Swissmedic IDMP Advisory Group

Minutes of the 2nd meeting of March 13 2024

Swissmedic, 2:00 PM – 5:00 PM; Wednesday, March 13, 2024
Moderator: Stephan Järmann, Swissmedic

Attendees

Stakeholders
- Jean-Michel Cahen, Novartis (jean-michel.cahen@novartis.com)
- Markus Müller, Astellas Pharma (markus.mueller@astellas.com)
- Jean-Gonzague Fontaine, GSK (jean-gonzague.x.fontaine@gsk.com)
- Enea Rosselli, Zambon Group (Enea.Rosselli@zambongroup.com)
- Quentin Darrasse, Roche (quentin.darrasse@roche.com)
- Deborah Cooper, MSD (deborah.cooper@msd.com)
- Frits Stulp, Deloitte/IRISS (fstulp@deloitte.nl)
- Nicolas Florin, Refdata (nicolas.florin@refdata.ch)
- Christian Kravogel, SeicoDyne (christian.kravogel@seicodyne.com)
- Franziska Sendfeld, FOPH (franziska.sendfeld@bag.admin.ch)
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Swissmedic
- Roger Rüegg, Program Lead TSP (roger.rueegg@swissmedic.ch)
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- Urs Eugster, IDMP Expert TSP (urs.eugster@swissmedic.ch)
- Robin Güttinger, IDMP Expert TSP (robin.guettinger@swissmedic.ch)
- Maren Eschermann, Data Architect TSP (maren.eschermann@swissmedic.ch)
- Stephan Järmann, Int. Standards Expert TSP (stephan.jaermann@swissmedic.ch)

Enclosures
1. Slides “Swissmedic IDMP Advisory Group Meeting 13.3.2024” (pdf)
2. IDMP Stakeholder Questions and Answers
3. Data Model FOPH *(status: March 2024)*
4. IDMP data model for pilot *(work in progress)*
5. Swissmedic-specific controlled vocabularies *(work in progress)*

Agenda

Minutes

1	**Introduction and stakeholder expectations** From the introductory round of the workshop, the expectations of the participants can be summarized as follows: • Understand national IDMP-initiatives, learn about the initiatives' data models and interdependencies, and leverage industry experience in this area. • Learn about Swissmedic's plans regarding IDMP and other regulatory requirements to ensure compliance and effective data management strategies • Explore potential synergies between Swissmedic initiatives and other R&D efforts to align strategies • Get to know the data models of the different IDMP-initiatives and the dependencies between them • Improve collaboration and information exchange among stakeholders, including participation in pilot projects and sharing of best practices.
2	**IDMP Initiatives in Switzerland** The presentations highlighted three key initiatives that have a particular focus on the implementation of the IDMP standards. • **SAI IDMP User Group by Refdata:** This initiative serves as a complementary effort to Swissmedic's advisory board, focusing on the exchange of structured product information in Switzerland. It involves a broad spectrum of participants, including health authorities, industry associations, healthcare providers, and software solution providers. Its goals include keeping stakeholders updated with the latest IDMP information, discussing practical questions and implementation experiences, promoting the use of FHIR (HL7) as the IDMP transmission standard. Accordingly, the SAI IDMP User Group has analyzed the datasets of the various stakeholders and is raising awareness of the importance of ensuring that Swiss sub-datasets are consistent with each other and integrate the ISO IDMP Standard to facilitate data exchange. • **Electronic Platform for Reimbursements (ePL) by FOPH:** The ePL project of the Federal Office of Public Health (FOPH) aims to digitize and streamline the processes related to the listing and reimbursement of medicinal products and medical devices in Switzerland. The project's vision includes creating a platform that contains the specialties list and medical devices list (list of medicinal products resp. medical devices that are reimbursed by the compulsory health insurance) and improves the efficiency and user experience of related processes. Key to this initiative is the standardization of data using IDMP coding where applicable and providing access to data through FHIR interfaces and APIs. • **Transformation of Swissmedic Platforms (TSP):** As part of its strategic goals for 2023-2026, Swissmedic is focusing on becoming a data-centered and agile authority. The TSP initiative is aimed at developing the Swissmedic portal to facilitate the transition from non-structured to structured data processing. This includes enhancing collaboration with stakeholders, adopting agile methodologies, and establishing a data analytics platform for better decision-making. The initiative also explores the use of IDMP standards both within Swissmedic's internal data model and at interfaces with stakeholders, with an overarching aim of standardizing processes to improve interoperability with external partners.
3	**Swissmedic's Approach** Swissmedic's architectural approach is to integrate both medicinal product and medical device lifecycles into a comprehensive Swissmedic portal. This portal will be the primary interaction channel for both internal and external users, streamlining processes and communication. The development strategy is that a significant portion of the work, approximately 80%, will be done in-house with a newly established software development department, working alongside external partners. The Swissmedic portal will be built in phases. The first implementation packages focus on licensing, specifically GMDP certificate ordering and establishment license applications, selected for their immediate business value and lack of electronic processing options

