14 July 2016
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Information Management

Minutes of IDMP/SPOR Task Force meeting

30 June 2016, 15:00-18:15 and 1 July 2016 09:00-16:00
co-chaired by Ilaria Del Seppia (EMA), Joris Kampmeijer (Netherlands), John Kiser (EFPIA)

Role	Name
Present	EUNDB: Thomas Balzer (Germany), Giovanni Ferretti (Italy), Andrea Johnson (UK) via teleconference, Jeffrey Martin (Sweden), Joris Kampmeijer (Netherlands) via teleconference, Kevin Horan (Ireland), Ly Rootslane (Estonia), Aziz Diop (France), Georg Neuwirther (Austria), Hans-Joachim Bigalke (EDQM), Paule Carnat-Gautier (France), Edit Tóthné Hajdu (Hungary), Martha Schei Hynne (Norway) NCAs Experts: Anja van Haren (Netherlands), Louise Petré Linder (Sweden), Dubravka Sudić (Croatia), Fabio Macchiagodena (Italy), Anne-Kathrin Gottzein (Germany), Triin Maesalu (Estonia), Philippe Durr (France), Jose Manuel Simarro (Spain), Catherine Russell (UK) Swissmedic: Philipp Weyermann (via teleconference) AESGP: Andrew Thornley, Christoph Kox Medicines for Europe: Remco Munnik, Kelly Hnat, Nora Weitbrecht, Vito Strasberger EFPIA: Neil Newman, Paul Mills, Joerg Stueben, John Kiser EuropaBio: Claus Lyng Nielsen, Andrea Hermann, Laurent Desqueper Vaccines Europe: Edouard Michoud, David Scanlon, Quentin Grignet EUCOPE: Dot Bruce, David Huggins EBE: Gordon Topping, Herve Rique, Lobna Lyngby ECI-EEIG: Eeva Ryky

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Role	Name
	IFAH Europe: Twan van Berkel EGGVP: Jaka Petrič Vendors/software providers: Andrew Marr, Barry Hammond, Christof Gessner, Gary Saner, Joel Finkle, Markus Pfahlert, Rune Ringsholm Bergendorff, Susan Metz, Ursula Tschorn, Wim Cypers EMA: Francisco Penaranda, Paolo Alcini, Ilaria Del Seppia, Agnieszka Laka, Jaume Gonzalez, Kepa Amutxastegi, Panagiotis Telonis, Jos Olaerts
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: agenda point on 2017 meeting dates, originally scheduled under A.O.B., was moved to the agenda point 1.

Introduction of new members and observer

Task Force welcomed new members:

- Representatives of Veterinary sector:
  - 3 NCAs colleagues representing France, Hungary and UK.
  - 2 participants representing pharmaceutical Industry nominated by International Federation for Animal Health Europe (IFAH) and European Group for Generic Veterinary Products (EGGVP). Nomination of third Industry delegate is still pending the decision of The Association of Veterinary Consultants (AVC).
- An observer from Norwegian Medicines Agency (EU Telematics Management Board is to decide if this observer role can be transformed to a full membership in the future).

The increase in the number of the Task Force members was triggered by the extension of the scope of SPOR. Primarily the Task Force was created to provide an advice and recommendation on ISO IDMP implementation for Human area only. However, various SPOR business cases were identified as valid for both, Human and Veterinary medicinal products, and it was decided to spread the Task Force membership among stakeholders specialised in Veterinary area.
EMA informed that Isabel Chicharo will take over as co-chair of the IDMP/SPOR Task Force in the planned absence of Ilaria Del Seppia.

Terms of Reference update and adoption

It was noted that the Terms of References document required some alterations, mainly generated by the change of the Task Force name to better reflect SPOR terminology and, also, to present additional membership and inclusion of Veterinary sector.
The Task Force decided to adopt the updated Terms of Reference, without amendment, and the document will subsequently be published on EMA ISO IDMP dedicated webpage.

Review of open actions log

The Task Force revised the open actions log and discussed the progress and outcome of recorded actions. Changes are reflected in the attached log.
The decision agreed by the Task Force co-chairs with regards to the membership changes and remote participation in the face to face meetings was communicated as follows: participation via teleconference is only possible for NCAs representatives; membership is considered as permanent and the need of inviting additional experts to attend meetings must be duly justified.

