23 March 2018
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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

23 March 2018, 9:00 to 17:00

Co-chairs: Isabel Chicharo (EMA), Neil Newmann (EFPIA)

Role	Name
Present	EUNDB: Jeffrey Martin (Sweden), Stina Wahlin (Sweden), Antonio Blazquez (Spain), Jose Manuel Simarro (Spain), Aziz Diop (France), Lionel Ridoux (France), Paule Carnat-Gautier (France), Catherine Russell (United Kingdom), Christopher Jarivs (EDQM), Dubravka Sudić (Croatia), Marko Suvak (Croatia), Edit Tóthné Hajdu (Hungary), Fabio Macchiagodena (Italy), Ly Rootslane (Estonia), Triin Maesalu (Estonia), Peter Bachmann (Germany), Marta Terron Cuadrado (European Commission). NCA experts: Hermanus Diederik (Netherlands), Ciska Matai (Netherlands), Frits Stulp (Netherlands). AESGP: Christoph Kox, Andrew Thornley, Andreas Franken. AnimalhealthEurope: Patrizia Oelker, Pauline Battaglia. EFPIA: Neil Newman, Paul Mills, Joerg Stueben. EGGVP: Jaka Petrič. EuropaBio: Andrea Herrmann, Laurent Desqueper. ECI-EEIG: Jean-Michel Cahen, Klaus Geldsetzer. Medicines for Europe: Nora Weitbrecht, Stuart Izod. Vaccines Europe: Edouard Michoud, Quentin Grignet. Bayer: Vada Perkins. K2pharmaconsulting: Kelly Hnat. ECHAMP: Gunther Pfeifer. EMVO: Andreas Walter. Vendors/Software providers: Barry Hammond, Christof Gessner, David Scanlon, Malin Jakobsson, Markus Pfahlert, Rune Ringsholm Bergendorff, Susan Metz, Ursula Tschorn. EMA: Francisco Penaranda, Isabel Chicharo, Paolo Alcini, Ilaria Del Seppia, Agnieszka Laka, Kepa Amutxastegi, Jaume Gonzalez, Panagiotis Telonis, Anne-

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Role	Name
	Christine Lantin, Katerina-Christina Deli, Korakianiti Evdokia.
Minutes	Inga Angelutsa

1. Welcome

The meeting was opened and participants were welcomed.

Adoption of draft agenda:

The updated draft agenda was adopted.

Membership update:

New members for the SPOR Task Force: Stuart Izod (Medicines for Europe); Peter Bachmann replacing Thomas Balzer (Germany); Marko Suvak replacing Darko Krnić (Croatia), Frits Stulp (Netherlands). Kelly Hnat continues her membership as an observer representing K2Pharmaconsulting.

Left SPOR Task Force: John Kiser (co-chair); Joris Kapmeijer(co-chair); Darko Krnić (Croatia); Thomas Balzer (Germany); Gordon Topping (UCB Biopharma); Andrew Marr (Marr Consultancy Ltd).

Co-chair replacements: Neil Newmann was introduced as industry representative replacing John Kapmeijer according the Industry nomination process for the co-chair in the SPOR TF meeting. As a NCA representative co-chair it was introduced Jeffrey Martin.

2. RMS and OMS status update

Kepa Amutxastegi presented the OMS status update. Since the SPOR portal was open to industry in December 2017 there has been good progress with the on-boarding of users, with just over 500 now registered. 450 Industry users have registered with 65% of these registered as Super Users. 83% of NCA users are registered as Super Users. SPOR API with its more complex on-boarding process has had 11 user registrations, 7 NCAs and 4 from Industry.

The initial 3-month period, post go-live, resulted in a number of issues with the Web Portal registration and process to request access to SPOR API. For the Web Portal the biggest issue was the 1st Industry Super User letter not being provided with Super User requests and also the initial users not requesting the “Super User” role. Additionally Industry have been informed about the importance of having a reserve Super User because back-up Super Users weren’t routinely being requested. The existing API user registration process is complex but EMA will aim to provide a more user-friendly approach.

SPOR team has also presented the update regarding number of received change request. Data was taken from June 2017 – 16th March 2018 for RMS and numbers totalled 152. It has been acknowledged that CR SLA compliance for RMS has been difficult to quantify because some issues included clock-stops for issue resolution and may result in inaccuracies in the time taken. OMS change request data was taken from 15th Dec 2017 to 21st March 2018 and there were 569 reported CRs. The majority of these related to updates on existing data. A review of the CRs made in this period for OMS identified that just under 85% of CRs were approved within 5 working days. The plan, moving forwards, is for all CRs to be actioned within 5 working days.

