16 October 2019
EMA/580947/2019
European Medicines Agency

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

16 October 2019, 9:00 to 17:00

Co-chairs: Isabel Chicharo (EMA), Laurent Desqueper (EuropaBio), Jeffrey Martin (Sweden)

Role	Name
Present	EUNDB: Georg Neuwirther (Austria), Anne-Kathrin Gottzein (Germany), Louise Petersen (Denmark), Hans-Joachim Bigalke (EDQM), Triin Maesalu (Estonia), Jose Manuel Simarro (Spain), Mourad Hassany (France), Marko Suvak (Croatia), Dubravka Sudić (Croatia), Herman Diederik (Netherlands), Frits Stulp (Netherlands), Kristine Aasen (Norway), Jeffrey Martin (Sweden), Johan Aulin (Sweden), Joris Kapmeijer (Netherlands). Human Industry Associations representatives: Andrew Thornley (AESGP), Christoph Kox (AESGP), Anjana Pindoria (Medicines for Europe), Nora Weitbrecht (Medicines for Europe), Remco Munnik (Medicines for Europe), Stuart Izod (Medicines for Europe), Patrick Middag (EFPIA), Joerg Stueben (EFPIA), Andrea Herrmann (EuropaBio), Laurent Desqueper (EuropaBio), Jean-Michel Cahen (ECI-EEIG), Karl-Heinz Loebel (EUCOPE), Elisabeth Godet (Vaccines Europe), Quentin Grignet (Vaccines Europe), Kevin Horan (BearingPoint), Urs Eugster (Swissmedic). Veterinary Industry Associations representatives: Patrizia Oelker (AnimalhealthEurope), Bernd Beutel (EGGVP). Additional experts: Vada Perkins (Bayer), Annet Rozema (CG-MEB). Vendors/Software providers: Anne Pouzet, Barry Hammond, Christian Hay, Malin Fladvad, Markus Pfahlert, Susan Metz. EMA: Francisco Penaranda Fernandez, Isabel Chicharo, Olivier Simoen, Carlos Aicardo, Jaume Gonzalez, Pedro Batista, Delia Matei, Gustavo Rodriguez, Anne-Christine Lantin.
Minutes	Inga Angelutsa

1. Welcome

The meeting was opened, and participants were welcomed.

Adoption of draft agenda:

Georg Neuwirther requested to update the SPOR TF on mandatory selection of OMS data in electronic application forms (eAF). The brief was included in the introduction part of the agenda.

The updated Draft Agenda was adopted.

Membership update:

New members of the SPOR TF were introduced as per following:

- Malin Fladvad replacing Malin Jacobsson representing World Health Organisation (WHO)
- Kristine Aasen representing Norway NCA, replacing Martha Schei Hynne until autumn 2020
- Catrina Stirling as an addition to Animal Health, completing the available space.

New observers of the SPOR TF were introduced:

- Kevin Horan representing Bearingpoint
- Karin Gröndahl representing Sweden NCA.

Apologies and backup for the SPOR TF were brought up for:

- Stina Wahlin represented by Johan Aulin
- Anja van Haren represented by Joris Kampmeijer
- Rune Ringshom Bergendorff represented by Anne Pouzet.

Members who left SPOR TF were mentioned Ly Rootslane and Jeffrey Martin announced his resignation.

Strategy and achievements:

Isabel Chicharo updated Task Force on SPOR data services, presenting the achievements of SPOR since it was set up in mid-2014 until current state and shared the strategy for the future.

Project wise, as well as from operational point of view SPOR realisations included:

- **Continuous engagement with Stakeholders:** through communication, engagement, awareness and preparedness to implement SPOR
- **Deliver solutions required by EU law:** deliver ISO IDMP EU IGs, ISO IDMP compliant data services, deliver information services for Human and Veterinary medicines, support NVR implementation
- **Produce data content:** cleanse and consolidate multiple sources of data
- **Maintain data:** process user change requests, process deltas/changes from source systems
- **Support users:** address incidents and questions, formalise and improve customer service
- **Improve data services:** address performance key performance indicators/service level agreements (KPIs/SLAs), formalise and improve Data quality management and reporting
- **Integrate SPOR data services:** deliver data services that support the full product lifecycle and integrate with EU regulatory processes to improve them

Additionally, there were presented the challenges for 2020 including capacity of team members due to staff loss, budget limitations and possible risks.