IDMP SPOR TF Actions Log.pdf

2017 meeting dates

EMA proposed following dates for EUNDB and the Task Force face to face meetings next year:

- 1-3 March or 8-10 March.
- 12-14 June.
- 18-20 October.

ACTIONS:

- Task Force members to check proposed dates and to report back any potential clashes with other meetings they need to attend. To be completed ASAP.

2. SPOR for Veterinary

Jos Olaerts briefed the group about latest developments in Veterinary area with regards to SPOR implementation. The update on the Draft Veterinary regulation, feedback from the Veterinary SPOR webinar (which took place on 22 June), status of Veterinary SPOR and way forward were presented.
The Draft Veterinary regulation was published in 2014 and the adoption is anticipated in 2017 whilst the implementation should happen two years later, hence by 2019. Major system to support the implementation is the Union Database for Products, as set up by the legislation. It was noted that all Veterinary systems will be integrated with SPOR in future. It was also stated that the Product Database will be a key system and needs to be fully integrated with GMP/Certificates database to allow linking the product with the certificates. It was also highlighted that the Agency aims to work towards one, unified product data system which will contain both, Human and Veterinary areas under SPOR.

SPOR webinar was organised to update Veterinary regulators and Industry on the current SPOR developments due to recent inclusion of Veterinary part in the programme scope. Webinar attendees were presented with an overall update on SPOR and it was emphasised that the Agency prioritised the implementation of R and O for 2016. EMA Veterinary colleagues currently work to ensure that all Veterinary specific systems will become compatible with SPOR and, where necessary SPOR, will need to take into account Veterinary specific requirements.
It was noted that the operating system for Veterinary products currently in use is the EudraPharm Vet, released in February 2015, and it is foreseen to use this system at least until 2020. Main objective for this system is to support signal detection activities however currently it is only possible for Centrally Authorised Products (CAPs) due to data incompleteness for products authorised locally in Member States. It was highlighted that for the purpose of signal detection there is no prior standardisation required hence Member States are requested to transfer Veterinary product data as authorised in the local language. In parallel there is ongoing work on the Union Database (name as identified in draft legislation Art.57). This system will be built in ISO compatible format as the result of the integration of Veterinary medicines within ongoing EU Telematics project on SPOR. The goal of the Union Database is broader and is to serve all requirements specified in the new legislation. It was noted that current Veterinary draft legislation requires Member States to submit the data within 12 months from the implementation of the legislation. To support the ongoing process the Agency is organising bilateral meetings with Member States, mainly with IT colleagues. It was also stated that some Member States started mapping activities. The user group, Consultative Group of Veterinary Product Data Systems (CGVPS) was established and it works on the topic of product data with the aim of providing Veterinary specific requirements for SPOR. The mapping of data fields (ISO IDMP to Eudrapharm) is ongoing along with the use case analysis as well as an option analysis (leading to a proposal for stepwise implementation).
Future steps in the Veterinary area include: liaising with Member States to ensure that data is provided by the end of 2016 for signal detection activities, participating in UAT, continuing analysis on use case and communicating with change liaisons. It was proposed and agreed to allow the CGVPS group taking on the role as the specific Veterinary PMS sub-group. From the project management perspective, the scope of S&P at the Agency will be extended to cover Veterinary part however Veterinary deliverables with be managed by S&P Veterinary sub-group. EUNDB strongly recommends the Member States to ensure data completeness in EudraPharm Veterinary database as this will serve as a source of information for PMS implementation.

3. Feedback on meetings

Joint IT Directors/HMA

During the HMA meeting in Rotterdam organised by the Medicines Evaluation Board (MEB) of the Netherlands, a combined HMA - IT Directors meeting was held on 1 June. Francisco Penaranda reported that specific focus during this meeting was on the SPOR project. This activity is now widely recognised as intensive and global initiative with a major impact on IT systems. It was noted that Member States currently work on data mapping and the Agency is facilitating additional webinars to provide detailed guidance on mapping best practises. The benefits of SPOR implementation were broadly recognised and the simplification of data related processes and increase in data quality and efficacy were specifically stressed. During the HMA meeting it was agreed to establish an EU multi agency cross functional working group for optimisation of regulatory processes (i.e. the Regulatory Optimisation Group). The group will

analyse processes and will propose measures to increase regulatory efficiency. One of the objectives is also to ensure the benefits of SPOR are implemented in all business areas and connected better with related scientific aspects. The lead in the group creation and its activities is with the Netherlands. Group composition and detailed timelines are under discussion. MEB colleagues will draft the Terms of Reference document for this group and the draft paper will be presented at HMA meeting in September for endorsement.

