4 December 2020
EMA/662833/2020

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

9 December 2020, 09:00 – 11:00 (CET time), remote

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

Role	Name
Attendees	EUNDB: Ana Lopez De La Rica (Spain), Anja van Haren (The Netherlands), Triin Mäesalu (Estonia), Mourad Hassani (France), Dubravka Sudić (Croatia), Marko Suvak(Croatia), Peter Bachmann (Germany), Katalin Burjan (Hungary, Vet), Paule Carnat-Gautier (France Vet), Kristine Aasen (Norway), Johan Aulin (Sweden), Christofer Jarvis (France), Bigalke Hans-Joachim (France). NCA Observers: Frits Stulp (The Netherlands), Annet Rozema (The Netherlands), Inti Van Eck (The Netherlands). 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), 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), Paul Mills (EFPIA). Veterinary Industry Associations representatives: Bernd Beutel (EGGVP), Jaka Petrič (EGGVP). Industry association observers: Christofer Kox (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), Karen Harry (Parexel). Additional experts: Stina Wahlin (SE-MPA), Karin Gröndhal (SE-MPA), Gunther Pfeifer (ECHAMP). EMA: Isabel Chicharo, Hilmar Hamann, Jaume Gonzalez Nogueras, Veronica Lipucci Di Paola, Pedro Batista, Debora Braga, Marcos Fernandez Gomez, Andrei Idu, Roelof Otterspeer, Sabine Brosch, Ilaria Del Seppia, Aleksandra Dacic.
Minutes	Stavroula Tsalapati

1. Agenda, Welcome & Ground rules

The agenda was adopted.

2. PMS - EU IG Updates

The EMA presented the following topics:

- A summary of the structure of the EU IG (Human) and the three foreseen rounds of consultation with the related versions of publication.
- The progress made on the EU IG v2 comment resolution following the consultation process occurred from July to September 2020
- The updated EU IG publication plan reviewed based on the volume of comment received and level of complexity of each topic to discuss
- The methodology applied to address the comments in particular related to approach currently applied to address comments on chapter 2 and 3 and the proposal to review the methodology applied to ensure the release of the Implementation Guidance for PMS.

In relation to the progress made on the comment resolution of the EU IG v2, the EMA announced that Chapter 1 is completed while chapter 8 is nearly completed. Several comments impacting chapter 8 are linked to Chapter 2 which comment resolution is going slower than expected similarly to Chapter 3. The reason supporting the reduced pace of comment resolution on Chapter 2 and 3 are related to the high volume of comments received and the level of complexity of the discussion to address the open points. Additionally, a significant volume of comments marked as must and should needs discussion with EMA IT experts and FG2&3. In order to streamline the comment resolution process to focus more on Chapter 2 and 3, the EMA has revised the methodology applied (reported later below).

In view of the 1356 comments received between the 18th and 23rd September 2020 and spread across 11 different files, additional activities were required to be performed in order to start with the comment resolution:

- **30 Sep**: EMA completed the De-duplication/triage of NCAs comments and sent to Industry volunteers;
- **15 Oct**: Industry completed the final super consolidation (Industry & NCAs) and sent back to EMA;
- **23 Oct:** EMA completed the identification of comments requiring EMA experts (business & technical) and started the relevant discussions
- **17 Nov:** EMA hosted the PMS SG workshop with SVG experts to discuss on vaccine substances (comments from EU IG v2 consultation)

As result of the super-consolidation between NCA and Industry comments a total of 206 duplicates were identified and 1150 pure comments resulted to be addressed. In parallel the comment resolution among

the FG8 and Fg2&3 member started in October, in addition to the resolution of comments on Chapter 1 merely performed by EMA.
Following the extra activity of super consolidation, the volume of comments received and the complex topics to discuss requiring time to be addressed, the publication plan initially announced in July 2020 has been reviewed and extended accordingly. The EMA announced the new dates for the release of EU IG v2.0 and subsequent releases v2.1 and 2.2.:

