



# Expression of Interest (EOI) Request Form

## Access Consortium New Active Substance Work Sharing Initiative (NASWSI)

Version	Description of Change	Author	Effective Date
v1.0	Original publication	ACSS NCE WG	September 2017
v 1.1	Update	ACSS NCEWSP	March 2018
v.1.2	Update	ACSS NAS WSI	January 2019
v.1.3	Update	ACCESS NAS WSI	January 2021
v.1.4	Update	Access NAS WSI	January 2026

## ***Expression Of Interest (EOI) Form to Participate in the Access Consortium New Active Substance Work Sharing Initiative (NASWSI)***

<b>NAS Information</b>				
Product Name (should be same as on product label):				
Active Pharmaceutical Ingredient:				
ATC Code:				
Additional Comments (e.g. PIP or Orphan designation in any jurisdiction, NAS used with a medical device):				
Pharmaceutical Form	Route of Administration	Strength(s) with units	Indication(s)	Dosage Recommendation
<b>Applicant Information</b>				
Company Name (Full legal name):				
Address:				
Contact Person:				
Tel:		Email:		
<b>Application/submission filing information</b>				
Please note that applications should be submitted to each participating agency simultaneously, ideally within 15 calendar days.				
Access NASWSI considers applications for New Products and for New Indications. Please specify the proposed NASWSI application type:				
<input type="checkbox"/> New Product <input type="checkbox"/> New Indication				
Timelines:				
<input type="checkbox"/> Standard				
<input type="checkbox"/> Promise <sup>1</sup> <input type="checkbox"/> Standard, in case Promise eligibility criteria are not fulfilled				
<input type="checkbox"/> Priority <sup>1</sup> <input type="checkbox"/> Standard, in case Priority eligibility criteria are not fulfilled				

<sup>1</sup> Please be advised that participating Access agencies will need to determine whether the eligibility criteria have been met in all countries.

Access Consortium agencies proposed for work-share are as follows:

- |  |                          |
|--|--------------------------|
| <input type="checkbox"/> Australia (Therapeutic Goods Administration (TGA))                          | Filing date of dossier*: |
| <input type="checkbox"/> Canada (Health Canada (HC))   | Filing date of dossier*: |
| <input type="checkbox"/> Singapore (Health Sciences Authority (HSA))                                 | Filing date of dossier*: |
| <input type="checkbox"/> Switzerland (Swissmedic (SMC))  | Filing date of dossier*: |
| <input type="checkbox"/> United Kingdom (Medicines and Healthcare products Regulatory Agency (MHRA)) | Filing date of dossier*: |

\* Please include proposed date of Promise/Priority review request if applying for Promise/Priority review.

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.

**Foreign regulatory status**

Please provide the regulatory status of applications for this New Product or New Indication that have been submitted (or are planned in the next 12 months) to international regulatory authorities other than the agencies proposed for inclusion in this work-share.

<b>REGULATORY AUTHORITY</b>	<b>PRE-SUBMISSION ADVICE</b>	<b>SUBMISSION DATE</b>	<b>STATUS</b>	<b>INDICATION (approved or requested)</b>
FDA	<input type="checkbox"/> Yes* <input type="checkbox"/> None received			
EMA	<input type="checkbox"/> Yes* <input type="checkbox"/> None received			
Access Consortium agencies not included in this work-share				

\* Please attach any meeting minutes and/or written pre-submission/scientific advice received.

**Consent to share regulatory information**

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

Name of Authorised Signing Official: \_\_\_\_\_

Title, Company: \_\_\_\_\_

Signature \*\*: \_\_\_\_\_

Date: \_\_\_\_\_

\* The Access Consortium comprises the medicines 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. The TGA publishes an Australian Public Assessment Report (AusPAR) for products containing new chemical entities, and for products evaluated under the work-sharing process, the AusPAR will make reference to the overseas evaluation report. Similarly, in other jurisdictions, 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.



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

The modules and numbering below reflect the ICH Common Technical Document format. For the tables related to regional differences between dossiers, the modules/sub-modules which are **identical** for the dossiers filed between agencies can be left 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 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 for market authorization.

## General Information

<p><b>Description of the molecule and mechanism of action</b></p> <p>(for example, synthetically or biologically derived, target receptor)</p>	
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## Module 3

### Summary of dossier contents

For NAS-related applications, please complete the following table or provide the same information via separate attachments. If available, complete module 2 summaries can also be provided as separate attachments.

If complete information is not provided at the time of filing the EOI request form then please provide an estimated date for filing an updated version that contains complete information: [DD/MM/YYYY]

<p><b>Summary of manufacturing process/flow chart for the drug substance</b></p>	
<p><b>Summary of manufacturing process/flow chart for the drug product</b></p>	
<p><b>Drug substance manufacturing site(s)</b></p>	



<b>Drug product manufacturing site(s)</b>	



**Summary of regional differences between dossiers**

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	
<b>Module 3</b>						
<b>3.2.S Drug Substance</b>						
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						
3.2.S.5 Reference Standards 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	
<b>3.2.P Drug Product</b>						
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						
3.2.P.8 Stability						



## Module 4

### Summary of dossier contents

Please complete the following table or provide a tabular list of non-clinical studies via separate attachment. If available, complete module 2 summaries can also be provided as separate attachments.

If complete information is not provided at the time of filing the EOI request form then please provide an estimated date for filing an updated version that contains complete information: [DD/MM/YYYY]

Study Number	Study Type	Study Description	Administration type	Test system	GLP compliance (yes/no)

### Summary of regional differences between dossiers

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	
<b>Module 4</b>						
4.2 Study Reports						



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	
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						
4.2.3.X Any other differences						
4.3 Literature References						



## Module 5

### Summary of dossier contents

Please complete the following table or provide a tabular list of clinical studies via separate attachment. If available, complete module 2 summaries can also be provided as separate attachments.

If complete information is not provided at the time of filing the EOI request form then please provide an estimated date for filing an updated version that contains complete information: [DD/MM/YYYY]

Study Number	Study Title	Phase	Study Design	Patient population, number of subjects enrolled	API, dose, route, regimen, comparator	Primary Endpoint(s)	Pivotal (Y/N); date efficacy results available

#### Pivotal Safety and Efficacy Findings

In the box below or via separate attachment, please provide a summary of the pivotal safety and efficacy findings. If the pivotal safety and efficacy data are not yet available, please provide an estimated completion date.



**Regional differences between dossiers**

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	
<b>Module 5</b>						
5.2 Tabular Listing of all Clinical Studies						
5.3 Clinical Study Reports						



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	
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						
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						



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	
5.4 Literature References						