	Currently, we are starting to implement IDMP-compliant processes for the KPA ("Komplementär- und Phytoarzneimittel", i.e. complementary and herbal medicinal products) Notification Procedure, as the current software is end of life. Also planned for this year is to start an implementation package for the inspection process and to perform foundational work such as laying the groundwork for document management and user access management. *KPA Notification Procedure* The division KPA is responsible for complementary and herbal medicinal products, operating under the Therapeutic Products Act (TPA) and related federal ordinances. While there are about 1'400 authorised complementary medicinal products, there are also around 11'000 complementary medicinal products without indications that are notified to Swissmedic. The notification process for these products has been handled by an outdated software, HOMANT, developed in 2006, which is now at the end of its lifecycle and needs to be replaced. With the TSP implementation package for the KPA notification procedure the data of the notified medicinal products are getting aligned with IDMP to get migrated to the new IDMP-compliant database "Medical store". In particular, the IDMP alignement of the homeopathic substances (specified substances) will be part of this implementation package. *Connections to eCTD 4.0, ePI, Accumulus and CTIS* IDMP is related to topics such as eCTD 4.0, ePI, Accumulus and CTIS. The status of the discussion at Swissmedic is as follows: • *eCTD 4.0:* Swissmedic plans to implement eCTD 4.0 in coordination with the EU timelines. There is an overlap with IDMP data, which leads to considerations to reduce the scope of Module 1 eCTD as soon as the electronic application form (eAF) is introduced. There are currently no plans to reduce the scope of Module 3, but Swissmedic will monitor ICH activities in this regard in M4Q. • *ePI:* Swissmedic is currently monitoring the progress in the EU, but no decisions have been taken yet on legal adaptations or electronic standards for implementation. • *Accumulus:* Swissmedic is exploring Accumulus as a regulatory cloud platform, with interests in Project Orbis and other international application procedures, although IDMP-specific connections are not yet established. • *CTIS:* The harmonization of clinical trials data with IDMP, including CTIS, is currently not a priority in Swissmedic's TSP project. In the discussion, Swissmedic emphasized that TSP focuses on the agile implementation of individual use cases to advance the practical application of IDMP and other data standards. Challenges for comprehensive integration with other standards are therefore partially deferred, although Swissmedic is aware of them.
4	**Swissmedic IDMP Implementation: Status** *Swissmedic Data Model* Swissmedic has further developed its internal data model over the last months to ensure IDMP compliance moving forward. The focus on interoperability and value for internal and external stakeholders was at the core of the new data model. Swissmedic is close to finalise a Version 1.0 of the IDMP data model but is currently still working in some areas, where further internal alignment is needed. These areas include: Granularity of Quality data, specified substances with a focus on complementary medicinal products and therapeutic indications looking at code systems. In regards to Controlled Vocabularies (CVs), 17 Swissmedic-specific list have been identified so far. Reasons for these specific CVs are legal requirements (e.g. Regulatory Authorisation Type), additional level of detail (e.g. Medicinal Product Category) and additional lists (e.g. Scoring). *Federal Office of Public Health Data Model* The Federal Office of Public Health (FOPH) is working on a data model based on IDMP but tailored to its specific needs. This IDMP model is intended to facilitate the exchange of information with insurance companies and other stakeholders and contains additional attributes that are important