The next steps for RMS are to action future CRs from NCAs and Industry, focusing on new lists for S-REPS and CT Portal projects as well as publishing new lists for SMS & PMS implementation and also the enhancement of some existing RMS lists e.g. Variation classification.

OMS data stewards will continue to work on expanding the OMS dictionary with new data sets consistent with the diagram on slide 9. CRs will continue to be actioned within the SLA. There will be updates to the OMS data in line with the latest changes to xEVMPD – Article 57 schedule for the end of Q4, 2018. Support will also be provided to the other projects which integrate with OMS e.g. S-REPS CRM. The data stewards will continue to support bug and data fix deployments in OMS whilst supporting the OMS Service desk with OMS business and technical requests.

The latest release contained a number of bug fixes for RMS as well as the automatic synchronisation between RMS and EDQM lists. In addition to this for OMS there is improved integration with the EMA Account management system, synchronisation will now occur every 10 minutes.

A proposal was made for a Key User Group to be set up for RMS and OMS. This would include both Industry and regulator members. The Terms of Reference (ToR), to include the composition of this Key User group, are to be drafted by the end of June 2018 with the aim of it being operational by the end of 2018. Although the group will not be able to make decisions it will be assigned the following tasks: analysing the lower level activities, monitoring the SLAs and investigating methods of improving the data quality standard for both OMS and RMS.

ACTIONS:

- EMA to provide clearer communication with regards to the responsible subjects for signing the supporting letter for the Industry super-user registration.
- Two new key user groups for RMS and OMS to be created by end of June 2018 and operational by end of 2018.
- Draft for ToR including the composition of the key user groups by end of June 2018.

02. RMS OMS update to EUNDB March 2018

3. SMS status update

Frits Stulp the project manager for the EU-SRS project presented SMS / EU-SRS update from the SMS workshop on 20th and 21st of March 2018. Substance management will be provided through a combination of SMS and EU-SRS, where baseline data will be available in SMS; optimised data will follow from EU-SRS for structurally diverse substances (leading to increased data quality). SMS and EU-SRS IDs will be aligned. EU-SRS will be aligned with FDA-SRS.

The Public facing SMS will be implemented by EMA and provide a data set which supports selection in regulatory processes and enables distinction between two or more similar substances. The EU-SRS system, which will be implemented by MEB (NL), is ISO IDMP compliant and contains ISO IDMP substance management data supporting the scientific identification of substances. In addition to public information the EU-SRS system will also contain confidential information.

The SPOR TF was also updated on the Project plan for the EU-SRS. The plan includes deliverables for 2018 – 2019: project set-up, Phase 1 (business case), Phase 2 (SMS suitable substance list) and Phase 3 which delivers EU-SRS. Business case is scheduled to be presented to the HMA in Q2 2018 for further decision making, it will define the scope, plan and effort to deliver EU-SRS.

In the business case EU-SRS builds and extends the EU single source of reliable, high quality substance data at sufficient level of details to support number of use cases. Number of use cases for substance management was presented according to the category must, should, could and wont.

Key to the EU-SRS is setting up the Substance Validation group, which will execute substance assessment, to be recorded in EU-SRS. This would be a virtual group to maintain substances at the relevant level of details, for re-use by the NCAs. There are still discussions that need to take place at NCA and EMA level, such as SVG organisation, its role and resources.

Concerns for veterinary substances have been noted and are under discussion. EU-SRS group will work towards a clear and valuable business cases to be presented at the HMA in June.

03a. EU_SRS_SPORTF.pdf

03b. SMS Update.pdf

4. PMS status update

Isabel Chicharo presented the high level plan for S&PMS for 2018-2019 covering the Phase 1 and Phase 2 and indicating a number of deliverables.

The analysis and design of phase 1 is currently being finalised, this will be closely followed by the start of phase 1A development in Q2. Phase 1A will extract the data from Article 57 which will be uploaded into PMS. Once this is complete the Data Quality Assurance, which is currently being conducted in Article 57, will be done using the new solution. The data will then be fed back into Article 57. Phase 1 will be primarily dedicated to Article 57 migration and the feedback loop for authorised human products only. Phase 2 Analysis and Design will start in parallel.

