Expression of Interest (EOI)

Form

Access Consortium

Biosimilar Working Group (BSWG)

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| Version | Description of Change | Author | Effective Date |
| V1.0 | Original publication | Access BSWG | January 2021 |
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***Expression of Interest (EOI) Form to Participate in the Access Consortium Biosimilar Medicines Work Sharing Initiative (BSWSI)***

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| --- | --- | --- | --- | --- | --- |
| **BSWSI 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, biosimilar 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 BSWSI considers standard timelines applications for Biosimilars. | | | | | |
| 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: | | | | | |
| 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. In each 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.

1. Module 1 of the CTD submission will be country specific.
2. It is expected that the formulation of the final product will be identical across all Access jurisdictions. Products with different formulations are not easily amenable to workshare and the sponsor should seek alternative pathway
3. The proposed manufacturing process and sites for the drug substance (DS) and drug product (DP) should be identical in the registration dossier to be submitted. If differences in manufacturing process and/or sites are envisaged this should be submitted separately as variation after the completion of the joint approval process.
4. For comparability assessment, we prefer that the key reference medicine (RM) be EU/US sourced. Please note that the EU/US-sourced RM may need to be bridged to specific Access country-sourced RM (see point 4 below).
5. There may be unique requirements for biosimilar comparability across different Access jurisdictions. Please complete Table 2 below to highlight these differences. While a broad-based comparability assessment would be attempted, please note that country-specific requirements will still have to be met.

| **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 |  |  |  |  |  |  |
| ***3.2.A Appendices*** | | | | | | |
| 3.2.A.2 Adventitious agents safety evaluation |  |  |  |  |  |  |
| ***3.2.R Regional Information*** | | | | | | |
| 3.2.R Biosimilar comparability evaluation |  |  |  |  |  |  |
| **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 |  |  |  |  |  |  |
| **Reference Medicine** | | | | | | |
| Reference Medicine Used |  |  |  |  |  |  |
| Indications approved for the reference medicine |  |  |  |  |  |  |
| Approved strengths of reference medicine |  |  |  |  |  |  |

**Table 2: Use/choice of reference medicine (RM) for biosimilar comparability**

|  |  | **Explanation and additional data location** |
| --- | --- | --- |
| 1. RM for comparability is EU/US-sourced? | Yes  No\* |  |
| 1. Would bridging data (or acceptable evidence) to demonstrate equivalence of the RM to relevant Access country-sourced RM be provided?\*\* | Yes  No |  |
| 1. RM registered in all Access countries based on full quality, safety and efficacy data? | Yes  No\*\*\* |  |

\*Please note that for ease of ACCESS biosimilars workshare, the preference is to use US/EU-sourced RM for main comparability studies

\*\*Please refer to individual ACCESS country requirements for bridging studies

\*\*\*If the answer to this is ‘No’, please specify which country in the table above.

1. \* If available, for biosimilar, 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)