15 December 2016
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Information Management

Minutes of the Identification of Medicinal Products (IDMP) and Substance, Product, Organisation and Referential (SPOR) Task Force meeting

13 December 2016, 09:30-17:00

co-chaired by Isabel Chicharo (EMA), Joris Kampmeijer (Netherlands), John Kiser (EFPIA)

Role	Name
Present	EUNDB: Thomas Balzer (Germany) via teleconference, Giovanni Ferretti (Italy), Andrea Johnson (UK), Jeffrey Martin (Sweden), Joris Kampmeijer (Netherlands), Kevin Horan (Ireland), Darko Krnić (Croatia), Ly Rootslane (Estonia), Antonio Blazquez (Spain), Aziz Diop (France), Georg Neuwirther (Austria), Hans-Joachim Bigalke (EDQM), Edit Tóthné Hajdu (Hungary), Marta Terron Cuadrado (EC) via teleconference, Martha Schei Hynne (Norway), Urs Eugster (Switzerland) NCAs Experts: Jasmin Muala (Netherlands), Louise Petré Linder (Sweden), Dubravka Sudić (Croatia), Fabio Macchiagodena (Italy), Anne-Kathrin Gottzein (Germany), Triin Maesalu (Estonia), Lionel Ridoux (France), Jose Manuel Simarro (Spain), Christopher Jarvis (EDQM) AESGP: Andreas Franken, Andrew Thornley, Christoph Kox Medicines for Europe: Anjana Pindoria, Kelly Hnat, Nora Weitbrecht, Vito Strasberger EFPIA: Neil Newman, Joerg Stueben, John Kiser EuropaBio: Andrea Herrmann, Laurent Desqueper Vaccines Europe: Edouard Michoud, David Scanlon EBE: Herve Rique IFAH Europe: Twan van Berkel

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Role	Name
	EGGVP: Jaka Petrič Vendors/software providers: Andrew Marr, Barry Hammond, Joel Finkle, Markus Pfahlert, Rune Ringsholm Bergendorff, Susan Metz, Ursula Tschorn, Wim Cypers, Christian Hay EMA: Francisco Penaranda, Paolo Alcini, Isabel Chicharo, Agnieszka Laka, Sabine Brosch, Kepa Amutxastegi, Panagiotis Telonis, Jos Olaerts, Herman Diederik, Olivier Simoen
Minutes	Malgorzata Durka-Grabowska

1. Welcome & announcements

The meeting was opened and participants were welcomed.

Adoption of draft agenda

Draft Agenda was adopted with one amendment: the update on SPOR timelines was added to the agenda point 2.

Review of open actions log

The Task Force revised the actions log discussing the progress and outcome of opened actions. Changes are reflected in the attached log.

IDMPSPOR TF Actions Log.pdf

2. Updates

HMA Meeting

Francisco Penaranda briefed the group on the SPOR discussion held at the last HMA meeting. The Heads of Medicines Agencies met in Bratislava, from 5 to 7 September 2016. The meeting was hosted by the State Institute for Drug Control and the Institute for State Control of Veterinary Biologicals and Medicaments. SPOR and other programmes to consume SPOR data along with changes in the regulatory business processes leading to regulatory network harmonisation were identified as the essential pillars. Global reliable database was recognised as a desired solution. To achieve this solution some changes in the current legislation might be required. It was stated that ROG (Regulatory Optimisation Group) will facilitate regulatory optimisation processes.
The need of integrating SPOR with other projects was highlighted as critical requirement to ensure SPOR benefits maximisation. The implementation of SPOR at NCAs level and the estimated financial costs were

discussed. It was noted that some investments, financial and in resources, are required at the beginning of SPOR implementation process but the rate of return, the profit is expected to be high.
During HMA meeting the focus on the integration of SPOR with electronic Application Forms (eAF) and Common European Single Submission Portal (CESSP) was acknowledged. Participants were informed about the updated version of eAF and about the CESSP which will deliver a single submission channel and will replace current eAFs in PDF technology with an online editing tool for application datasets.


