24 May 2019
EMA/404389/2019
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

24 May 2019, 9:00 to 17:00

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

Role	Name
Present	EUNDB: Peter Bachmann (Germany), Anne-Kathrin Gottzein (Germany), Louise Petersen (Denmark), Christopher Jarvis (EDQM), Ly Rootslane (Estonia), Triin Maesalu (Estonia), Ana Lopez De La Rica Manjavacas (Spain), Jose Manuel Simarro (Spain), Aziz Diop (France), Mourad Hassany (France), Marko Suvak (Croatia), Dubravka Sudić (Croatia), Herman Diederik (Netherlands), Frits Stulp (Netherlands), Martha Schei Hynne (Norway), Jeffrey Martin (Sweden), Stina Wahlin (Sweden), Luke Wakefield (United Kingdom). Human Industry Associations representatives: Andrew Thornley (AESGP), Andreas Franken (AESGP), Anjana Pindoria (Medicines for Europe), Nora Weitbrecht (Medicines for Europe), Remco Munnik (Medicines for Europe), Stuart Izod (Medicines for Europe), Patrick Middag (EFPIA), Neil Newman (EFPIA), Joerg Stueben (EFPIA), Herve Rique (EBE), Andrea Herrmann (EuropaBio), Laurent Desqueper (EuropaBio), Jean-Michel Cahen (ECI-EEIG), Karl-Heinz Loebel (EUCOPE), Elisabeth Godet (Vaccines Europe), Quentin Grignet (Vaccines Europe). Veterinary Industry Associations representatives: Patrizia Oelker (AnimalhealthEurope), Pauline Battaglia (AnimalhealthEurope), Bernd Beutel (EGGVP). Additional experts: Kelly Hnat (K2pharmaconsulting), Gunther Pfeifer

Role	Name
	(ECHAMP), Vada Perkins (Bayer), Annet Rozema (CG-MEB). Vendors/Software providers: Barry Hammond, Christof Gessner, Christian Hay, Malin Jakobsson, Patrick Revelle, Rune Ringsholm Bergendorff, Susan Metz, Wim Cypers. EMA: Francisco Penaranda Fernandez, Isabel Chicharo, Ivo Claassen, Agnieszka Laka, Carlos Aicardo, Jaume Gonzalez, Delia Matei, Gustavo Rodriguez, Olivier Simoen, Paolo Alcini.
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:

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

- Elisabeth Godet representing Vaccines for Europe replacing Edouard Michoud,
- Mourad Hassani representing ANMV replacing Lionel Ridoux,
- Wim Cypers representing Aris Global (previously a SPOR TF member) replacing David Scanlon.

New observer of the SPOR TF was introduced Louse Petersen representing Denmark.

Sarah Jochmann representing Actelion left the SPOR TF.

Herman Diederik's Dutch Royal award

Isabel Chicharo reported that, Herman Diederik, a SPOR TF member, was assigned Royal decoration as Officer in the Order of Orange-Nassau. This decoration is due to Herman's early work on IT use in pharmacies, his contribution to the development of the ISO standard and efforts in the global network to implement the standard.

The **Order of Orange-Nassau** is a chivalric order awarded at the discretion of the **Dutch monarch**.

It is open to "**everyone who has earned special merits for society**". These are people who deserve appreciation and recognition from society for the special way in which they have carried out their activities.

The Order of Orange-Nassau has two divisions, *civil* and *military*, and within the civil division it has 6 classes: *Knight Grand Cross*, *Grand Officer*, *Commander*, ***Officer***, *Knight*, *and Member.*

Herman thanked the SPOR TF for fruitful collaboration in the implementation of the ISO IDMP standard.

1. HD award.pdf

Achievements, constraints & impact in 2019

Francisco Penaranda presented SPOR TF with an overview of the SPOR Data services, achievements and constraints for 2019.

