Swissmedic IDMP Advisory Group

Minutes from the Meeting of March 6th, 2023

Swissmedic, 1:30 PM - 4:30 PM; Monday, March 6th, 2023
Moderator: Stephan Järmann, Swissmedic

Attendees

Stakeholders:
- Jean-Michel Cahen, Novartis (jean-michel.cahen@novartis.com)
- Raphael Sergent, Novartis (raphael.sergent@novartis.com)
- Laurent Desqueper, MSD (laurent.desqueper@merck.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)
- Patrick Middag, Deloitte (pmiddag@deloitte.com)
- Nicolas Florin, RefData (nicolas.florin@refdata.ch)
- Christian Kravogel, SeicoDyne (christian.kravogel@hcisolutions.ch)

Swissmedic:
- Philipp Weyermann, Regulatory Assessment (philipp.weyermann@swissmedic.ch)
- Ingo Beckert, Transformation of Swissmedic platforms (ingo.beckert@swissmedic.ch)
- Stephan Järmann, Regulatory Operations & Development (stephan.jaermann@swissmedic.ch)
- Rolf Hotz, Veterinary Medecines (rolf.hotz@swissmedic.ch)
- Martin Ziak, Complementary and Herbal Medicines (martin.ziak@swissmedic.ch)

Excused:
- Urs Eugster, Regulatory Assessment (urs.eugster@swissmedic.ch)
- Ronald Hediger, Transformation of Swissmedic Platforms (ronald.hediger@swissmedic.ch)

Enclosures:
- Presentation “Swissmedic IDMP Advisory Group Meeting” (pdf)
- IDMP Pilot Data Model (Excel-File)
- Explanation to the data model (pdf)

Agenda

1	**Introduction** Swissmedic welcomes the stakeholders to the first meeting of the Swissmedic IDMP Advisory Group. The meeting has 3 objectives: 1. to provide information on Swissmedic's approach to IDMP implementation and the current status of the work 2. discuss stakeholder questions and interest of the stakeholders **3.** prioritization of topics for the next meeting(s).
2	**IDMP as part of the digital transformation of Swissmedic** Digital transformation is part of Swissmedic's strategy period 2023-2026. Swissmedic aims to become an agile and data-oriented company. To achieve this, the company plans to increasingly exchange structured data with stakeholders while relying on national and international standards. Ensuring the integrity, legal compliance and availability of data will be a key concern, as will digitally transforming work processes.

	Swissmedic is currently undergoing a program to transform digital platforms across the organization. This also affects processes and culture. The program was launched last year and will include several projects. A core element of this transformation is the establishment of a state-of-the-art portal for communication with stakeholders, such as pharmaceutical companies and other authorities. In the future, the portal will be the main hub for communication and will include, in one way or another, the exchange of data on IDMP. Discussion points: • *Cultural change:* Activities are currently focused on early end-user involvement and the use of agile methods such as Scrum for project management. In the future, assessors are also expected to rely more on structured data in the review than is the case today. The aim here is to close the gap between the use of documents and data for the assessment. It is not an either-or question. • *International procedures: The* focus at Access and Orbis is currently on the modernization of the existing platform and the automated exchange of information as well as the joint creation of work results such as the assessment report. IDMP is not yet a focus there, but could be one of the next topics. • *Portal solution:* Swissmedic currently plans to build up the knowledge for the development and maintenance of the portal in-house - also to avoid vendor dependency.
3	***Swissmedic's approach to IDMP implementation*** *Swissmedic's approach* Compliance with the IDMP requires structured data, therefore in the future the electronic application forms will be closely linked to IDMP. In terms of scope, the focus is on the use of data relevant to Swissmedic rather than the total of more than 500 data fields offered by the IDMP data model. A Swiss IDMP implementation guide that takes into account the specifics of the Swiss legal requirements is considered necessary. The scope of the first iteration will probably be similar to the EU and the creation of the data model is one of the first priorities for the Swissmedic IDMP activities. Swissmedic also plans to use IDMP to allow stakeholders to access their approved data on the portal. Stakeholders will have access to their current IDMP dataset in Swissmedic and can download it for their own purposes. *Discussion points:* • *SmPC data:* Dealing with different SmPC data of the same product in the EU is currently a challenge. This should be considered in the EU as well. • *Data corrections:* Swissmedic foresees minor data corrections in IDMP datasets to avoid time-consuming resubmissions. However, regulatory relevant corrections have to be made by the companies. • *Timing of IDMP data submission:* We see little value in receiving data post-approval in the marketing authorization process. Therefore, Swissmedic strives to obtain the data at the time of submission. • *Data only submissions:* Swissmedic also sees value in data only submissions that doesn't generate additional eCTD sequences (e.g. in the labelling phase). Although the harmonization with the eCTD life-cycle is an open topic there. *Networking: Coordination with IDMP bodies* Swissmedic strives to align its solution with global standards and actively participates in ISO TC 215 and regional mirror committees of the Swiss and European Standards Organisations. Swissmedic is additionally involved in several groups dealing with implementation, including the Refdata user group, as well as the GIDWG, which collaborates on global Substance-IDs and PhPIDs. In addition, Swissmedic contributes in IPRP to the information exchange between regulatros. We are also aware of several industry-sponsored or non-profit organizations focused on IDMP implementation, education, and information exchange, but cannot be involved everywhere due to resource constraints.