ISO Plenary and HL7 Working Group

Paolo Alcini briefed the group about activities carried out during the last ISO Plenary, held from 2 to 6 May in Amsterdam. Review process of five ISO standards approved in 2012 is now in progress along with the finalisation of technical specification for Pharmaceutical product information (PhPID) and for Substances. The attendees requested ISO management to consider the possibility of creating a bundle of ISO documentation to allow purchase at a lower price. Report from ISO management on this option is expected during next plenary in Lillehammer. The question regarding copyright was also raised. It is specifically important for the regulators as they aim to create and publish guidance or web tools based on ISO standards content. The discussion was concluded with the action to liaise with ISO secretariat in order to receive the direction with regards to the copyright as the IDMP implementation guides will be re-used in the numerous databases, tools and training materials by regulatory agencies. Feedback is expected during the next plenary. The risk associated with a potential delay in publishing the final edition of substance guidance was acknowledged. It was also noted that S&P project is currently paused and when it resumes the outcome of next ISO plenary should be known e.g. the status of the final substance guidance. That will serve as a basis for proper project planning and option analyses in order to facilitate substance implementation.

Panagiotis Telonis informed the group about last HL7 working group meeting held in Canada in May 2016. The main meeting outcome is the publishing of HL7 models and schemas; SPL7 common product model version 3 is a part of the above release. Access to these documents requires membership with HL7. Potential copyright issue between HL7 and ISO was noted. This is caused by the necessity to share the documents with different fora to facilitate the implementation. It is expected that EUNDB colleagues will further investigate this matter and will report back to the Task Force.

ACTIONS:

- EMA to include the HL7 web link in the meeting minutes.
- Paolo to investigate about the plan to align Veterinary requirements with ISO IDMP scope.

POST MEETING NOTE:

HL7 download link: http://www.hl7.org/memonly/downloads/v3edition.cfm

4. EU Implementation Guides

SPOR benefits for variations

Remco Munnik provided report to the group from latest Industry workshop. Industry is fully committed to the successful implementation of SPOR solutions and for this reason an analysis was carried out to identify

the business cases for which high benefits will be realised in the short term for both Industry and regulators. The analysis identified the following four areas:

- Optimisation of Variations Process (with specific focus on the Variation type IA).
- Pharmacovigilance (PSUR/ICSR).
- Falsified Medicines Directive.
- Article 57 Database successor.

The presentation was concluded with the proposal of organising another face to face meeting with small group of dedicated experts that run the regulatory procedures to ensure an effective progress. It was also suggested to use the Task Force forum for status report and communication purposes only. Industry colleagues proposed as well to reduce the number of weekly sub-groups teleconferences and replace them with more goal-oriented face to face meetings.

Feedback from Industry workshop on EU IGs developments and planning

Gordon Topping followed up on the feedback from Industry meeting with regards to work on EU Implementation Guide (EU IG). He confirmed the main objective was to focus on successful implementation of SPOR and to better identify values for the IDMP implementation. It was stated that current EU IG table of content demonstrates high risk of the final document being not readable or too comprehensive for the recipients on both sided – Industry and regulators. Smaller and more practical guidance delivering real value needs to be produced. It was agreed to cleanse the current document and to share it with the Task Force in next couple of weeks. Industry colleagues also finalise workshop minutes to provide clear meeting summary. The need of more often face to face meetings with small group of designated experts was emphasised. This is considered as a crucial activity to accelerate project progress. Gordon suggested organising the workshop in September with the limited number of experts focusing on EU IG drafting and reviewing four business cases. Small face to face meetings proved to be the most effective way forward.
EMA informed that the Task Force should focus on the SPOR data management and that the new EU multi agency cross functional working group for optimisation of regulatory processes established based on recent HMA decision should handle the optimisation of the regulatory process using the SPOR data. This is to ensure that aspects beyond remit of the Task Force are covered, specifically regulatory business processes.