SPOR started in 2014. Since then the SPOR change liaisons network was set up and recently the veterinary stakeholders have been involved in the progress of SPOR. First two services OMS and RMS went live in 2017 and started on-boarding users.

SPOR data has been re-used by several applications. Among them are: eAF, EV user registration, IRIS for both OD and PD, and IAM.

Other achievements were mentioned for both SPOR API and PMS EU Implementation Guide (EU IG):

- SPOR API v1 was released
- SPOR API specifications for v2 are under consultation
- PMS EU IG (Human) consultation.

Data literacy for SPOR has been highlighted as a critical skill to leverage value of data.

Constraints for the implementation of SPOR were highlighted to the SPOR TF members. Among them were enumerated:

- Brexit relocation to the Netherlands delivered, however the loss of staff had and continue to have an impact on Agency's activities.
- Impacts on existing projects/operational activities in the Business/Data Department:
    - It's unclear when the replacement of the staff who left will take place
    - Learning curve for newcomers
    - R&O&S Operational work (change requests) has been prioritised
    - P&S project keeps focus on minimising external dependencies – SPOR API, EU IG.
    - Changes to Governance (SPOR TF ToR, RMS and OMS key user group (KUG)) is still not prioritised as insufficient staff to kick-off and support this work stream.

1. Introduction - SPOR 2018-2019.pdf

2. New Veterinary Regulation Update

Ivo Classen, Head of Veterinary Medicines Division at the EMA, has introduced to the SPOR TF the New Veterinary Regulation (NVR), the Union Product Database (UPD) expert working group, and highlighted the NVR potential impact on SPOR.

New Veterinary Regulation (NVR)

NVR/Regulation (EU) 2019/6 was published on 7th of January 2019 and came into effect on 28th of January 2019.

It was reported that 3 years are foreseen for the implementation period, as the NVR is expected to be applicable from January 2022. Additionally, it was mentioned that approx. 20 Implementing or Delegated Acts are anticipated to be developed during the implementation period.

SPOR TF members were presented with 7 mandates for recommendations/scientific advice from European Commission with regards to NVR. Up to 9 more mandates are expected in June 2019, resulting in overlapping work on at least 16 mandates in 2019.

SPOR TF was also presented with a number of actions for the NVR to be defined in the implementing act in Article 55 (3), relating to the so-called 'Union Product Database'.

2.1. The Union Product Database (UPD) expert working group

Composition and organisation of the UPD expert working group is expected to be established by the end of August 2019.

The UPD is composed by 6 NCA members, 3 EMA members from which 2 representing business and 1 representing IT, and oversight from European Commission.

The UPD expert working group met in Paris on 13th to 14th May 2019 and plans to meet on 6th June at the EMA. Additionally, it was reported that the UPD expert group meets online in virtual meetings every 2 weeks.

Ivo Classen presented to the SPOR TF both the mandate and the objectives of the UPD. Phase 1 is planned to mandate Governance and to define the scopes of both the UPD short and long term goals. During Phase 2, considering the outcome of the Phase 1, focus falls on recommending:

- High-Level Business and Functional Requirements
- High-Level Architecture Model
- Interoperability and Interface
- Contingency Arrangements under point (d) of Article 55(3)
- Additional Information under point (e) of Article 55(3).

The reference architecture model is expected to be delivered by the NVR UPD expert group by 31st of August 2019. Further decision on technology, transition and implementation planning are still subject to confirmation, but anticipated to be delivered by the end of 2019.

The UPD is viewed as cornerstone of several IT systems:

- Union Pharmacovigilance
- Manufacturing and wholesale distribution database
- Sales and use data for antimicrobials
- MRL databases
- NCA/EMA databases.

SPOR TF members were presented more details on the UPD timeline.

The NVR was published on 7th of January 2019 and entered into force on 27 January 2019. The European Commission mandate was received at the end of February 2019. Both Phase 1 and Phase 2 are expected to be completed until 2021 at the very latest, when the UPD development is planned to start if the publication of the relevant implementing act on the technical specifications is awaited. The initial input from Member States (MS) has to be completed by end of January 2022 (Article 155).

