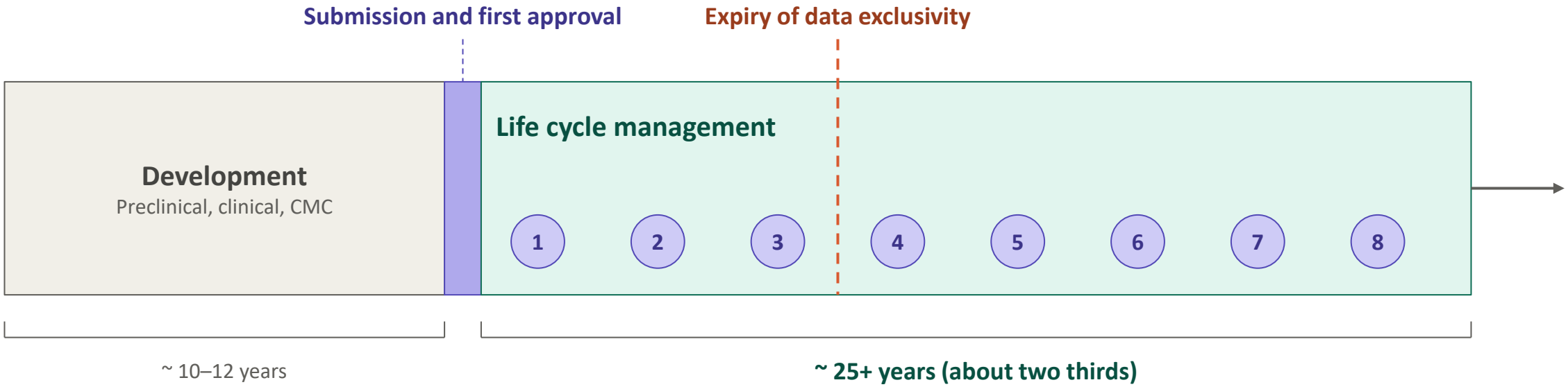
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Cooperation instead of isolation
Life cycle management in international regulatory networks

Ulla Grauschopf, Division Head Quality Assessment

Role of life cycle management throughout the life cycle of a medicinal product



Examples of post-approval changes (numbered on the timeline)

1. Additional manufacturing site
2. Replacement of outdated analytical method
3. Name change of CRO / test lab
4. Shelf-life extension of finished product
5. New indication / label extension
6. New dosage strength or dosage form
7. Safety update (labeling, RMP)
8. Marketing authorization renewal

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How do we approach LCM from a regulator's perspective?

Updated EU variations catalogue implemented in Switzerland
- Regular exchange with EMA re. Q&As and open issues
- So far positive experience by Swissmedic

PACMP (Post-Approval Change Management Protocol) as a widely used tool

Newly introduced but rarely used: the **PLCM** (Product-Life Cycle Management Document)

Post-Approval Change Management Protocol (PACMP)

- Both the applicant and the regulatory authority invest effort upfront
- Particularly beneficial when planned change is clearly defined and expected to be implemented shortly
- Manufacturing and testing site changes as the most commonly submitted PACMPs

➢ Challenge for assessors**:** Lack of clarity in PACMP descriptions hinders the assessment of future acceptance criteria.

CASSS CMC Strategy Forum Europe, 2026:
Roundtable Session "To PACMP or Not to PACMP"
Facilitator: Martin Umhang, *Swissmedic*
Scribe: Ulla Grauschopf, *Swissmedic*

Challenges raised by applicants within the global environment

Seen from a **regulatory agency's side**



Seen from a **company's side**



driven by
national frameworks
not by science globally

One PAC requires prior approval by multiple countries that have ***different*** reporting thresholds, ***different*** requirements, and ***different*** timelines.

First to last country approval can be often 3-5 years or more

Realistic paths forward

ICMRA PAC Pilot→ GRACE

EMA OPEN

Reliance pathways

ICMRA
INTERNATIONAL COALITION OF MEDICINES REGULATORY AUTHORITIES





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Swissmedic embraces different forms of leveraging regulatory work



Reliance on decisions and assessments of other authorities

Swissmedic relies on decisions and assessments issued by other authorities with comparable control of human medicinal products (Art 13 and Art. 14 para.1 letter a^{bis} TPA and internal reliance).



Providing decisions and assessments for other authorities

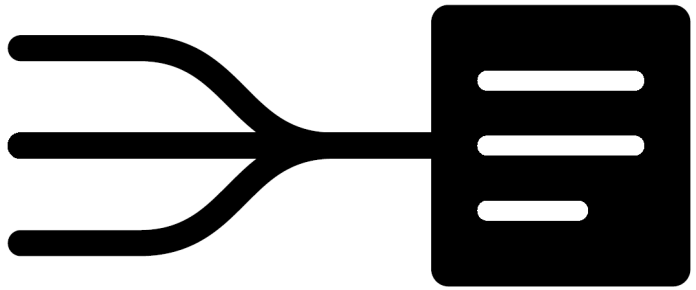
Swissmedic provides its decisions and assessments to other authorities, which may subsequently rely on them (e.g. MAGHP).