HMA update on SPOR.pdf

ROG

Joris Kampmeijer reminded that ROG was established in June 2016 during HMA meeting in Rotterdam and briefed the Task Force on the recent events. ROG discussed the main scope of their activities and, also defined expected skill-sets for participating experts, highlighting specifically the need of recruiting experienced business analysts from the Network. HMA provided some feedback on initial ROG actions to support better group definition and noted that the group remit and membership must be clearly defined and include, both, IT and business aspects. EMA participation in ROG is welcomed, so EMA participation as a full and permanent member of the ROG is important for the success of the ROG. Official ROG reporting channel was defined: ROG priority lead and support lead will directly report to HMA. The need to formalise group remit and to set the timelines in the official Terms of Reference (ToR) document was expressed.
ROG deliverables for 2016 include full installation of the group, defined membership profile, ToR creation and endorsement, in addition concept plan for next year. Joris informed that the expected ROG working process is to, primarily, identify the challenges and next to prioritise them to recognise the most urgent cases. Business and process analysis to find possible opportunities for optimisation will follow next. Identified business case, and the recommended way forward, will be presented at HMA forum where the body responsible for the execution phase will be decided. There was some discussion about the fact that ROG makes proposals (including who should carry out the tasks and how) but does not execute them. It was also discussed that it was unclear who would have the responsibility to execute and monitor those proposals. The body implementing the specific business case will be responsible for providing HMA with regular status monitoring reports to track the progress on the identified business cases. The ROG will monitor the business case implementation/execution. The Task Force noted the need of wide NCAs involvement in ROG activities to ensure right cross-stakeholder support.
Jos Olaerts noted that while certain ROG proposals may be considered difficult to achieve under the current legislative requirements, for Veterinary the revision of the legislation is underway and it is therefore important to ensure feedback from the ROG discussions, in particular to the ongoing discussions in the Council. The revision of the veterinary legislation specifically aims at reducing the administrative burden and increasing efficiency, hence similar aims than ROG. It was suggested for a member of ROG to feedback directly to the presidency on proposals that would be relevant to the veterinary legislation.


Update ROG.pdf

SPOR High-level timelines

Olivier Simoen updated the Task Force on the current RMS and OMS projects status. As announced earlier, OMS and RMS Users Acceptance Testing (UAT) were postponed to ensure proper system stability and to allow the time needed to solve system performance issues. It is expected to run EMA internal UAT in March 2017 and external UAT in April 2017. Exact UAT dates are expected to be announced in February 2017 to guarantee resource mobilisation. API connectivity testing was initiated by some Member States and, it is planned, in the next weeks to open API testing to some MAHs, as a part of UAT.
It was noted that OMS/RMS internal releases went live and are already available to EMA Data Stewards.
Isabel informed that the activities with S&P sub-group were resumed and it is expected to have re-defined and fully operational sub-group to support the project by February 2017. The major focus of the sub-group early in 2017 will be on high-level Target Operating Model (TOM), on high level processes and on the definition of the approach and scope of the project. Initial business case needs to be re-formulated to consider changes in the project scope to cover other use cases, not only Art.57. The installation of the EU G-SRS software, SMS project milestone, is scheduled for 2017.
It was confirmed that RMS and OMS will go live in 2017 providing the users with a suite of services which allow content browsing, downloading and requesting new and updates of terms/organisations. No changes in the current business processes, involving submission of R & O data, are foreseen at this point in time. From SPOR go-live to SPOR becoming mandatory, in a given regulatory process, a period not shorter than six months is granted. Some changes in the current submission processes are being explored and consulted with concerned stakeholders of Art.57, eAF and CESSP with the intention of introducing the mandatory use of SPOR data and processes in those regulatory procedures.
With regards to PMS and SMS projects currently expected date for Iteration 1 go-live is Q2 2019. This is reflecting the delayed projects start caused mainly by focusing resources on implementing RMS and OMS, and also by the inclusion of Veterinary area in the scope. It was noted that from publication of the EU IG (the European Union Implementation Guide) to PMS/SMS go-live, there is a minimum twelve months period followed by a period of six months to SPOR enforcement in Art.57 process. The Task Force was informed that all timelines are indicative and the revised plan for SPOR implementation will be published in coming weeks following detailed re-planning and will be available on the Agency's SPOR dedicated webpage. Comprehensive information on timeframes and activities is planned for cascading down through SPOR Change Liaison Network.