Number of PMS dependencies has been identified and relevant mitigations have been proposed. If these dependencies materialise re-planning may be needed or there may be delays. PMS projects activities will be closely monitored. Dependencies are:

PMS TOM:

- PMS Phase 2 Analysis and Design (A&D) cannot start if TOM is not final. Phase 2 A&D will collect the requirements/use cases to deliver such TOM
- PMS EU IG have to be changed if approved TOM changes
- PMS EU IG drafting cannot be complete without TOM

ROG & TIA simplification:

- Vartiation Type 1A simplification Business Case needs approving for Manufacturer data to be mandatory in PMS > Impact on EU IG, business rules

Relocation:

- Changes to EMA systems cannot be deployed as there is a freeze and unavailability of environments and deployments during defined periods in Q3-Q4 2018

The group was also informed that in January 2018, the EU Telematics Enterprise Architecture Board (EU TEAB) endorsed using the draft international data standard known as Fast Healthcare Interoperability Resources (FHIR) as the basis for the application programming interface (API) for the PMS. This means that in future FHIR will be the data standard that supports the exchange of information about medicinal products, substances, and related reference data in the European medicines regulatory network.

It was also mentioned the There was some discussion about FHIR, the nature of the messaging standard and concerns about its maturity and being fit for purpose.

Dependencies which are monitored now: On the PMS side there are dependencies on the TOM. Kelly Hnat will provide the confirmation if the product is registered before or after the authorisation which will affect the new solution design. Other aspects about the strategy on legacy data validation will be reported by Jeffrey Martin.

Furthermore, Kelly Hnat presented the updates from the PMS Workshop mentioning the discussion of the EU Implementation Guide plan and structure. As highlights from the Phase1 of the EU IG it was stated the intention to address primarily the Art. 57 to PMS mapping and migration including the feedback and backwards compatibility. The version 1 draft is meant to start to be drafted by the end of June 2018 capturing the change in process for Referentials and Organisations before xEVPRM submission. The 'to be' processes of the TOM are meant to be tackled in version 2 of the EU IG.

EU IG Plan/Structure discussion included the following:

- Authoring of IG initial version
    - Agency is driving the drafting of the guidance
    - Initial version will be done by EMA business group & IT group, according to the scope of the EU IG
    - EMA will lead the maintenance of the documents
- Version 2 will require involvement of NCAs – Q4 2018
    - Action for the PMS team to prepare NCA resource requirements & to be approved via EUNDB
- EMA will lead the process to amend documents and release new versions
- RACI matrix in IG Plan spreadsheet.

EMA Phase1 Data migration key overview points included:

- There will be a Transition period where XEVPRM and PMS messages will be accepted by the agency
- Key message: only one message type will be accepted per organization.
    - This will be at the sender level, not MAH level. From an Industry prospective each company will need to determine when they are going to make the transition and prepare for it all their products at one time.
- Two-way flow of data will be required to support existing integrations/uses
    - ART 57 to PMS and vice versa
- New web interface to replace the existing one for the Art. 57 is intended be available at the beginning of the transition period. This is intended tol be CESSP – still need to confirm the plan for CESSP as this is a key dependency.

- Note: Migration timeline is for human side only.

A need to confirm the timelines was highlighted during the PMS workshop. Confirmation of the timelines will be iterative, due to complexity and dependencies, EMA will be able to confirm each phase/year.

Following action items for vendors and industry were raised:

- Vendors to prepare the “boilerplate” timeline to demonstrate critical path work to implement a change in vendor package
- Industry to conduct the implementation
- Understand dependencies of each EMA implementation phase
- Include preparation of composition for products.

In the PMS Workshop Industry presented concerns regarding the migration and validation strategy and backwards & forwards compatibility. Additionally industry raised questions related the ability to generate IDs, limitations for the migration to new formats, and concerns related to MAH switchover to PMS submission

During the PMS discussion there were signals which indicated common base understanding amongst the members needs to improve. Taking some actions will help establishing a baseline to support the ability of industry & NCAs to best contribute in the relevant activities.

ACTIONS:

- For the EMA Data Migration: Industry & vendors prepare a boilerplate timeline to demonstrate critical path work to implement a change in vendor package →industry implementation etc
- For the Migration validation and strategy, backwards & forwards compatibility: Industry to collate detailed list of questions/concerns to bring to PMS teleconferences for discussion. EMA to plan a follow-up discussion in greater detail.