Swissmedic embraces different forms of leveraging regulatory work



Collaboration through worksharing procedures

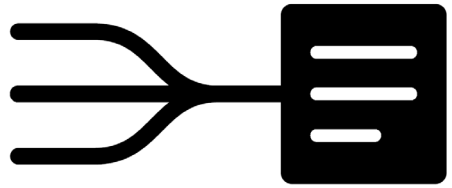
Swissmedic collaborates with other authorities within the framework of worksharing procedures, delegates parts of the assessment to partner authorities and shares assessments that other authorities can leverage (e.g. Access Consortium)



Parallel assessment& exchange targeting aligned LoQ

Swissmedic collaborates with partner agencies within the framework of a parallel assessment, and alignes its LoQ with partner agencies (e.g. ICMRA PAC Pilot, & EMA OPEN)

The ICMRA PAC Pilot: How it Works



- **Submission of application** to the ICMRA PAC Working Group
- **Eligibility Check** by ICMRA PAC Working Group
- Within the WG: identification of the **lead agency**
- Optional as needed: clarification meeting with lead agency and the applicant
- Confirmation of **Assessment starting point** within the participating agencies (not trivial!)
- …time runs
- Meeting of the participating agencies to discuss and align the questions/concerns with the target of a **joint LoQ** → Issuing LoQs to applicant
- Evaluation of the answers received and further discussion/alignment → optional additional LoQ
- **Final evaluation and timely communication of the decision by all participating agencies**

https://icmra.info/drupal/en/strategicinitatives/pqkms/collaborative_pilots_extension_19mar2025

Example and experience: Swissmedic as «lead agency»

- **Introduction of a new WCB (working cell bank)** for a Biologics (antibody), coupled with the submission of a «WCB qualification master protocol" for future submissions
- **8 participating agencies**: FDA, EMA, TGA, Israel, MHRA, Swissmedic, PMDA and Health Canada- highest number ever in such a pilot!
- **Very well prepared submission documentation**
- Efficient alignment among agencies facilitated by Swissmedic
- **Decision in less than 50 days** (standard-timeline of 120 days)

From pilot to standard ICMRA programme

→ Global Regulatory Assessment and Collaborative Evaluation (GRACE)

The pilots demonstrated that structured, multi-regional collaboration in the evaluation of the same dossier for post approval changes is possible within the existing regional regulatory frameworks and can lead to highly aligned science- and risk-based regional outcomes.

Scope:

1. **Post-approval changes impacting drug supply**
2. **Innovation to support manufacturing of high-quality medicine and strengthening their availability**

..and a few words regarding „clouds“

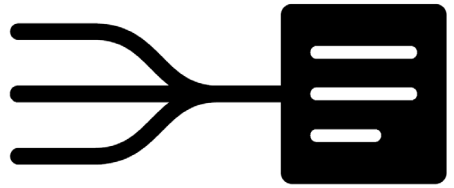
Applicants may propose cloud-based platforms for parallel reviews by multiple authorities. Swissmedic only uses such platforms within established international cooperation initiatives involving Swissmedic. Platform selection is coordinated with partner authorities and requires prior internal assessment and approval.

Assessment criteria for the use of cloud platforms

- Demonstrated added value and implementation effort
- Cybersecurity, data protection, and data sovereignty
- Governance, funding model and operational sustainability
- Vendor dependencies and exit strategies
- Auditability and access control
- Preservation of regulatory independence and autonomy

Swissmedic will not use applicant-proposed cloud platforms for individual procedures unless they are part of an approved international collaborative initiative involving Swissmedic.

EMA OPEN for post-approval changes: Example



Introduction of an **ID platform method through a Multi-Product PACMP**: highly complex, involving more than 15 impacted products

- 3 OPEN partners and additional observing authorities
- Independent assessment of the PAC by a Swissmedic Quality Assessor
- Early sharing of the EMA AR and participation in EMA alignment meetings (e.g. the Biologics Working Party, BWP), with the opportunity to provide comments on the EMA AR
- Excellent opportunity for regulatory convergence and for contributing Swissmedic expertise, enabling a joint List of Questions (LoQ) with as few region-specific supplementary questions as possible

EMA OPEN for post-approval changes: Perspective

- Good predictability for applicants, as all OPEN partners align with the EMA timelines.
- The very short timelines are challenging
- high degree of flexibility required
- Following the successful completion of the procedure, the applicant initiated a unilateral reliance process to which an additional 46 regulatory authorities were invited.

→ Joint publication of the experience and key learnings is planned with EMA, participating authorities and the applicant.

→ Swissmedic is developing its own EMA OPEN Playbook, which will serve as a framework not only for PACs but also for future OPEN procedures.

Perspective of the responsible SMC Senior Quality Assessor

"**Selecting the right PACs for the OPEN framework** is key to an efficient and effective process. The reduced complexity of PACs as compared to full initial applications lends itself well to rapid scientific alignment between participating regulators. At the same time, **PACs should have relevant impact to justify the effort for regulators and marketing authorization holders**. For Swissmedic specifically, close alignment with EMA in terms of variations classification, PACMP acceptance and scientific evaluation, enabled efficient and quick evaluation and rapid turnaround of PACs within the OPEN framework."

The Swissmedic Article 13 procedure: A popular and widely used pathway for post-approval changes



- Robust, well-established and highly predictable reliance pathway
- Fast, cost efficient and effective
- > 90% of Art.13 TPA applications relate to post-approval changes
- Partial assessments are rare and generally limited to areas of concern: Swissmedic retains regulatory independence and makes its own decision

➢ From Swissmedic's perspective, this pathway is preferred over alternative applicant-initiated reliance pilots

Guidance Authorisation human medicinal products under Art. 13 TPA

..and what about the future?

- Broader use of the existing instruments
  - Broaden the adoption of PACMPs: Broader awareness of the PACMP concept, e.g. shared by experienced agencies, will help to drive timely approvals of global post-approval changes
  - ICMRA PAC Pilot → GRACE
  - EMA OPEN

- Discussions with Access partners on post-approval changes ongoing


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Thank You!