ACTION:

- EMA to organise a workshop in September with the aim of identifying the business need and value and progressing with the work on EU IG, specifically on data elements for Iteration 1. Only limited number of experts should attend.

5. MedDRA -SNOMED- ICD 10 mapping

Feedback on MedDRA Management Board on 12 June 2016

Dr David J Lewis, Global Head of Pharmacovigilance in Novartis, joined the Task Force to update the group on recent developments in Facilitation of Coding of Evidence including feedback from recent MedDRA

Management Board meeting. David noted that there is a possibility of formalising the mapping activities, currently done manually, by using The Innovative Medicines Initiative (IMI) support. Request for IMI support needs to be accompanied by formal and detailed work programme and targeted towards deliverables e.g. validated mappings. It is also expected that MSSO will maintain mappings and will make it available without charging stakeholders for additional licenses. The presentation was concluded with a call for colleagues willing to participate and being able to commit time to this project. If approved by IMI, the estimated time for this project to deliver is approximately 2-2.5 years. It is expected that one of the major benefits would be a significant reduction in manual efforts for mappings. It was also confirmed that the outcome of this activity will be highly beneficial not only for pharmacovigilance area but also for actions related to e-prescription.

ACTION:

- Industry colleagues to report back to their associations and check if some support could be committed to this project. Finding to be reported back to David Lewis who will follow up by teleconferences with interested parties and will lead proposal drafting to be presented to IMI.

6. Feedback from Task Force sub-groups

Referentials sub-group - Status update and next steps

Jaume Gonzalez updated the Task Force on the activities carried out since the last meeting in February 2016. The R sub-group organised monthly teleconferences for its members, some of which were open to all Task Force participants, depending on the topic discussed. Ad-hoc webinars, dedicated to specific topics, were also organised along with joint sessions with other Task Force sub-groups.
Regarding joint discussions between RMS and OMS, five new lists will be created in RMS (party category, party category type, title, OMS request reason and OMS request rejection reason) and another three lists, already existing in EUTCT, will be required and therefore were migrated to RMS. Jaume confirmed that UAT is currently moved to Q4 2016 due to complexities in the implementation of RMS and OMS. UAT preparation was however started and is ongoing. Test plan and test cases were drafted and over 100 testers representing all stakeholder groups were nominated. A webinar to onboard all UAT testers is expected on 19 July 2016.
With regards to joint RMS and S&P activities, three new lists will need to be created (materials, individual roles and organisation roles). The S&P sub-group will need to confirm if the materials list should be created or if the substances list should be used instead to describe materials. A decision will be required as well on the need for a separate RMS list for ATC-like codes and other national classification systems.
The R sub-group also continued discussions with EDQM regarding the scope of standard lists and the management of change requests. It was stated that EDQM and RMS lists serve a similar purpose. However, while the lists will be vastly overlapping some differences were acknowledged regarding use cases as well as the publication of provisional, nullified and non-current terms. Nevertheless, a consensus was reached between EMA and EDQM with regards to the management of change requests including the management of multiple requests for the same or a similar term, requests for EUTCT/EV terms and management of terms that move across lists.
As per EUNDB recommendation from 2015, BfArM is the EU maintenance organisation for the Units of Measurement (UoM). As a provisional measure, EMA will go live with a data model and will act as interim maintenance organisation for UoM. This was decided to allow BfArM sufficient time to prepare and take up

the role.
The R sub-group also held monthly teleconferences with WHO to discuss and fully understand the maintenance of ATC lists. EMA-WHO dialogue also focuses on the management of change requests and the functionalities that will be available in RMS regarding ATC lists. The possibility for NCAs to provide translations of ATC lists will be further discussed.
An overview of the full RMS operating model was provided, including details on the possibility for both NCAs and Industry to download lists, submit change requests and provide translations.
With regards to R project progress it was confirmed that all design work was completed for release 1 and release 2. Release 1 (internal release, not available for external users) went live on 15 June 2016 and was considered the foundation for future SPOR services. Preparatory activities for release 2 are in progress, e.g. tools configuration, system testing and drafting of training materials.
Jaume informed the Task Force that the R sub-group requested NCAs to start mapping Dosage Forms, Routes of Administration and Packaging. No mapping is currently required from Industry side as Industry is using data from xEVMPD and EMA will do the mapping for Industry. Concerning the engagement with Veterinary area, the cooperation was only started recently and requires further definition and planning.
The presentation was finalised with information on future R sub-group activities. Future course of action also includes further discussion with maintenance organisations, close cooperation with other Task Force sub-groups and in addition planning and execution of the UAT.

