FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Australia-Canada-Singapore-Switzerland	**Agency Name:** ACSS Consortium	
Name of FRP: ACSS New Active Substance Work-Sharing Initiative		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: Click here to enter a date.		
1. Facilitates activities during development	**2. Accelerates the regulatory review process**	**3. Relies on or recognizes a prior regulatory decision**
☐	☒	☐

Is a Guidance or SOP describing how to apply this FRP publicly available?	Yes- see reference below
When should the FRP be requested?	Before the marketing authorisation submission
Does the agency provide assistance/advice to the sponsor?	Yes- For any product type
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	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 they are planning to submit their application.
Must the product address an unmet medical need or serious condition?	Negotiable
If a fee is required, what is the amount (in US$ equivalent)	There are no fees for this work-sharing initiative. The applicant only has to pay the application and evaluation fees set by each regulatory authority. A considerable amount of coordination and resources are used to facilitate the international work-sharing initiative, therefore cost-recovery needs to be maintained by the regulatory agencies.
Total target (agency) time for assessment (calendar days)	Regulators will provide clarity to the Sponsor on the work sharing approach and establish key milestones at the earliest opportunity.
Total target (company) time for responses to agency questions (If stated)	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 questions 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. The timeframe in which a response is required from a sponsor is dependent on the requirements of the regulator performing the lead evaluation for the allocated module i.e. TGA, 30 or 60 days, as agreed prior, or Health

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	Canada 15 days.	
Select one of the following (* see definitions at end of document)		
Is this a verification review (a recognition pathway)?*	**Is this an abridged* review (selected dossier portions)? (a reliance pathway)?***	**Is this a full* review of all parts of the dossier?**
☐	☐	☒
If this is a reliance or recognition pathway, what are the accepted reference agencies?	Not applicable. This is a work-sharing initiative involving 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.	
How many reference agency decisions are required?	This is a work-sharing initiative involving 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. 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.	
Does this FRP require submission of Assessment Reports from prior decisions?	Not applicable	
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Not applicable	
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Not applicable	
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	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.	
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Not applicable	
How are queries to the companies sent?	In batches	
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.	
Post-authorization study commitments	Always required	

FRPath.org Country and FRP Information Input Form	
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- The ACSS Consortium consists of various projects that aim to help meet the challenges faced by regulatory authorities, including timely access to safe therapeutic products within a limited resource capacity. The ACSS uses a network of bilateral confidentiality agreements and Memoranda of Understanding to conduct their work. - The purpose of the consortium is to build synergies and share knowledge amongst the regulatory authorities therefore enhancing efficiency of regulatory systems. - The Consortium explores opportunities for information and work-sharing initiatives in areas including: assessing therapeutic product manufacturing sites; post-market surveillance of therapeutic product safety; assessment reports for medicinal products; development of technical guidelines and regulatory standards; and collaboration on information technology (IT). - Advance Notice: Early interactions with regulators are important for assessing whether work sharing is a feasible option, and for assisting with alignment and planning discussions. Industry is invited to submit an Expression of Interest (EOI) at least 3 months before the intended filing date. If possible however, sponsors should provide the EOI up to 6 months in advance, in particular for a priority review submission or when seeking a technical pre-submission meeting. - Coordinated Filing: Sponsors are required to file separate applications to each regulator where a market authorization is intended: independently within a two-week window of each other; and to the same pathway (i.e., standard or priority) across all partner regulators. - Consistency in Submission Information Provided: The content of submissions across partner regulators should be consistent, with the exception of select nation-specific application requirements which should be noted in the EOI. A sponsor seeking consideration for a priority review will need to indicate that interest when filing the EOI with each partner regulator. - 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.
Date of this update	26 July 2020
References	1. ACSS Consortium. Accessed on 26 July 2020. 2. EU Regulatory Roundup: Swissmedic Authorizes First Drug Under International Work Sharing Initiative. https://www.raps.org/news-and-articles/news-articles/2020/2/eu-regulatory-roundup-swissmedic-authorizes-first Accessed on 26 July 2020. 3. ACSS - NAS work sharing initiative. Accessed on 26 July 2020. 4. ACSS - NAS work sharing initiative: Q&A. https://www.tga.gov.au/acss-nas-work-sharing-initiative-qa Accessed on 26 July 2020.

*Definitions:

Verification review: A checklist review based on recognition of a prior regulatory decision. Recognition is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of economy A is sufficient to meet the regulatory requirements of economy B.

Abridged review: An abbreviated review of selected portions of the dossier and the reliance on prior assessment decisions. Reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Full review: A comprehensive review of all components of the dossier. This may or may not be CPP-dependent. This may form part of a reliance or recognition pathway.