



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 June 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

22 June 2018, 9:00 to 16:00

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

Role	Name
Present	<p><u>EUNDB:</u> Jeffrey Martin (Sweden), Jose Manuel Simarro (Spain), Ana Lopez De La Rica Manjavacas (Spain), Aziz Diop (France), Lionel Ridoux (France), Paule Carnat-Gautier (France), Catherine Russell (United Kingdom), Luke Wakefield (United Kingdom), Dubravka Sudić (Croatia), Marko Suvak (Croatia), Edit Tóthné Hajdu (Hungary), Ly Rootslane (Estonia), Martha Schei Hynne (Norway), Georg Neuwirther (Austria), Hans-Joachim Bigalke (EDQM), Marta Terron Cuadrado (European Commission), Frits Stulp (Netherlands).</p> <p><u>Human Industry Associations representatives:</u> Christoph Kox (AESGP), Andrew Thornley (AESGP), Remco Munnik (Medicines for Europe), Neil Newman (EFPIA), Joerg Stueben (EFPIA), Andrea Herrmann (EuropaBio), Laurent Desqueper (EuropaBio), Jean-Michel Cahen (ECI-EEIG), Edouard Michoud (Vaccines Europe), Quentin Grignet (Vaccines Europe).</p> <p><u>Veterinary Industry Associations representatives:</u> Patrizia Oelker (AnimalhealthEurope), Bernd Beutel (EGGVP).</p> <p><u>Additional experts:</u> Vada Perkins (Bayer), Kelly Hnat (K2pharmaconsulting), Gunther Pfeifer (ECHAMP).</p> <p><u>Vendors/Software providers:</u> Barry Hammond, David Scanlon, Markus Pfahlert, Rune Ringsholm Bergendorff, Susan Metz, Ursula Tschorn.</p> <p><u>EMA:</u> Francisco Penaranda Fernandez, Isabel Chicharo, Agnieszka Laka, Kepa Amutxastegi, Jaime Gonzalez, Anne-Christine Lantin, Jos Olaerts, John Fisher,</p>



Role	Name
	Katerina Bursikova.
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:

Ana Lopez De La Rica Manjavacas (Spain) was introduced as a new Task Force member. It was also noted that Fabio Macchiagodena (Italy) and Antonio Blazquez (Spain) stepped out for other assignments.

2. PMS status update

Kelly Hnat, Jeff Martin, Georg Neuwirther and Isabel Chicharo presented to the SPOR Task Force (SPOR TF) the outcome of the Products and Substances subgroups (P&S SG) workshop held on 19th -20th of June, 2018 at the EMA premises.

It was reported that the workshop was focused on current key activities of the PMS project: Iteration 1, Target Operating Model (TOM), Legacy Data Validation, and National Competent Authorities (NCA) Data Pilot followed by the Project plan update/status check.

The work progressed significantly for the above mentioned areas however it was noted, further steps are required to define implementation plans and the alignment with the overall PMS implementation plan.

Jeffrey Martin clarified the differences between Legacy Data Validation and TOM processes:

- Legacy Data Validation/PMS data cleansing aims to improve the quality of data in Product Management System (PMS) after its migration from Art. 57 (eXtended EudraVigilance Medicinal Product dictionary - xEVMPD). Product Data Quality means that product data is reviewed / approved according to data quality criteria and is the same across Industry, Regulators and EMA. Legacy Data Validation is likely to be a set of activities outside/parallel to the regulatory context.
- "TOM is a business process model to optimise the exchange of application data between regulators and applicants within the regulatory network. TOM isn't a validation/cleansing/standardisation process for Legacy Data"; it is a mechanism simplifying regulatory submissions (one message to many users/procedures). It covers new products and variations/changes.

2.1. Legacy data validation

Jeff Martin highlighted three main use cases which will benefit from improved quality of data and data standardisation in the PMS: legal requirements for Pharmacovigilance, regulatory efficiency with Regulatory Optimisation Group (ROG) and Cross-border e-Health for both Human and Veterinary purpose. To support these business cases the generation of reliable Identifiers, particularly MPID and PHPID was emphasised.

The calculation of the PHPID and the Cross-border use case will both benefit from data standardisation when the strengths in the composition of the substances is expressed using the same standard.