01. Introduction - SPOR 2019-2020.pdf

2. NVR-UPD Update

Anne-Christine Lantin presented updates on the New Veterinary Regulation (NVR), including Union Product Database (UPD), role of the European Medicines Agency (EMA) in implementing the NVR and the timelines for the UPD.

The NVR was published on 7th of January 2019. A period of three years it is envisaged for its implementation since it came into effect on 28th of January 2019. The NVR is expected to modernise the existing rules on authorisation and use of veterinary medicinal products (VMP) in EU. It contains new measures for increasing availability and safety of VMP also enhances EU action against antimicrobial resistance.

The role of the European Medicines Agency (EMA) is to contribute to discussions on implementing delegated acts. In particular, EMA provides **scientific and technical recommendations** as and when requested by the European Commission.

In February 2019, EC requested EMA to provide advice on the measures and arrangements required to deliver technical and functional analysis allowing the development of the UPD. The advice was prepared by a group of experts and has been delivered on 31st of August 2019.

The timeline for UPD show that the specifications of the UPD Implementing act started on 8th of January 2019 and will continue until 27th of January 2021.

Mandate Governance and Scope definition of the UPD falling under Phase 1 of the UPD, started on 1st of March 2019 and ended on 31st August 2019.

Phase 2 took place from 1st of June 2019 to 31st of August 2019 and the high-level requirements (functional and non-functional); high level architecture model; data fields, contingency arrangements were defined. The development of the UPD is envisaged to start in 2020 and continue until 2021. In January 2021 the date for the Go-live is set and initial input from Member States is expected to be completed.

More insight of the advice prepared by the expert group on the scope of the UPD, definition and objectives of the UPD and the UPD concept was given to the SPOR TF.

Additionally, it was mentioned that the UPD expert group held discussions on several matters including interoperability and interface; data exchange mechanism and format for electronic submission; contingency arrangements and phasing of initial entry.

It was emphasised that the UPD stays at the cornerstone of the following IT systems in the regulatory network:

- NCA and EMA databases
- Union Database on Manufacturing and wholesale distribution
- Sales and use data for antimicrobials
- Union Pharmacovigilance system

- Already existing tools and databases
- MRL Database.

While the objectives, as described above, include making available a system that is ready for integration with other system, the development of any other NVR systems or functionality requirements within those systems, e.g. to make the consumption of product data possible, remain out of scope of the UPD system concept. This includes, but is not limited to:

- Pharmacovigilance database and related business processes
- Database for collection of sales and use data for antimicrobials
- Manufacturer and Wholesale Distributor Database.

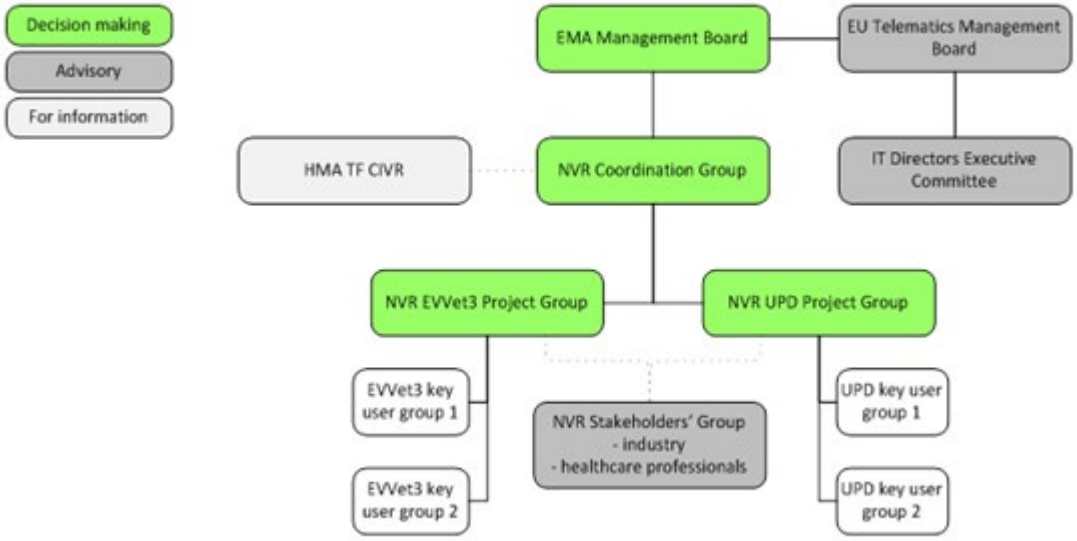
It was expressed that once the requirements for the UPD are established, some adjustment may be needed, though the work on these has not started yet.

