Expression of Interest (EOI)

Request Form

Access Consortium

New Active Substance (NAS) Medicines

Work Sharing Initiative (NASWSI)

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| --- | --- | --- | --- |
| 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 |

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

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| **NAS Information** | | | | | |
| 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 |
|  |  | |  |  |  |
|  |  | |  |  |  |
| **Applicant Information** | | | | | |
| Company 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. | | | | | |
| Access NASWI considers applications for New Products and for New Indications. Please specify the proposed NASWI application type:  New Product  New Indication  Timelines:  Standard  Priority | | | | | |
| Access Consortium agencies proposed for work-share 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\*:  United Kingdom (Medicines and Healthcare products Regulatory Agency (MHRA)) Filing date of dossier\*:  \* Please include proposed date of priority review proposal to each jurisdiction if applying for 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. | | | | | |

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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 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. |

**Summary of Differences between dossiers**

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 filing of the applications.

| **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** |
| **Module 3[[1]](#footnote-2)\*** | | | | | | |
| ***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 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 |  |  |  |  |  |  |
| 3.2.P.8 Stability |  |  |  |  |  |  |
| **Module 4[[2]](#footnote-3)\*** | | | | | | |
| 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 |  |  |  |  |  |  |
| 4.2.3.X Any other differences |  |  |  |  |  |  |
| 4.3 Literature References |  |  |  |  |  |  |
| **Module 5[[3]](#footnote-4)\*** | | | | | | |
| 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 |  |  |  |  |  |  |
| 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 |  |  |  |  |  |  |

1. \* If available, for NAS, please provide an overview of the type of molecule, mechanism of action, summary of manufacturing process/flow chart for the drug product and drug substance and manufacturing site. [↑](#footnote-ref-2)
2. \* If available, please provide a list of Non-Clinical Studies (number, type, title and description) [↑](#footnote-ref-3)
3. \* If available, please provide a list of Clinical Studies (number, type, title and description) [↑](#footnote-ref-4)