The SPOR TF was updated on the three key topics of the discussion during P&S workshop:

- 'Data blocks'/phased approach cleansing. The scope was to identify use cases and other considerations in order to group the data fields for each data block.
- Identification of potential challenges for the phased approach in the living database; indication of the method(s) to manage the identified challenges.
- Requirements and recommendations for the communication between NCAs and Industry during the cleansing process.

In conclusion, the SPOR TF was updated on the positive outcome reached during the P&S SG workshop.

Main outputs are:

- Common agreement was reached to master the cleansing process using 'data blocks'. This will help bringing NCAs on board without being overwhelmed by a volume of work. As examples for the identified data blocks (DB) were given: DB1 - Marketing Authorisation (MA) number, DB2 - essential product information, DB3 - active substance/ingredients; other DB to be identified and prioritised.
- Key elements were identified for DB1. These are elements owned by the NCAs (MA#, Authorization Status, Procedure Number).
- Data ownership for remaining data elements still needs to be agreed.
- Process for NCAs to communicate data cleansing issues/corrections is being defined.
- Reference document(s) Summary of Product Characteristics (SmPC) or Module 3/Part 2 to support the PMS data remain(s) unresolved.
- Next step is to establish milestones for the data cleansing, in alignment with other components of the SPOR PMS project.
- It is ideal that the data points required to support ID generation are reviewed and cleansed before both, PMS and the TOM, go live but it was accepted that PMS TOM can be implemented even if no legacy validation has occurred.

2.2. PMS Target Operating Model (TOM)

PMS TOM concept has continued to mature through the work of the NCA team. Incorporating industry process steps in the requirements analysis had positive results.

Georg Newirther mentioned that the design of PMS TOM met the objectives stated below and will result in high quality of PMS data. PMS TOM should:

- be introduced in the short term without triggering significant changes of the regulatory processes;
- be implemented in the Human and Veterinary domain;
- support all procedure types (Centralised Procedure (CP), Mutual Recognition Procedure (MRP), Decentralised Procedure (DCP) and National Procedures (NP));
- allow sharing workload in the regulatory network and must consider specifics (like MRP, DCP etc.);
- work with a minimum requirements for NCAs/EMA and applicants;

- support the re-use of data for PMS and NCA/EMA databases;
- re-use existing technology frameworks for implementation.

With regards to TOM implementation, different aspects were highlighted for consideration. These particulars include: defining clear and simple business processes; grouping the application data and describing responsibilities for each group; improving the collaboration within regulatory network and with concerned stakeholders.

For the Marketing Authorisation Application (MAA) lifecycle and different submission procedures, five data groups, to be collected through TOM at different phases of the MAA, were identified:

- EU phase data group (identical data for all concerned regulators).
- National phase data group (non-identical data on Member States level).
- NCA data group (contains approval information).
- MAH data group (contains post marketing data).
- Additional data group (contains additional information).

The concept of the data groups brings clarity on related data attributes and on responsibilities for the data entry in different phases of the regulatory process. The list of data attributes for each data group is being drafted. The SPOR TF was presented with details and examples on the sequence for different data sets to be created and mastered within TOM.

Subject to improvement, few changes regulatory changes are expected as a consequence of the TOM. These regulatory changes refer to the resubmission process of an updated data set and are expected to be mandatory in order to ensure the consistency of data within the regulatory network. There is an overall agreement on TOM design, enabling the work to move forward. Industry, NCA and EMA should collaborate together in defining business requirements for TOM.

Kelly Hnat complemented the feedback from the P&S SG workshop by mentioning that industry concerns related to the TOM architecture were addressed. It was highlighted that the approval of TOM by CMDh, CMDv and Heads of Medicines Agencies (HMA) should be obtained by Q3 2018 as TOM is a critical component for the EU Implementation Guide (EU IG), version 2, planned to be available by the end of 2018.

2.3. Other PMS Topics

Jeff Martin updated SPOR TF on the **NCA Data Pilot** and presented the composition of the Data Pilot group, proposed deliverables and current achievements. NCAs are conducting the Data Pilot with the goal to further understand the ISO IDMP standard and PMS Iteration 1 implications. There will be meetings held in September and November to prepare a conclusion before launch of the EU IG consultation in Q4 2018.