Targeting Operating Model

The PMS Workshop has discussed the current draft of the TOM and raised the concerns to be addressed, one of them being the review of TOM for the new MAs & variations.

As per current draft TOM addresses control of approved data through submission to PMS via CESP and the standing question is whether CESP or some more persistent solution should be used to manage the data during review process.

It was also discussed the process and preparations for the TOM approval by Telematics governance including HMA/CMDh/CMDv.

For the Data Quality (DQ) assurance Industry is expected to define technical requirements for communicating changes related to data quality review. DQ feedback during legacy validation process is important. TOM obviates a feedback process like 3rd ack (acknowledgement) as the data quality will be addressed during the normal submission review process.

Jeffrey Martin also explained the current TOM, the roles and responsibilities within various phases of the model, the approval process on the validation, initial data standardisation also the notification process. There are still outstanding issues that need to be identified.

Review of EMA activities and LDM around Iteration 1

EMA presented the work in progress document showing database cardinality for fields included in current LDM by category (EMA, eAF, CESP, Art. 57, Vet)

Number of related actions was mentioned:

- Align table format for review of fields
- Make changes as suggested during discussion
- Reconcile Art. 57 column to ensure alignment to current requirements
- Input from NCA data pilot as available
- Make changes to the LDM document to reflect accurate alignment with eAF and CESP mid-April. (Action on Remco)
- Review/compare existing Iteration 1 spreadsheet with the data base (DB) report list to ensure completeness
- Identify what are the technical and legal conformance criteria to be fulfilled

As the current document is technical, the need to complete a business requirements document around the data fields/entities and business use of each–was expressed. The business requirements are expected to be completed by the PMS team and will include definition for each entity for initial registration, maintenance activities, and validation of legacy data.

Veterinary area (VET)

In the discussion around the VET side presented to the EUNDB it was agreed to include VET in the NCA data pilot. Other concerns raised were related to how VET will fit into the TOM, highlighting that some agencies use single data base for both human and veterinary sides and prefer to make changes only once.

04. PMS Workshhop Summary 20-21 Marc

Legacy Data Validation

Jeffrey Martin presented the updates from the Legacy Data validation. The PMS subgroup highlighted the issues related to the PMS Data Quality e.g. limitations related to the data standardisation, Data pilot, TOM for new products and variations and also concerns related to the Article 57 legacy data.

To illustrate the issues a relevant example was given when a product originates from different countries and it is expressed in different ways. This is mainly due to the “traditional” ways of each country is expressing the strength and the composition of a product. This is seen as a major concern in the context of the cross border prescriptions.

Moving to the EU standardised way of expressing a product composition would facilitate the understanding of the composition cross border and minimise the risk of miscalculating doses to be prescribed.

Another discussion point was the concern around the maturity of the ISO IDMP knowledge amongst the group. The need to conduct an additional, more extensive data pilot by NCAs, EMA and Industry was also discussed. The proposal, as a starting point, is the analysis of data collected from a number of about 20–30 products, including cases from multiple manufacturers. The data will enable analysis of the information about products and understand how it fits into the Data Model. The aim will be to collate the information about real products from various countries and data from public sources and use the information to further improve understanding of the IDMP. The results will be presented to the Task Force with potential input for the EU Implementation Guide. The pilot will be led by the Swedish, Norwegian, Spanish, Estonian, German, Austrian, and French Medicines Agencies.

The current data validation process in the Article 57 and its limitations were discussed and concerns were expressed in relation to the Validation of Article 57 legacy data after migration to PMS.

Solutions related to the role of NCAs and EMA in the validation process for the non-central and centrally authorised products were proposed. Considering the quality assurance challenges expected during the validation process it was proposed a strategy on data processing according to the roles assigned to the validating bodies.

05a. PMS Data Quality PMS subgroup

05b. TOM_Variations v 0,2

5. ROG updates: CEP / T1A

Evdokia Korakianiti the Regulatory Optimization Group (ROG) member presented an update on ROG.

This is a cross-functional group, consisting of regulatory, business and IT experts from NCA, EMA and industry, both from human and veterinary areas. The group is focused on regulatory/business optimisation and its primary role it is to identify / evaluate opportunities to improve the operation of the network, present problem statements and business cases to HMA for their review and approval.

