17 March 2017
EMA/186147/20177
Information Management

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

10 March 2017, 09:00-17:00

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

Role	Name
Present	EUNDB: Thomas Balzer (Germany), Giovanni Ferretti (Italy), Andrea Johnson (United Kingdom), Joris Kampmeijer (Netherlands), Aziz Diop (France), Paule Carnat-Gautier (France), Georg Neuwirther (Austria), Edit Tóthné Hajdu (Hungary), Marta Terron Cuadrado (EC) via teleconference, Hans-Joachim Bigalke (EDQM), Martha Schei Hynne (Norway), Urs Eugster (Switzerland) via teleconference NCAs Experts: Anja van Haren (Netherlands), Louise Petré Linder (Sweden), Dubravka Sudić (Croatia), Anne-Kathrin Gottzein (Germany), Triin Maesalu (Estonia), Lionel Ridoux (France), Jose Manuel Simarro (Spain), Christopher Jarvis (EDQM) AESGP: Andreas Franken, Andrew Thornley Medicines for Europe: Nora Weitbrecht, Vito Strasberger EFPIA: Neil Newman, Joerg Stueben, John Kiser EuropaBio: Laurent Desqueper Vaccines Europe: Edouard Michoud, David Scanlon, Quentin Grignet EBE: Gordon Topping, Lobna Lyngby EMVO : Andreas Walter Vendors/software providers: Andrew Marr, Barry Hammond, Christof Gessner, Markus Pfahlert, Rune Ringsholm Bergendorff, Susan Metz, Ursula Tschorn, Wim Cypers,

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Role	Name
	Christian Hay S&P sub-group experts : Laetitia Le Letty (FR), Ciska Matai (NL), Anjana Pindoria (Medicines for Europe), Daiana Chrila (Medicines for Europe), David Wilson (EFPIA), Patrick Middag (EFPIA) EMA: Alexis Nolte, Francisco Penaranda, Paolo Alcini, Isabel Chicharo, Agnieszka Laka, Sabine Brosch, Kepa Amutxastegi, Panagiotis Telonis, Herman Diederik
Minutes	Malgorzata Durka-Grabowska

1. Welcome

The meeting was opened and participants were welcomed. Alexis Nolte, Head of Information Management Division, joined the meeting opening part to re-confirm the SPOR implementation is unchangeably considered as a top priority programme for the Agency and for the network. To ensure that both, IT and business aspects are aligned, the necessity for a close SPOR – Regulatory Optimisation Group (ROG) collaboration was highlighted.
It was noted that the extent of the impact of Brexit on the Agency's operations and location is uncertain. Depending on the outcome of the negotiations, this could cause significant disruption to the Agency's operations and business continuity plans will need to be in place. The Agency will continue carrying out impact assessment to identify the main risks and propose mitigating measures to maintain the Agency's main core activities and top priorities. Moreover, as a result of the withdrawal of the UK from the EU, the Agency may have to relocate. All these circumstances will impact SPOR implementation in a way that it is impossible to estimate at this moment. Taking the above into consideration, it is particularly important to retain the pragmatic and sensible approach while planning the future SPOR way forward. The implementation phases need to be carefully assessed to minimise any possible disruptions connected to the current situation. SPOR is not a project but a programme and some features of first PMS Iteration may be postponed to a later stage in order to deliver in the first Iteration the minimum viable product with a significant business value. The minimum viable product, to serve as a foundation for future programme capabilities, needs to be defined by May 2017. This is to ensure uninterrupted phased programme implementation with possibly reduced scope, regardless the Agency's relocation disruptions. The discussion was concluded with a statement that the data sets for P and S Iteration 1 and Target Operating Models (TOMs) need to be agreed before May 2017 to allow proper, well timed project planning and execution.
The reassurance that EMA is fully committed to implement SPOR across entire network with its complete benefits and scope was welcomed by Task Force members, specifically in the context of the investments already made in the infrastructure and processes.

Adoption of draft agenda

The updated Draft Agenda was adopted.

