12 November 2020
EMA/523839/2020

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

25 September 2020, 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), Jose Manuel Simarro (Spain), Mourad Hassani (France), Dubravka Sudić (Croatia), Marko Suvak(Croatia), Georg Neuwirther (Austria), Peter Bachmann (Germany), Katalin Burjan (Hungary, Vet), Marta Terron Cuadraro (DG SANTE, EC), Paule Carnat-Gautier (France Vet), Gunnhild Vikhamar (Norway), Kristine Aasen (Norway), Johan Aulin (Sweden), Louise Petersen, (Denmark). NCA Observers: Frits Stulp (The Netherlands), Annet Rozema (The Netherlands), Urs Eugster-Swissmedic (Switzerland). Human Industry Associations representatives: Laurent Desqueper (EuropaBio), Patrick Middag (EFPIA), Quentin Grignet (Vaccines Europe), Andrea Herrmann (EuropaBio), Ursula Tschorn (Pharmazie), Stuart Izod (Medicines for Europe), Karl-Heinz Loebel (EUCOPE), Kevin Horan (BearingPoint), Nora Weitbrecht (Medicines for Europe), Remco Munnik (Medicines for Europe), Elisabeth Godet (Vaccines Europe), Rodrigo Palacios (EFPIA), Paul-Etienne Schaeffer (AESGP), Angela Mueller (AESGP), Jean Michel Cahen (ECI-EEIG), Andreas Franken (AESGP), Anjana Pindoria (Medicines for Europe), Sabrina Conti (Medicines for Europe), Laurent Louette (EUCOPE). Veterinary Industry Associations representatives: Bernd Beutel (EGGVP), Jaume Colomer (AnimalhealthEurope), Jaka Petrič (EGGVP).

Role	Name
	Industry association observers: Vada Perkins (AESGP). Vendors/Software providers: Barry Hammond (Terminologeze), Markus Pfahlert (LORENZ Life Science). Interested parties: Wim Cypers (ArisGlobal), Christof Gessner (Gematik), Niels Buch Leander (NNIT), Christian Hay(GS1 Global Office), Malin Fladvad (WHO). Additional experts: Kelly Hnat (K2 Consulting), Karin Grondhal (SE MPA), Gunther Pfeifer (ECHAMP). EMA: Hilmar Hamann, Francisco Penaranda Fernandez, Isabel Chicharo, Olivier Simoen, Jaume Gonzalez Nogueras, Carlos Aicardo, Veronica Lipucci Di Paola, Pedro Batista, Debora Braga, Mihaela Sisu, Gustavo Rodriguez, Idu Andrei, Anne-Christine Lantin, Barbara Freischem, Marek Lehmann, Melanie Lovedy, Marcos Fernandez Gomez, Delia Matei.
Minutes	Stavroula Tsalapati

1. Agenda, Welcome & Ground rules

The agenda was adopted.

2. EU PMS IG v2 consultation

Veronica announced the closure of the second round of consultation of the EU PMS IG (Human) launched in early July 2020 and the related results and feedback from the previously held PMS SG Workshop.

The structure of the EU PMS IG as well as the updated status of each of the ongoing activities and the consultation process were reminded to the audience. Subsequently, the results of the feedback received from each of the stakeholder's groups involved in the consultation process for the EU PMS IG v2 were presented to the TF members. Reference was made to the presentation of the comments classified per chapter and type of category by the two stakeholders' groups, NCA and Industry, respectively. Additionally, the combined volumes from both NCAs and Industry was provided in addition to the main key messages highlighted by each Stakeholder's Group.

In this regard, two aspects should be taken into consideration when analysing the comments received: the first was the possibility to have duplicates among NCAs set of comments and between the consolidated NCA set vs the Industry's one. The second referred to the 28 comments provided by the Industry not being classified as per the provided methodology. During the meeting it was anticipated that out of 28 comments: 25 resulted being "Would" and 3 "Could".

The resolution approach was proposed to the TF members for discussion and adoption. The following principles regarding the EU IG v2 were agreed:

- Start addressing the first level of priority of "Must" and "Should" comments and later the other;

- EMA experts to involve colleagues from both business and technical areas in order adequately to address each type of comments;
- EMA to consolidate the NCAs set of comments into 1 single file;
- Industry volunteered to perform the super consolidation among the NCAs and Industry comments by mid-October following consolidation of NCAs comments performed by EMA;
- Industry to classify the 28 not classified comments;
- To reinstitute and expand the scope of both the Focus Groups: 2 (to cover chapter 2 and 3) and 8 (to cover also the activity on the RMS lists);
- NCAs to check whether additional experts may be needed to participate in the Focus Groups;
- EMA to address the comments on Chapter 1 and to organize ad-hoc meetings to continue the discussion on the outstanding PMS activities;
- To review plan by the end of October based on the analysis on the efforts/complexity to resolve the comments and NCA-Industry de-duplication.