- **EU IG v2.0** will be published on **22 Feb 2021** to address: All Must and high priority Should comments
    - **27/Jan-3 Feb:** Final wrap-up/ consolidation comment replies (EMA)
    - **3 Feb:** Consolidated draft & Comment resolution circulated (EMA to SPOR co-chairs)
    - **10 Feb:** Deadline for comments on consolidated version (SPOR Co-Chairs to EMA) to highlight on the most critical aspects to be address prior the publication
- **EU IG v2.1** is **estimated** to be published at the **end of Q2 2021** to address: remaining should and could comments
- **EU IG v2.2** is **estimated** to be published at the end on **Q3 2021** to address all the remaining comments

Of note:

- the release of the EU IG v2.1 and v2.2 will not be subject to consultation
- following the publication of EU IG v2.0 discussions with the new FGs will start to cover the aspects related to the PMS process and data
- the date to start drafting of EU IG v3 will be confirmed at later stage, by Q2 2021.

Related to the methodology applied, the EMA communicated to the SPOR TF members the level of involvement of the FGs members who is currently working on the comment resolution, the willingness to address all comments to improve the readability and enhance the level of quality of the Implementation Guidance. It was noted that some of the must and should comments were occasionally incorrectly assigned.

For this reason and in order to ensure the comments with the highest priority can be timely address prior the publication, the updated mitigation plan to resolve the comment was presented which consist of: EMA to focus on the *Must* and *Should* having the highest impact in PMS Iteration 1, EMA to continue in seeking opinions and having discussion with FGs members limited to 2-3 critical topics, willingness of FG8 members to support the FG2&3 members on the relevant comment resolution.

Following the announcement, concerns were expressed by the members of the SPOR TF in relation to the impossibility to timely resolve all the comments, leading to a certain level of unclarity on the aspects being classified as should which resolution and implementation will be postponed to the next release of the EU IG (at least to mid-2021 to have published the EU IG v2.1). EMA clarified that due to the hard time currently faced, the announced plan has been developed in order to allow the network to at least be prepared on the most critical aspects (Must and high priority should) and main concerned raised during the consultation process. In alternative, the entire EU IG v2 would not be available by end of Q3 2021 if requires all comments to be implemented.

Members of SPOR TF can contact the relevant SPOR Co-Chair(s) to express their concerns. The concern will be discussed at the SPOR Co-Chair meeting in order to look for alternative solutions.

The SPOR TF members acknowledged the communication and recognized the effort made in publishing the EU IG v2.0 by end of February 2021.

3. SMS vs EU-SRS flow

The goal of this presentation is to clarify the joint work between EMA and SVG on substance management activities.

Isabel started by presenting the (draft) target operating model for substance management with involvement of EMA, SVG and FDA.

Frits presented the future substance dataflow starting in requestors, with data manged in SMS and EU-SRS and ending in Telematics and EMA consuming systems (EudraCT, eAF, XEVMPD, etc.).

Pedro presented the differences between the SMS Project and EU-SRS Project. Afterwards, it was presented the activities within the scope of each project and also in SMS Operations.

Annet presented the percentages of total substance by type and by use in Human Products. It was pointed that the current focus of SVG cleansing (i.e. chemicals, proteins and vaccines) correspond to 72% substances used in Human Products. The next class to be cleansed will probably be polymers and, after that, 93% of substances used in human products will be cleansed. It was also pointed out that homeophatics correspond to a high percentage of substances (26%) but to a low percentage of substances used in products (0.3%). Annet also presented the impact of substance data cleansing in products: substances linked to human products need to be relinked they can be made non-current (nullified) . This limitation is not applicable to veterinary substances since there is currently no product link. Afterwards, Annet presented the expected timelines for data cleansing.

Isabel presented the project dependences between PMS, UPD, EU-SRS and SMS. These dependences have impact in NCA veterinary mapping (Vets have been prioritized) and cleansing outcomes (nullification of human substances not possible at the moment).

Annet presented a proposal to expand the scope of SMS Subgroup and the planned activities for 2021, such as involvement in data cleansing of chemicals. Supporting information for proteins and vaccines might also be requested. In addition, other operational topics such as substance confidentiality and change request process improvement will be discussed. Discussions related to SMS project (e.g. SMS Portal) will be on hold until the project resumes.

Frits concluded the presentation by focusing on the joint work between EMA and SVG done so far. Frits also highlighted the needs of further NCA support for SVG, EMA project budget and EMA resources.

4. Q&A