Expression Of Interest (EOI) Form

Access Consortium
Generic Medicines Work Sharing Initiative (GMWSI)

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
v 3.0	Updated to include process enhancements, addition of UK's MHRA and feedback from stakeholders	Access Generic Medicines WG	2022-10-30

Expression of Interest (EOI) Form to Participate in the Access Consortium Generic Medicines Work Sharing Initiative (GMSWI)

Generic Product Information		
Product Name (should be same as on product label):		
ATC Code:		
Additional Comments:		
Pharmaceutical Form	Strength(s) with units	Route of Administration

Active Pharmaceutical Ingredient (API) Information		
API (including salt and solvated form, if applicable):		
☐ Sterile	☐ Semi-synthetic	☐ Fermentation
How many Active Substance Master File (ASMF)/Drug Master File (DMF) will be submitted?		
How many Certificates of Suitability (CEP) will be submitted?		

National Reference Product Information	
Product Name	Authorisation Holder/Sponsor

Comparator product used in bioequivalence study		
Product Name	Authorisation Holder/Sponsor	Country of origin

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

Application/submission filing information

Access Consortium agencies proposed for this Initiative application are as follows:

☐ Australia (Therapeutic Goods Administration (TGA)) Proposed filing date:
☐ Canada (Health Canada (HC)) Proposed filing date:
☐ Singapore (Health Sciences Authority (HSA)) Proposed filing date:
☐ Switzerland (Swissmedic (SMC)) Proposed filing date:
☐ United Kingdom (Medicines and Healthcare products Regulatory Agency (MHRA)) Proposed filing date:

Please note that applications should be submitted to each participating agency simultaneously or as agreed with the participating agencies. If applicable, the ASMF/DMF must be submitted to each participating agency in advance of the filing of the application.

Nominated response time to List of Questions (LoQ):

○ 30 calendar days
○ 60 calendar days

Please note that the agencies will negotiate an evaluation plan with the applicant.

Consent to share regulatory information (to be signed by the applicant)

The undersigned hereby acknowledges and gives consent to the sharing of assessment reports and information with all Access Consortium agencies*.

Name of Authorized Signing Official:

Title, Company:

Signature**:

Date:

*The Access Consortium comprises the regulatory agencies from the following jurisdictions: Australia, Canada, Singapore, Switzerland and United Kingdom.

**Signatures (including digital/electronic versions, where permitted) must comply with the legal requirements of the jurisdiction(s) in which the EOI is being submitted.

Publication of the Registration Decision

For products evaluated under the international work-sharing process, an assessment report or similar documentation which supports the regulatory decision will be published, as per the standard process in each jurisdiction, where applicable. Agencies may publish a Public Assessment Report for products evaluated under the work-sharing process which may make reference to a foreign evaluation report. Similarly, where applicable, a publication process to support the regulatory decision will also be completed. All decisions will be published when an evaluation has been completed as part of the application.

Please indicate your understanding of this publication process

- ☐ I understand that all regulatory decisions relating to my application and product will be published across all jurisdictions, where applicable, involved with the international work-sharing process.

Consent to share regulatory information on the Restricted Part of the ASMF/DMF (to be signed by the ASMF/DMF holder)

The undersigned hereby acknowledges and gives consent to the sharing of assessment reports and information on the restricted part of the ASMF/DMF with all Access Consortium agencies*.

Name of Authorized Signing Official:

Title, Company:

Signature**:

Date:

*The Access Consortium comprises the Regulatory Agencies from the following jurisdictions: Australia, Canada, Singapore, Switzerland and United Kingdom.

**Signatures (including digital/electronic versions, where permitted) must comply with the legal requirements of the jurisdiction(s) in which the EOI is being submitted.

Summary of Differences

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

Modules and numbering reflect the ICH Common Technical Document. For modules/sub-modules which are **identical** for the dossiers filed between agencies, leave cell blank to report no differences. Where minor differences exist for any particular module/sub-module **a brief summary** of the differences should be described, and an X included in the corresponding cell(s). All differences in the dossier must be identified. 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 pre-submission teleconference.

Module	**Information in application to be filed with the proposed agencies (specify TGA, HC, HSA, SMC or MHRA):**					**Brief discussion of differences**
	TGA Australia	**Health Canada**	**HSA Singapore**	**Swissmedic Switzerland**	**MHRA UK**	
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, SMC or MHRA):					Brief discussion of differences
	TGA Australia	Health Canada	HSA Singapore	Swissmedic Switzerland	MHRA UK	
3.2.S.5 Reference Standard or Materials						
3.2.S.6 Container Closure System						
3.2.S.7 Stability						

Module	Information in application to be filed with the proposed agencies (specify TGA, HC, HSA, SMC or MHRA):					Brief discussion of differences
	TGA Australia	Health Canada	HSA Singapore	Swissmedic Switzerland	MHRA UK	
3.2.P Drug Product						
3.2.P.1 Description and Composition of the Drug Product						
3.2.P.2 Pharmaceutical Development						

Module	Information in application to be filed with the proposed agencies (specify TGA, HC, HSA, SMC or MHRA):					Brief discussion of differences
	TGA Australia	Health Canada	HSA Singapore	Swissmedic Switzerland	MHRA UK	
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 Standard or Materials						
3.2.P.7 Container Closure System						
3.2.P.8 Stability						

Summary of Bioequivalence Studies Differences						
	TGA Australia	**Health Canada**	**HSA Singapore**	**Swissmedic Switzerland**	**MHRA UK**	**Brief discussion of differences**
Synopsis of Biostudy(ies)						
Reference Product Used including details of source country of Reference Product						
Indications approved for the reference product						
Approved strengths of reference product						

Additional Module 4/5 Differences						
Additional Modules	**TGA Australia**	**Health Canada**	**HSA Singapore**	**Swissmedic Switzerland**	**MHRA UK**	**Brief discussion of differences**
(Additional Module-1)						

Additional Module 4/5 Differences						
Additional Modules	**TGA Australia**	**Health Canada**	**HSA Singapore**	**Swissmedic Switzerland**	**MHRA UK**	**Brief discussion of differences**
(Additional Module-2)						
(Additional Module-3)						
(Additional Module-4)						