The proposal made by the Industry members of the PMS SG was also presented to the members of the SPOR TF, regarding the creation of a dedicated Focus Group - to address the discussion on the Target Operating Model (TOM) mentioned in chapter 3 of the relevant guidance. Due to the EMA limited capacity in running several groups in parallel it was suggested to include this type of discussions into Focus Group 2 during 2020 and to create a dedicated Focus Group on Process from 2021 onwards that will cover aspects of the process as well as legacy data.

The possibility to have EU IG V3 available as of Q4 2021 was also presented to the members. Reference was made to the composition of the Focus Groups set from 2021 onwards to cover any aspects related to data and process, respectively, as well as the creation of the outstanding chapters in conjunction to the possibility to update the currently available ones. The proposal to set up two Focus Groups, one on Data and the other on Process was also supported but further need for discussion on mandate and workplan before final agreement.

The Group requested clarification on the possible discontinuation of XEVMPD. It was clarified that the current XEVMPD database will not be discontinued as it will support the Pharmacovigilance processes. Only the xEVPRM (message) will be discontinued, initially for CAPs only and eventually extended to non-CAP products, however further details will be provided at later stage.

3. Feedback from PMS Workshop

Veronica presented the feedback from the PMS Workshop held on the 23rd of September 2020. Considering that the results from the EU IG v2 were presented in the previous slot, the presentation mainly focused on the outcomes of the discussions held about the Legacy data/ enrichment and validation aspects. In this regard, the SPOR TF members were updated on the rational to have the migrated data (from the current XEVMPD database) to be enriched in PMS as well as the main driving goals. Information on the two established processes of data submission in PMS were provided (i.e. Regulatory Data submission, Legacy Data submission and Supplementary Data ('Enrichment Process'), in addition to the linked process of data validation in step 1 and 2 and related impact for the Regulators. Regarding this aspect, the Group pointed out the importance to ensure that product

data/information should also be adequately standardized and harmonised across similar existing product data for consistency purposes.

Agreement among the members was reached on the main principles following the statement of both NCA and Industry's views and concerns below reported:

- CAs should only receive, assess and validate data related to the applied procedure and label as *Approved/Validated.*

- Willingness from the Industry to submit the full data set instead of fragmented data

- Agreement on new Application Type: *Enrichment* to be used by Industry to submit extra information to enrich. Considered to apply specific labels on the submitted data depending on what is validated (i.e. *unvalidated / uncertain*)

- Validation of data may differ based on the authorization procedures (i.e. CAPs: validation against the dossier – part of eCTD M3 and SmPC; Non-CAPS: validation against the submitted data if within TOM or against the available product information i.e. SmPC if without TOM.

- NCAs data to be used in priority to Industry data. No specific comment was raised by the

Industry in this regard.

- Industry should check/confirm and correct/update all migrated data before the first data submission.

Overall, the Group agreed to have a dedicated enrichment application type to submit the core set of product data in PMS, with the condition that the data can be labelled as *unvalidated / uncertain* when the validation does not occur,Agreement on the Industry responsibility to check/confirm and correct/update all migrated data before the first data submission was also mentioned. There is the need to continue the discussions on Legacy data aspects specially to explore the FHIR granularity (eg. for Variations) and the feasibility to submit as part of the FHIR message only the necessary data related to the regulatory procedure as outlined in the respective legislations. The Industry's concern in submitting fragmented product data and related difficulties in implementing the discussed workflow was also reported.

The Group asked the EMA intention to set up a dedicated Focus Group to discuss the aspects on legacy data. As previously announced, a Focus Group will be set up to discuss any aspects related to PMS processes including the legacy data/enrichment and related use cases to support. In conclusion, additional meetings will be held to further define the processes and seek the applicability of the potential solutions related to the data submission and validation.

4. SPOR Programme update

Isabel framed the programme activities into the agreed 2 step implementation plan. She updated the group by providing an overview of all SPOR workstreams and contributing initiatives followed by a drill down into each SPOR domain. The main activities were highlighted but also the relevant dependencies. She also highlighted benefits and expected actions for Industry and NCAs.