SPOR high level timelines.pdf

3. SPOR for Veterinary

Jos Olaerts presented the group with the update on the recent activities in the Veterinary area. The main Veterinary drivers for SPOR implementation were identified and, in terms of the legislation it is mainly the

draft Veterinary Regulation, published in 2014 and expected to be implemented by 2019. In terms of the systems main drivers are: CESSP, EudraVigilance Vet, EU Vet Medicines DB (i.e. EudraPharm), EVDAS and, eventually PMS.
With regards to Veterinary S&P Data Model, the analyses of the use cases are being finalised, however, more detailed studies are required for Veterinary specific areas such as species / ATC Vet / route of administration and immunologicals. For OMS, the data is sourced from an internal EMA corporate system related to CAPs MAHs and MRL applicants only due to the fact that Art.57 database is not available in Veterinary area. For manufacturers, they are sourced from EudraGMDP as well as the EMA corporate system to support CAPs as well as NAPs. It is considered that the EU Vet Medicines database might also be used to deliver organisation data as soon as the data is loaded into the system by Member States in the future. With regards to RMS, species list, needed in the future and in the existing MRL related lists, are being defined. Current and proposed future operating models were presented. It was noted that for the upcoming operating model, CESSP is expected to become SPOR compliant and to act as one of the main drivers. In order to consume SPOR compliant data, each Veterinary agency must become also SPOR compliant. It was highlighted that Member States and Industry need to progress with mapping to R. Veterinary stakeholders are invited to participate in CGVPS discussions (consultative group focuses on processes and operating model) to keep the knowledge on project progress and related activities up to date.


SPOR Veterinary.pdf

4. Referentials

Project status update

Isabel Chicharo briefed the Task Force on RMS project activities undertaken in last moths.
Regarding collaboration with the maintenance organisations, close and productive partnership with EDQM was acknowledged. The discussions related to the affected processes were finalised and the only ongoing activities concern the inclusion of RMS IDs. As for the cooperation with Bfarm, originally proposed to become a maintenance organisation for Units of Measurements (UoM), currently it is being investigated whether Bfarm can support EMA with change requests in the interim. For some specific UoM requests, where particular expertise is required, EMA was advised to consult CMDh and CMDv. Effective cooperation with WHO was noted with regards to ATC codes. ATC translations, as provided by NCAs can be included into RMS but will not be reviewed or adopted by WHO. Moreover, some discussions with Kew Gardens were initiated, mainly to support SMS implementation.
RMS sub-group activities were reduced in the last period, still few sessions were held in summer to prepare for the UAT and to run through the system mock-ups (receiving positive feedback from participants which will be used in the production of training materials). Final API specifications were published in October and some Member States already started the API testing prior UAT.
One of the last RMS sub-group recommendations was related to the translations and to the question whether Industry should be allowed to enter and request provisional translations. Current process allows only NCAs to submit translations of Referentials. Sub-group noted the limited benefit for Industry and

other users coming from the ability to request provisional translations. Consequently it was recommended not to include this capability within the system for Industry. Sub-group also decided to publish the list of materials within RMS, as it was considered valuable for some use cases. The discussion on the ATC-like codes was concluded with the recommendation not to issue any separate list with these codes or to include them in the WHO list. This decision, however, might be a subject to change during PMS/SMS implementation.


