ACSS CONSORTIUM
AUSTRALIA
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SWITZERLAND

Expression of Interest (EOI) Request Form

ACSS Consortium
New Chemical Entity (NCE) Medicines Work Sharing Pilot (NCEWSP)

Version	Description of Change	Author	Effective Date
V1.0	Original publication	ACSS NCE WG	September 2017
v 1.1	update	ACSS NCEWSP	March 2018

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Expression Of Interest (EOI) Request Form to Participate in the ACSS Consortium NCE Medicines Work Sharing Pilot

NCE Information			
Product Name (should be same as on product label):			
Active Pharmaceutical Ingredient:			
Pharmaceutical Form	Route of Administration	Strength	Indications

Applicant Information	
Sponsor Name (Full legal name):	
Address:	
Contact Person:	
Tel:	Email:

Application/submission filing information

Please note that applications should be submitted to each participating agency simultaneously, ideally within 15 calendar days.

ACSS Consortium agencies proposed for this pilot are as follows:

- ☐ Australia (Therapeutic Goods Administration (TGA)) Filing date of dossier:
- ☐ Canada (Health Canada (HC)) Filing date of dossier:
- ☐ Singapore (Health Sciences Authority (HSA)) Filing date of dossier:
- ☐ Switzerland (Swissmedic (SMC)) Filing date of dossier:

☐ A Summary of Differences between the submitted dossiers is included as part of this EOI request.

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Consent to share regulatory information
The undersigned hereby acknowledges and gives consent to the sharing of assessment reports and information: ☐ with all ACSS Consortium agencies*:_____ Name of Authorised Signing Official: _____ Title, Company:_____ Signature**:_____ Date: _____ * The ACSS Consortium comprises the medicines regulatory agencies from the following jurisdictions: Australia, Canada, Singapore, and Switzerland. ** Signatures (including digital/electronic versions, where permitted) must comply with the legal requirements of the jurisdiction(s) in which the EOI is being submitted.

ACSS Consortium

Australia-Canada-Singapore-Switzerland Consortium

Summary of Differences between dossiers

This form must be completed and submitted to each ACSS Consortium agency proposed in the EOI Request.

Modules and numbering reflect the ICH Common Technical Document. For modules/sub-modules where there are no differences between the dossiers filed between agencies should be reported as "No differences" (ND). Where minor differences exist for any particular module/sub-module, **a brief summary** of the differences should be described.

If complete information on the differences between dossiers is not available at the time of the filing of the EOI request form, the form should be completed with the available information; the remaining information should be provided at a later time, but prior to the filing of the applications.

Module	Information in application to be filed with the proposed agencies (specify TGA, HC, HSA, or SMC):				Brief discussion of differences
	TGA Australia	**Health Canada**	**HSA Singapore** *(if applicable)*	**Swissmedic** *(if applicable)*	
Module 3 ***3.2.S Drug Substance***					
3.2.S.1 General Information					
3.2.S.2 Manufacture					
3.2.S.3 Characterisation					
3.2.S.4 Control of the Drug Substance					

Module	Information in application to be filed with the proposed agencies (specify TGA, HC, HSA, or SMC):				Brief discussion of differences
	TGA Australia	**Health Canada**	**HSA Singapore** *(if applicable)*	**Swissmedic** *(if applicable)*	
3.2.S.5 Reference Standards or Materials					
3.2.S.6 Container Closure System					
3.2.S.7 Stability					
3.2.P Drug Product					
3.2.P.1 Description and Composition of the Drug Product					
3.2.P.2 Pharmaceutical Development					
3.2.P.3 Manufacture					
3.2.P.4 Control of Excipients					
3.2.P.5 Control of Drug Product					
3.2.P.6 Reference Standards or Materials					
3.2.P.7 Container Closure System					

Module	Information in application to be filed with the proposed agencies (specify TGA, HC, HSA, or SMC):				Brief discussion of differences
	TGA Australia	Health Canada	HSA Singapore *(if applicable)*	Swissmedic *(if applicable)*	
3.2.P.8 Stability					
Module 4					
4.2 Study Reports					
4.2.1 Pharmacology					
4.2.2 Pharmacokinetics					
4.2.3 Toxicology					
4.2.3.1 Single-dose toxicity					
4.2.3.2 Repeat-dose toxicity					
4.2.3.3 Genotoxicity					
4.2.3.4 Carcinogenicity					
4.2.3.5 Reproductive and Developmental Toxicity					

Module	Information in application to be filed with the proposed agencies (specify TGA, HC, HSA, or SMC):				Brief discussion of differences
	TGA Australia	**Health Canada**	**HSA Singapore** *(if applicable)*	**Swissmedic** *(if applicable)*	
4.2.3.X Any other differences					
4.3 Literature References					
Module 5					
5.2 Tabular Listing of all Clinical Studies					
5.3 Clinical Study Reports					
5.3.1 Reports of Biopharmaceutic Studies					
5.3.2 Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials					
5.3.3 Reports of Human Pharmacokinetic (PK) Studies					
5.3.4 Reports of Human Pharmacodynamic (PD) Studies					

Module	Information in application to be filed with the proposed agencies (specify TGA, HC, HSA, or SMC):				Brief discussion of differences
	TGA Australia	**Health Canada**	**HSA Singapore** *(if applicable)*	**Swissmedic** *(if applicable)*	
5.3.5 Reports of Efficacy and Safety Studies					
5.3.6 Reports of Post-Marketing Experience					
5.3.7 Case Report Forms and Individual Patient Listings					
5.4 Literature References					