Isabel noted that there was an initial desire to make OMS mandatory in eAF but a final date had not been agreed. In any case OMS would in practice become mandatory under the Veterinary Medicinal Products Regulation (VMP-Reg), Regulation (EU) 2019/6 in January 2022. AnimalhealthEurope asked that this would be phased between H & V domains so as not to have a surge in change requests.

The group asked for further clarification in terms of the dependencies with ePI as well as IRIS vs UNICOM/application dataset. It was clarified that the Application Dataset Integration (DADI) project to replace the eAF covers the scope of parts of UNICOM WP3 but not the complete Project as there are also more workstreams in UNICOM. It was agreed that this will be elaborated at a next SPOR TF together with the relationship of DADI with SPOR and ePI.

5. Statement from Sponsors

Hilmar provided an overview of activities that contribute to turning SPOR into a data foundation integrated into regulatory processes. He explained about the new Application Dataset Integration telematics project which will replace the current PDF-based application forms with new web based application forms using the ISO IDMP Standard, FHIR as the transport tool for data and defintions agreed by the EU Implementation Guides of the SPOR programme. This will serve as the basis to better integrate the application data with SPOR and with the various regulatory systems across the network. Several benefits are expected from this such as the reduction of duplicate data entry, the avoidance of copy and paste between documents, etc.

He also mentioned a new Programme being set up at EMA, the "Regulatory Process Optimisation", focused on regulatory processes within the EMA and in particular on the business outcomes rather than technology. The Application Dataset Integration is one of the workstreams in this programme. SPOR is a platform that underpins the regulatory activities.

He explained that the EMRN is in early discussions about the update of the Telematics Roadmap, which may be an opportunity to clarify SPOR deliverables as well as benefit and business outcomes that will be delivered over the coming years.

Hilmar elaborated on the role of SPOR as an enabler of the EMRN strategy and the Regulatory Process Optimisation by being the single source of truth and the foundation for lifecycle data management. Supply chain, shortages, nitrosamines and COVID are examples of areas where SPOR could demonstrate its value.

Finally, he explained how EMA, particularly the IM division future proofing effort, better supports this vision with 3 departments focusing on key areas: one department focusing on Stakeholders (Customer Advocacy and Delivery), one department focusing on technology (Strategic Platforms) and one on data (Core Services).

Peter Bachman raised the need of a reliable Roadmap i.e. a clear plan with what is delivered vs what it supports, that is underpinned by milestones, resources and budget. Hilmar noted that the main driver will be the Telematics Strategy and, once that is defined, he will ensure that there is enough capacity to support the required work.

Rodrigo asked how Industry can help and it was reiterated that this group is a good example of collaboration. Hilmar clarified that there is ongoing discussion of membership in other groups and he would value Industry collaboration on the Application Dataset Integration to replace the eAF. This would bring value not only to regulators but also to industry.

Joris stressed that he is missing a strategic/business discussion with business sponsors and asked Hilmar on his experience in US in terms of bring IT and business together. Hilmar noted that Business partners are usually more focused on their public health issues and it is important to understand what problem they are trying to solve and to show how data can support them. He reminded that data efforts are not quick efforts, it is an ongoing process putting processes on the right path to increase

gradually the quality of data. This is an area that brings value over time but requires continued investment. Ultimately data is a business service. It was acknowledged that there is no short-term solution so further discussion will be held at co-chair level to see how to take this forward and increase the interactions with our counterparts on the business side as this may be key in getting SPOR up and running.

Georg pointed out the importance to be part and influence the outcome of the Network Strategy, which should be endorsed towards the end of 2020.

Laurent pointed out that it is important that there is an alignment between EMA and NCAs to progress with SPOR, including timelines and benefits, so that topics do not keep being re-opened. Hilmar reminded that there is a focus at EMRN for SPOR being an enabler. Georg will describe the specific initiatives for achieving this in a workshop planned for October. Feedback will then be provided back to this group to initiate the discussion on the next steps

Finally, there were a few suggestions of points for clarification in subsequent sessions particularly:

1) SPOR and Big data initiative and how they can enrich each other– follow up with Peter Arlett

2) Update and Governance in UNICOM and application dataset – by Georg

3) Network Strategy Workshop in Oct - by Georg

4) Definition and expectations of "single source of truth" – discussion to start at EUNDB

6. Q & A

7. Feedback from SMS Workshop

In terms of Operational status update, Pedro presented the substance dataflow, which hasn't changed since the last SPOR Taskforce. He also presented the statistics on substance requests and SLAs which showed that most requests haven't been processed in 5 working days. The SPOR Taskforce participants raised concern for the lack of resources in SMS and asked which measures are being put into place. Isabel clarified that although a new colleague is being trained to support the SMS team and that, next year, some SMS activities will be outsourced this is a complex area and new resources are not operational in a short term. Pedro then informed that the SPOR team has also been busy with COVID-19 substances and registration of legacy substance data and that the go-live of the new SMS interface in Service Desk Portal to submit change requests is currently on hold due to lack of capacity for change management.

