FACILITATING ACCESS WORK SHARING FOR BIOSIMILARS

Building on the experience of international work sharing initiatives under the Access Consortium, this document outlines key information for industry in filing an international work sharing submission for biosimilars. Access work sharing offers sponsors:

- **Streamlined process** – internationally coordinated review to reduce duplication and burden
- **Increased Access** – possibility of simultaneous access to markets of multiple countries
- **Flexibility** – adaptability in how regulators organize collaboration amongst each other on a given review and which countries a company chooses to submit applications
- **Predictability** – pre-determined milestones and targeted review timeframes

Pathways

New drug submissions filed with <u>two or more</u> partner regulators for a **new biosimilar**.

Guidance for Industry

1. **Advance Notice**: Early interactions with regulators are important for assessing whether work sharing is a feasible option, and for assisting with alignment and planning discussions.

    - If possible, sponsors should provide the Expression of Interest (EOI) form up to *6 months* in advance, in particular when seeking a technical pre-submission meeting.

    - Industry is invited to submit an EOI form *at least **3 months*** before the intended filing date.

    - Interested applicants are invited to participate by contacting their regional regulatory authority.

        - Canada: hc.collaboration.sc@canada.ca
        - Australia: streamlinedsubmission@health.gov.au
        - Singapore: HSA_TP_Enquiry@hsa.gov.sg
        - Switzerland: Networking@swissmedic.ch
        - United Kingdom: access-mhra@mhra.gov.uk

    Communications via email should include "Access Consortium – Biosimilars Work Sharing" in the subject line.

2. **Coordinated Filing**: Sponsors are required to file separate applications to each participating regulator *within a **two-week window** of each other*[1]

3. **Consistency in Submission of Information Provided:** The content of submissions across partner regulators should be consistent, with the exception of select nation-specific application requirements that should be noted in the EOI form.

Regulatory Commitments

[1] In some instances, earlier filing to some jurisdictions may be needed due to differences in screening procedures.

1. **Predictability and transparency:** Sponsors will be informed (typically within 6 weeks) of the potential for work sharing prior to the filing of the dossier. Partner regulators will identify the following: the lead regulator; project milestones; review stream leads; and model of collaboration deemed appropriate for the submission. Regulators will then inform the Sponsor on the work sharing approach and the key milestones at the earliest opportunity.

2. **Coordinated approach:** Sponsors can expect key communications from regulators according to the project milestones and using the standard communication modes (e.g. clarification requests, announcements of positive decisions or authorizations).

3. **Sovereign Processes and Decisions:** Countries will maintain their sovereign processes and decision-making. For example, national procedures will be followed at : i) at the validation/screening stage; ii) at the labelling stage (e.g. indication, PM, container labels) and iii) at the stage of authorization or rejection of market authorization.