ACSS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND

# Expression Of Interest (EOI) Form

## ACSS Consortium
## Generic Medicines Work Sharing Trial (GMWST)

| 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 |
| | | | |

# *Expression of Interest (EOI) Form to Participate in the ACSS Consortium Generic Medicines Work Sharing Trial*

**Product Information**

**Product Name (should be same as on product label):**

**Pharmaceutical (dosage) Form:**

| Pharmaceutical Form | Route | Strength(s) |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

**Active Pharmaceutical Ingredient**

Name (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?

**Applicant Information**

| | |
|---|---|
| Name (Full legal name): | |
| Address: | |
| Contact Person: | |
| Tel: | Email: |

**Application/submission filing information**

Proposed Reference Regulatory Agency (RRA):

Please also 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.

ACSS Consortium agencies proposed for this Trial 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:

| **Consent to share regulatory information (to be signed by the applicant)** |
| --- |
| The undersigned hereby acknowledges and gives consent to the sharing of assessment reports amongst the ACSS Consortium agencies*.<br><br>Name of Authorized Signing Official:<br><br>Title, Company:<br><br>Signature**:<br><br>Date:<br><br>*The ACSS Consortium comprises the Regulatory Agencies from the following jurisdictions: Australia, Canada, Singapore, and Switzerland.<br><br>**Signatures (including digital/electronic versions, where permitted) must comply with the legal requirements of the jurisdiction(s) in which the EOI is being submitted. |

| **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 on the restricted part of the ASMF/DMF amongst the ACSS Consortium agencies*.<br><br>Name of Authorized Signing Official:<br><br>Title, Company:<br><br>Signature**:<br><br>Date:<br><br>*The ACSS Consortium comprises the Regulatory Agencies from the following jurisdictions: Australia, Canada, Singapore, and Switzerland.<br><br>**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 -** Modules and numbering reflect the ICH Common Technical Document. Sections where there are no differences between the products filed with the RRA and the other agencies should be reported as "No differences". Where minor differences exist for a listed Section, **a brief summary** of the details should be described.

If the complete information on the differences is not available at the time of the filing of the EOI form, the form should be completed with the available information and the remaining information should be provided at a later time prior to the filing of the application.

| **Summary of Quality Differences** | | | | | |
|---|---|---|---|---|---|
| | **Information in application to be filed with the proposed RRA (please specify TGA, HC, SMC or HSA):** | **Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):** | **Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):** | **Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):** | **Brief discussion of noted differences** |
| **Module** | | | | | |
| ***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 | | | | | |
| 3.2.S.5 Reference Standard or Materials | | | | | |

| Summary of Quality Differences | | | | | |
|---|---|---|---|---|---|
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| 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 Standard or Materials | | | | | |

| Summary of Quality Differences | | | | | |
|---|---|---|---|---|---|
| | **Information in application to be filed with the proposed RRA (please specify TGA, HC, SMC or HSA):** | **Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):** | **Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):** | **Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):** | **Brief discussion of noted differences** |
| 3.2.P.7 Container Closure System | | | | | |
| 3.2.P.8 Stability | | | | | |

| Summary of Bioequivalence Studies Differences | | | | | |
|---|---|---|---|---|---|
| | **Information in application to be filed with the proposed RRA (please specify TGA, HC, SMC or HSA):** | **Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):** | **Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):** | **Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):** | **Brief discussion of noted differences** |
| Synopsis of Biostudy(ies) | | | | | |
| Reference Product Used | | | | | |
| Indications approved for the reference product | | | | | |
| Approved strengths of reference product | | | | | |