Organisations sub-group - Status update and next steps

Kepa Amutxastegi updated the Task Force with recent activities undertaken within O sub-group and also thanked sub-group members for their commitment and support. Multiple teleconference were organised with extensive discussions and analyses on possible business scenarios for Organisations data management and for CVs applicable for O implementation. It was noted that the proposal for a Change Request for supporting documentation requirements was drafted, e.g. the list of documents needed when submitting a change request. During O sub-group teleconference in March, attendees were presented with screen mock-ups run through of the functionality currently available in OMS: searching, viewing, submitting change requests, exporting, etc. A demo session open to entire Task Force is likely to take place before the UAT. It was emphasised that OMS is necessary to implement the user management in the future.
It was also reminded that a parallel project is run at the Agency, the Identity and Access Management (IAM), and this project is developing the solution which will be integrated with OMS. Kepa noted that there will be more teleconference sessions to discuss and develop understanding of user population creation process. It was also confirmed that UAT preparation work is ongoing and over 100 testers were nominated for each of RMS and OMS UATs. UAT plan and test cases are drafted and are pending the review which should follow after the webinar scheduled for 19 July 2016. This part of presentation was summarised by confirming that system use cases, logical data model, detailed requirements and process model are signed off and were shared with all the stakeholders. In addition to the development work around the web portal and the MDM solution, a set of user guides and training materials are being drafted. All this documentation will be shared in the future.
A report on product data mapping in the context of Art.57 was provided. Five different data sources to provide input to OMS will be used in the scope of the current OMS project. Art.57 data was recognised as having the most complete list of MAHs for Human NAPs and CAPs and therefore EMA proposed to use existing Art.57 data maintenance activities to support data mapping. The scope of data mapping for the

initial content of the dictionary is to ensure the completeness regarding MAHs data only. The recommendation to MAHs is to wait until EMA communicates about the release of the OMS dictionary content before commencing any mappings against organisation IDs. It is proposed that EMA will undertake mapping of NCA product data against Art.57/xEVMPD via product data comparison exercise. The objective of this exercise is not only to evaluate and improve compliance but also to prepare OMS solution by ensuring data completeness. Product data comparison approach recommended to NCAs was presented to the Task Force for information. MAHs might still be contacted by EMA as part of this exercise in order to request them to submit missing product data. In the meantime MAHs are advised to continue Art.57 data submission as per current process and requirements and to await EMA information confirming the release of OMS dictionary content before any mapping against organisation IDs. It was stated that the purpose of this activity covers only data completeness and not data correctness or quality.
OMS status update was concluded with planned next steps. The need to finalise users' population procedure and UAT execution was highlighted. The initial release date for OMS is September 2016 and it relates to Master Data Management internal EMA tool. This will be followed by UAT in Q4 2016.

ACTION:

- EMA to organise an information session for Task Force members on IAM processes and tools in the context of OMS topic webinar.

Products and Substances sub-group - Report on current activities and Progress report on Business case for PMS Iteration 1 scope

Ilaria Del Seppia briefed the Task Force about recent activities within S&P sub-group. Three main streams of work were carried out during the teleconferences:

1. Providing input to Controlled Vocabularies required for Iteration 1 PMS e.g. based on the 80 data elements as endorsed by the Task Force at its last meeting.
2. Extensive discussions related to EU IG Table of Content due to two options approach: business and regulatory process oriented approach (further debated during recent Industry workshop) and, the option recommended by the Agency concentrating on SPOR – modular approach.
3. Definition of the business cases listing valid for PMS Iteration 1 that is proposed to be shared with EUNDB for review. Consequently business cases will be mapped against 80 data elements.