SPOR TF was presented additional updates on the UPD status:

- Advice was published on Commission website
- The Commission will draft the implementing act and further consultation periods are foreseen (organised by the Commission)
- The Agency intends to initiate the NVR-UPD development project in agile methodology in early 2020, in collaboration with the member states
- Governance structure was approved, nomination still has to be reviewed
- NVR-UPD project group is expected to start working on:
    - Detailing business requirements
    - Detailing future architecture and development of the UPD concept, interconnection, data exchange and key functions
    - Detailing data specification
    - Defining legacy data to be provided for the initial input
- First meeting NVR UPD Project Group expected to take place during the week commencing 28 October 2019
- EU Telematics governance meetings are planned for the following dates:
    - 15 October 2019: TEAB - Start discussion on the architecture for UPD
    - 02 December 2019: TEAB - Agree on the architecture for UPD
    - 29 October 2019: IT DEC Presentation UPD project
    - 07 November (Date still TBC): EUTMB - Presentation UPD business case
- Start of the UPD implementation in January 2020
- During 2020 – 2022 is envisaged the agile development of the requirements in the product backlog, as prioritised by the NVR UPD Project Group and /or Key User Groups: Sprints of (e.g.) 15 days, delivering testable cumulative functionality
- On 28 January 2022, according to the Reg. 2019/6, Art 155, the initial input to the product database is expected to be completed by competent authorities

- Test system is envisaged to be available in advance.

The Governance for the development of the UPD was presented as below:



To support the UPD development, it was highlighted that member states can already start performing a number of activities and in particular:

- **Identify** nationally authorised products that will need to be sent to the Union product database (Authorised veterinary medicinal products; Registered homeopathic products; Veterinary medicinal products intended for animals which are exclusively kept as pets; Parallel traded products)
- Considering that Advice on UPD is published, member states can start to:
    - **Check** that the fields identified in the Data fields section are available for the products
    - **Check** when fields should have reference terms, whether this is the case for the products
- **Map** the reference terms.

All the above actions will support the final goal to send relevant product data to Union Product Database by date of application (DoA) of the NVR.

It was highlighted that once the development project on the NVR-UPD will be established and launched, more practical details will be communicated, for instance, whether a testing environment will be available beforehand for Member States to test sending data, whether all categories of products will need to be sent at the same time or whether there might be some stepwise approach, and most importantly what mandatory fields will be required to support legacy data.

Additional emphasis was put on criticality of the data mapping process (process of matching data objects between two or more distinct sets of data):

- Mapping is a **pre-condition** for NCAs which use or plan to **use SPOR through a system/data integration**

- EU **harmonised** vocabularies and **comprehensive** organisations dictionary **depend on NCAs completing their mapping**
- **Products and Substances cannot be implemented** in the Network without harmonised vocabularies and organisations

02. SPOR TF NVR UPD update 161019.p

3. PMS Update – part 1

Jeffrey Martin updated the SPOR TF on the Telematics Enterprise Architecture Board (TEAB) meeting held at the EMA on 15th of October in order to discuss potential recommendation for UPD to use SPOR technology including other mixed scenarios.

During the meeting it was mentioned that the NVR legislation has clear requirements on data specification and management aspects but not on the specific use/selection of technologic solutions to fulfil the UPD concepts (see previous presentation).

