Terms of Reference
Version 1.2

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Terms of Reference

Access Consortium (Australia, Canada, Singapore, Switzerland and United Kingdom)

Context

With globalisation, the rapid emergence of new technologies, increasing resource needs, and regulatory gaps both domestically and internationally, collaborating with trusted regulatory counterparts can improve the current modus operandi and foster greater global regulatory synergy. The intent of the Access Consortium is to improve the efficiency and effectiveness of domestic regulatory systems to expedite decisions in an effort to safeguard and enhance the health of communities around the world.

1. Purpose

The Access Consortium is a cooperation of like-minded, medium-sized regulatory authorities with similar levels of regulatory maturity and capabilities. All members align with international standards required of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) for Good Manufacturing Practice (GMP) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The participating authorities face very similar challenges, such as increasing workload, increasing complexity and at the same time increasing pressure on the available resources.

The purpose of the consortium is to build synergies that increase the effectiveness and efficiency of domestic regulatory systems and the interface between each. It constitutes a multilateral forum to facilitate and promote interaction using respective bilateral and multilateral agreements as the foundation for which to identify and implement collaborative initiatives.

The consortium capitalises on the expertise and knowledge from each country to better address each country's area of strength, address gaps in science, and leverages resources to help expedite risk assessment processes while maintaining or raising quality and safety standards. The consortium builds on existing international networks, initiatives and mechanisms to advance work and information sharing along health product lifecycles.

The consortium can also serve as a "testing ground" for new and innovative collaborative approaches and can act as a pilot group for larger international

initiatives.

2. Ways we collaborate

Collaboration within the Access Consortium entails making use of work-sharing, reliance and information sharing to leverage our collective resources and expertise while retaining the sovereignty to make independent decisions and maintaining high quality and safety standards.

- **Work-sharing[1]:** a process by which regulatory authorities of two or more jurisdictions share activities to accomplish a specific regulatory task. The opportunities for work- sharing include, but are not limited to jointly assessing applications for clinical trials, marketing authorizations or product manufacturing site inspections, joint work in the post-marketing surveillance of medical product quality and safety, joint development of technical guidelines or regulatory standards, and collaboration on information platforms and technology. Work-sharing also entails exchange of information consistent with the provisions of existing agreements and compliant with each agency's or institution's legislative framework for sharing such information with other regulatory authorities.
- **Reliance[1]:** the act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

3. Objectives

The objectives of the Access Consortium are:

- To provide an effective and efficient alternative to participating regulators working independently on similar scientific and regulatory work.
- To enable participating regulators to draw on the very best scientific and technical data, information, expertise and resources from around the world to better inform regulatory decisions including risk assessments, along the product lifecycle.
- To improve each participant's effectiveness and efficiency as a regulator by providing a framework for identifying work-sharing, reliance or information-sharing opportunities, opportunities, facilitating action and achieving tangible results.

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1 Definitions are taken from the WHO draft Good Reliance Practices Guideline: https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS20_851_good_reliance_practices.pdf?ua=1

- To provide participating regulators with a mechanism to share with other regulatory authorities their unique knowledge in specific scientific areas, i.e., compliance and enforcement and post-market surveillance, as well as best practices, thereby making a significant contribution to addressing global health and safety issues.
- To create or complement existing communication networks and an increased dialogue and understanding of the basis of scientific advice between regulators and decision makers throughout the lifecycle of products.
- To explore new initiatives and concepts.

4. Principles and key success factors

Agreed upon principles guide the consortium's deliberations, such as respect, transparency, openness, flexibility, equality, and resource equity. The concept of an international collaborative consortium is based on the premise that each country has something to offer the other members. All Access Consortium members have equal status in terms of engagement and decision-making and may "opt-out" from any work plan activities. This could, for example, occur due to constraints presented by existing regulatory systems or because the specific project addresses the concerns of only a subset of members.

Information shared within the Consortium should be considered as non-public information and handled in confidence by all members, unless this is otherwise indicated. Details are provided in the respective bilateral / multilateral arrangements.

Confidential documents and information are shared between all members through a secure information sharing platform (e.g. SharePoint).

A key success factor is to ensure that no duplication exists with other international tools and mechanisms.

5. Membership

The members of the Access Consortium are:

- The Therapeutic Goods Administration, Australia
- The Health Products and Food Branch at Health Canada, Canada
- The Health Sciences Authority of Singapore
- Swissmedic, Swiss Agency for Therapeutic Products, Switzerland
- Medicines and Healthcare products Regulatory Agency, United Kingdom

6. Governance

The Access Consortium is steered and directed by the heads of the participating regulatory authorities. The **Heads of Agencies (HoA)** act as the Steering Committee and meet at least two times a year, preferably face-to face. For

practical reasons, these meetings take place in conjunction with other meetings, such as the DIA Annual Meeting or the Summit of Heads of Medicines Regulatory Agencies and ICMRA Meeting.