Referentials project status report.pdf

5. Organisations

Project status update

Kepa Amutxastegi confirmed that OMS project was mainly focused on the implementation of the technical solutions in the last months. First, internal OMS release went live on 24 October 2016. Currently EMA Data Stewards progress with the cleansing, consolidating and assigning IDs to the loaded organisation data. This is to prepare the content of the dictionary for the public go live. Similarly to RMS, API interface was released and some NCAs have initiated a connectivity testing. With the support of some OMS subgroup industry colleagues, a pilot test of EU Survey Portal took place in September. Following the success of this pilot testing the EU Survey Portal was chosen as the tool to use to support UAT testing. The tool allows the consolidation of the feedback provided by all testers in a structured and efficient manner. Therefore, the original plan for key UAT contacts to gather feedback from their respective UAT testing group is no longer required. The Task Force was briefed on the steps taken to master the organisations data uploaded to OMS. This exercise is processed in a phased approach and will be completed prior to going live. First, organisations will go through the cleansing, de-duplication and consolidation process, which will end with assignment of the Organisation IDs. At this stage, locations are only grouped under consolidated organisation (no IDs assigned). The next phase will be focused on consolidating locations grouped under the same organisation. This will entail the de-duplication or merging process followed by verification of the addresses and, when appropriate, data enrichment. Finally, the locations will be assigned with the location ID.

The guidance, setting out the principles on the OMS data quality standards, is currently being drafted. This document will include rules related to organisation naming, location verification, telephone and email address standardisation. It is planned to, first, share this guidance with OMS sub-group during February, and then, release it to the wider audience.

With regards to UAT, it was confirmed that, irrespective of the timelines shifting, the process itself did not change. Currently the test cases are ready for finalisation and it is foreseen to complete them in January and February 2017. The data, to be used in UAT, will be a copy from production environment. This will encompass the organisations which have already been mastered (with Org_ID and Loc_ID) in production by the EMA data stewards. It is planned to present the demo of the solution prior to the UAT kick-off to ensure familiarity with the tool, its functionality and the test scenarios. The number of testers originally reported to participate in UAT is quite large and, due to the timeframe changes, it is important now to re-confirm their availability. This verification will take place once precise UAT dates are announced. The

testing period is expected to cover two consecutive weeks and will be followed by system fixes, which will be re-tested by EMA (no second round of UAT is planned). A UAT report will be shared with all stakeholders, which will summarise the UAT outcome and the list of introduced fixes (grouped according to their importance and urgency), and bug fixes and change requests which were not implemented for that particular release. This is considered as a final UAT process step.

ACTION:

- Following UAT dates announcement, EMA to verify and to update the list of testers originally reported to participate in UAT (for Web UI & API).


Organisations project status report

6. Substance & Products

Project(s) and sub-group update

Paolo Alcini presented to the Task Force an update on the S&P activities. Main project deliverables were listed: the review of the Target Operating Models (TOM) along with the identification and revision of mandatory data elements and business cases to support the implementation of each iteration. Also, the EU Implementation Guide drafting and change management process creation was noted. Paolo summarised activities already completed within S&P, e.g. design of TOMs and identification of 80 data elements for Iteration 1 and their discussion at the Task Force. Formulation of the EU IG modular table of content and organisation of IDMP workshop in August 2016 to recognise business cases was mentioned. The need to revisit and to review previously agreed TOMs and data elements was highlighted. Paolo noted the necessity to include Substance Advisory Board, to be established by the EU Network and EMA, in the updated TOM for Substances. With regards to the creation process of the EU IG, it was proposed that the process oriented content will be drafted by Industry but technical and business specifications will be prepared by EMA on the basis of SPL message. It is planned to extensively support the EU IG with examples and diagrams.
In the view of the recent project re-start, the revision of the S&P sub-group membership is required. This is to ensure only active participation of the experts with proper background and experience. The priority will be given to the Task Force members; however specialists outside the group might also be nominated. To guarantee the effective work progress, the size of the sub-group needs to be limited. It was decided to restrict the number of participants to maximum 20 members representing Industry and other interested parties for Human and vet area. With regards to the participation of EMA and NCA representatives, no restrictions with regards to the numbers were suggested. Preliminarily, the expected level of commitment is estimated approximately as a minimum of two days per month to be dedicated for preparatory work; in addition, as three hours per month to attend the sub-group webinars. Moreover, it is planned to measure the level of engagement for each S&P expert and, based on the outcome, to suggest amendments in the group composition. This is to allow the participation in the sub-group only to the experts who can commit required amount of time and are wishing to proactively contribute to project progress.
The Task Force was also briefed on the upcoming S&P actions. It is planned to commence the EU IG