Alternatives for UPD data repository are:

- A new product database
- Existing EudraPharm-based Veterinary Medicinal Product Database
- Using PMS as starting point

Overall it was agreed that there is a need to get representation of the SPOR TF under the UPD project in order to make recommendations on previous points and establish synergies between human and vet domains in the area of medicinal product data management.

03. Architectural alternatives human a

Laurent Desqueper presented industry perspectives on the IDMP PMS TOM and its vision for an integrated approach with SPOR. A concept paper, endorsed by EFPIA, AESGP, MfE and EuropaBio, was sent to both EMA and TMB end of July 2019. Topics addressed in the concept paper were:

- Need for data quality to serve multiple use cases (i.e. more than PV)
- Submit data once, assess by relevant CA, store and reuse
- Reinforce Industry support for first TOM phase starting at PMS go live
- No Industry support for current Article 57 process
- Promote an end-to-end program covering SPOR/IDMP, TOM and NVR.

It was expressed that current Article 57 process for data quality is not supporting the expected quality of data and that all stakeholders EMA, NCA and Industry are willing to implement TOM. Though, TOM implementation needs both pragmatic approach and agreement within Regulatory Network.

An insight on both the TOM Implementation – CESSP Approach and TOM Implementation – EMA 'fallback' proposal was given to the Task Force in slides 5-6 of the presentation. A comparison for the benefits and risks in implementing either of the above mentioned approaches was presented.

In conclusion, Industry shared the proposed option forward for all procedure types, centralised procedure and MRP/DCP/NP including the expected benefits if the proposed options are approved. Additionally, the PMS TOM Phased approach considering the transition of the XEVMPD to IDMP FHIR was shared with the Task Force.

03 b. IDMP PMS TOM 16-Oct-2019.pdf

4. PMS Update – part 2

EU Implementation Guide

Carlos Aicardo Muñoz briefed SPOR TF on the European Implementation Guide (EU IG) progress for the submission of human medicinal products. The consultation on the EU IG draft v1 was launched in January 2019 with expectations to be published in June 2019. Considering the high number of comments received during the consultation period the publishing date was postponed to November 2019 in order to ensure all comments from stakeholders were addressed.

The PMS business lead shared with the SPOR TF the EU IG timeline and gave a reflection of the progress of the EU IG process for comment resolution. It was mentioned that in order to resolve the comments a continued collaboration with different stakeholders was maintained through regular PMS SG meetings.

In addition, for certain controversial or complex topics, requiring more frequent communication, a temporary EU IG focus group with both industry and NCA was created being a successful tool for collaboration.

It was highlighted that agreement with stakeholders has been reached on many areas of the EU IG, however a number of topics raised during the consultation procedure cannot be resolved in first version of the guidance and will be considered for resolution as part of EU IG v2.

Following publication of EU IG v1, the work on EU IG v2 will focus on drafting remaining chapters and addressing outstanding issues not resolved as part of EU IG v1. Chapters 1, 2, 6 and 7 may be further amended. Chapters 3, 4, 5 and 8 have to be created, consulted and released in future versions. It was highlighted that some of them may need to be reviewed, hence will be included in discussions with the PMS SG to agree on the next steps.

More concise view on next steps and publication of the EU IG v2 taking into consideration main dependencies on a Target Operating Model, were shared with the SPOR TF.

SPOR TF raised their concerns on the fall-back solution involving an operating model similar to current xEVMPD model where data from regulatory procedures submissions are separated. EMA stressed the need to implement TOM in steps in parallel with other projects (e.g. UPD project)

In conclusion, an overview and feedback of the consultation of the EU IG v1 was shared with the Task Force and suggestions for a more efficient consultation for EU IG v2 were expressed.

04. EU IG _2.pdf

S&PMS Plan & Progress - update to SPOR TF

Olivier Simoen, the SPOR project manager, briefed the Task Force on the project status, achievements reached in 2019 and shared the S&PMS project plan.

- A strong recommendation to use S&PMS for the NVR was mentioned. Either PMS will be used as a database storage building block of the UPD is subject to the UPD Project Group recommendation and NVR Coordination Group approval.
- Few clarifications on the import of the veterinary data from EudraVigilance to PMS were given. It was mentioned that assumptions made at time of the planning of the S&PMS were that the core set of information like name, product number, procedure number and authorisation numbers can be used as key identifiers to a later stage when the information is overwritten. In those cases, there will be no need to recode the information on the EVVET part.

