ACSS CONSORTIUM
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Operational Procedures (OP)

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

Introduction

This document outlines operational procedures and recommendations for the planning and implementation of the Generic Medicines Work Sharing Trial (GMWST) for the regulatory agencies within the ACSS Consortium - Generic Medicines Working Group (GMWG). The GMWST is based on Europe's Decentralised Procedure. One agency acts as a Reference Regulatory Agency (RRA) and will evaluate Modules 2-5. Each of the other participating agencies will act as Concerned Regulatory Agencies (CRAs) and, with the RRA, will evaluate their respective Module 1. The CRAs will perform a peer review of the Assessment Reports (AR) provided by the RRA on Modules 2-5 and the application and provide supplementary comments (as needed).

Each agency makes its own sovereign decision based on the recommendations contained in the assessment reports. Although not anticipated, where during the process, it becomes apparent that there are insurmountable issues with the data that the participating agencies are unable to reconcile, the agencies have the option to seek additional information and undertake further review.

Applicant and Application selection

An applicant wishing to participate in this innovative work sharing trial will be required to submit an Expression of Interest (EOI) form to each agency proposed for this trial.

The applications for this trial should be submitted simultaneously to at least two, but preferably more, of the ACSS Consortium members.

It is preferable that the applicant plans to submit the same data set for Modules 2-5 to all agencies. However, it is not a requirement and if there are differences the completed "Summary of Differences" table (included in the EOI form) should be submitted, outlining the differences in the Quality and Bioequivalence study information provided to each participating agency. It is acknowledged that Module 1 will continue to be different for the dossiers filed in the different ACSS jurisdictions (as per regional requirements).

The applicant will be given the option to propose their preferred RRA. The ACSS Consortium agencies will take this preference into consideration, as well as other factors such as operational needs in choosing the RRA. Communication with potential applicants will clarify that the dossiers submitted should comprehensively address the requirements of all jurisdictions and that they need to work collaboratively with the agencies. While this might seem to make the application process more onerous initially, to achieve authorisation in more than one jurisdiction, the development of a single dossier that covers broader issues than for just a single agency can represent a reduction in regulatory burden and a return on the investment of effort for the applicant. Further, this trial not only provides the applicant with an opportunity to potentially access four markets at once, but also an opportunity to have their application assessed in a more efficient timeframe.

Any pharmaceutical (dosage) form would be eligible for this trial.

Operational approach

This section outlines the process steps and issues that will need to be considered as part of the implementation. The process needs to work concurrently within the regulatory systems of the participating agencies.

All timelines/days subsequently discussed in this Operational Procedures document 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.

Pre-submission teleconference

Once an EOI form is submitted, the participating agencies will convene to discuss the application, suitability, RRA and CRAs and the next steps. A pre-submission teleconference will be scheduled with the applicant and the ACSS agencies. It is recommended that the teleconference takes place at least two months prior to the filing of the application as it is important to discuss and confirm the logistics and expectations related to requirements, timelines, process and allow the agencies to respond to any queries from the applicant. The applicant will be requested to provide a list of queries for the ACSS agencies on the GMWST at least one week in advance of the pre-submission teleconference.

Submission of Application

Applications should be submitted to each agency simultaneously or as agreed with the agencies.

If applicable, the Active Substance Master File/Drug Master File will need to be submitted to each participating agency in advance of the filing of the application with the appropriate local forms.

Acceptance of Application

After receipt of the application, the RRA and CRAs would perform the technical and administrative screening of the data to ensure that their legislation and data requirements are met (e.g. application forms, user fees) to be accepted for assessment.

The RRA and CRAs will send a communication to the local applicants informing them of the acceptability of the application for assessment. The day of acceptance of the application for assessment by the RRA is “Day 0” of the process.

Timeframe: 10 days
(from filing to acceptance for assessment)

Assessment of Application

Assessment by RRA

RRA evaluates Modules 2-5 and prepares an Assessment Report (AR) and a List of Questions (LOQ). In parallel, the RRA and CRAs evaluate Module 1 and prepare a LOQ for Module 1. RRA shares the AR and LOQ on Modules 2-5 with the CRAs.

Timeframe: 40 days

Peer Review by CRAs

CRAs conduct a peer review of the AR and LOQ, consult the modules (as needed) and share additional questions on Modules 2-5 with the RRA.

Timeframe: 15 days

Finalisation of Assessment Reports and LOQ

RRA and CRAs discuss the LOQ and any additional questions. The additional questions of the CRAs follow the LOQ of the RRA and the questions are separated by agency.

RRA prepares the consolidated LOQ on Modules 2-5. RRA and the CRAs forward the consolidated LOQ on Modules 2-5 and their respective LOQ on Module 1 (including questions on product information and labelling) to the local applicant.

Timeframe: 10 days

Submission of Responses to the LOQ by the Applicant

Applicant sends complete responses to the consolidated LOQ on Modules 2-5 to RRA and CRAs via the respective local applicants. Concurrently, applicant sends responses to LOQ on Module 1 to the respective agencies.

Timeframe: 30-60 days

Assessment of Responses to LOQ

RRA prepares an AR of the responses on the consolidated LOQ for Modules 2-5 and shares it with the CRAs. Concurrently, RRA and CRAs prepare AR of responses to their respective LOQ on Module 1.

Timeframe: 30 days

Peer Review by CRAs of Responses

CRAs conduct a peer review of the AR of the responses and provide feedback. If necessary, RRA prepares an additional LOQ, which each agency sends to the local applicant (if applicable) or make recommendation for clearance.

Timeframe: 15 days

Submission of Responses to Additional LOQ by Applicant (if applicable)

Applicant sends responses to additional questions to RRA and CRAs.

Timeframe: 15 days

Assessment of Responses to additional LOQ (if applicable)

RRA prepares an AR of the responses to the additional questions.

Timeframe: 10 days

CRAs conduct a peer review of AR of the responses and provide feedback.

Timeframe: 10 days

National Steps

Each agency makes final decision (or seeks further clarification on issues separately before making final decision) and undertakes necessary administrative steps to finalise process domestically. Depending on each agency's assessment outcome, an authorisation letter or additional questions will be issued.

These communications may not be simultaneous.

Total maximum elapsed timeframe from the time after acceptance of the application to the start of the National Steps: 175-205 calendar days

Schematic representation of the expected milestones and timelines for the various steps in the process: