12 July 2021
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Minutes of the European Union (EU) International Organization for Standardization (ISO) for the identification of medicinal products (IDMP)/Substance, Product, Organisation and Referential data (SPOR) Task Force meeting

12 April 2021, 09:30 – 16:30 (CET time), remote

Co-chairs: Isabel Chicharo (EMA), Joris Kampmeijer (NCAs), Laurent Desqueper (Industry)

Role	Name
Attendees	EUNDB: Ana Lopez De La Rica (Spain), Joris Kampmeijer (The Netherlands), Anja van Haren (The Netherlands), Triin Mäesalu (Estonia), Mourad Hassani (France), Dubravka Sudić (Croatia), Marko Suvak (Croatia), Georg Neuwirther (Austria), Peter Bachmann (Germany), Paule Carnat-Gautier (France Vet), Gunnhild Vikhamar (Norway), Kristine Aasen (Norway), Johan Aulin (Sweden), Harold Landras (France), Stina Wahlin (Sweden), Christopher Jarvis (EDQM-France), Louise Petersen (Denmark). NCA Observers: Frits Stulp (The Netherlands), Annet Rozema (The Netherlands), Karin Gröndahl (Sweden), Bjorg Overby (Norway). Human Industry Associations representatives: Laurent Desqueper (EuropaBio), Patrick Middag (EFPIA), Quentin Grignet (Vaccines Europe), Andrea Herrmann (EuropaBio), Stuart Izod (Medicines for Europe), Karl-Heinz Loebel (EUCOPE), Nora Weitbrecht (Medicines for Europe), Remco Munnik (Medicines for Europe), Elisabeth Godet (Vaccines Europe), Rodrigo Palacios (EFPIA), Paul-Etienne Schaeffer (AESGP), Angela Mueller (AESGP), Christoph Kox (AESGP), Jean Michel Cahen (ECI-EEIG), Andreas Franken (AESGP), Anjana Pindoria (Medicines for Europe), Paul Mills (EFPIA), Joerg Stueben (EFPIA). Veterinary Industry Associations representatives: Jaka Petrič (EGGVP), Elsa Vecino (EGGVP), Patrizia Oelker (AnimalhealthEurope).

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Role	Name
	Interested parties: Barry Hammond (Terminologeze), Wim Cypers (ArisGlobal), Niels Buch Leander (NNIT), Christian Hay(GS1 Global Office), Malin Fladvad (UMC), Karen Harry (PAREXEL International), Christopher Gessner (Gematik). Ursula Tschorn (DACON), Markus Pfahlert (LORENZ Life Science). Observers: Vada Perkins (EFPIA). Kevin Horan (Extedo), Kelly Hnat (K2 Consulting), Gunther Pfeifer (ECHAMP). EMA: Hilmar Hamann, Christoph Pillichshammer, Isabel Chicharo, Aleksandra Dacic, Jaume Gonzalez, Veronica Lipucci Di Paola, Pedro Batista, Debora Martins Braga, Mihaela Sisu, Gustavo Rodriguez, Marcos Fernandez Gomez, Panagiotis Telonis, Barbara Freischem, Elias Tavares, Sara Teiken, Jana Schalansky, Ana Cochino, Alessandra Lolato.
Minutes	Stavroula Tsalapati

1. Agenda, Welcome & Ground rules

The group requested the need to update the rules for recordings and data protection. There was discussion about where to find published versions of the minutes and having a formal process to adopt the minutes and Q&A at the beginning of each meeting. This is for future consideration, agenda/timing allowing. A few extra topics were briefly discussed, and the agenda was adopted to proceed as proposed.

2. EU IG updates

The overview of the new contents of the EU IMDP Implementation guide v2.0 released in February 2021 were presented to the members of the SPOR Task Force.

The main updates are related to the PMS Data Model requiring a significant update of:

- EU IG Chapter 2. This chapter was updated to reflect the latest agreement on the new data elements to introduce, the business rules to follow and the technical details to allow the EU network to face the preparatory phase announced to start after the release of the EU IG v2.0.
- The introduction chapter was also proposed to be updated with general information about the scope, use and future plan foreseen for PMS EU IDMP Implementation Guide.
- Chapter 1 was updated to introduce the new PMS roles to support the access and use of the PMS database from a user perspective. Additionally, details about the training, registration, accessibility requirements were introduced in the new version of the guidance. Along with Chapter 1 also the SPOR Onboarding of user roles has been updated.

Among the new chapter introduced as part of the EU IG v2.0 there are:

- EU IG Chapter 3 created to describe the process related to the product submission into PMS;
- EU IG Chapter 8 developed to support the user in gaining more clarity on how to perform the data entry based on the different and complex scenario;
- EU IG Chapter 9 was also agreed to be developed with the scope to provide detailed information on how the PMS system should be populated following the data load from the current system (i.e. xEVMPD database). However, this Chapter is due to publication in EU IG v3.

EMA also clarified that the release of v2.1 and v2.2 is deemed necessary in order to finalize to address all the remaining issues identified to improve the quality of PMS and its guidance.

In this regard, EMA announced that v2.1 will be released at the end of June 2021 while v2.2 at the end of September of the same year.

In order to timely address the remained issues in a more efficient approach, EMA announced the previous Focus Groups (Ch8 and Ch2&3) are replaced by the set up of the Data and Process Focus Groups of which composition was announced (please refer to topic 3).

The PMS governance was clarified to the member of the meeting. It was explained that the Telematics Governance was consulted for approval of process/approach to ensure due diligence/representation, however this is not required to provide additional approval of content of the EU IG. SPOR Co-chairs are involved in the reviewing the contents of v2.0 release and no further consultation is expected to release v2.1 and v2.2.

Additionally EMA announced the additional activities required in order to progress with the development of the PMS system such as the completeness of the database to design, confirmation and test of the migration rules, load product data from XEVMPD/SIAMED to PMS as well as the need to perform the relevant UATs to be successful prior the relevant Go-Live.

Clarifications were provided in relation to the go-live process and future announcements. In summary, a minimum of 12 months from the EU IG v2.0 release will be given to allow the stakeholder to prepare for the implementation of PMS and start submitting the product information to the database. An implementation plan will be released in due course to provide further indication of Go-live and its timelines.

PMS Electronic Submission Process

The overall process for the submission of data to xEVMPD or PMS was presented.

For CAPs, the FHIR format is the format to be used and the presence of an eCTD closing sequence at the end of the regulatory process defines the submission workflow.

For non-CAPs, FHIR submissions are optional, and if used, submissions should be done through the API.

It was also described the different FHIR provenances:

- Regulatory Submission – Initial: Submissions linked to Initial Marketing Authorisation Application and other procedures such as Extension Applications (new PMS IDs are generated)
- Regulatory Submission – Maintenance: Submissions linked to regulatory procedures where the medicinal product data is updated due to post authorisation regulatory activities
- Notification: Submissions linked to updates of data not linked to regulatory procedures such as QPPV, PSMF, marketing status updates, etc
- Amendment: Submissions linked to correction of data for specific FHIR resources where no regulatory assessment is needed
- Enrichment: Submissions linked to the completion of the full FHIR dataset as per ISO IDMP and EU PMS IG rules
- Nullification: Submissions to flag as "nullified" entities created by mistake

3. PMS FGs updates

During 2020 and 2021, there were two different Focus Groups whose goal was to generate the draft EU IG v2.0. These groups were the FG EU IG Chapter 8 and the FG EU IG Chapter 2 and 3.

In 2021, and after the publication of v2.0, new FGs were created: FG Data and FG Process. The members were presented and a call for volunteers from the NCAs was raised.

FG Data is created to focus on EU IG Chapter 2 open topics as well as Chapter 8 and Annex I to provide an improve the examples. One of the topics of this group is to discuss the different RMS lists that are needed to report data to PMS. Other topics were presented.

The FG Process should focus in Chapters 3 and 9, mainly focus on the discussion of the submission process. A list of topics was also presented.

The different PoCs were presented and explained. All the PoCs will focus on Step 1 as this is the priority for the moment.

In relation to the Process, a GAP Analysis is needed before any PoC can start.

In relation to Data, there are three different PoCs:

- Identifiers: theoretical PoC conducted by Industry. Outcome will be used to update Chapter 2.
- Data elements: define the source of information for each data element present in Chapter 2. Sources can be SmPC, m3, Art 57, etc).
- FHIR PoC: technical PoC to define how the FHIR message should look like. To be performed by Industry.

4. PMS Step 1

IC started by reminding that the aim is to have a reliable plan for step 1 for which certain conditions need to be met but also that the groups agreed to start on this journey knowing that it can continue. The project team is therefore putting in place key building blocks (IT components) that will be necessary for step 2 and are looking into ongoing projects (DADI) to align these deliveries. Aligning the SPOR plans with DADI is expected to ensure smoother transition to STEP 2.

The current plan covers EU IG development, POCs to prepare for step 1 implementation, the plan for delivery of IT components needed for step 1 implementation, but can also be used for step 2 and identified the work that will be carried out under DADI (eAF replacement), SPOR and an internal workstream on EMA business process management (processes & tools). The team has identified dependencies, critical paths across those projects and is working on aspects of change management and roll-out.

This plan has been discussed with co-chairs who are fine tuning it. They will consult with their stakeholder groups to collect any feedback/concerns. The SPOR TF will also have the opportunity to discuss the plan.

The intention is to have the plan aligned with DADI and agreed by different parties to indicate the approximate Go-live date. A separate announcement can occur closer to go live (not more than 1 month notice) when we have done development and possibly UATs, to say month/day of when the system will go-live. IC emphasised the need to continue preparations.

5. Q&A

6. Substance Updates

With regards to SMS Operations the statistics for substance change requests have improved in the past months. Outsourcing of simpler substance tasks (e.g. implementation of SVG cleansed data, management of translations, enrichment exercises, etc.) will start soon in order to increase capacity and further improve SLAs. Support to Vet NCAs is ongoing with webinars and substance mappings for UPD.

The SMS Project still on hold and timelines will be communicated as soon as agreed.

The Substance Validation Group (SVG) is proceeding with data cleansing at full speed. The missing substance types have been addressed by the SVG and are expected to be fully implemented in SMS in May. At this moment, 75% of the work on chemicals is completed. Cleansing of Veterinary vaccines is completed and Human Vaccines are being built directly in EU-SRS. Cleansing of proteins also has started, the team first focuses on monoclonal antibodies. Where possible, US (GSRS) public data is reused.

EU-SRS is moved to EudraNet. This allows entry of confidential data, applicable to – for example – proteins and vaccines. The team is preparing to start testing the data load script; with this script, it is the intention to automatically load cleansed records to the live environment. Regarding the Global vaccines initiative, WHO-UMC, FDA/NCATS and the EU-SRS team have joined forces to investigate if a global approach is feasible w.r.t. vaccines substances. Industry is also involved. In this pilot project, the feasibility of global substance identification is investigated. Are we able to align working methods, build vaccines in the same way in the SRS software and exchange vaccines substance records between the three parties? Interim results will be shared early June. The final conclusions and advice on next steps are expected in October 2021.

The group also discussed Stakeholder management. To this regard, in order to increase Industry involvement on substance matters, and to present a more harmonised reporting between SMS and EU-

SRS, a new approach for stakeholder management has been presented. Substance Work Group(s) will replace the SMS-Subgroup as a more dynamic and frequent group(s) on specific substance topics. It is expected active participation/input from these members. In addition, "Substance Days" will replace "EU-SRS days" as a more informative forum for all substance matters.

7. OMS/KUG activities

An overview on ongoing activities for OMS, as well as activities planned for the remaining of 2021, was presented to the group. The overview included details on operational work, technical and documentation updates, mapping activities, as well as ongoing and planned work related to EMA projects that will be consuming data from OMS (i.e. UPD, PMS, CTIS and EVVET3).

The presentation included a slide showing communication activities in the OMS front over the last year, including 3 webinars covering topics such as introduction to OMS, submission of Change Request, Service Desk and Data Quality Management. In addition, we have been supporting Vet NCA's with monthly surgeries, where we clarify any outstanding questions related with business rules or OMS processes.

The final OMS topic was an overview of Key User Group (KUG) interactions with OMS and respective governance - how OMS data is managed and how OMS data is used in the business process. In particular, a summary of main activities taking place at the guidance, process level, necessary reviews of our Data quality standards and proposals for IT improvement were presented, as well as topics planned for future discussions.

8. RMS/KUG activities

An overview on the ongoing activities for RMS as well as the planned activities for the remaining of 2021 was presented to the group. The overview included details on operational work, technical updates, mapping activities as well as ongoing and planned work related to EMA projects that will be consuming data from RMS (i.e. UPD, PMS, CTIS and EVVET3).

To illustrate the range of activities in RMS and the complexity of some of these activities, a more in-depth overview was presented on the topics of the mapping exercise of standard terms from the xEVMPD (Art. 57 database) and RMS, as well as on the discussions taking place within the Vet Expert Group on the Legal status for the Supply list in RMS.

The presentation included a slide showing the communication activities on the RMS front in the last 18 months approximately, including 4 webinars covering topics as introduction to RMS, RMS operating model, submission of change requests, submission of translations and mapping of referentials.

Another topic covered was the interactions between the Key User Group (KUG) and RMS. In particular, the proposals for improvement from the KUG were presented, as well as the planned topics for future discussions.

The final RMS topic was an overview of the planned activities for RMS, including SPOR/RMS maintenance activities but also other activities such as mappings, update of the SPOR-related documentation on the corporate website, creation of new RMS lists, etc.

9. Q&A