	for public health, such as information on reimbursements and restrictions. Currently the FHIR Implementation Guide is created and extensions will be used to add the additional attributes. The subsequent discussion of possible deviations from the ISO data model with Swissmedic- and FOPH-specific requirements, shows that it is important for MAHs that, as far as possible, only legally mandatory adjustments to the data structure are made, that the names for attributes are adopted from ISO and the European Medicines Agency (EMA) and that the CVs are based on international terms such as RMS, EDQM or MedDRA. *Data Exchange Pilot* The upcoming pilot project - expected to start in mid-2024 - aims to test the compatibility of data models between Astellas (as a participating pharmaceutical company), Swissmedic and downstream Refdata and FOPH. The pilot seeks to identify potential challenges in this data flow and consistency, particularly regarding CVs and specific data fields unique to Swiss regulation. EDQM will be used as a basis for international CVs because the option of using EMA's RMS list is not guaranteed. For the initial pilot, a limited data set (<59 data elements) will be used and 2 Astellas products will be tested. Additional pilots with a bigger data scope, with additional industry partners and products are foreseen. *Swissmedic Implementation Guide* For the Implementation Guide (IG), Swissmedic plans to use chapter 2 of the EU IG as blueprint and outline changes. It is foreseen to review the progress of the IG on a regular basis with stakeholder groups and seek feedback. The IRISS IDMP Group and also other stakeholders would be interested to get involved at an early stage. To get support and feedback in terms of international harmonisation, IRISS and CTADHL are recommended.
5	**Discussion about stakeholders involvement** The discussion on future stakeholders involvement can be summarised as follows: • TSP already involves stakeholders in the implementation package for licensing through a user group. For the IDMP implementation, the most relevant activities will be those related to the authorisation processes and the "Medical Store" database. The first version of the Medical Store is planned for Q4 2024. New features and updates to the Medical Store database will be added in subsequent releases. • Topics for stakeholder involvement identified so far are the alignment of the data model, the Swissmedic IG, the data exchange pilot between Astellas, Swissmedic, Refdata and FOPH and later also the user guidance in the Swissmedic portal. Understanding the differences in the data models (Swiss IDMP Pilot / ISO IDMP / EU IDMP IG Chapter 2) can be a starting point for collaboration. Marketing authorisation holders also see a significant benefit in data-only submissions and harmonised designations for data fields. • EMA was highlighted by the stakeholders as an example of organising quarterly system demos and specific information events where recorded sessions are offered for stakeholders engagement. The discussion also touched on how FOPH handles user engagement, mainly through overview presentations due to the urgency of its projects. • It was also suggested that forums such as IRISS be used to inform and prepare software vendors for upcoming changes in a timely manner, and the need for clear timelines to motivate software vendors to participate and adapt was emphasized. • It was agreed that creating value for stakeholders by aligning data models, involving them in the pilot and shaping the Swissmedic IG will in turn facilitate and accelerate the transition of sponsors and software vendors to IDMP.
6	**Next Steps** • Swissmedic compiled a list of the stakeholder questions that were received in advance and answered them individually. The list will be attached to the minutes. • The future exchange should take place at shorter intervals in accordance with the previous discussion on stakeholder involvement. As soon as results are available in TSP that are suitable for a stakeholder review, Swissmedic will inform the IDMP Advisory Board and establish a more regular exchange.