In terms of Project update, Pedro informed the group that two new functionalities have been deployed in SMS: bulk searches and simple nullification. The SMS Long term plan has been presented with the known timelines for change requests, system changes, legacy data and data enrichments.

Pedro then moved on to update on the status of the /implementation of SVG data cleansing work and how it has been reflected in SMS. No new SVG cleansed Human substance data has been loaded into SMS since the last SPOR Taskforce. Datafixes are currently being planned. The status of veterinary substances cleansing has also been presented. All legacy veterinary data has been registered in SMS. Proteins cleansed has been completed. Vaccine cleansing is ongoing and planned to be finalised by the end of the year.

8. EU-SRS status update

Annet informed the group that Phase 1 of the implementation of EU-SRS is half way and provided details on the different workstreams.

With regards to cleansing work:

- The first version of the data cleansing guide was recently published on the internet, together with a list of changes processed in SMS, including the type of changes.
- Chemicals data cleansing is running behind schedule. The team is currently investigating options to increase the SVG resources involved in data cleansing and this looks promising.
- Cleansing of vaccines is also a bit behind and is going slower than anticipated. The team is working on ways to increase the speed of the scientific discussions regarding vaccines.
- Cleansing of veterinary vaccines is on track, as well as cleansing of proteins.

The discussions on the future process are also a bit behind schedule, but these have recently started. System-related activities are on track. Other activities are proceeding according to plan.

A key item for agreement in the team is the go-live strategy particularly when will EU-SRS go live and with what data. No final conclusions are possible at this moment.

9. KUG

The SPOR Key User Group, including EMA, NCAs and Industry, conducted a data quality pilot on manufacturer data in OMS with the kind support of CorrIT, who provided access to the tool SPORIFY. Via trade associations (EFPIA and Medicines for Europe), manufacturer data address data have been collected anonymously, filtered for duplicates and analysed for alignment with the OMS service. The results of this large dataset of about 24000 records (approx. 66% of OMS) were triaged using the categories matched, organisations matched, multiple choice, suggested and not set.

The triage resulted in 24% of organisations assigned to the category matched, which from a practical perspective means that they can be used without further pre-submission processing. In 13% of cases, the organisations could be assigned, but not the locations. With a number as high as 61%, the majority of cases was assigned to the category suggested, which means that human action is needed to evaluate the information and perform a mapping or necessity for a change request.

In addition, it became obvious that special care has to be taken by organisations used by multiple other companies, such as CMOs, as there is a risk for blocked/rejected or ping-pong change requests. Risk mitigation means have been proposed by the KUG for these issues.

Lastly, the pilot revealed a small number of around 4% data quality issues like inconsistent address formats, duplicate locations or duplicate languages, which already have been addressed by the OMS team in the meantime – a great example for the successful collaboration between all KUG stakeholders.

Other topics that will need to be addressed in the KUG OMS:

1. Alignment OMS and EudraGMDP
2. Industry alignment with OMS

3. NCA alignment with OMS
4. Establish standard approach for non-EU manufacturers (e.g. plot numbers)

10. VMP-Reg/UPD

Olivier Simoen informed the SPOR Task Force on the Status of the UPD project, noting that both UPD Access Policy and the Veterinary EU Implementation Guide Chapter 2 have undergone consultation, and the UPD Project Vision has been finalised.

An informal testing of the UPD Data Repository and API is ongoing with some NCAs. Also, the testing of the mechanism (NCA UI and API) and format to upload legacy data is being tested with some NCAs. He also reported that the first components of the UPD, i.e. the UPD Data Repository and Application Programming Interface (API), became available on 24 September 2020. These components provide IT systems of National Competent Authorities with automated access to the Union Product Database. The functionality made available at this point is limited to reading information on centrally authorised products and automatically creating MRP/DCP/NAP product information.

11. Q & A