13 May 2020
EMA/316413/2020
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

24 April 2020, 9:30 - 16:30

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

Role	Name
Attendees	EUNDB: Ana Lopez De La Rica (Spain), Georg Neuwirther (Austria), Joris Kampmeijer (The Netherlands), Louise Petersen (Denmark), Johan Aulin (Sweden), Triin Maesalu (Estonia), Mourad Hassani (France), Marko Suvak (Croatia), Dubravka Sudić (Croatia) Peter Bachmann (Germany), Katalin Burjan (Hungary, Vet), Paul Carnat-Gautier (France, Vet), Marta Terron Cuadraro (DG SANTE, EC), Hans-Joachim Bigalke (EDQM), Wahlin Stina (Sweden). 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). Veterinary Industry Associations representatives: Bernd Beutel (EGGVP), Jaume Colomer (AnimalhealthEurope), Pauline Battaglia (AnimalhealthEurope), Jaka Petrič (EGGVP). Industry association observers: Vada Perkins (Bayer). Vendors/Software providers: Barry Hammond, Christian Hay, Markus Pfahlert. Interested parties: Malin Fladvad (WHO-UMC), Wim Cypers (ArisGlobal), Christof Gessner (Gematik). Additional experts: Kelly Hnat, Karin Grondhal. EMA: Francisco Penaranda Fernandez, Isabel Chicharo, Olivier Simoen, Jaume Gonzalez, Carlos Aicardo, Ilaria Del Seppia, Pedro Batista, Anne-Christine Lantin, Inga Angelutsa, Gustavo Rodriguez, Marek Lehmann, Idu Andrei.

Role	Name
Minutes	Maria-Grazia Di Marco (NCI)

1. Agenda, Welcome and Ground rules

The co-chair from EMA explained that the first session of the SPOR TF meeting was about the joint agreement on the Target Operating Model (TOM) and the second session was about updates on projects and initiatives related to SPOR Programme. The agenda was adopted.

2. Updates from SPOR co-chairs (Why: SPOR needs/expectations, use cases; What: SPOR plan & Long-term strategy; How: Process/steps view; Change management)

The co-chair from NCAs, Joris Kampmeijer, presented the joint views on the drivers behind the SPOR activities. Digital business transformation was clarified as an outcome of the increased use of data within this area. The guiding principles for the plan were introduced and shared, including joint buy-in from all three co-chairs, building upon SPOR as a (master) data backbone, allowing flexibility in speed of adoption and in combination with optimization of the process. It was clarified that the contents of the plan and process are not final and open for consultation, as presented later in the presentation. Furthermore, the outlined steps connect the various building blocks (e.g. CESP version 2) in achieving the next version of the landscape.

The co-chair from Industry Laurent Desqueper (MSD) presented the proposed 2-step approach for the Target Operating Model (TOM). The proposed TOM approach is articulated around 2 network milestones in line with SPOR timelines and EU Network strategy.

At IDMP/SPOR Iteration 1 Go Live (expected Q4 2021), Step 1 implements the submission, assessment and approval of Product Dataset by EMA for products authorised under Centralised Procedure (CP). At that time, the other procedure types (MRP/DCP/NP) are validated post-approval by EMA.

When CESP Phase 2 is available (IDMP-compatible Application Forms, expected Q4 2023), EMA and NCAs implement the submission, assessment and approval of Product Dataset for all procedure types. Industry must transition from current Article 57 standard and process (XEVPRM) to IDMP/SPOR Iteration 1, between Step 1 and the Enforcement date (expected Q4 2022).

It is acknowledged that several topics are still under discussion for this TOM approach.

The co-chair from EMA Isabel Chicharo gave the general SPOR updates which served as an introduction to the topics that would be discussed in the afternoon in further detail.

On EU-SRS it was noted the HMA acceptance of results from EU-SRS PoC and endorsement to proceed with the implementation of EU-SRS. The afternoon session would cover details of this plan.

SMS project work is on hold due to resources/funds diverted to NVR and capacity allowing, priority will be given to the functionality to nullify substances. On SMS operations side there is a proposal to revise the SLAs and to start a pilot process involving the SVG and further details would also be shared in afternoon.

RMS and OMS operations are working fine and within SLAs and an update was given on the progress of manufacturers data cleansing and on KUG activities.

4a. PMS & EU IG

The components, development and progress of EU IG v2 were presented. Based on the previous experience with the EU IG v1, the PMS SG established the need to have a closer collaboration in the development of certain sections and chapters of the EU IG. As a consequence, Focus Groups are taking place on a weekly basis ensuring collaboration of all stakeholder groups.

In terms of timelines, the EU IG is scheduled to be published in Q4 2020. Currently it is suffering from delays in the progress on certain chapters which required a decision on the TOM. However, further details will be needed as TOM business case is generated and it is likely that further updates on EU IG will be needed. Due to limited resources, changes are not excluded in the timelines.

A number of learnings and challenges are being extracted from EU IG v2, including the need for the creation of a specialised group with practical experience on implementation and interpretation of IDMP. This helps increase the active collaboration from all stakeholder groups and the communication with other initiatives using IDMP data.

4b. SMS updates

The number of new substances requested has increased, mainly due to the increased number of regulatory procedures supported by SMS (i.e. OD, SA, PRIME, ATMP, CT), as well as the increased complexity of the substances used in the above-mentioned pre-submission regulatory procedures.

The number of SMS FTEs has remained the same which led to broken SLAs. It was proposed to extend the SLA for creation of substances/addition of aliases to 5-10 WD and for addition of translations to 10-15 WD. Mitigation measures like outsourcing and robotics will be implemented in 2021.