Isabel Chicharo briefed the SPOR TF on the workshop discussion related to the Logical Data Model and updated the group on the status of the P&SMS Plan.

The **scope of the PMS Iteration 1** is fairly stable in terms of the number of fields. Certain fields, such as manufacturers and shelf life, became mandatory to support certain use cases. The confirmation of mandatory fields is not expected to be completed before Application Programme Interface (API) consultation starts at the end of 2018. These rules are anticipated to continue evolving until the start of

the PMS API User Acceptance Test (UAT), planned for end of 2019. In addition it was acknowledged that the PMS API will develop gradually in each phase and therefore will be subject to change control.

The necessity to provide stakeholders with the extensive communication regarding status, direction, changes and risks of the activities undertaken was highlighted. Careful consideration is needed on the best interim communication format to reach concerned stakeholders outside the SPOR TF in order to achieve clarity of the Iteration 1 scope.

In conclusion Francisco Penaranda emphasised that SPOR remains high priority for the Agency and its implementation will continue regardless the EMA relocation.



02. PMS Update for
22 June SPOR TF Meeting

3. SMS status update

Frits Stulp updated the SPOR TF members with the feedback on the business case for the EU-SRS implementation presented at HMA II meeting, held on 20th of June 2018 in Sofia, Bulgaria.

Material prepared to support the request for HMA endorsement contained: a cover note describing contents of the business case, a presentation deck summarising the business case and requesting decision (including backup materials) also other supporting documents.

Following three main cases were presented to the HMA:

1. Endorsement of strategic direction of the EU-SRS (as part of Telematics strategy Concept Paper) in compliance with ISO IDMP where EU-SRS provides high quality data on substances also from a scientific point of view.
2. Endorsement of the Substance Validation Group (a group of key experts comprised from NCAs and EMA members) and its strategic role in the EU-SRS.
3. Endorsement of the decision to use G-SRS (system developed by FDA, USA in collaboration with several European experts) as a baseline for the EU-SRS, subject to adaptation to the latest EU requirements and to the requirements of the structurally diverse substances.

Approval was reached for the first two key points related to the strategic direction for EU-SRS and for the Substance Validation Group. Regarding the third point presented for the endorsement, the decision is expected to be taken at the HMA II November meeting in Vienna. It is planned to progress with the following activities to support the HMA decision:

- To investigate German experience using the G-SRS (about 44000 substances managed).
- To prepare for system hand-over to EMA.
- To discuss funding (direct and in kind).
- To prepare project initiation:
 - To finalise architecture assessment (with EMA).
 - To align with FDA development plans.

- To start installation of Substance Validation Group, including drafting the Terms of Reference, call for participation & on-boarding.

The SPOR TF members were presented with an overview of the strategic role of the EU-SRS, Substance Validation Group and G-SRS in delivering high quality data for the usage in Substance Management System (SMS).

In conclusion, the benefit of using the EU-SRS for the EU set of substance data to support various use cases, was highlighted.



03. EUNDB_HMA
EU-SRS Business Cas

4. HMA updates

On behalf of the **Regulatory Optimisation Group (ROG)**, Ana Lopez de la Rica updated the SPOR TF on the last HMA meeting outcome. The business case presented by the ROG at the HMA meeting, and positively endorsed, was the **optimisation of the Type IA notification process**.

The SPOR TF members were briefed on the role of the ROG in the regulatory network and its business process. Furthermore, details were shared on the content of presented business case as well as the recommendations from ROG for the optimisation of the Type IA notification process.

The ROG is a cross-functional group, consisting of regulatory, business and IT experts from NCAs, EMA, CMDh, CMDv and Industry, from both Human and Veterinary domains.

The ROG business cases are strategic concepts aiming to identify benefits to the regulatory network. The delivery of each project is subject to endorsement from the established governance, for example: EUNDB for IT Projects, committees for regulatory projects etc. The ROG engages with stakeholders ensuring that relevant groups are informed during the development and consulted on draft business cases in a manner that risks are addressed.

In the context of the Type IA business cases, the Type IA variation according to the art. 2.2 of regulation 1234/2008 are defined as minor variations having a minimal impact, or no impact at all on the quality, safety or efficacy of the medicinal product.