Action:

- Clearer representation of the plan including priorities for each (ex. mentioning that Phase 6 is for the NVR improvements).

Presentation 191016 - SPOR TF Tc

5. UMC & PhPID

Malin Fladvad, representative of the Upsala Monitoring Centre (UMC), reported SPOR TF on joint UMC and WHO workshop on the IDMP implementation which took place in Geneva on 11th and 12th of September 2019 with the aim to articulate the benefits and challenges of the global maintenance of PhPID and establish ways of collaboration to bring the initiative ahead.

During the workshop it was acknowledged that the implementation of the IDMP with local solutions such as local assignment of substance ID, local controlled vocabularies, and local variations of the PhPID to fit local use cases may bring challenges.

A need for a proactive approach such as the implementation of a global PhPID, which will limit unnecessary local variations in the data, was expressed.

To support the use and the maintenance of the global PhPID, WHO came forward with two proposals including (1) WHO collaborating centre and Uppsala Monitoring Centre (UMC) to take on the responsibility for the day-to-day operations of the global PhPIDs and (2) to form a working group to investigate the requirements for global substance registration.

Malin Fladvad shared the next steps to go forward for the global PhPID and emphasised the need for promotion of global consistency of IDMP.

With regards to the global Substance ID, it was mentioned that, a separate group should define the objective, expertise and membership needed to form a working group for creation and maintenance of global substance IDs.

Additionally, it was mentioned that the algorithm to generate the PhPID is an open source and can be used to generate both local and global PhPIDs. The components of the algorithm are built according to ISO standards. Additional mapping process may be necessary to link the PhPIDs.

During SPOR TF meeting it was suggested for NCA representatives to be invited in future meetings related to the global PhPID.

05. Report from IDMP workshop EU IC

6. EU-SRS POC update to SPOR-TF

Frits Stulp and Annet Rozema, business leads for the EU-SRS projects, updated SPOR TF on the project status, data cleansing and EU-SRS development. The SPOR TF members were informed on both the outcome of the face to face Substance subgroup (S-SG) meeting held on 15th of October 2019 and the advice prepared for the HMA reflecting the ways forward for EU-SRS project.

The EU-SRS Project was reported to be on schedule and more details were shared in the presentation. Overall the following

The EU-SRS PoC Steering committee was established and both on-boarding Substance Validation Group (13 members) and project team were completed. The data cleansing process has started on 1st of August 2019 and it was being performed using a commercial tool 'Sporify'. More figures on the data cleansing process were shared with the group.

An overview of the timeline of the data cleansing process showing past activities, current position and next planned steps were presented to the SPOR TF.

It was highlighted that one of the key project deliverables consist in gathering the EU-SRS user requirements and considering the following factors:

- What should the EU-SRS be able to do in order to facilitate the regulatory network in EU
- The user requirements must be set-up with the future business process in mind, such as
- User requirements will be used as a basis to perform the gap analysis of GSRS software:
- Confirm if the GSRS software is fit for purpose, the minimal viable product
- Identify possible gaps, and discuss & analyse the gaps with FDA/NCATS
- Draft a plan for required software development (if any).

Furthermore, members of the SPOR TF were informed that next presentation for the HMA is being prepared and will cover a summary of the deliverables and the advised ways forward for the EU-SRS aiming to deliver cleansed data to EMA.

It was mentioned that the SMS SG face to face meeting held on 15th of October 2019 was focused on industry participation mainly. During the meeting, industry put forward a proposal with regards to the signature fields. The project team deemed the proposal acceptable and a follow-up will now be planned.

Consolidation of feedback from selected industry members on substance signature fields was shared in the SMS SG:

- Per substance class, the agreement per field was clarified
- For a selection of fields full consensus from industry was already reached, for others conditional comments were provided.

Next steps include both confirming the acceptance of the proposal in detail in the S-SG (with EMA, NCA and industry representation) and addressing any open issues, and comments. Two examples referring to the proposed signature fields for chemicals and proteins were mentioned to the SPOR TF.