framework review and also to progress with the definition and adjustment of high-level business processes. The revision of TOM is already progressing within the sub-group however the drafting of the technical and business specifications needs to be still initiated.
Kelly Hnat reported on the two day IDMP workshop, held in August 2016. This meeting was attended by EMA, NCAs, Industry and vendors representatives. The purpose was to finalise the first iteration of process and data elements necessary for IDMP and to agree on scope of version 1 of the EU IG. The work was conducted within two main streams: Pharmacovigilance and Variations. The group was briefed on the working method applied in each of the workstream and about the key outcomes. Detailed workshop summary was prepared by Industry attendees and was circulated to the Task Force members for information.

ACTIONS:

- All parties to review their membership in S&P sub-group.
- EUNDB/NCAs representatives to express the interest in sub-group participation by sending an email to Malgorzata.Durka-Grabowska@ema.europa.eu by beginning of January 2017.
- John Kiser to coordinate the nominations from Human Industry and Interested Parties and to provide the list to EMA by beginning January 2017.
- Jos Olaerts to liaise with Veterinary Coordination Group (VCG) in order to coordinate the nominations from Veterinary Industry and Interested Parties. Jos Olaerts to provide the list by beginning of January 2017.
- Kelly Hnat to share with the Task Force the Industry position paper on Full Presentation Name Component Part Fields.


S&P project and subgroup status upda

7. SPOR impacts on processes

Main processes where SPOR will be enforced in medium-term

Business process overview diagram, illustrating the expected evolvement of processes in time, was presented to the Task Force. Main milestones were identified at the top of the diagram and it was stressed that their position does not reflect any specific time magnitude or timelines, which are dependent on concerned project deliverables. SPOR system go-live milestones solution delivery. SPOR system enforcement milestone indicate that a specific use of SPOR became mandatory in a given business process. Between SPOR go-live and SPOR enforcement there will be a period of not less than six months. During this time SPOR process will co-exist with current processes and after this period the new SPOR process will be enforced. The left hand side of the diagram reflects the impacted stakeholders and the main regulatory process driving SPOR implementation. Green blocks represent current activities and orange blocks represent evolved "to be" processes. Detailed instructions on how to operate within new "to be" SPOR processes will be communicated to the concerned stakeholders. It was stressed that presented

timelines are indicative and details are being agreed amongst different stakeholders however it is the intention to present which business processes will be prioritised or impacted first.
The most extensive discussions were focused on the submission of the authorised product information to Art.57 and EMA intends to enforce the pre-registration of R and O for Art.57, xEVMPD (IMP), eAF and CT application regulatory processes around the same time. This change will result in a single R and O data registration. These data will be then re-used across Art.57, IMPs, eAF, EudraCT. Six months after the PMS go-live date, the Art.57 database system will no longer be used to submit/receive Authorised Medicinal Product information and it will be replaced by PMS. Submission of the medicinal product information, as specified in Art.57 of the PhV legislation, will be the first process where ISO IDMP format is used.
It was asked whether the EU portal (Clinical Trial Regulation) would be satisfied with xEVMPD data as-is in the period until PMS go-live for investigational products. This was confirmed to be the case as CT Portal solution will be based on xEVMPD as-is. Furthermore, Industry should expect that investigational products must be handled in xEVMPD beyond 2019 and until there is a PMS Iteration 2.
Changes to xEVMPD (both pre and post authorisation modules) will be kept to a minimum to ensure that all relevant business processes are functional and that the integration needs with other systems are satisfied.
Clear communication of the revised SPOR timelines, designed specifically for the stakeholders not present at the Task Force, is currently being prepared. This was recognised as necessary step to allow all interested parties proper planning and execution of the essential activities to facilitate SPOR implementation considering SPOR scope extension. The communication plan will be prepared by EMA in January 2017 and will be distributed via SPOR Change Liaison Network.

