International Cooperation
Project Orbis und Access

Chantal Walther, Leiterin Einheit 4, Regulatory Assessment
Cornelia Bigler, Stv. Leitung Einheit 4, Regulatory Assessment
Collaboration amongst agencies?

Are the European Medicines Agency, US Food and Drug Administration, and Other International Regulators Talking to Each Other?

Tania Teixeira, Sandra L Kweder, Agnes Saint-Raymond

Affiliations + expand

PMID: 31449664  PMCID: PMC7028217  DOI: 10.1002/cpt.1617
International Regulatory Agencies Collaborations

**Medical Product Review Concepts of leading agencies**

### Past

- **Cluster Collaboration Concept**
  - Agency A
  - Agency B
  - Agency C

### Present

- **Parallel Review Concept**
  - Agency A
  - Agency B
  - Agency C

- **Prototype for Cancer**
  - Faster Patient Access
  - 2019

- **Reliance Concept**
  - Agency A
  - Agency B
  - Agency C
  - Agency D

- **Prototype for all Disease Areas**
  - Work Sharing between Agencies
Collaborations match Swissmedic Strategic Objectives

«Time-critical processes are accelerated»
(..Expectation of patients…fast authority)

«Reliance on results of other authorities and work sharing»

Prototype for all Disease Areas

Prototype for Cancer

Faster Patient Access

Work Sharing between Agencies
Swissmedic (SMC) and Project Orbis

«Time-critical processes are accelerated»
(..Expectation of patients…fast authority)
When is Orbis successful for Swissmedic?

*Faster Patient Access to innovative Cancer Treatments*

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**No Orbis**

- Submission Gap
- Drug Assessment

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**Availability for Swiss Patients**

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**PROJECT ORBIS**

- Subm. Gap
- Drug Assessment

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**FASTER Availability for Swiss Patients??**
Orbis 2.5-Years Update 7/2022: 41 submissions

- Completed (29) : 8 NAS, 21 IE
- In Assessment (8) : 3 NAS, 4 IE
- Accepted (4) : 3 NAS, 1 IE

*NAS=New Active Substance, IE=Indication Extension
Reduction of Swiss Submission Gap

anti-cancer NAS (2019-2021) - CIRS (n=40)

All submitted Project Orbis (n=37)
Reduction of Assessment time via Orbis (N=22)

- Regular SMC timelines: 100%
- All approved Project Orbis (n=22): 56%

44% reduction compared to regular SMC timelines.
Orbis is successful for Swissmedic

Faster Patient Access to innovative Cancer Treatments

FASTER Availability for Swiss Patients

Submission Gap  Drug Assessment

2021  2022

Full Implementation to SMC processes
Swissmedic and Access Consortium

Prototype for Cancer

Faster Patient Access

Prototype for all Disease Areas

Work Sharing between Agencies
Access Consortium

... a truly global network!
Access Strategic Plan 2021-2024

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

• Strategic Objectives
  ◦ Strengthening Access work-sharing initiatives
  ◦ Expanding lifecycle approach
  ◦ Regulatory innovation that integrates a healthcare systems approach
Access Working Groups (WG)
Swissmedic and Access Work-sharing

- **2016**: Generic Medicines Work-sharing
- **2019**: New Active Substance Work-sharing
- **2021**: Biosimilar Work-sharing
- **2023**: Access Priority Procedure “Promise”
New Active Substance Work-Sharing Initiative (NASWSI)
Requirements NASWSI

- Simultaneous submission to at least two of the Access Consortium Agencies

- New active substance application OR
- New indication application

- Identical datasets for Modules 2-5
- Country-specific Module 1
Role determination for Access partners

- NASWSI: Agencies consider their operational needs when allocating review responsibilities

- GMWSI (Generic Work-Sharing Initiative): Applicant can propose a Lead Agency
NASWSI Applications at Swissmedic April 2019 - July 2022

- Completed (12)
- In Assessment (6)
- Pipeline (3)

N=21 (18 New active substances, 3 indication extensions)
Completed applications until 07/2022

- **Oncology**
- **Hematology**
- **Metabolism**
- **Cardiology**
- **Neurology**
- **Dermatology**
- **Retinal disorders**
- **Asthma**
- **Infectiology**

Bar Chart:
- 2020: 1 completion
- 2021: 7 completions
- 2022: 4 completions
Reduction of Assessment time via Access NASWSI (N=10)

<table>
<thead>
<tr>
<th>Swissmedic</th>
<th>428 days = 100%</th>
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<tbody>
<tr>
<td>median NAS</td>
<td></td>
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<tr>
<td>Access</td>
<td>360 days = 84%</td>
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-16%
CIRS: Access applications submission gap and approval time

Figure 11: Median submission gap and median approval time for all NASs approved compared to those approved via the Access Consortium between 2018-2021

- **Health Canada**
  - All NASs (131) Submission Gap: 328 days, Approval Time: 341 days (Overall: 640 days)
  - Access NASs (9) Submission Gap: 59 days, Approval Time: 330 days (Overall: 420 days)

- **Swissmedic**
  - All NASs (132) Submission Gap: 331 days, Approval Time: 473 days (Overall: 783 days)
  - Access NASs (4) Submission Gap: 45 days, Approval Time: 376 days (Overall: 458 days)

- **TGA**
  - All NASs (118) Submission Gap: 345 days, Approval Time: 347 days (Overall: 705 days)
  - Access NASs (12) Submission Gap: 121 days, Approval Time: 310 days (Overall: 481 days)

- **HSA**
  - Other NASs (40) Submission Gap: 395 days, Approval Time: 414 days (Overall: 769 days)
  - Access NASs (4) Submission Gap: 154 days, Approval Time: 367 days (Overall: 544 days)
Summary: Swissmedic View
Successful Collaborations: to be continued in future!
Summary: Swissmedic View
Successful Global Collaborations and Impact

New drug approvals in six major authorities 2012-2021:
Focus on facilitated regulatory pathways and internationalisation

Swissmedic

18.08.2022
Advice for applicants

- Good internal communication
- Well structured submissions
- Close exchange with authorities
Weitere Informationen

Orbis
- Swissmedic approves first new active substance as part of Project Orbis
- Project Orbis: findings after the first year (swissmedic.ch)
- Swissmedic permanently involved in Project Orbis

Access
- Access Consortium (swissmedic.ch)
- NASWSI Operational procedures
- Access Strategic Plan 2021-2024
- International cooperation on therapeutic products (swissmedic.ch)

Centre for Innovation in Regulatory Science (CIRS) Briefing
- R&D Briefing 85 28 June 2022
- Authorisations of human medicinal products with a new active substance and additional indications 2021 (swissmedic.ch)
Access Work-sharing: Pros & Cons for the pharmaceutical industry

✓ Strengthening and expanding international cooperation
✓ Evaluation plan specified in advance
✓ A less time-consuming procedure thanks to the submission of a joint dossier
✓ Consolidated List of Questions*
✓ Shorter timelines
✓ Simultaneous market access in several countries
✓ Opportunity to make a contribution to innovation in the area of regulation

X Coordination across several time zones
X Increased coordination efforts for affiliates

*Country-specific questions still possible
Access Work-sharing: Pros & Cons for Swissmedic

✓ Reduced workload due to splitting review/modules between agencies
✓ Sharing of resources and expertise across jurisdictions
✓ Positioning of Swissmedic as 1st-wave-agency
✓ Faster access for patients in CH

✗ Coordination across several time zones
✗ Increased coordination efforts for Regulatory Assessment