ACCESS CONSORTIUM

AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

Access Consortium

Strategic Plan 2021-2024

Access Consortium
Strategic Plan 2021-2024

Vision

Our vision is to provide faster access to safe, effective and high quality medicines for all our populations.

Mission

Our mission is to align our regulations and policies to facilitate work-sharing on medicines and reduce duplication to ensure our populations have access to the health products they need for better health and wellbeing.

Introduction

The Access Consortium 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, Switzerland
- Medicines and Healthcare products Regulatory Agency, United Kingdom

The Consortium is committed to maximizing collaboration by aligning regulatory and policy approaches, reducing duplication, and facilitating our populations' access to high quality, safe and effective health products. This group originally consisted of the regulatory authorities in Australia, Canada, Singapore and Switzerland (previously referred to as ACSS). With the addition of the United Kingdom's Medicines and Healthcare products Regulatory Agency, a leading international medicines regulator, in October 2020, the Consortium changed its name to Access, reflecting the principal goal of increasing our populations' access to health products through international collaboration and work-sharing. The Access Consortium now represents a collective population base of 150M.

Background

To help achieve the Consortium's mission, we continue to focus on enhancing our systems to enable work-sharing of applications for the registration of medicines containing new active substances, generics and biosimilar medicines. To date, Access has successfully evaluated numerous new medicines, with many more under active review or assessment for work-sharing. Many Access sponsor applications include first-in-world medicines, with major medicines regulators performing the evaluation at the same time or only just ahead of the Access Consortium.

Regulatory innovation has become increasingly important as health products evolve, increase in complexity or become more personalized. Greater regulatory agility and international alignment

by sharing of scientific resources and expertise, while at the same time maintaining independent regulatory decision-making within each authority, will reduce a product's time to a wider market. Exploring collaboration with national health technology assessment organizations (and similar) by Access countries also serves to improve patient access to safe and effective health products.

The COVID-19 pandemic triggered rapid regulatory innovation to address the urgent need for specific health products. Through agile regulatory processes, Access partners have collaborated to make these health products and medical supplies available. We now have an opportunity to build upon the learnings from COVID-19 and apply these agile practices to our work in Access.

The 2021-2024 Strategic Plan will guide us toward enhanced efficiency of our national regulatory systems, while optimizing synergies and alignment between regulatory authorities and reducing duplication for industry. With our combined populations of 150M the Consortium aspires to be regulators of choice.

Strategic Objectives

The following are the strategic objectives for 2021-2024 to guide the Access Consortium in achieving its vision and mission.

Strengthening Access work-sharing initiatives

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

- Increase the number of applications assessed by Access work-sharing initiatives
- Increase the variety of health products assessed within Access
- Optimize work-sharing through greater alignment of regulatory approaches and technical and scientific requirements
- Strengthen collaboration by supporting Access participation in international initiatives
- Explore best practices with optimal use of resources for assessment collaboration
- Capture lessons learned from the COVID-19 experience to innovate together and improve work-sharing

Expanding lifecycle approach

Maximizing collaboration throughout the health product lifecycle:

- Consider collaboration on clinical trials design and/or sponsor advice
- Explore the use of real-world data and real-world evidence in clinical trial design and regulatory approaches
- Establish collaboration and scientific information sharing within Access on risk management, pharmacovigilance and post-market safety
- Explore the use of pharmacovigilance and real-world data to support early entry on the market of vaccines and therapeutics for COVID-19 and other diseases
- Consider further collaboration, including work-sharing, on global Good Practice (GxP) inspections complementary to existing international initiatives

Regulatory innovation that integrates a healthcare systems approach

Increasing regulatory capacity while collaborating with key national healthcare systems partners to facilitate uptake of innovative health products:

- Strengthen and leverage regulatory scientific capacity within Access for emerging technologies and innovative products
- Explore collaboration with national health technology assessment organizations (and similar)
- Explore a more collaborative aligned “systems” approach to regulating innovative products by:
    - integrating national healthcare system partners throughout the lifecycle of innovative products, and
    - fostering links between healthcare system needs and regulatory oversight of innovative products

Indicators of Success

The Access goal to become regulators of choice will be measured by the following indicators of success:

- Increase in applications to Access at the same time or soon after being filed with other major medicines regulators
- Increase in number of products made available to patients via Access
- Increase in diversity of products assessed via Access
- Decrease in average time to market for products assessed under Access
- Reduced effort and duplication for both regulators and industry
- Increased collaboration on the alignment of products with healthcare system needs that are made available to patients via Access
- Increased collaboration on global GxP inspections
- Increase in number of ICH guidelines implemented through Access collaboration