ACSS CONSORTIUM
AUSTRALIA
CANADA
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ACSS Consortium
New Chemical Entities Work-Sharing Pilot (NCEWSP)

Questions and Answers (Q&A)

Version	Description of Change	Effective Date
v 1.0	Document	September 2018

Frequently Asked Questions and Answers

1. What is the scope of the work-sharing pilot?

As part of the work-sharing pilot, a joint-review may be considered for new chemical entity or new biological entity applications that are submitted to more than one ACSS regulator. Application pathways considered for the work-sharing pilot are the standard and priority review pathways.

Applicants considering taking part in the work-sharing pilot should initiate early communication with the ACSS regulators in the countries where you are planning to submit your application.

2. What types of dosage forms are acceptable for this pilot?

Any pharmaceutical (dosage) form will be considered for this work-sharing pilot.

3. Does an application need to be submitted to all four ACSS regulators?

No. In the Expression of Interest (EOI) Request Form (available at https://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Western_Medicines/Worksharing.html), you can select which of the ACSS regulators you wish to submit your application for joint-review. Applications under a joint-review should be submitted to each regulator simultaneously or as agreed with the participating regulators.

4. Do Modules 2-5 of the dossier have to be identical in each country?

No, Modules 2-5 do not have to be identical across countries, but it is preferable that the same dossier be submitted to all the participating regulators. Where there are differences, the 'Summary of Differences between dossiers' (included in the EOI form) should be completed outlining the differences in information provided to each regulator. The participating regulators will discuss these differences with the applicants to determine if the application is suitable for the work-sharing pilot.

5. How will the joint-review be conducted?

Before the application is accepted for the work-sharing pilot, the participating regulators will negotiate a division of labour and develop a joint-review timeline that allows all regulators to meet their legislative obligations and/or performance standards. As an example, the joint-review could consist of one regulator evaluating Module 3 data, a second regulator evaluating Module 4 data, and either/both of these regulators evaluating Module 5 data.

Each regulator will evaluate their assigned Modules, and will discuss issues and share the outcomes with the other regulator(s) in the joint-review via scheduled teleconferences throughout the evaluation period.

6. Will the work-sharing process follow different evaluation timelines to the current pathways?

The timeline for the joint-review will depend on the pathway applied for by the applicants - standard pathway or priority review pathway. A joint timeline that adopts many of the milestones from the current pathways will be developed by the regulators involved in the joint-review. The regulators will seek agreement from the applicants if any changes to the evaluation timeline are required, e.g. changes to application response times to regulator questions.

7. How will regulator questions be handled?

The expectation is that all parties participating in the joint-review (regulators and applicants) will receive copies of regulator questions for Modules 3-5. Responses to regulator questions should be provided by the local applicant to the respective local regulator only where the local regulator has asked the question; for example, a response to Therapeutic Goods Administration (TGA) questions should be provided by the Australian applicant to the TGA, and a response to Health Sciences Authority (HSA) questions should be provided by the Singaporean applicant to HSA. The dossier must be updated in all jurisdictions to ensure that the application is complete, so a 'catch-up' sequence should be provided towards the end of the evaluation process that includes any updated data for Modules 3-5.

For joint-review of an application under the priority review pathway, regulator questions raised during the evaluation period will be 'rolling questions' throughout the evaluation period.

For joint-review of an application under the standard pathway, regulator questions will be consolidated and sent to all local applicants simultaneously at the end of the Round 1 evaluation.

Questions specific to a given jurisdiction, such as those related to labelling, will be sent as needed and only to the corresponding local applicant.

8. Will the work-sharing pilot impact the decision date?

Each regulator will retain the ability to make an independent decision on the market authorisation of the application. The decision date under the joint-review will be provided in the evaluation timeline, and is as agreed by the participating regulators and applicants. Each regulator is committed to meeting the required legislated timeframes and performance standards.

9. Will both regulators make a collective decision on the application?

No. Although it is anticipated that the joint-review may lead to the same decision, each regulator will maintain independent decision-making. Market authorisation or refusal of market authorisation by one regulator will not affect the decision or the timing of the decision by the remaining participating regulators.

10. Will product labelling be part of the joint-review process?

No. While there may be discussions between regulators about product labelling during the evaluation phase, different laws and frameworks exist in each country which affects regulatory decisions related to product labelling. It is likely that product labelling will differ from one jurisdiction to another.

11. When does the work-sharing pilot end?

It is anticipated that this work-sharing initiative will become a routine option for the review of applications submitted in multiple jurisdictions. Changes may be made to the process over time as participating regulators and industry build confidence in the process.

12. How do the regulators share information?

The ACSS regulators share information under a network of bilateral confidentiality agreements and Memoranda of Understanding. Information is shared through a secure collaborative document storage and management platform that is only accessible by authorised members within each ACSS regulator.