Ivo Classen shared more information on both the NVR and UPD progress. It was reported that the UPD Art. 55 scope has been defined in the NVR. Additional 15 high level requirements were also defined and were considered by the expert group based on both the prioritisation and content with outcome expected by August 2019.

With regards to its strategic options, UPD envisages either to use SPOR to support the implementation of the NVR or to remain open to a different approach if suggested by relevant groups of the telematics governance. It is not necessary to take this decision in the preparation of the recommendation of the technical specifications to be included in the relevant Implementing Act.

2. SPOR TF - NVR update.pdf

3. PMS Update

Jeff Martin presented the Target Operating Model (TOM) updates to the SPOR Task Force members. It was mentioned that TOM was initiated to fulfil the need of feeding high quality data into PMS. As outcome of recent meetings it was acknowledged, particularly by a number of TF members, that there was lack of clarity on several aspects of the TOM mainly on the business case to develop to drive the TOM:

- Level of ambition of business process needed to support Art. 57 in EudraVigilance
- Data quality needed to support existing pharmacovigilance business processes
- Clear indications on what the PMS/UPD data is envisaged to be used for.

Additionally, it was recognised that TOM should be presented for endorsement to the HMA, EMA Management Board and to European Commission. It was acknowledged that a responsible person to lead and present the mentioned items to the HMA, EMA MB and EC has to be nominated.

Jeff Martin mentioned to the SPOR TF that a call from EC under Horison 2020 programme to use IDMP in Europe was initiated. The implicit assumption was that IDMP would be used to support cross-border purposes. It was reported that several NCA's and organisations submitted a joint bid to Horison 2020 to get support on several concerns regarding IDMP; nevertheless the response from Horison 2020 was still pending in that moment in time.

NVR, cross-border cases and mainly different alphabets used to submit product data continue to increase the need of having harmonised data across various systems.

Assuming, that the existing quality check of Art. 57 for Pharmacovigilance purposes is not sufficient for all use cases benefitting from SPOR, and it is both costly and time consuming, it was expressed the need of putting in place a process (TOM) that will ensure better data quality into PMS. EMA and/or NCA

should be included in this process, in a manner that at the end of a submission procedures, an electronic version of quality checked data is available to be fed back into PMS.

To support the purpose of feeding high quality data into PMS, two proposals from both Industry and NCA were presented to the SPOR TF:

- Proposal from industry - the Minimum Viable Product envisages having a separate tool that is FHIR compatible, supports creation of a full Iteration 1 dataset and submits it to the NCAs along with the eAF/CESP dataset.
- Proposal from NCA - the existing TOM based on expanded CESP data set module.

SPOR TF members were presented with more details, including the Pros and Cons of the mentioned proposals which support submission of both new products and variations:

Industry – Minimum Viable Product:

Pros:

- Not dependent on CESP delivery and timeframe
- FHIR message from the beginning
- Could be used to submit non-regulated information (sales, availability, QPPV, etc)
- Industry would be responsible for the tool.

Cons:

- Two product data sets: one in eAF, one from FHIR tool
- Tool has not started to be developed; multiple data sets need to be developed: new human, new vet, variations, parallel trade/import, etc
- NCAs need to look at two data sets and compare with Module 3
- NCAs potentially receive two data deliveries for one application procedure
- How do we ensure that the data set submitted from the FHIR tool is exactly what the NCAs have approved?

NCA TOM based on CESP DM version 1:

Pros:

- Tool already under development
- Tool for comparison of two data set version already in scope
- No extra tool to train on and maintain
- NCAs only need to compare one data set to Module 3
- Common process for human and vet.