<u>*Discussion points:*</u>

- *Exchange on IDMP in the Access consortium*: There is currently no common initiative in terms of IDMP with TGA, HC, MHRA or HSA, but there is information sharing through the Access IT Working Group.
- *Exchange on IDMP with Accumulus:* IDMP does not appear to be a priority for Accumulus at this time. However, there are overlaps with IDMP and the DataX/CMC initiative regarding data that could be considered at a later stage of development.
- *Use cases as drivers of the IDMP implementation:* IDMP is currently mainly driven by the use case of the electronic application forms, but there is a need to link IDMP to other areas such as case reporting and pharmacovigilance later as well. Especially the PhPID will be of relevance in these areas.

IDMP Pilot Project (Astellas, Swissmedic, HCI Solutions)

The pilot project aims to exchange information on Astellas' pharmaceutical products between Swissmedic, Astellas, and HCI Solutions and allows to gain experience with IDMP data sets and familiarize stakeholders with tools and data models. The data will be also used to provide information for a Swiss IDMP implementation guide.

The pilot will start in the spring and will last for three to four months. But initial results show already that there are several data fields and code lists that are specific to Switzerland and are not covered by the international standards or the implementation used in other regions.

<u>Discussion points:</u>

- *Code lists:* Stakeholders emphasize the need for a common set of attributes for all regions. Swissmedic's goal will be to harmonize as much as possible, but there are regulatory requirements and differences to be considered here, e.g. application types, but also specificities such as information on orphan drugs, genetically modified organisms, and others. It will therefore be necessary for Swissmedic to maintain certain code lists. How this will be implemented, however, is still open.
- *Data model:* Swissmedic's internal data model will have to be revised for the adaptation to IDMP (e.g. adaptation of the data structure for packages, or the mapping of PhPIDs on all 4 levels). Above all, however, IDMP has an external interface data model, which Swissmedic would like to prioritize in the upcoming project and will be part of the Swiss IDMP Implementation Guide. The findings from the pilot project will be an important input for this.
- *Master Data for Substances:* It is currently not clear which substance database will be the master for Swissmedic in the future (e.g. the planned WHO database, FDA-GRS, EU-GRS). For the pilot, we are using our substance list, which is mostly mapped to UNII codes. Also, whether the substance data can merely be referenced, or whether they must also be stored on a Swiss server, still needs to be legally clarified. What is certain, however, is that Swissmedic does not want to become a registrar of substance data.
- *Timeline for the pilot:* The first pilot will likely launch in May or June and last 3 to 4 months. There is a limited time frame for the pilot projects. If something cannot be covered in this pilot phase, then it should be considered in the next pilot phase. E.g. topics regarding ATMP or complementary medicines.
- *Timeline for the IDMP introduction:* Swissmedic cannot yet give a date for the implementation of IDMP. This depends on many factors, including the implementation guide, the development of the portal, and the readiness of internal databases. Stakeholders point out that a transition period of several years will also be required on their side to adapt systems and processes.
- *Swissmedic's migration strategy:* It has not yet been decided whether Swissmedic will at some point request a baseline for existing medicinal products in order to obtain IDMP data. Swissmedic currently has a quite reasonable data quality at the moment. So a migration would have its advantages, but on the other hand, the data are certainly not complete and need to be enriched. It could also be a combination of the two approaches, depending on what kind of data we are dealing with.

4	**Questions and interests of the stakeholders** Based on the discussion of the previous topics, many questions could already be answered. The remaining discussion points were the following: • *IDMP and eCTD 4.0:* The current eCTD 4.0 specification does not include much metadata in advance to keep the overlap between IDMP and eCTD regarding data low. However, with a Module 3 that includes structured data, this may change in the future. ICH is currently addressing this topic. • *IDMP and Clinical Trials:* At the moment, the investigational medicinal product is most probably not part of iteration one. But we just recently moved the clinical trials to the same platform that we are using for regulatory approval. At least the data that we collect for clinical trials is now in the same system and we use e.g. a common substance list. • *Reconciliation of data with the EU PMS or eCPP*: The discussion revealed that it is important to use and compare data not only from the OMS but also from the PMS. One possible use case is drug shortages. With regard to electronic certificates for pharmaceutical products (eCPP), Swissmedic plans to automate the process as much as possible. The certificates should rely on the IDMP data in the system. At the moment Swissmedic is already obliged to use OMS identifiers to upload data in EudraGMDP, therefore we ask for OMS identifiers in the application forms. • *FHIR message compatibility:* Message compatibility: Swissmedic's IDMP solution may require the adaptation of existing FHIR resources. However, the creation of new FHIR resources should be avoided in order not to make the technical implementation even more complex. Swissmedic expects more insights on this topic with the piloting. • *Harmonistion with eHealth:* The terms used in the IDMP are related to eHealth. Currently, the FOPH has established a group that aims to harmonize terminologies and standards in eHealth for Switzerland (in response to the European Health Data Space Initiative). It would be useful if Swissmedic could also harmonize its IDMP terms with this group to avoid national divergences. • *IDMP and reliance:* Reliance applications (e.g. according to paragraph 13 TPA) may use IDMP datasets from other authorities. Swissmedic will have to consider how to deal with this.
5	**Feedback and Topics for the next meeting** Swissmedic is in the process of strengthening its IDMP activities and is open to feedback and offers of support. The approach of reaching out to stakeholders in a timely manner is generally welcomed by stakeholders and seen as valuable. The slides are considered good information, and Swissmedic states that they are happy to share them. In addition to the pilot project, Swissmedic plans to develop a Swiss IDMP implementation guide. So far, the following topics have been identified for the next meeting: • Update on the Swissmedic activites and plans • Update on the IDMP pilot • Collaboration on the development of the Swiss IDMP implementation guide. • Discussion on the possibility of sharing system resources and the need for technical considerations. A next meeting is planned in a period of 6 to 9 months.