ACTIONS:

- Task Force members to provide to Isabel Chicharo the comments on SPOR impacts in Regulatory Processes diagram.
- Isabel Chicharo to liaise with Telematics Enterprise Architecture Board to check when systems/processes (ICSR/PSUR) not covered in the presented diagram will be technically aligned with SPOR.
- Isabel Chicharo to identify and to communicate to NCAs and Industry all upcoming mapping activities needed to be processed by the stakeholders. Also, to liaise with IT Directors to inform NCAs about upcoming mapping workload at its next meeting.


SPOR Impacts on Processes.pdf

8. S&P TOM in the next 2-5 years

Workshop

The objective of this Task Force working session was to realistically identify confident goals to be accomplished in the next 2 to 5 years and to find a reasonable path to achieve these objectives. The Task Force members split into two groups: first group was to discuss substance topics and second group was

focusing on product related area. To facilitate the discussion, Industry participants organised workshop preparatory meeting and the outcome was summarised the attached presentations.
For the workshop discussion topic, clarification and verification of current Industry assumptions with regards to the timelines, processes and activities was suggested. It was also noted that previously agreed TOM may require some review process and, possibly, amendments to ensure all deliverables are achievable. Participants noted it is important to re-evaluate the programme scope and dependencies while reviewing TOM. With regards to the implementation approach, it was proposed to investigate how to minimise the dependencies between Product implementation and Substance implementation.
As the workshop conclusion, the key role and great value of TOM for the success of project implementation was confirmed. The need of cooperative work on future model was stressed. Participants agreed that TOM is to act as a main driver in identifying the realistic path to the future structured data and in recognising the benefits from additional use cases.

ACTIONS:

- Neil Newman to deliver workshop outcome summary for Products, by January 2017, this will serve as basis for the follow-up discussions.
- Andrew Marr to deliver workshop outcome summary for Substances, by January 2017, this will serve as basis for the follow-up discussions.
- EMA to organise follow-up workshop to further discuss and develop TOMs.

Post meeting note: workshop outcome summary for Substance is enclosed for information.

Summary of Substance Sessions.d

9. Communication

Update

Agnieszka Laka, on behalf of SPOR Change Team, briefed the Task Force on the main communication activities since last meeting. From July 2016, numerous events were organised to inform, update and educate stakeholders; these include: webinars, broadcasts, face-to-face meetings with Change Liaisons and, also, regular reporting at other fora. Modifications in the communication plan, caused by the changes in O and R implementation timings, resulted in the amendments in the training and stakeholder engagement plans. It is foreseen to complete the revision of these plans in January 2017. Reviewed schedules will be shared with NCA and Industry SPOR Change Liaisons.
SPOR Confluence was presented to the Task Force. This space will act as a central place for sharing key project information, updates and communication materials. It is for the use of SPOR project and change team, NCA and Industry Change Liaisons and members of SPOR Task Force. The users with granted access to Confluence will use it as a reference while seeking up to date materials and messages and to cascade them down to all concerned stakeholders. The system will also act as a place to search for the answers by performing keyword searches or browsing the FAQs section. The content will be expanded over time with new information.

Communication update was concluded with the report on the upcoming activities plan and related indicative timings.

Communication update.pdf

10. A.O.B.

Proposed meeting date change: 10 March 2017 to 5 April 2017

It was decided to keep originally selected date, 10 March 2017, as next Task Force face-to-face meeting (all dates are subject to further confirmation).