Having a high volume of the Type IA variations, the objective of the business case presented for the HMA endorsement was to propose solutions that offer a substantial reduction in the time and capacity currently consumed on the Type IA variation.

The ROG recommendations for the Type IA business case are to simplify the current process and to review the classification scope. It was highlighted that Industry fully supports the realisation of the ROG proposal for the Type IA variations. The variation optimisation process shall not undermine financial stability of the regulators and the regulators shall monitor costs' allocation.

A number of solutions for the optimisation of the Type IA variations with certain conditions to be respected were presented for the HMA endorsement.

The HMA endorsed:

- Use of SPOR database and PMS TOM to automate some Type IA changes:

- Further clarification on the process and consultation is needed with ROG, SPOR, CMDx etc.
- Inclusion of manufacturer's data and adding a role in SPOR database:
 - This is perceived as the “mandate” for SPOR to make Manufacturer and the new role mandatory (includes manufacturer of Active substance/excipients and Finished product) for Human only.
 - The new veterinary regulation includes in the product database information about manufacturers of the concerned Veterinary Medicinal Products (VMPs) (i.e. authorised VMPs including those authorised under a national procedure, parallel import products, VMPs for pets with no authorisation and registered homeopathic products). Other database will include information about manufacturers and wholesalers.
 - In the product database it is necessary to clarify if this information includes the production of active substances or it includes only the information about both: manufacturers of finished products (all the manufacturers of the product should be included) and the link with the other database. Clarifying this information will help brainstorm on the management of variations not requiring assessment (new term for minor variations in the vet domain). Many of the minor variations concern the address or the name of the manufacturers, including the manufacturers of active substances and also update of CEP of active substances. If the manufacturers' of active substances are not included in the product database, the management of variations with a record in the database won't be possible.
- Optimisation of specific Certificates of Suitability to the monographs of the European Pharmacopoeia (CEP) updates:
 - Although there was explicit reference to SPOR, it is still perceived as a “mandate” to be considered in SPOR as optional.



04. ROG
presentation to HMA

5. Vet updates

Jos Olaerts updated the SPOR TF members on the New Veterinary Regulation (NVR) and its impact on the IT/Telematics. On 5th of June 2018 the final (draft) text of the 'Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products' was agreed at the trilogue by the European Commission, the Council and the EU Parliament. The following high level Telematics requirements supporting the NVR were identified:

- the implementation of three union databases for:
 - Pharmacovigilance.
 - Product (PMS).
 - Manufacturing/wholesale distribution and inspections.
- the execution of additional IT tools and business processes in line with the new requirements for monitoring of antimicrobial resistance.

Currently, the administrative work, legal review and translations for the publication of the NVR are taking place. A phase of three years will be dedicated to the development of the IT solutions with the aim for the NVR to be fully applicable by the end of 2022 when also, all three union databases are expected to be up and running.

The European Commission performed an impact assessment for the NVR implementation and concluded that implications are higher than initially predicted. Regarding the IT solutions development, there were identified a number of risks conditional to the delayed implementation of the three union databases. It was emphasised that the readiness of the PMS data base plays a key role in the implementation of the NVR.

Anne-Christine Lantin updated the SPOR TF on legacy data for veterinary medicinal products. After the Veterinary Experts group meeting, the P&S SG workshop and the EUNDB on 21st of June, a number of steps to be taken by NCAs were agreed, including populating PMS with legacy data as it would be required by the NVR.

No migration from EudraPharm to PMS will take place. EudraPharm will still be operational for at least the next three years, until PMS is implemented. The minimum set of core mandatory fields for legacy data to be submitted to PMS was identified and some of these fields are non-standardised (free text). NCAs are recommended to start mapping the existing legacy data in local databases against OMS, RMS & SMS. The mandatory set of data should be treated as a draft work until the implementation act of the NVR is endorsed. The work to classify how exactly each field will be populated is on-going. For new data, more mandatory fields are to be expected, however this should not exceed the level currently required from electronic Application Form (eAF). Review of submission of other essential data (QPPV, Master file, sales related info) is planned at a later stage.

