swissmedic

COLLABORATIVE ASSESSMENT PROCEDURES

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INTRODUCTION

In addition to standard authorisation procedures, Swissmedic offers or participates in a number of international authorisation procedures with the aim of accelerating access to medicines for patients in Switzerland and collaborating countries.

Collaboration with other national regulatory authorities allows Swissmedic to strengthen its international collaboration, to share knowledge and expertise across jurisdictions and to promote regulatory convergence. Depending on the procedure, applications are simultaneously or subsequently submitted to Swissmedic and collaborating authorities, and are assessed across multiple countries.

The scientific dialogue facilitates the independent decision-making process. In all procedures, Swissmedic makes its own sovereign decision on the applications based on Swissmedic's standards of quality, safety and efficacy.

ACCESS CONSORTIUM WORK-SHARING INITIATIVES

PROCESS | WHAT IT IS

Work-sharing initiatives are a novel form of transnational collaboration between regulatory authorities offering streamlined pathways for marketing authorisations to the pharmaceutical industry. Work-sharing for marketing authorisation reduces the workload for regulatory agencies and accelerates the assessment.

Swissmedic is part of the Access Consortium, along with regulatory authorities of Australia (TGA), Canada (Health Canada), Singapore (HSA) and the United Kingdom (MHRA).

The vision is to provide faster access to safe, effective and high-quality medicines for our collective population of over 150 million.

Each agency makes its own sovereign decision based on the recommendations contained in the assessment reports.

SCOPE AND ELIGIBILITY

Work sharing is suitable for companies that submit an authorisation application for

- New active substances (NAS)
- New indications
- Generics
- Biosimilars

Applications submitted under the standard or Priority review pathways may be eligible. Interested applicants should submit an Expression of Interest (EoI form) at least 3 months in advance of their anticipated filing date to each agency proposed for work-sharing.

BENEFITS

- Shorter timelines, faster access for patients
- Simultaneous market access in several countries
- Consolidated List of Questions
- Predictability: evaluation plan specified in advance
- Strengthening and expanding international cooperation
- Regulatory convergence
- Sharing of resources and expanding expertise across jurisdictions

LINKS

Operational Procedures NASWSI

Operational Procedures GMWSI

Swissmedic Access consortium work-sharing authorisations

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PROJECT ORBIS

PROCESS | WHAT IT IS

Project Orbis is an international collaborative initiative of the FDA Oncology Center of Excellence (OCE) providing a framework for a parallel submission and review of oncology product applications among participating international regulatory authorities.

Swissmedic joined Project Orbis in 2020 and is now part of this initiative together with the regulatory authorities of the United States of America (FDA), Australia (TGA), Canada (Health Canada), Singapore (HSA), the United Kingdom (MHRA), Brazil (ANVISA) and Israel (IMoH).

Project Orbis provides an opportunity for the participating agencies to perform a parallel review of the application and to collaborate through exchanges and knowledge sharing to optimise the review process. However, each authority retains its independent decision-making power, ensuring that Swissmedic maintains its high standards of safety, quality, and efficacy when assessing the applications.

SCOPE AND ELIGIBILITY

Project Orbis aims to facilitate the assessment of New Active Substance applications (NA NAS) and indication extensions (IE) for oncology treatments.

Requests for review of Project Orbis applications are submitted to the FDA and are evaluated on criteria such as breakthrough designation, impressive results and the unmet need for the intended treatment. The FDA may also recommend an application for Project Orbis.

Swissmedic accepts all Project Orbis applications that are nominated by the FDA and for which the applicant has selected Swissmedic as participant.

BENEFITS

Faster access to innovative therapies for patients:

- Simultaneous submission and review of cancer treatments across multiple countries (reduced submission gap)
- Accelerated approval process (expedited review)

Faster access to the Swiss market for the applicant.

Enhanced international collaboration:

- Increased cooperation with counterpart agencies like the FDA and other regulatory authorities
- Shared knowledge and expertise, optimised review process, no duplication of questions to the applicant

LINKS

Project Orbis | SMC

Project Orbis | FDA

Guidance document Project Orbis

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OPENING PROCEDURES AT EMA TO NON-EU AUTHORITIES (OPEN)

PROCESS | WHAT IT IS

In 2020, EMA initiated the OPEN initiative pilot during the COVID pandemic to increase international collaboration in the assessment of COVID medicines and vaccines. From its onset, Swissmedic participated in the initiative.

At present, regulatory authorities of Australia (TGA), Brazil (ANVISA), Canada (Health Canada), Japan (PMDA), Republic of Korea (MFDS) and the World Health Organization (WHO) participate in the OPEN initiative. All OPEN Partners have signed confidentiality arrangements with the EMA.

Being an OPEN partner, Swissmedic and the other participating regulatory authorities receive the applications from industry at the same time as the EMA which allows Swissmedic to perform a parallel assessment.

An application is accepted within the OPEN framework if industry submits an application to EMA and at least on OPEN partner.

EMA and participating regulatory authorities remain independent in their decision-making process.

SCOPE AND ELIGIBILITY

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

BENEFITS

- Close collaboration with EMA experts and to actively participate in Emergency Taskforce (ETF) and Committee for Medicinal Products for Human Use (CHMP) meetings
- No submission gap
- Swissmedic aims to take a decision within the same timeframe as the EMA

LINKS

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

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MARKETING AUTHORISATION FOR GLOBAL HEALTH PRODUCTS (MAGHP)

PROCESS | WHAT IT IS

The MAGHP offers a collaborative pathway for the assessment of essential medicines for populations of the global South. It is based on the approach of actively involving affected National Regulatory Agencies (NRAs) and the World Health Organisation (WHO) in the Swissmedic assessment process. MAGHP contributes to building capacities within the participating NRAs, establishes trust and confidence in the collaborative process and is expected to facilitate the granting of national marketing authorisations following Swissmedic's approval.

The procedure consists of two independent components:

- Scientific Advice:
  To clarify scientific questions in the development phase regarding the planned submission.

- Marketing Authorisation:
  Standard Procedure: The procedure follows the regular Swissmedic marketing authorisation procedure, with the same time frames, procedural steps and evaluation criteria.
  Light Procedure: This special procedure is applicable to all applications in the fast track and temporary authorisation procedures.

SCOPE AND ELIGIBILITY

The MAGHP focuses on medicinal products targeting a concrete medical need that disproportionately affect the global South, with the goal of accelerating access to those medicinal products in endemic regions. There is no restriction to specific therapeutic areas.

Following authorisation applications are eligible for the MAHGP

- New active substances (NAS)
- New indications
- Known active substances

BENEFITS

- No restriction to specific indications
- Building capacities and establishing trust and confidence in the process
- Consolidated assessment reports, with country-specific considerations
- Shorter timelines for authorisation by NRAs through "well-informed reliance"

LINKS

MAGHP Procedure

Guidance Document Authorisation Procedure MAGHP

Guidance Document Scientific Advice MAGHP

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