the RRA selected?

The applicant can propose the RRA and the ACSS Consortium agencies will take this preference into consideration in making the decision. Other considerations will also be taken into account such as operational needs within the ACSS Consortium.

5. Do Modules 2-5 have to be identical in the applications submitted to all the participating agencies?

No. It is preferable for the same dossier to be submitted to all the participating agencies. However, if there are differences, the 'Summary of Quality and Biopharmaceutic Studies Differences' (included in the EOI form) should be completed outlining the differences in information provided to each participating agency. The ACSS Consortium agencies will discuss these differences with the applicant to determine if the application is suitable for the work sharing trial. Applications should be submitted to each agency simultaneously or as agreed with the agencies. If applicable, the Active Substance Master File/Drug Master File (ASMF/DMF) must be submitted to each participating agency in advance of filing of the application with the appropriate local forms.

6. What types of dosage forms are acceptable for this trial?

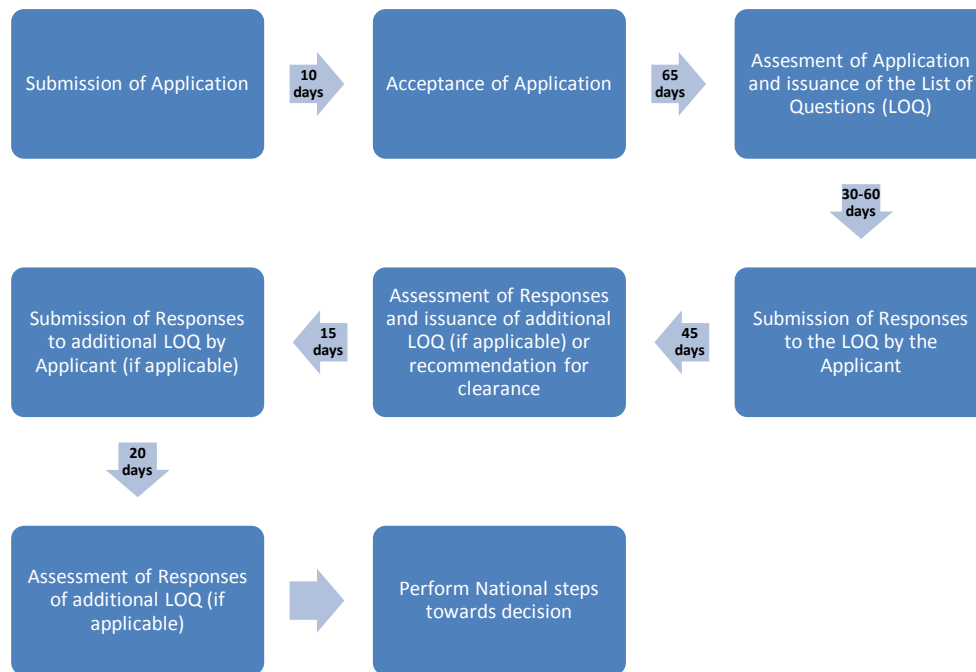
Any pharmaceutical (dosage) form would be considered for this work sharing trial.

7. What are the expected milestones and timelines for the various steps in the process?

Upon receipt of the EOI form, details of the application process, including expectations, requirements and timeframes for this trial will be discussed with potential applicants via teleconference and emails. It should be noted that very short timelines are suggested for this trial in order to gain experience on the potential opportunities associated with work sharing. It is acknowledged, however, that these timelines will not be representative of the process for the actual work sharing model when implemented. The proposed timelines and milestones for the trial are outlined below. All timelines should be interpreted as "calendar days". If a milestone falls on a weekend or a national holiday, the milestone will be the preceding business day.

- The time to respond to the first List of Questions (LOQ) is stated to be 30-60 days. The applicant will be able to respond any time after 30 days and before 60 days.

- The process allows for the possibility of a second LOQ and responses. If approval can be recommended after the assessment of the responses to the first LOQ, this step will be omitted.
- Thus, it is envisioned that the time from after acceptance of the application to the start of the national steps will take 175 to 205 days (or approximately 6 to 7 months), but this will be shorter if a second LOQ is not required.
- Following is a schematic representation of the expected milestones and timelines for the various steps in the process:



8. Will the participating agencies make a collective decision on the application?

No. Although it is anticipated that the procedures will lead to the same decision, each agency will make its own sovereign decision. Market authorisation or refusal by one agency will not affect the decision in the remaining participating agencies.

9. Will the applicant receive one List of Questions?

No. A List of Questions will be sent simultaneously by each agency to the respective local affiliate. The List of Questions will include identical questions regarding Modules 2-5. In addition, the communication to the local affiliate will include the country-specific questions regarding the Module 1 filed with the local agency. The applicant is expected to send the responses to all questions simultaneously to each of the respective agencies.

10. When will the clock for the timelines start to run?

The day of acceptance of the application for assessment by the RRA will be considered “Day 0” of the process.