10 July 2020
EMA/345505/2020
Information Management

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

10 July 2020, 9:30 – 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), Triin Mäesalu (Estonia), Mourad Hassani (France), Dubravka Sudić (Croatia) Peter Bachmann (Germany), Katalin Burjan (Hungary, Vet), Marta Terron Cuadraro (DG SANTE, EC), Christopher Jarvis (EDQM). NCA Observers: Frits Stulp (The Netherlands), Annet Rozema (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), Christoph Kox (AESGP), Joerg Stueben (EFPIA), Karl-Heinz Loebel (EUCOPE), Kevin Horan (BearingPoint), Nora Weitbrecht (Medicines for Europe), Remco Munnik (Medicines for Europe), Elisabeth Godet (Vaccines Europe), Rodrigo Palacios (EFPIA), Patrick Middag (EFPIA), Paul-Ethienne Schaeffer (AESGP), Jean Michel Cahen (ECI-EEIG), Andreas Franken (AESGP), Maren von Fritschen (EUCOPE), Anjana Pindoria (Medicines for Europe), Sabrina Conti (Medicines for Europe). Veterinary Industry Associations representatives: Bernd Beutel (EGGVP), Jaume Colomer (AnimalhealthEurope), (AnimalhealthEurope), Jaka Petrič (EGGVP), Patrizia Oelker (AnimalhealthEurope), Jaka Petrič (EGGVP). Industry association observers: Vada Perkins (Bayer). Vendors/Software providers: Barry Hammond, Markus Pfahlert. Interested parties: Malin Fladvad (WHO-UMC), Wim Cypers (ArisGlobal), Christof Gessner

Role	Name
	(Gematik), Rune Bergendorff (NNIT A/S), Karen Harry (Parexel). Additional experts: Kelly Hnat, Karin Grondhal, Gunther Pfeifer. EMA: Hilmar Hamann, Alexis Nolte, Francisco Penaranda Fernandez, Isabel Chicharo, Olivier Simoen, Jaume Gonzalez Nogueras, Carlos Aicardo, Veronica Lipucci Di Paola, Ilaria Del Seppia, Pedro Batista, Debora Baga, Mihaela Sisu, Delia Matei, Inga Angelutsa, Gustavo Rodriguez, Idu Andrei.
Minutes	Maria-Grazia Di Marco (NCI)

1. Agenda, Welcome & Ground rules

The agenda was adopted.

2. Statement from Sponsors

Alexis Nolte, Head of Human Medicines Division in EMA (and previous Head of Information Management Division), clarified that while he is still the Sponsor for SPOR, the SPOR Provider is now Hilmar Hamann, the new Head of IM Division.

Alexis also provided a reminder of the driver for the creation for the four domains in data management, beginning with the ISO IDMP standards. PMS is a very important business case as it is the link between master data and regulatory procedures in order to be able to get high quality and reusable data. UPD is another more recent and very important business case which is in working progress. There is high commitment from the Management Board to continue working towards the completion of the S&PMS projects.

Hilmar Hamman provided a description of the structure of the newly created I Division as well as an explanation of the main objectives for each one of the 3 newly created departments within the I Division (Customer Advocacy and Delivery Department, Strategic Platforms Department and Core Services Department). He highlighted the importance of SPOR as the data foundation that underpins the regulatory data to be used at the EMA.

Concerns were raised on the need for a holistic plan which takes into account all ongoing and planned projects that have interdependencies with the SPOR programme. In order to cover this and to be able to successfully and reliably coordinate the different projects over the coming years, an EU Telematics strategy and implementation roadmap is required.

Francisco Penaranda explained that as 'Ad-interim' Head of the Customer Advocacy and Delivery Department he will be responsible for ensuring that the needs from the SPOR stakeholders (i.e. NCAs, Industry and business at EMA) are understood and captured, aligning requirements to common capabilities

when possible, and coordinating with other relevant departments to meet those needs.