It was also stated that next steps involve updating the different phases of the SPOR timelines in order to reflect the agreement with NCAs sending legacy data directly to PMS. Further investigation is needed to understand how to link PMS to EVVET. Additionally, the installation of the Veterinary Task Force for the implementation of the NVR was envisaged.

Regarding the EU IG, it was stated that work is ongoing on the Human side. It was pointed out that whilst some of the chapters (related to the message format, API/UI specifications, pre-registration requirements, maintenance activities etc.) reflect information that could be applicable for both Human and Veterinary domains, with regards to the chapter on "initial submission", there should be a Veterinary specific one. This chapter will be reviewed by the Veterinary expert group and it was proposed that NCAs should take the lead in drafting it.

ACTIONS: To circulate the version of the adopted legislation on 1st of June to all the SPOR TF members.



05.a - S-PMS



05.b - Presentation

subgroup workshop - JO to PMS on NVR im

6. Telematics strategy and use of SPOR in Projects

Stefan Blixen-Finecke presented the current Telematics strategy, extended until 2019 and updated the group on the premises and dependencies supporting the implementation of a new Telematics strategy covering 2020 - 2025.

Taking into account the planning and budget cycles, the development of the new Telematics strategy beyond 2019 is expected to start soon. This is to ensure that the vision for information management and technology is clearly described and represents appropriately the European Medicines Regulatory Network's (Network) business needs.

In November 2017 the EU Telematics Management Board (EU TMB) and the chair of EMA Management Board (EMA MB) met in a workshop to clarify and understand the business needs of the Network and to also define the input necessary to start updating the Telematics strategy. At the workshop it was decided to draft a Concept Paper for Telematics strategy 2025.

The purpose of the Concept Paper is to outline and assure adequate top-down strategic direction for business changes that the Network is expected to introduce over the covered period of time. Its role is to also serve as a direction for bottom-up consultation as well as a foundation for developing the Telematics strategy 2020-2025. The Concept Paper was prepared as a result of common input of the IT DEC, EU TMB and Telematics Forum. The Concept Paper is subject to both, the HMA and the EMA MB, approvals.

On 23rd of May 2018 the Concept Paper was submitted to the EU TMB for adoption. Subject to the EU TMB's approval, the Concept Paper was expected to be presented for the HMA endorsement in July 2018. Pending the HMA's approval, a written procedure was envisaged to be initiated in July for the EMA MB endorsement.

To prepare the documentation supporting the new Telematics strategy, there is a number of meetings and workshops with industry planned from August 2018. Telematics strategy 2025 is expected to be ready by the end of 2019.

It was highlighted that the Concept Paper incorporates both Master Data Management and SPOR as key contributors for the Telematics strategic objectives. SPOR implementation continues within the current roadmap and the final phases of SPOR will be incorporated in the new Telematics strategy.

The Telematics strategy 2025 envisages all new projects to use SPOR data. A concrete example was presented for Scientific and Regulatory Evaluation Procedure Support (S-REPS) which is delivering a solution to help with orphan designations. SPOR has provided a number of services to support S-REPS. Among them are the OMS, RMS, substances from European Union Telematics Controlled Terms (EUTCT) and the Identity and Access Management (IAM).

ACTIONS: EMA to provide better visibility of the upcoming projects that will consume SPOR data.

7. Industry points

Neil Newmann, Susan Metz and Laurent Desqueper presented the Industry updates to the SPOR TF members.

The valuable work performed during preceding P&S SG workshop was acknowledged.

Industry representatives re-confirmed their commitment to collaborate with other members of the SPOR TF for successful SPOR implementation.

Industry addressed a number of requirements in order to start data preparation for the Iteration 1. With regards to the final list of data fields for the Iteration 1, the EMA confirmed that it remains the same. Currently, the work is progressing on the definition of the fields needed for Type 1A variation. Common agreement to publish updated materials with regards to the Iteration 1 status was expressed.

Additionally, Industry requested clarification on sources to be used for some Iteration 1 fields. Mixed opinions were expressed on Module 3 further use. From the EMA perspective, using Module 3 for

substance composition, can serve as a backup, supporting the pharmacovigilance purposes until TOM is fully operational. Industry members suggested drafting a proposal, exploring other solutions, to serve as a potential alternative.