Membership update

Luke Wakefield, representing the Veterinary Medicines Directorate in the UK, and Patrizia Oelker, representing IFAH Europe (taken the place of Twan van Berkel) were introduced as new Task Force members.
The Task Force agreed with EMA proposal to change the membership status from "observer" to "full member" for Andreas Walter representing the European Medicines Verification Organisation (EMVO). It was stated that the EMVO, as the representative of the European supply chain, fully supports SPOR implementation and is committed to effective collaboration safeguarding efficient projects connections. On the Task Force request, Mr Walter agreed to provide a short update on the current status of the implementation of the Falsified Medicines Directive (FMD) during this meeting. The Agenda was amended accordingly.
This Task Force meeting was also attended by S and P sub-group experts who participated in the preceding two-day workshop.

ACTIONS:

- EMA to present the membership status change of EMVO representative to the EU Telematics Management Board for adoption.
- EMVO to investigate if any technical specifications, documenting the system being built, can be shared with the Task Force.

Review of open actions log

The Task Force revised the opened actions. Updates are reflected in the attached log.

IDMPSPOR TF Actions Log.pdf

2. PMS & SMS Overview

Isabel Chicharo provided the Task Force with the update on PMS and SMS implementation plans. It was reminded that the PMS project was originally initiated to deliver the solution required by the EU law with the initial scope to implement ISO IDMP standards, to support Pharmacovigilance activities and then was extended to implement the new Veterinary legislation. Whereas IDMP is only mandated for Human products, SPOR (particularly PMS) should be a common solution for both Human and Veterinary products although not necessarily identical.
The project was also focused on the data quality and, consequently, on the involvement of NCAs in the validation of product data.
Providing stakeholder value approach was mentioned as another area where particular attention is paid. Moreover, as agreed during the S&P workshop in August 2016, the simplification of Type IA variations was identified as a quick win with significant business value, similar to the simplification of Qualified Person for Pharmacovigilance (QPPV) and Pharmacovigilance System Master File location in Art. 57. Although simplification of Type IA variations has not yet been formally approved, the need to simplify processes and

create efficiencies is supported by ROG and by Heads of Medicines Agencies (HMA). Collaboration on ePrescription, shortages and cooperation with Falsified Medicines hub were recognised as further SPOR priorities.
The Task Force was briefed on the project risks, its impacts and planned mitigation measures. The need to introduce and to focus on the minimal viable solution was reminded, as a measure reducing the danger of delayed and over complexed implementation. Insufficient stakeholders' engagement was mentioned as one of project risk generated by lack of benefits realisation among interested parties. The necessity to invest in the communication proving the SPOR business case benefits and increasing the awareness among all concerned stakeholders was highlighted. With regards to the measures to mitigate the risks related to Brexit and possible Agency's relocation, it was suggested to focus the project implementation on Products to overcome possible shortages in resources and to materialise first SPOR benefits in a shorter perspective.
The main building blocks of draft solution architecture to be available upon SPOR Iterations 1 completion by mid-2019 were presented. The SPOR integration with GSRS is currently out of scope though EMA commitment to implement GSRS solution was re-confirmed and this is included in the Agency's long-term road map. The need to fully understand how the GSRS operates is essential for resources planning, proper software implementation and maintenance process definition; therefore a dedicated GSRS pilot will be run with the Nederland's lead. As a pre-requisite/input to the GSRS pilot and with the aim to minimise the risks related to the implementation of GSRS in EU (with its related business process), it was decided to organise a Substance Pilot in order to evaluate feasibility, time, cost, TOM, resources, HMA approval, etc. This Substance Pilot will be based on substance data provided by a set of volunteering NCAs and by FDA but only using excel; NCAs and MAHs will be actors in this pilot.
Subject to a successful Substance and GSRS Pilots completion - GSRS implementation plan (including business processes) will be presented, jointly with ROG, for the endorsement at the HMA meeting.
SMS Iteration 1 scope elements were presented as supporting the minimum viable product concept in regulatory processes across EU network. Among the other elements covered by Iteration 1, the very unique to Europe process of substance names translations was mentioned as a capability supporting substance data management. Iteration 1 also includes: the migrated data from EUTCT Human, EUTCT Vet, EV Human and EudraPharm Vet, creation of a consolidated Human and Veterinary list and ability to receive the updates from external sources.
With regards to PMS Iteration 1 scope following elements are included: data migration from Art.57 database and from EudraPharm Vet, addition of the new data fields, creation of the EU Implementation Guide, revision of Art. 57 business processes and functionalities, processing of the new messaging in ISO IDMP compatible format, new capabilities to control data quality and also providing NCAs with the access to the interface that will be used by EMA to view and validate the data.
The feasibility of providing the ability to receive and automatically compare the product information within the eCTD final sequences with the product information received in PMS will be also assessed. The possibility of the integration with CESSP will be also evaluated.
With regards to the project timelines, the need to take high level decisions on processes by May 2017 was emphasised as these decisions are needed to frame the project scope. It is still planned to go-live with PMS and SMS by mid-2019. For the enforcement of Type IA simplification within SPOR solution, it is currently not possible to estimate the implementation date due to uncertainty on related processes and their duration (specifically on the manufacturers' data validation). It was reminded that all presented timelines are indicative.