Cons:

- Uncertain financing and delivery time frame
- Data in new XML format, not FHIR compatible
- Data set not complete
  - QC/Art 57 process will be needed for data missing in data set
- No variation form in development yet
- Variation eAF based on present form has little structured data – new concept for form needed
- Tool needed to submit non-regulated data: CESP|QPPV, sales, availability etc.

In conclusion, it was remarked that indifferently of the chosen process for the data quality, either TOM or Minimum Viable Product, the data quality is envisaged to improve significantly and could stay at such a high level during the life cycle of a medicinal product.

3. Target Operating Model. May 2019.pdf

4. PMS Update (continuation)

Carlos Aicardo Muñoz, the new PMS business lead, presented SPOR TF with an update on the PMS TOM context and submission of product data. Carlos also stressed out factors affecting TOM and provided more details on a potential phased implementation of the TOM considering the aspects previously discussed (section 3 of these minutes).

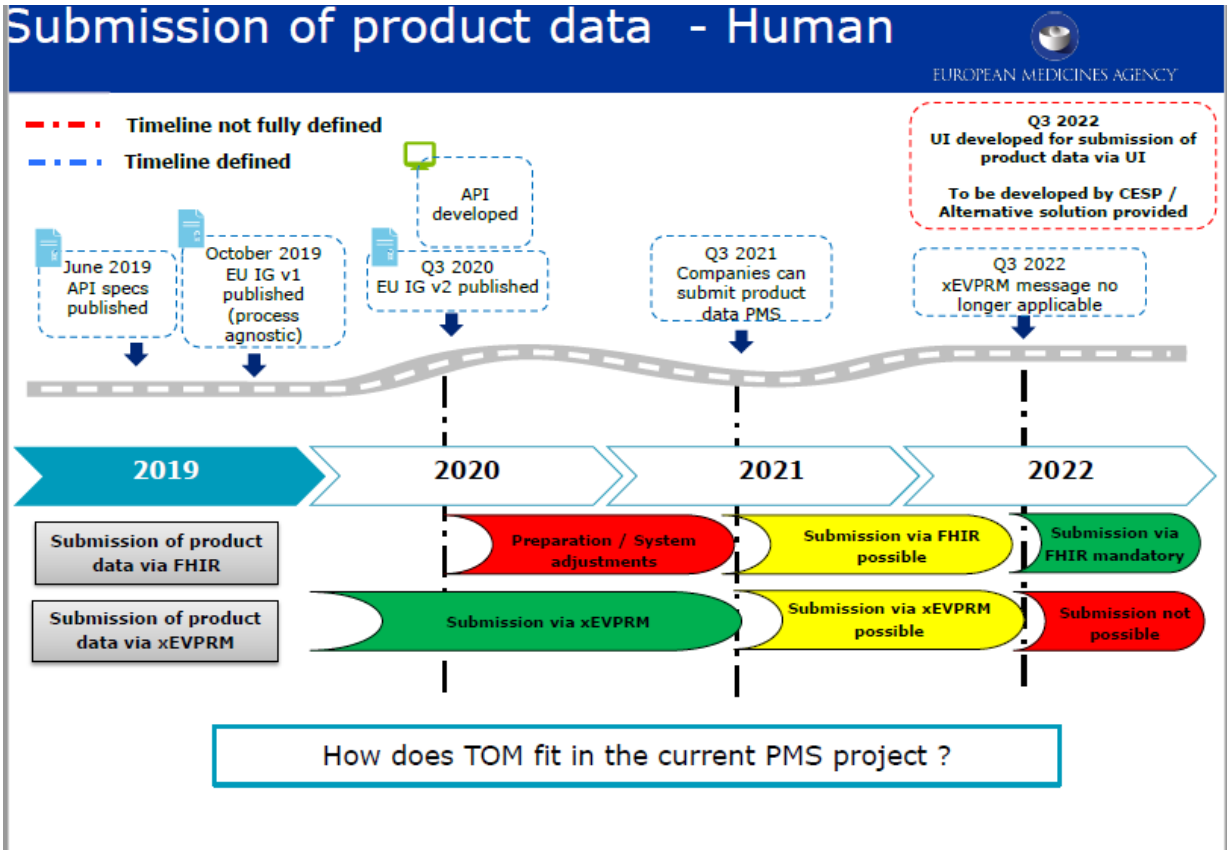
It was highlighted to the SPOR TF members that there is a legal obligation for Industry to make use of the terminologies defined in ISO IDMP standards: Regulation (EU) No 520/12012 (art. 25 & 26).