Other addressed point concerned the necessity of attaching the SmPC in the new product submission. The EMA reinforced that the SmPC needs to be sent as it is used for the data validation but also is required to be published on the medicines web portal.

Between Medical Dictionary for Regulatory Activities (MedDRA) and Systematised Nomenclature of Medicine (SNOMED), as a source for PMS, it was highlighted that MedDRA takes priority for the use cases supported by the EMA.

In the response to the clarifications required with regards to the OMS, it was confirmed that the OMS data is public and it can be consumed as master data for other processes. Additionally it was clarified that the key user group topic and the Terms of Reference (ToR) draft are under the attention within 2018. Service Level Agreements (SLAs) for the data cleansing are indicative for the time being.

It was agreed that the EMA will record a training session on the submission of OMS change requests process. The video will be made available on the EMA website and the publication will be communicated via change liaisons.

ACTIONS:

- Consolidation of the material to be published with regards to the Iteration 1. Industry is in charge to prepare the disclaimers and EMA to prepare the list of fields for the Iteration 1.
- Industry to draft a proposal for other solutions which could serve as stepping stones for the transition period until TOM is fully operational and used by all involved parties.
- Agree on Industry involvement in the TOM workshop.
- EMA to record and publish training session for the process of submitting OMS change requests.



07. Industry Topics
for 22 June SPOR TF

8. Business Change Management

Agnieszka Laka briefed the SPOR TF on the RMS & OMS user registration status highlighting an increased number of registered users since March 2018.

In March 2018 the SPOR TF meeting, a number of issues related to the user registration process was reported. In particular, it was noted that the cover letter was often missing as attachment to the registration request. There was no clarity on the person responsible for signing the cover letter. Other highlighted concerns were related to requesting the 'Super User' role.

To address these reported issues, the EMA set up dedicated webpage for the SPOR user registration, available on the EMA website, in Human regulatory domain.

The schedule for the upcoming webinars in June and September 2018 was communicated. The webinars will be recorded and presentations will be provided additionally to the recorded material.

Furthermore, the overview of the published guidance for the OMS & RMS on the SPOR portal and the EMA corporate website was shared.

9. Meetings in 2018-2019

Industry and NCAs expressed the continuous interest to collaborate with the EMA for the consolidation of current processes and brought up recommendations to support the design of both Legacy Data Cleansing and TOM requirements. The benefit of organising face to face workshops was highlighted. It was proposed to arrange similar meetings for the Legacy Data Cleansing and TOM with a small group of participants, including Industry, in order to progress more efficiently during the EMA relocation. To keep the group small, and efficient, limited number of Industry representatives, nominated by the Industry Associations, was suggested. The EMA highlighted that in terms of face to face meetings there are no resources allocated from the Agency to provide support or to physically participate. This is due to the EMA relocation activities. The EMA representatives are expected to join the discussion, for relevant topics of the agenda, via teleconference.

Considering the uncertainty of various factors related to the Agency move, the virtual meetings and teleconferences can potentially also be put on hold for the relocation time. Further details on the progress of SPOR within the transfer period will be communicated.



08. Business Change
Management.pdf

10. Conclusions

As meeting summary all the achievements and the positive outcomes of the common hard work and commitment for the SPOR implementation were recognised. It was noted that on 20th of June 2018 SPOR completed one year of live service and remains the highest priority for the EMA.

In this first year of SPOR a number of implementations for the RMS & OMS took place along with the integrations with electronic Application Form (eAF), EudraVigilance (EV) registration system and orphan designation. The consolidation with Art.57 and Clinical Trials was initiated.

Significant progress has been made over the past few months regarding P&SMS scope, processes and strategy for data quality improvement. Although SPOR implementation continues, the programme is already seen as an essential asset to the regulatory network.

At the HMA meetings ROG appreciated the role of SPOR in achieving the simplifications for the Type IA variations while EU-SRS attained endorsement to support SPOR in accomplishing goals for the regulatory network.

SPOR has the highest priority in terms of business continuity planning and was also identified as a key component supporting the Network strategic objectives.

It was noted that the concrete impact of the EMA relocation is still unknown and delays can be expected. However, given the Network support, SPOR implementation is expected to continue steadily.