P&SMS Overview.pdf

3. SMS Implementation plan / Pilot / Target Operating Model / High Level Business Plan

Isabel Chicharo and Andrew Marr reported, on behalf of SMS sub-group, the outcome of the discussions taken place during the last team meeting. During the workshop, necessary components needed for IDMP implementation in substances were identified; these include the definition of the simple substance list, business case review, Pilot phase execution, creation of TOM and business processes outline. It was added that the simple substance list will be supplemented in future with the ISO IDMP compliant list created in EU GSRS. This list will be defined according to ISO criteria and will also be reflected in simple substance list with the same granularity level. Another important workshop conclusion was made on the Specified Substance Categories and business cases relevant for SMS implementation. These elements were gathered in four groups according to the assigned priority level (high, medium, low and none). It was noted that substances, Specified Substance Group 1 (SSG1) and manufacturer IDs were identified as a high priority data set needed for Iteration 1.

The need to test if the data from different sources could be gathered together, in a respectable quality and consumable format, to ensure efficient business case support was noted. To proof this capability the sub-group recommended running a Pilot. Correct level of data granularity to be used in this exercise needs to be identified. Through this Pilot study it is aimed to estimate the effort needed for the substance validation process and the approval steps in terms of volume and skills needed. Pilot scope will include substances used in the Human and Veterinary Authorised Medicinal Products as actives, excipients and adjuvants. Moreover, it will specifically focus on Substances and SSG1. The work on the development of substance list for Pilot is planned to commence in April 2017 and the list will be sourced with Art.57 and EUTCT Vet. Next, it is intended to enrich gathered data with FDA and NCAs information. It is expected to determine the confirmed list of Pilot substances by mid-September 2017. Participants, taking part in the Pilot, will be provided with the report on the data missing in their databases. The regulators will start working on this report by end of September 2017 and next, similar activity will be carried out by the companies. It is foreseen to obtain the consolidated Pilot result by February 2018 and it will serve as a basis for the completion of Iteration 1 elements. The Pilot is planned to close by February 2018 and deliver a report with recommendations on effort for the lists set up. The Pilot report will be presented to HMA together with a ROG recommendation on the Substance Business Case and TOM.

In April/May 2017 it is intended to organise a survey for all NCAs to assemble the information needed to most appropriately assist Substance Advisory Board foundation and also, to clarify and to define related processes. The survey mechanism and precise scope of survey questions are still to be defined.

With regards to future TOM, it was confirmed that it will incorporate the Substance Advisory Board, with its experts nominated and approved by HMA. Furthermore, the two-step approval process was recommended. This method combines two stages: the registration of provisional terms and the process of validation and moving them through to the approved terms. The alignment with FDA data was recognised as a long term goal, out of Iteration 1 scope.