In Q3 2020, EMA will start a pilot exercise to involve SVG members in substance requests for vaccines and ATMPs. A new substance request form will be created in the EMA Service Desk and a training demo will be organised in due time.

SMS project work for 2020 is expected to be minor due to resources/funds being diverted to NVR. Capacity allowing, EMA will develop the functionality to nullify Human substances (not linked to products) and Veterinary substances, to support the SVG data cleansing.

4c. EU-SRS

The Heads of Medicines Agencies (HMA) endorsed the EU-SRS Implementation plan and accepted the results of the EU-SRS Proof of Concept project. EU-SRS implementation plan is included in the Telematics Strategy & Roadmap. The EU-SRS implementation project hast wo phases; phase 1 ends Q1/2021, with a validated EU-SRS system, with a significant amount of cleansed records loaded into the database.

It is important to ensure long-term funding of SVG; the current funding (partially through Unicom, partially in-kind contributions) cannot be seen as long-term solution.

Project Kick-off meeting will take place on May 18-20 (virtual meeting). Preparations include the installation of EU-SRS version 2.5.1 at BfArM. Initial discussions with veterinary team will take place on May 6, to align plans and planning of veterinary-related substance work.

4d. NVR/UPD

It was firstly provided an update on the Veterinary Medicinal Products Regulation (VMP-Reg), focusing on the Union Product Database, a reminder on the goal and main timelines (applicable

from 28 January 2022) of the Regulation (EU) 2019/6, as well as a high level overview of the regulatory system, placing the UPD at the core, and the high level draft programme schedule.

The building blocks composing the UPD concept were also reminded: access management, data submission, UPD portal, management of approval of variation without assessment, data repository. An update on the status of the UPD was provided, highlighting that a governance has been put in place and meetings of various groups are taking place.

The following points were also highlighted: the VMP-Reg CG has endorsed the Programme Vision and Change Management Strategy; the UPD project group has defined the mandatory fields for upload of the legacy data and reviewed the business processes in the context of the UPD; the Product Owners (group) are elaborating the detailed requirements; the UPD project development has started; the Vet expert group is drafting the EU Vet IG.

The UPD conceptual and logical data models were also shared. A focus was then put on the 21 mandatory fields which have been identified for provision of legacy data, how they have been chosen and that a description of how to populate them will be provided in the Vet EU Implementation Guide.

In addition, it was explained that the current business processes were being looked at on the fringes of the activities of the UPD Project Group (Project Board): regarding provision of product information, there would be no change to the existing processes, the NCA would provide the product information to the UPD after conclusion of the regulatory process. Concerning the Provision of information on sales, availability, etc. This is still being investigated, as well as the management of variations not requiring assessment.

Finally, a status update on the drafting of the EU veterinary implementation guide, the timeline for its completion and methodology of review were also given.

4e. UNICOM

It was recalled that the UNICOM project is composed of 19 countries, including 26 national Drug and eHealth Agencies which will working in the project over the next four years. Stakeholders are involved through their associations.

It was highlighted that the HORIZON 2020 innovation action will give a powerful impulse to the implementation of ISO IDMP standards in the EU. Once the EU-interoperable data on medicines taken by patients become available, further benefits will accrue through better health data for improved clinical decision support, patient empowerment, public health and clinical research. New opportunities will arise for pharma industry, software developers, SMEs providing smart apps and other tools fostering their innovation capacity and competitiveness.

It was highlighted the EMRN's leadership and high involvement in three workpackages. The Workpackage 2 is supporting the Implementation of EU-SRS, Workpackage 3 is focused on Implementation of IDMP compatible application forms and Workpackage 4 is on the adaption of national IT systems at regulator level towards IDMP.

A detailed description of Workpackage 3 was provided. Applying for authorisations for medicinal products and managing their life cycles is a regulated process supported by **electronic application forms** and **supporting electronic tools**. Presently, neither application forms nor the tools for initial authorisations, variations and renewals are **compliant** to the IDMP standards. Thus, it is not possible to start, automate and feed regulatory processes with IDMP compliant/structured data and easily re-use the data in EU-wide eHealth services. This workpackage will technically implement IDMP compatible application forms in a webtechnology. The organisational roll-out will be organised outside UNICOM.

4f. KUG

Patrick Middag (*deputy industry co-chair of the SPOR Task Force*) presented a progress summary on the SPOR Key User Group (KUG), primarily for information. This included an updated version of the Terms of Reference and a summary of the completed and ongoing discussions. While the SPOR KUG will eventually cover the four master data domains, right now the primary focus is on OMS. Worth noting is the fact that the OMS principles have not been endorsed by the industry but rather accepted as the frame of operation. Going forward the focus is on articulating improvements in several areas: dealing with OMS discrepancies in regulatory assessments, communications and overall data quality.

5. Q&A

The EMA Co-chair summed up the intentions of the meeting. The afternoon session was mainly informative on the status of projects and initiatives. The morning session with the co-chairs' joint proposal on TOM was particularly relevant because it was about the proposed approach on the human target operating model which should not conflict with the VET side.

SPOR TF members were invited to send suggestions for improvements to their respective co-chairs by May 8th. Industry associations were invited to compile their comments per association; software vendors were also invited to compile their inputs and liaise with the trade associations.

The date of next SPOR TF meeting was announced for May 29th, where an update on inputs received for the TOM proposals will be also given.

Upon request of one the participants during the Q&A session, the following document "Questions on chat of SPORT TF 2020-04-24" is enclosed for information.

Questions on chat SPOR TF 24.04.2020.p