



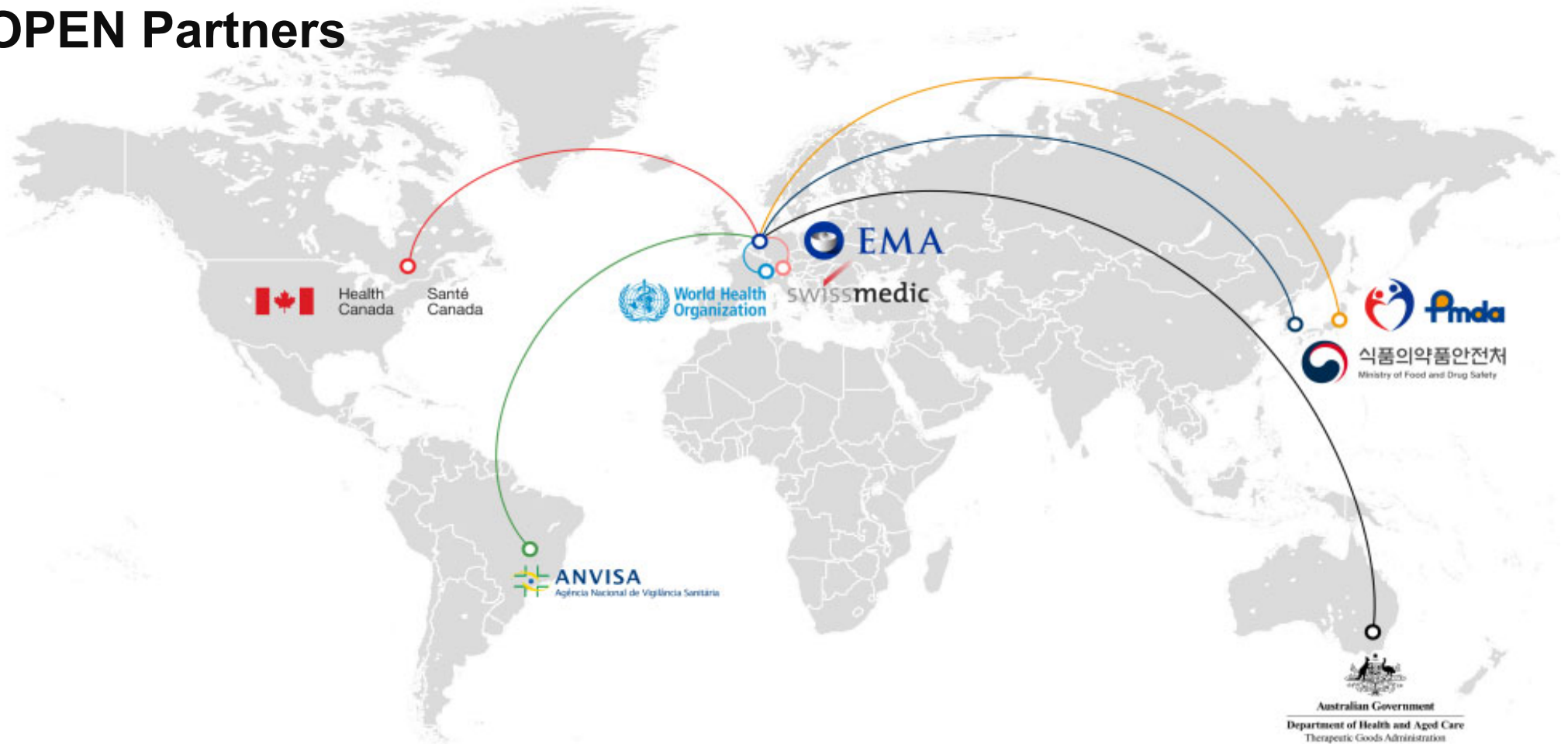
Opening procedures at EMA to non-EU authorities (OPEN) initiative

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What it is

- **OPEN initiative:** Opening procedures at EMA to non-EU authorities (OPEN) initiative
- Initiated as pilot in 2020 during the pandemic to **strengthen international collaboration**
- Collaboration based on **confidentiality arrangements** between EMA and OPEN partners
- Enhanced **scientific exchange** and alignment of regulatory approaches
- Parallel submission to EMA and OPEN partners – **reduced submission gap**
- **Independent decision-making**

OPEN Partners



Scope and eligibility

- Originally, the OPEN initiative focused on medicines preventing or treating COVID
- Since July 2023, the scope was extended covering medicines
 - intended to help combat **Antimicrobial Resistance**;
 - designated under the **PRIME**: priority medicines scheme (temporarily excluding Advanced Therapy Medicinal Products), and other products that address a high unmet medical need;
 - intended to address **public health threats** and **public health emergencies**

What it means for industry and how to participate

- EMA accepts an application if submitted to **EMA and at least one OPEN partner**
- Submission **in parallel** to EMA and the participating OPEN partners
- The applicant agrees that
 - Regulators exchange scientific information / views / assessment reports
 - Participating OPEN partners attend in EMA meetings

What it means for Swissmedic

- Intensified collaboration with EMA
- Objectives:
 - Parallel assessment
 - Consolidated List of Questions (LoQ) of major concerns
- Allows further alignment of regulatory approaches

Experience with the OPEN initiative today

- During the pandemic: collaboration on therapeutics and vaccines
- With extended scope: two applications

Current consideration

- How to best implement the OPEN initiative in Swissmedic's authorisation procedure landscape

For more information

- [Opening procedures at EMA to non-EU authorities \(OPEN\) initiative | European Medicines Agency \(EMA\) \(europa.eu\)](#)
- [Questions and Answers on the Pilot Project 'OPEN' - phase 3 \(europa.eu\)](#)
- [One-year review of the OPEN pilot and recommendations \(europa.eu\)](#)
- [Swissmedic participation in the European Medicines Agency \(EMA\) OPEN initiative](#)