The Task Force was briefed about the recent development on High Level Business Processes. It was stated

that some processes use existing RMS capabilities enabling NCAs substance translations. Presented diagram will be used to further elaborate and design the processes.
In terms of substance migration, the priority will be given to active ingredients and the excipients will follow next. It is estimated that the mapping exercise will be completed by 2019.
The group also noted key aspects to communicate to Industry. The first point refers to the fact that entry to the EMA substance list will be done and controlled by regulators, Industry does not need to deliver substance information in a structured form and the substance information to be delivered will not go beyond the content of current dossier information. It was also noted that the scope for Investigational Substances in Iteration 1 is restricted to name or code and identifier.


SMS to Task Force.pdf

ACTIONS:

- NCAs members of the Task Force are to provide nominations for the participation in the Pilot to EMA by end of March 2017.
- EMA to define the "consumable format" of data needed for Pilot execution, including the list of required fields and data format, by end of March 2017.
- Joerg Stueben to coordinate the nominations from the Industry members of the Task Force for the participation in the pilot by end of March 2017.
- NCAs members of the Task Force are to nominate a representative to join the survey preparatory work.

4. Verification of Medicinal Products in Europe (EMVO) update

Andreas Walter informed that the EMVO taken the responsibility for advancing the formation of the European Medicines Verifications System (EMVS). The EMVS is in accordance with the EU's Falsified Medicines Directive (FMD) and Delegated Regulation (DR) and ensures the implementation of a functioning, secure, interoperable and cost effective system across Europe. EMVO is a joint initiative of EU stakeholders representing manufacturers, wholesalers, community pharmacists and hospitals. The European Hub, facilitating these requirements, is already operational. It serves as a single point of data entry for manufacturers however it holds product master data only. Next, the data is loaded from the European Hub into national repositories. The legislation anticipated full EMVS implementation by February 2019. EMVO fully supports SPOR programme and sees opportunities for collaboration in the field of product master data in order to release the manufacturers from the data upload. EMVO will offer EMA an observer seat in their governance structure and will invite the Agency to participate in their technical workstream. Official EMVO communication will be issued shortly.


EMVO Update.pdf

5. PMS Target Operating Model / High Level Business Process

Gordon Topping summarised the output of the two-day PMS workshop. It was confirmed that the PMS goal is to provide the minimum viable product by mid-2019 through delivering Pharmacovigilance use cases and creating additional stakeholder value via Type IA variation data submissions, Veterinary products integration and efficient validation mechanism for NCAs. The work commenced with the identification of following five segments which need to be delivered as first priority: High level Business Process (HLBP), Iteration 1 data elements, EU Implementation Guide and data migration plans.
The PMS work on HLBP and TOM is not concluded yet; presented diagram characterises the progress made up to now and is based on the P sub-group discussions. The chart also incorporates the input received from ROG. Three phases of a product life cycle were distinguished on a high level: clinical trials phase, marketing authorisation application phase, post authorisation phase. TOM model includes now the marketing authorisation application phase and the post authorisation one. Three potential scenarios were identified for the implementation: the update of CESSP form with Iteration 1 fields and upload to PMS, product info pre-registration in PMS and linking to CESSP form via ID and the last option could be a combination of the above.
Similarly, there is still an on-going discussion within the sub-group to define the mechanism for MAHs to transmit Iteration 1 data elements to the competent authorities, including determination of the messaging standard. It is important to notice that all messaging options need to consider different contexts for Veterinary and Human Medicines and will be consulted with EU Telematics Enterprise Architecture Board (TEAB). Technical messaging standards were evaluated in terms of pros and cons and to ensure all stakeholders will be able to implement this message standard in the given timeframe. The messaging formats, with the pros and cons, will be discussed at the TEAB and a decision will be taken by the IT Directors.
The P sub-group revisited the Iteration 1 data elements; a subset of fields ws generally accepted and new fields were identified as potential candidates, depending on the business cases which PMS will support. The requirement to closely collaborate with eHealth network for the successful and harmonised implementation of ePrescription project was highlighted. A concrete list of fields is not yet agreed upon and will not be finalised before publication of EU Implementation Guides (EU IG),
With regards to the progress on the EU IG, the Task Force was informed about an initial version of the guide along with the first review round. Received comments approved general structure of the document and provided some valuable, practical observations, particularly related to the processes and procedures. The content will continue to be elaborated in subsequent iterations of the document.
The ongoing negotiations with the European Committee for Standardization (CEN) with regards to the using and linking the ISO standards in the SPOR documentation and training materials were noted. It is specifically important to clarify the position at the earliest, allowing extensive access to SPOR specifications to the stakeholders.
As for the next steps, the need to prioritise, carefully assess and prepare the migration plans and options was stressed as these plans have significant impact on timelines, workload, quality and costs. Costs and benefits for each migration option need to be evaluated and only then the final decision can be taken.
Extensive discussion on the originally proposed migration strategy, EMA to migrate the Art.57 data and MAHs to update the migrated data with missing data fields, proved many aspects need more assessment to reach the consensus.
Further direction from ROG on the approach to validating Type IA Variation for regulatory process