In addition to face-to-face meetings the HoA have periodic and ad hoc

web/teleconferences. The HoA group:

- review the progress of the ongoing work and projects;
- make decisions on behalf of the Consortium;
- define the strategic direction;
- identify and prioritise challenges to be addressed and collaborative activities;
- authorise resources in support of advancing the Access Consortium's goals and objectives.

All parties are committed to the goals and objectives of the Access Consortium and to making best efforts to reach consensus.

For the management of the ongoing business, each agency nominates a

Coordinator. This person:

- acts as the primary contact;
- is responsible for the preparation and organisation of meetings of the Heads of Agencies;
- ensures effective communication between the members; and
- coordinates the work of the experts in the Access Consortium **Working Groups** (WGs).

7. Meeting Chair

The responsibility for acting as Chair of Heads of Agency meetings will rotate evenly between all Members. The chair will rotate every 6 months, or as agreed by the Heads of Agency, in alphabetical order by Agency.

8. Scope of Activities

The products covered are medicinal products for human use and medical devices. Sample discussion topics might include scientific and technical requirements related to efficacy, safety or quality for medicines marketing (registration), regulatory oversight of clinical trials and manufacturing sites, electronic data strategies, and other issues of emerging concern.

9. Collaboration Mechanisms

A. Working Groups (WGs)

The HoA may establish WGs to undertake certain work on identified/selected topics or projects, chaired by a member. These WGs shall have clearly documented mandates and specific activities. Participation in the groups is open to all members and is voluntary. The WGs are chaired by one of the Access Consortium members, and wherever possible the burden to chair WGs should be

equally distributed amongst the members. Assigning the WG chairs and defining their term is left to the consensus of the WG members. The coordinators are informed about changes in the rapporteurship.

Chairs of the groups are expected to keep the HoA updated on a periodic basis, or upon request. The work plans of the WGs are updated annually; the mandate when necessary (e.g. in case of a change of scope/goals of the WG).

The Chairs of the WGs are also responsible for keeping the contact information of their group members up-to-date.

WGs meet regularly via telephone conference in order to progress the work as outlined in the work plan. Face-to-face meetings are encouraged when deemed necessary, and should take place in conjunction with conferences or meetings or other initiatives. Face-to-face meetings have to be approved by the HoA in the context of the approval of the work plan.

B. Project Proposals

All members may propose, in writing, projects and work items to the HoA for consideration. These recommendations can come through formal submissions or through presentation at a meeting of the HoA. As a basis decision-making, a mandate and initial work plan for the group have to be prepared and proposed to the HoA. Decision-making on new project proposals at the HoA should aim at consensus wherever possible.

C. Informal Networks

For the ongoing exchange and sharing of information, the Access Consortium may establish informal networks to share information. These networks may be formed by key focal points from each of the members. Working Groups may evolve into an Informal Network should the specific task or reason a Working Group was originally established no longer remain. An Informal Network allows members to come together periodically to share information or discuss specific issues, but there isn't a need for formal on-going work to be undertaken by the group.

10. Communication

A. Public Statement

Following a HoA face-to-face meeting a public statement is issued at least once per year to communicate major achievements and decisions. This statement is published on each member's website.

B. Requests by media / requests for publication

Requests by media or requests for publication about Access Consortium activities should be sent to all Coordinators for alignment. Depending on the importance and urgency, the matter is referred to the HoA for decision by e-mail or at their next meeting (telephone conference or face-to-face).

C. Presentations

Presentations at international meetings or fora about activities of the Access Consortium should be aligned with the Coordinators prior to the event.

D. Language

The working language within the Access Consortium is English. Meetings will be conducted in English and documents will be distributed in English. It is each member's responsibility to translate any documents into additional languages as needed.

11. Support of activities

Members are responsible for their own travel and accommodation costs.

12. Withdrawal clause

Members may withdraw from the Consortium with a written notice to be given 6-months prior to the withdrawal.

13. Review of Terms of Reference

The Terms of Reference will be reviewed and approved annually by the HoA or when necessary

14. Membership Criteria

Requests to join the Consortium may be received from other regulators.

Any requests to join Access need to be considered in terms of the skills, capabilities, and competencies of the requesting agency against the following criteria:

- The regulatory framework of the requesting country is substantively similar to those of existing Members.
- The regulatory science capabilities and capacity of the requesting agency are substantively comparable to existing Members.
- The requesting agency undertakes de novo evaluations/assessments against internationally recognised standards that align with those used by existing Members.
- The reports/evaluations/assessments prepared by the requesting agency are completed in English.
- Evaluators/assessors within the requesting agency are proficient in English language.

In addition to the above criteria, the following requirements must be met:

- The Access Heads of Agency will balance the operational complexities of increasing the size of the Consortium against the benefits and advantages of adding additional Members.
- Any new membership must be unanimously agreed by Heads of Agency.
- Only one new Member may join at any given time. The Heads of Agency will determine an appropriate length of time between the acceptance of a new

Member to the Consortium and the consideration of additional requests to join.

- There is no provision for Observers to join the Access Consortium.