It was highlighted that the EU-SRS project strongly appreciated this proactive input and will incorporate this in the materials to be presented to the HMA.

06. EU-SRS-POC update SPOR-TF-Oct

7. SMS Update

Pedro Batista, Subject Matter Expert and Jaume Gonzalez, SMS business lead, presented the latest updates on the Substance Management System (SMS) to the SPOR TF.

SMS Phase 1 went live on 26th July 2019. No new bugs were found in production environment and all functionalities were working as expected. Review of outstanding bugs identified during the UATs has been completed and will be addressed in maintenance releases in 2020.

The only change for Industry was the blocking of registration of development substances in xEVMPD (IMP). Substances for clinical trials have to be requested (pre-registered) via EMA Service Desk before use in regulatory submissions. Consequently, EMA will register these substances as approved substances to ensure the use of the same substance ID across the whole lifecycle of the medicinal product.

Next steps for the SMS will include the migration of Veterinary substance data from SIAMED to SMS, expected to be completed in the coming months.

Holistic review of SMS Phase 2 Use Cases (SPOR Portal + merging & nullification functionalities) completed. Development is planned to start in Q1 2020 and Go-Live in Q3 2020 – subject to project budget and prioritisation.

It was highlighted that ongoing discussions regarding substance confidentiality and impact on eAF/CESP are taking place. Two main topics were highlighted:

1. Publication of veterinary substance names before product approval.

Proposed solution: Register veterinary substances with company code until marketing authorisation is granted.

2. In eAF company codes can't be identified by NCA

Proposed solution: Adding SMS ID and link to SPOR Portal in the eAF dropdown list to allow NCAs to access the full substance data.

The SPOR TF members were presented with the SMS statistics reflecting the ratio of requests per various request types until September 2019.

In 2019 the SMS team started registering substances for pre-authorisation procedures internally since SMS go-live. This process will be rolled-out externally in 2020 (mainly PRIME, ATMP and eligibility for centralised procedure).

07. SMS Update.pdf

8. NCA points

Mandatory selection of OMS data in electronic application forms (eAF)

Georg Neuwirther informed about the plan to make selection from OMS data mandatory in the eAFs. No concrete timetable has been worked out yet. The eAF MG and OMS team will jointly plan the roadmap.
The roadmap will be based on the progress of data extension (e.g. manufacturers) and indicators on OMS data quality.
Thus members are asked to raise tickets about OMS findings. Indicators and statistics will be based on EMA service tickets.

Additional updates were given on CESP, project to replace the pdf version of the original eAF for both human and veterinary forms. Phase 1 was on hold for 2 months due to re-planning. Resuming the activities is expected in due time. CESP project team will send relevant information and updated timeline to the stakeholders.

NCA Data Pilot

Jeffrey Martin briefed the SPOR TF on NCA Data Pilot. Despite challenges encountered by the data pilot group, progress was made. Publishing of the Data Pilot will be delayed, and the date will be communicated to the stakeholders.

Jeffrey Martin highlighted his retirement and proposed Joris Kampmeijer as next NCA co-chair. Gratitude was expressed for the Jeffrey Martin's hard work in supporting SPOR and Task Force conveyed their appreciation to the NCA co-chair.

9. Industry Points

Laurent Desqueper reiterated industry points from the previous SPOR TF meetings highlighting the industry willingness to contribute to the PMS, nevertheless, higher expectations from industry with regards to the current progress in PMS were expressed.

Consensus was reached with regards to the exercise proposed during the SPOR TF involving the industry, NCA and EMA.

It was evoked that the objectives of the exercise should focus on following network ambitions and continuing delivering PMS in parallel to the NVR implementation. If such exercise shall take place, it was suggested that during the exercise all stakeholders shall bring forward their capacity and resources available to continue supporting PMS delivery.

It was emphasised that collaboration between both veterinary and human industry and network involvement is necessary for future success of the SPOR.

10. A.O.B

During the A.O.B. discussions related to TOM approval took place. SPOR TF members expressed their interest in obtaining approval for TOM, as the TOM is expected to deliver improved quality of data.