simplification is required in order to support the definition of the business case. It is considered that only the variations that do not require NCA validation are in scope and ROG additional recommendation on this matter is expected. Concerns were expressed that Type IA variation simplification had not yet been approved and there is a risk that PMS may provide limited tangible benefits until such point.


PMS IDMP TF presentation.pdf

ACTIONS:

- Gordon Topping to circulate HLBP in Visio format to the Task Force.
- Laurent Desqueper to share the excel file with PMS data fields for Iteration 1 with the Task Force.
- Christoph Gessner to investigate if he can act as a liaison person between eHealth network and Task Force to ensure all aspects needed for cross-border ePrescription implementation are considered.
- Paolo Alcini/Christian Hay to follow up on the discussion with CEN regarding the access to the ISO standards documents and copyright issues.
- Paolo Alcini to follow up on the organisation of the PMS face to face workshop prior to May 1st at EMA premises.
- Francisco Penaranda to contact ROG chair making a proposal to prioritise the type IA variation presentation to HMA. Also, informing about PMS planned progress and deliverables to be achieved before May 2017 and requesting ROG view.

6. Communication

Agnieszka Laka updated the Task Force with the recent developments in the SPOR Change management activities and also briefed the group on 2017 communication highlights. NCAs and Industry expected involvement throughout SPOR was extensively communicated to the stakeholders with the focus placed on the key milestone activities and the integration with Telematics systems. It was emphasised that mapping remains the critical activity for the network in 2017. SPOR implementation questionnaire was issued last year with the aim to measure the awareness, planning and mobilisation. The survey proved different level of speed in mapping across NCAs and, therefore, it was strongly advised to intensify mapping activities this year. In order to better facilitate this exercise, NCAs will be asked to nominate mapping coordinators and mapping champions to closely cooperate with EMA SPOR team and to report any obstacles. This initiative was accepted by EUNDB and IT Directors.
NCAs representatives, who attended last IT forum on 1 and 2 March 2017, were presented with the outline of fundamental SPOR information including: high level timelines, benefits and deliverables and key NCAs activities. The need to engage all Member States throughout the NCAs change liaisons was stressed.
The engagement with the working parties and committees was noted. It started with the update given to CMD(h) and will continue with remaining groups. In terms of increasing awareness of SPOR among stakeholders, it is planned to commence number of actions to specifically on-board the small and medium-sized enterprises (SMEs).
The update on developing new and updating existing SPOR materials and content was presented. Newly

created materials will include web user manuals for RMS and OMS and document on the high level mapping processes.
The necessity to actively distribute the SPOR related information was emphasised. Explicitly, NCA change liaisons are expected to play a key role in dispensing SPOR facts on the national level. This active contribution in cascading down the information is crucial to assure the information reaches all stakeholders. The need to further promote SPOR with its full benefits realisation was stressed to ensure the same level of awareness and understanding among the network. It was also noted that the engagement of national trade associations might be valuable in terms of reaching out to the national companies. The discussion was concluded with the statement that targeted communication on national level is required.


Comms update to SPOR TF.pdf

ACTIONS:

- Edit Tóthné Hajdu to confirm if she can take up the role of the NCA mapping coordinator as a representative of Veterinary agency.
- EMA SPOR Change Management team to consider targeted communication to reach stakeholders on the national level and attempt to engage national trade associations (newsletters, information days, etc.)