The group was informed that EMA is currently discussing internally the change management plan from the current processes into the new RMS, OMS and PMS preparation processes. The aim is to provide all concerned stakeholders with comprehensive information on expected actions and timelines on which process should be used at each point in time during SPOR implementation. With regards to SMS implementation it was stated that currently all available EMA resources are focused on the ISO Annex for substances finalisation. In addition a mission to US-FDA is going to take place for two weeks in September when the EMA colleagues will analyse the G-SRS system as initial input into the project when it will be resumed.
As next steps, it was confirmed that a two day workshop will be organised in September with specific purpose to review and finalise Iteration 1 scope and to complete the plan for the drafting and finalisation of the EU IGs for Iteration 1. It is expected that the main focus will be on:

- pharmacovigilance use cases to validate Iteration 1;

- type IA variations;
- e-prescription;
- EU IG.

Specific dates and participants are to be confirmed however the aim is to keep the group small, focused and productive. The outcome of this workshop will be reported to EUNDB and to the Task Force.
As the answer to the question from Veterinary Industry colleague, it was confirmed that P&S project is expected to be resumed towards the end of 2016. S&P project was put on hold to prioritise and focus all resources on the implementation of R and O. With regards to specific S&P Veterinary aspects, although the project will be managed under the same S&P umbrella already established for Human, the content and the implementation will be fully managed by Veterinary colleagues. Detailed project plan will be prepared when the project recommences (i.e. towards the end of 2016).

7. Falsified Medicines

Status update

Paolo Alcini reported to the Task Force the latest developments regarding Falsified Medicines. On 27 June EMA hosted a dedicated multiple stakeholder meeting to discuss the most effective way of linking with the European Medicines Verification System (EMVS) to support the implementation of Falsified Medicine Directive (FMD) and SPOR system. The key sections of the FMD delegated act were discussed along with the status of ISO IDMP implementation. After extensive discussion the group drafted three possible options and recommended the following to the Task Force: to link SPOR and FMD via the Data Carrier Identifier in the ISO IDMP Model.

8. Communication & Change management Plan

Status update & Change Liaisons, Survey report, Change Management Plan

Agnieszka Laka informed that currently the change management workstream is focusing on two key areas: communications/engagement and training. Other parts are: change impact assessment and benefits planning and review. As for the change impact assessment the work was conducted as part of the Training Needs Analysis exercise to identify key impacts resulting from RMS and OMS projects. With regard to benefits planning and review stream, the high level benefits were identified, however the activity is currently on hold as dedicated resource is required to manage benefits planning and monitoring.
It was highlighted that there will be four mechanisms to cascade information to NCAs and to Industry to increase the reach across the stakeholders. These are: NCA change liaisons, Industry change liaisons, stakeholder department at EMA and EMA SME office. EMA will provide centralised communications to change liaisons and to EMA stakeholder department and they will cascade the information. The group received also an update on key engagement actives run between March and June 2016 indicating upcoming activities from the engagement plan.
The Task Force was also briefed about the SPOR implementation questionnaire which was conducted to track progress of implementation of SPOR across the Network. It covered three areas: awareness, planning and mobilisation. Key findings from the survey were presented alongside with the actions that

were taken to address the major conclusions.
The group received a progress update on the training approach and the next steps. The high level change impacts, training needs analysis were conducted and training curriculum was developed. Next steps are to develop a training development plan, training material and training delivery plan.
A need to have a platform to view and share documents and information materials with all Task Force members was expressed by Industry colleagues.

ACTION:

- Agnieszka Laka and David Scanlon to follow up on possible use of SharePoint.

EU IGs consultation and sign off processes

It was suggested to further discuss the sign off process during the workshop scheduled for September. Previous discussions at EUNDB proposed to follow Telematics governance for endorsement. As for the consultation phase it was noted that, following the business cases definition, proper consultative fora will be identified.

9. A.O.B.

It was stated that in order to progress more effectively with the projects, the duration of the Task Force meeting could be reduced and replaced with more often, smaller and task oriented groups workshops. The Task Force meetings should be used mainly for reporting purposes and to prepare consolidated recommendations for the approval by Telematics governance.