Its first business case proposes to HMA solutions to optimise Type IAs variation process. The business case is supported by the analysis of as-is process, taking into consideration volume, time and resources spent during the execution of the process. The results of the analysis have been used to identify improvement opportunities and to optimize the process and enable better use of resources.

The group needs to work with the relevant stakeholders that are responsible for elements that will enable the realisation of benefits: SPOR, CESSP/eAF, EDQM, EC, CMDs on aspects relating to the optimisation of regulatory guidance. The actual solutions will be delivered by the relevant stakeholders.

06. ROG- IAs Business case- SPOR

6. Industry points

Neil Newmann on behalf of industry and vendors presented number of points for discussion. Current assumptions around mandating RMS and OMS in particular in the context of expanding of the dictionary were stated.

It was highlighted that industry sees a value in having Industry/NCA/EMA Key user group to aid adoption and for future requirements. Although RMS and OMS are implemented there is a need to progress with new requirements, bug fixes and future road map.

Kepa Amutxastegi supplemented the discussion with information related to data cleansing, standardisation and consolidation and plans to add manufactures to the dictionary. Isabel Chicharo acknowledged that there is a need to show the lifecycle of the Manufacturer data and frame it in the context of OMS. Relevant information will need to be prepared and disseminated to stakeholders.

Neil continued the topic reassuring that the Industry engagement is steady and that currently more companies desire to fill the gaps in sub groups. Companies typically are focusing on IDMP use first and after on the SPOR. Also the following have been highlighted:

- Risks to adopting the core of IDMP are assessed as high by industry
- Industry desire to engage more in creation of work products
- Key risks perceived as being largely outside of industry control
- Contingency or alternatives to mitigate key risks are unclear to industry.

07. Industry Topics_For_Task_For

7. Veterinary updates

Anne-Christine Lantin provided the feedback from the webinar with NCAs and Industry, held back in February 2018. In the webinar the SPOR Operating model, SPOR Timelines and the addition of the veterinary sub group reporting directly to SMS and PMS subgroups (change in the SPOR Telematics Governance) were presented to give the participants an overview of their impact on the veterinary area. A status update on the main features of SPOR from a veterinary perspective was also provided in order to understand any concerns and agree on any resultant actions. The feedback from the presentations by the National Competent Authorities AGES and ANSES-ANMV and also the Veterinary Industry were also shared in addition to the actions that came out of these sessions.

The key messages that were communicated for all the areas of SPOR emphasized the fact that, as systems are being developed, now would be the time to take into account all the specific veterinary needs. With regard to veterinary non-CAPs MAA/MAHs, it was confirmed that Industry would populate OMS via change requests from September 2018.

08. SPOR impact on Veterinary stakeholde

8. Communication & training update

Frits Stulp representing the IRISS forum provided and update on the IRISS. Its mission, vision and composition were outlined. It was stressed that amongst the several topic groups, the IDMP TG members represent a significant number.

The scope of the IRISS IDMP topic group is to support interchangeability, interoperability of information from different parties e.g. regulators, MAHs, sponsors but also health care professionals, pharmacists etc. The focus of the IDMP topic group is regulatory developments concerning IDMP however it is open to other Data Interoperability topics.

A proposal was presented for the IRISS IDMP to become a communication medium within the IDMP environment and act as facilitator on collection and consolidation of the information on various topics. This will facilitate effective, one-voice information that can be handed back to relevant groups playing a role in IDMP.

Attendees were informed how they could make a request to become a member of the IRISS IDMP.

09. IRISS IDMP TG Introduction.pdf

9. A.O.B

Details of work to address were discussed in addition to concerns raised at the PMS & SMS Workshops, EUNDB and SPOR TF. These can be summarized as:

- PMS TOM is mature enough to start the discussion on the other Telematics groups and CMD(h) CMD(v).
- SMS List is good enough to start mapping
- EU-SRS to be approved by HMA level will improve the data quality in SMS. Communication should begin immediately to share the benefits to different groups, prior to HMA approval.
- Key user Group for OMS and RMS to be set up
- Change liaisons to plan additional webinars particularly covering the lifecycle on the manufacturer's data and also about how EMA foresees the manufacturer's data relates to all the regulatory processes from manufactory authorisation, Inspection, EAF, Variations etc.