ACSS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND

ACSS Consortium New Active Substance Work-Sharing Initiative (NASWSI)

Questions and Answers (Q&A)

Frequently Asked Questions and Answers

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

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

Applicants considering taking part in the work-sharing should initiate early communication (3 – 6 months prior) with the ACSS regulators in the countries where you are planning to submit your application.

2. What are the benefits to the pharmaceutical industry?

The sponsor will be provided one set of consolidated questions per module across the regulatory agencies; this will generally mean a reduced number of questions. It will also provide the opportunity for the sponsor to use a global dossier and global resources for a global market access through a simultaneous evaluation process.

3. Are there additional fees for work-sharing?

No.

4. 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/international-collaboration/therapeutic-products/acss), 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 of the nominated regulators simultaneously or as agreed with the participating regulators.

5. What is the approach taken for pre-submission meetings and the project management in international work-sharing?

The international work-sharing pathway differs to standard pathways available in each jurisdiction, and hence sponsors could benefit from an early pre-submission meeting between regulators and affiliates to address any operational/logistical questions. A further technical pre-submission meeting may also be required as per the normal process in the relevant jurisdiction.

The technical and logistical meetings can be combined, but often technical queries can be different in the different jurisdictions, and having a combined meeting may not be an efficient option for the applicant.

6. 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 initiative.

7. How will ACSS determine which regulatory agency evaluates a particular module(s) and what impact will this have on the decision date?

Before the application is accepted for work-sharing, 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. Once the sponsor has nominated the regulatory agencies for the joint-review, the agencies will commence discussions to identify available resources, timeframes and

application specifics. Several factors influence the division of labour and this will differ with each application.
The decision date under the joint-review will be provided in the evaluation timeline, and is as agreed by the participating regulators and then communicated with applicants. 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.

8. What is the communication style and information sharing approach ACSS takes with work-sharing?
ACSS takes an open and transparent approach to communication, and encourages sponsors to ask questions about the process. Sponsors will be provided lead contact details for their submission, and will also receive email correspondence from the case manager regarding next steps and timeframes.
Though not all four regulatory agencies may be nominated for the joint-review, information is shared amongst all ACSS partners facilitating open and transparent communication.

9. What impact does priority vs standard pathway have on the list of questions?
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.
Generally, for a joint-review of an application under the standard pathway, regulator questions are often 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, are sent as needed and only to the corresponding local applicant.

10. How will the joint-review be conducted?
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.
The ACSS regulators share information under a network of bilateral confidentiality agreements and Memoranda of Understanding. Information is shared through a secure collaborative document exchange platform that is only accessible by authorised members within each ACSS regulator.

11. How will topics related to more than one module (e.g. impurities) be managed and shared with the applicant?
Sometimes there are impurities noted in clinical or quality data that need toxicological assessment, and this is easily managed through our open transparent communications with all jurisdictions throughout the process. If a toxicological assessment of impurities is required, it will be directed to the jurisdiction that is responsible for the non-clinical review in the work-sharing.
Bioavailability data is evaluated by different groups within the different jurisdictions; as such which partner evaluates the bioavailability data will be determined on a case by case basis.

12. How and when will the work sharing process end?
The work-sharing process normally concludes at the end of the evaluation phase as the process enters into the national steps. However, the jurisdictions may continue to canvass issues via email as the labelling and package material are being negotiated.

13. What is the process for LoQ and the timeframe requirements for sponsors to respond?
Participating regulatory agencies engage in discussions and evaluator teleconferences to draft common questions. The common and country specific (labelling/product information/risk management plan etc.) questions are provided to the sponsor to provide a response, the time in which question are provided is

dependent on the type of questions (rolling or batched), this process is agreed upon through the application pathway and ACSS- sponsor negotiations.

14. What are the expectations of the sponsor and the regulator in regards to LoQs?
Responses to LoQs 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 TGA questions should be provided by the Australian applicant to the TGA. The dossier must be updated in all jurisdictions to ensure that the application is complete. With respect to evaluation of the responses, this will be conducted by the country which has been allocated the specific module(s).

15. When reviewing a specific module does the regulatory agency responsible for that module take into consideration national guidelines solely for that country? Or will the national guidelines from the other health authorities be considered?
The national guidelines applicable to the specific jurisdiction are considered by the evaluating authority. If there are additional requirements or guidelines that need to be considered, a further abridged evaluation may be required by the other jurisdiction, and this is easily managed through regular teleconferences between the jurisdictions throughout the process.

16. What would be the process if there are any unresolved issues after the applicant had submitted all responses for the consolidated list of questions?
Any unresolved issues should be addressed in the national steps. Should there be major issues, each jurisdiction may make a sovereign decision on the basis of the information before them, or may seek further sponsor and/or expert comment.

17. 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. Therefore, regulatory decisions on product labelling will usually take place later in the review process, during or after the evaluation phase.

18. Will regulatory agencies accept a common label across jurisdictions?
No, refer to question 17.

19. Will all regulators involved in the joint-review make a collective decision on the application?
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.

20. Will there be any external/public communications on the ACSS website or via other media for the application, either after submission or after approval?
Yes. It is anticipated that communication regarding the application will be published.
Additional information regarding the ACSS initiative can be found:
TGA:
https://www.tga.gov.au/australia-canada-singapore-switzerland-acss-consortium

Health Canada:
https://www.canada.ca/en/health-canada/services/drugs-health-products/international-activities/australia-canada-singapore-switzerland-consortium.html

Swissmedic:
https://www.swissmedic.ch/swissmedic/en/home/about-us/international-collaboration/multilateral-co-operation-with-international-organisations---ini/multilateral-co-operation-with-international-organisations---ini.html