3. SPOR Programme update

Isabel Chicharo reminded the group of the main driver: "Digital Business Transformation" the plan discussed and agreed in previous meetings. She explained that to achieve this goal many projects are needed, not just the ones lead by SPOR and also described how those projects are coordinated.

Since the SPOR plan was agreed the EMA team had made great progress in terms of planning 2020 activities. The main focus is on 1) finalising the EU Implementation Guide and API specs to provide stakeholders the necessary guidance on implementation, 2) making data and API available to external stakeholders early 2020 to enable stakeholders to progress with their development/testing and 3) continue to address open points such as Legacy submission/enrichment and legacy validation.

The EMA team has also started to prepare the delivery of Step 1 (CAPs) and there has also been some collaboration with other projects/initiatives towards building a joint plan for Step 2.

Isabel finalised by showing a visual of the planned activities for 2020 and the work identified for 2021.

4. EU IG v2 consultation

Carlos Aicardo announced the launch of EU IG v2 consultation process from 10th July 2020 until 18 September 2020 and presented the EU IG consultation logistics, rules, chapters under consultation and collaborative approach to EU IG v2. EMA strengthened the message that Industry needs to send a single list of comments prioritised by impact and that EMA will have limitations on the number of total comments that can resolve without an impact on the timelines.

Questions were raised on timelines for missing chapters for which EMA indicated that different priorities are given depending on the chapter (e.g. Legacy data is a key chapter that needs to be developed due to its operational implications).

There were also questions regarding the consideration of EU IG as a living document. EMA raised that major changes to EU IG with greater impact to stakeholders will certainly need of consultation (e.g. finalisation on chapter on legacy data). Once the project goes live, regular and minor updates similar to other regulatory and procedural guidance are expected and for which a wide consultation beyond SPOR TF is not foreseen and needed.

5. NVR/UPD Updates

An update of VMP-Reg programme and UPD project was provided. The main updates from a programme-level activities perspective are that VMP-Reg Stakeholder meetings took place on 31 March and 25 June and that the VMP-Reg Programme Vision was adopted on 8 April by the VMP-Reg CG. Based on the latter, the Project Vision for EVVet3 is being updated and the Project Vision for UPD is being created.

At project-level, the following progress was reported: The Vet EU Implementation Guide (Webinar on 15 July to launch the consultation on chapter 2); The UPD Access Policy will go in consultation in September; The UPD Project Vision is being finalised; The Product Owners (group) are elaborating the detailed requirements (Use Case Model, Use Case Scenarios..) and have already finalised the requirements for the Data Repository component and for Access management. The requirements gathering for the Web UI for provision/management of product information by NCAs is still ongoing.

It was highlighted that business/data feeding processes for provisioning of information on sales, availability, etc. is still being investigated. Contributions have been done by the Project governance, VMP-Reg Stakeholders Group and Vet Expert Group of the SPOR TF. The process to manage variations is not requiring assessment, has been defined by the UPD PG. They are working out the details. Iterative development is ongoing and initial releases of the UPD Repository and API are already ready for informal testing. A proof-of-concept for the upload of legacy data is ongoing. A format is being defined and some NCAs will test this out.

6. Q & A

7. Feedback from PMS Workshop

Carlos Aicardo introduced the conclusions of the PMS workshop that took place on 07 July 2020. Three main topics were discussed during the workshop which is also relevant to be communicated to the SPOR TF including:

(a) Results of the pre-consultation with PMS SG before the launch of EU IG v2 consultation. PMS SG in agreement to launch consultation. Some other topics such as the need for inclusion of authorised dose form were also discussed. No comments/concerns were raised by SPOR TF attendants.

(b) Inclusion of Data carrier identifier: The concept of data carrier, potential process and benefits were discussed. NCAs (including EMA) have different view

from industry on whether data carrier is to be included in PMS or as part of other projects. Data carrier is maintained in the guidance and therefore comments can be received but decision to maintain this datafield in PMS is to be taken including further discussion among authorities. Concerns were raised by industry that this datafield should not be removed base on the potential value (e.g. shortages).

