ACCESS CONSORTIUM

STRATEGIC PLAN

2025 - 2028

ACCESS CONSORTIUM

AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

Access Strategic Plan for 2025 – 2028

Vision

To provide faster access to safe, effective and high-quality medicines for all our populations.

Mission

To facilitate work-sharing and regulatory collaborations to ensure our populations have access to the health products they need for better health and wellbeing.

Introduction

Access is a collaborative initiative of the following governmental authorities that regulate human medicines and other health products:

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

Access is committed to maximising collaboration by:

- aligning regulatory and policy approaches
- reducing duplication of regulatory reviews
- streamlining and transforming regulatory processes
- serving as a "testing ground" for innovative collaborative approaches and acting as a pilot group for larger international initiatives

Access builds on existing international networks, initiatives and mechanisms to advance work- and information-sharing, as well as mutual reliance across the health product lifecycle. This approach harnesses our collective resources and expertise, while retaining the sovereignty to make independent decisions, and maintaining high quality and safety standards.

Access represents a collective population base of approximately 150 million as of end 2024 and aims to be an example of a successful regulatory collaboration, putting the interests of patients first.

The strategic plan for 2025-2028 builds on Access's strengths and acknowledges where we can improve in our goal to provide faster access to safe, effective and high-quality medicines for patients. To help achieve our vision for the future, we will continue to prioritize collaboration and further enhance our systems to enable better work-sharing of applications for the registration of medicines.

Achievements and Performance

Leveraging work sharing collaboration and Access joint application pathways enable Access to meet its goal of facilitating quicker patient access. It has reduced duplication of effort by both the industry and regulators and allows for near simultaneous approval in up to 5 Access markets.

The COVID-19 pandemic highlighted Access's agility in responding to global health challenges and underscored the importance of regulatory collaboration in an increasingly complex environment. Access partners swiftly evaluated and approved the first COVID-19 vaccines in 2021, maintaining rigorous regulatory standards despite the urgency. Key initiatives included releasing crucial guidance on vaccine modifications and confirming the suitability of immunobridging studies for vaccine authorisation. These efforts not only addressed immediate needs but also positioned Access for success in future challenges. Moving forward, Access will continue to build upon these pandemic learnings to enhance its collaborative approach to global health crises.

Many Access new active substance applications include first-in-world medicines, with evaluation by Access occurring simultaneously to or only just after evaluation by other large regulatory agencies.

- Access achieved aligned decisions among participating partners to approve 26 [1] medicines through the New Active Substances Work Sharing Initiative, with 2 of these medicines approved through a 5-way application mechanism and 5 through the 4-way application.

Access continues to work with the sponsors of generic medicines and biosimilars, to ensure affordable products are available.

- Access achieved aligned decisions among participating partners to approve 8[2] generic medicines through the Generic Medicines Work Sharing Initiative.

The Access Promise Pathway, introduced in December 2023, offers aligned priority review for life-saving medicines within an even shorter published target turnaround time of 180 days compared to 300 days via New Active Substances Work Sharing Initiative[3]. Access Consortium invites applicants with life-saving medicines to explore this expedited pathway. The Advanced Therapy Medicinal Products (ATMP) Working Group, established in 2023, expands Access's scope of collaboration to cell and gene therapies and tissue-engineered products. These initiatives aim to expedite approvals for critical treatments while evolving regulatory collaboration to accommodate emerging therapies.

Regulatory innovation continues to be important as health products evolve, increase in complexity or are tailored to individual patients. Sharing scientific resources and expertise within Access will help reduce the time to market for innovative products. In addition, joint pipeline meetings allow Access to prioritise its resources to facilitate important applications for our markets.

[1] Figure accurate as of 18 Dec 2024
[2] Figure accurate as of 18 Dec 2024
[3] Access Consortium NAS work sharing initiative operational procedure

Strategic Objectives for 2025 – 2028

The following strategic objectives for 2025-2028 will guide Access in achieving its vision and mission.

(1) Strengthening Access Work-sharing Initiatives

Make Access a competitive and efficient submission pathway of choice for industry, supported by regulators through:

- Optimising work-sharing through greater alignment of regulatory approaches and technical and scientific requirements
- Leveraging best practices and technology for optimal use of resources for assessment collaboration
- Establishing effective and efficient infrastructure to support collaboration
- Improved predictability of work-sharing procedures

(2) Expanding Lifecycle Approach

Enhance Access collaboration throughout the health product lifecycle by:

- Exploring collaboration and information sharing on clinical trials and upstream scientific advice and review opportunities for joint working on assessment
- Strengthening collaboration and scientific information sharing within Access on pharmacovigilance, and post-market safety, including risk management plans
- Considering further collaboration on global Good Practice (GxP) inspections complementary to existing international initiatives

(3) Supporting Regulatory Innovation

Collaborate to enable timely access to innovative health products by:

- Strengthening and leveraging regulatory scientific capability and capacity within Access for emerging technologies and innovative products
- Sharing and learning from each other on novel regulatory approaches for innovative products
- Promoting regulatory sciences and process innovation
- Leveraging joint pipeline meetings to support innovative products and novel therapeutic approaches

(4) Enhancing Engagement

Strengthen communication and consultation by enhancing engagement, transparency and reporting through:

- Developing and implementing an effective communication strategy to stakeholders
- Developing and monitoring a stronger online presence for Access
- Establishing regular reporting to stakeholders on Access work-sharing initiatives, major achievements and decisions

Indicators of Success

Our success in being recognised as a pathway of choice will be measured by the following indicators:

- Increase in number of products and risk management plans[4] assessed through Access collaboration
- Decrease in the median submission gap[5] and median approval time
- Reduced duplication of effort for both regulators and industry
- Increased collaboration to support access to innovative health products
- Increased awareness of Access among external stakeholders

The Future of Access

Looking forward, Access remains committed to maximizing our collaboration. Streamlining Access procedures provides greater efficiencies for both industry and Access members and expedites access to safe and effective quality medicines to patients. By working together, Access creates a more attractive market opportunity for global companies than any of the countries on their own.

Under this renewed strategic plan, Access will realize the benefits of international collaboration by solidifying processes. Access will also work with industry to align expectations leading to more predictability in Access pathways. In addition, Access will work toward strengthening our communication strategies to ensure appropriate up-to-date and timely information on Access initiatives is readily available.

Access work-sharing initiatives will be supported by a first-of-its-kind collaboration technology platform, a cloud-based workspace allowing multiple regulators to conduct reviews in a joint environment. This solution will not only enhance the way we work together, but it will also facilitate a faster, more collaborative review process.

Access remains focused on to encouraging more joint applications, particularly 5-way applications involving all member countries. This approach maximises the collaborative potential of Access and offers the greatest benefit to both industry partners and patients across our member countries. By promoting and facilitating these joint applications, we aim to create a more streamlined and efficient regulatory process that spans the entire Access network.

[4] The New Active Substances Working Group successfully piloted the work-sharing of the risk management plan (in addition to Modules 3-5) for a 5-way application reviewed through the New Active Substances Work-Sharing Initiative.

[5] Submission gap is calculated as the time from the date of submission at other major regulators (e.g., US FDA and EMA) to the date of regulatory submission to Access.