FACILITATING ACSS WORK SHARING FOR NEW CHEMICAL AND BIOLOGICAL ENTITIES

Building on the experience of international work sharing pilots under the Australia Canada Singapore Switzerland (ACSS) Consortium, this document outlines key information for industry in filing an international work sharing submission. ACSS 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 two or more partner regulators for a **new chemical** or **biological entity.**

Two potential pathways, *upon agreement of all partner regulators*, to which a submission was filed:

i. Standard

ii. Priority (expedited, e.g., for drugs with an unmet medical need) [1]

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.
   - Industry is invited to submit an Expression of Interest (EOI) *at least **3 months*** before the intended filing date.
   - If possible however, sponsors should provide the EOI up to *6 months* in advance, in particular for a priority review submission or when seeking a technical pre-submission meeting.

2. **Coordinated Filing**: Sponsors are required to file separate applications to each regulator where a market authorization is intended:
   - *independently within a **two-week window** of each other[2]; and*
   - to the *same pathway (i.e., standard or priority[3]) across all partner regulators.*

3. **Consistency in Submission Information Provided:** The content of submissions across partner regulators should be consistent, with the exception of select nation-specific application requirements, which should be noted in the EOI. A sponsor seeking consideration for a priority review will need to indicate that interest when filing the EOI with each partner regulator[1].

[1] Priority designation remains a sovereign decision (i.e., industry has to apply to each jurisdiction) and receive priority designation in all of the jurisdictions to which they applied. If different decisions are made, a sponsor must choose if they wish to proceed with only the regulators who have made it a priority or whether they wish to apply to all regulators under the standard pathway.

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

[3] There are different jurisdictional processes for priority designation – sponsors will need to consider any additional lead-time required in a particular jurisdiction where a priority pathway requires designation before filing of dossier.

Regulatory Commitments

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

2. **Coordinated approach** - Sponsors can expect coordinated key communications from regulators. Partner regulators will have protocols for when, and in what form, key communications would be transmitted to sponsors and/or the public across regulators (e.g., clarification requests, announcements of positive decisions or approvals).

3. **Sovereign Decisions:** Countries will maintain sovereign decision-making. Some specific areas where national decision-making procedures should be noted: i) determination/designation of a submission under the "priority" pathway; ii) acceptance at the validation/screening stage; iii) approval or rejection of market authorization; and iv) labelling content (e.g., indication), if approved. Regulators will aim to issue their sovereign decisions within agreed to timeframes.