(c) Legacy data and enrichment: a brain storming session on the concepts for legacy data and enrichments, previous proposals and needs of each stakeholder group were discussed. This topic is identified as key priority by all stakeholders.

There was also discussion about the bi-directional flow of data between Art 57 and PMS and although technically there is a bi-directional link, in practice for each product there is only one way the data flows to avoid conflicts. At each point in time the company either submits the data to Art 57 and it gets migrated to PMS or there is a direct submission to PMS which is fed-back to Art 57.

8. Feedback from SMS workshop

With regards to SMS Operational, the current dataflow of substances from SMS to all consuming systems was presented. There was an increase in substance requests in 2020, data enrichment exercises and COVID-19 support, which lead to a decrease in SLA compliance. The new SMS SLA are applicable from 1st July. It has also been informed the incoming process changes such as Scientific Advice in IRIS (September) which will require registration of substances in SMS. Also, the new EMA Service Desk interface for substance requests is expected for September. Training and guidance documents will be provided in due course.

With reference to the SMS Project, it was told that the new functionalities planned for this year are automatization of bulk substance searches (expected for July) and simple nullification (expected for September).

An analysis of SVG substance data cleansing has also been presented. Most of the proposed changes have already been implemented in SMS and propagated to all consuming systems. A report listing the cleansed substance records will be published soon. EMA is expecting to implement the SVG proposed data changes in SMS and update the cleansed records report every quarter.

An analysis of Veterinary substances cleansing has been offered too. The majority have been identified as duplicates and will be nullified. The valid substances will be analysed by the SVG. The focus for this year is chemicals, proteins and vaccines to support NCAs mapping for UPD. The remaining active substances and excipients will not be analysed before 2021.

A question was asked about nullifications and the impacts on possible mappings It was said that the SPOR TF will be informed of massive Nullifications/cleansings. To find out which substances have been impacted the Organisations need to see which are nullified and correct their mappings. For

Nullified substances there is normally an indication on one/many replacement substances.

9. EU-SRS updates

Annet informed the group that a EU-SRS kick-off meeting was held on May 18, 19, 20 and was productive.

In terms of the SVG the group has re-started the Data cleansing and is moving ahead at full speed. The group is also progressing well in terms of discussions on the Human / veterinary vaccines.

In terms of the EU-SRS systems and IT work, the system validation preparations have started.

A question was asked on the scope of data within SMS, what data would be loaded in EU-SRS and SMS and who would have access to Eu-SRS. It was clarified that all data are already within SMS but only cleansed data will be re-imported to SMS and loaded into EU-SRS. At Eu-SRS go-live only NCAs will have read access to it due to the confidential nature of the data.

10. KUG updates

The presentation covers organisational changes in the Key User Group (replacement of the chair) and a call for additional NCA members to balance the group. The topics of the first face to face meeting such as OMS Principles and Processes, Data Quality Criteria and Metrics, Data Ownership, and Usage of Address Doctor, Industry issues associated with this tool and a Fear or Fact discussion are reported.

More details are given on three important KUG topics in the first two quarters which all are interconnected.

The first one is the Data Pilot to assess the quality of OMS data by mapping these data to industry data using SPORIFY. The first results of this pilot will be available soon and will allow to estimate the number of necessary change requests to get OMS data up to date.

Secondly, the joint discussions between CMDh/CMDv, eAF/CESSP MG and KUG on the mandatory use of OMS will be presented on a high level, since these discussions are still ongoing. A few points such as a KUG actions to mitigate the risks of delayed or rejected applications can be shared. A question was raised in terms of this group mandate and the fact that it is producing recommendations on how to use OMS data rather than how to manage it. It was noted that these recommendations help to inform decisions and ultimately the group has no deciding power as it is still up for CMDh/CMDv to decide.

Lastly, the KUG maintains a list of potential system improvements such as for example a direct link between OMS and the EudraGMDP database or a notification system to follow up on changes made to OMS data will be reported.

11. NCA engagement/mapping survey

Due to time constraints it wasn´t possible to address this topic. The survey results will be presented in the next opportunity.

12. Q & A