The use of internationally agreed terminology, format and standards should facilitate the interoperability of systems used for the performance of pharmacovigilance activities and avoid the duplication of encoding activities concerning the same information. It should also allow for an easier information exchange between regulatory authorities on an international level" Commission Implementing Regulation (EU) No 520/2012.

Additionally, it was emphasised that the IDMP standards are relying on Master Data. *Master data is any non-transactional information that is considered to play a key role in the core operation of a business and is re-used for multiple purposes.*

Key elements to support a TOM which links product data submission and validation within regulatory procedures are beyond master data. These include dates, assessment phases, user access/functionalities marked by both various steps of procedures and procedure types.

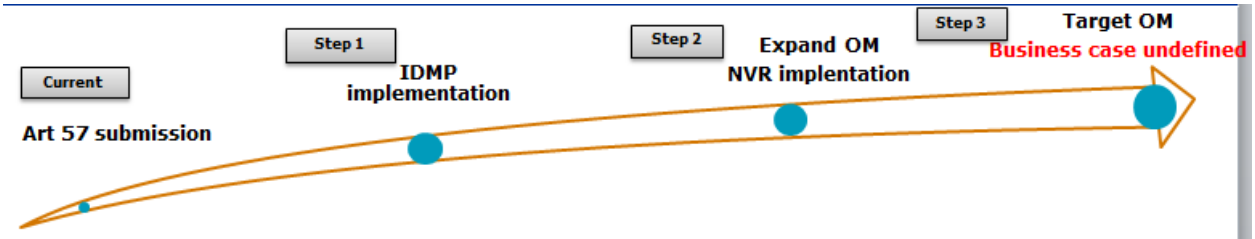
More information on the timeline for the submission of product data for human products was shared with the SPOR TF.



It was highlighted that the main benefits of TOM include the re-usage of master data on different processes and the validation of product data linked to regulatory procedure. Nevertheless of its benefits, as presented in previous SPOR TF meeting, it was acknowledged, particularly by a number of TF members, that TOM is complex operating model.

Further steps in continuing developing TOM, its future version and additional funds were reported to be subject to the HMA/Telematics governance approval. It was acknowledged that the TOM has to be driven by a business case.

Carlos Aicardo Muñoz shared with the SPOR TF how established timelines and planned deliverables for the PMS project fit into TOM phased implementation. At first step, the implementation of TOM will focus on IDMP implementation, possibility to expand data quality assurance using modules 3/SmPC and data submission. Data quality assurance is envisaged to take places once regulatory procedure is finalised. As second step, and depending on the scope of the implementation of NVR this model could be expanded for product data validation by NCAs during regulatory procedure.



Current – Art 57. submission	Step 1- IDMP implementation	Step 2 – Expand OM implementation	Step 3 – Target OM
Product data de-coupled from regulatory procedure - after procedure is finalised	Product data submission at possible at any time of the procedure – optional, likely for CAPs	Submission of Product data linked to regulatory submission	Submission of Product data linked to regulatory submission – full integration
Quality assurance of Product Data by EMA	Quality assurance of Product Data by EMA after regulatory procedure (Validation during procedure for CAPs can be explored)	Validation of product data during regulatory procedure by NCAs for NAPs and EMA for CAPs	Validation of product data during regulatory procedure by NCAs for NAPs and EMA for CAPs
Use of SmPC	**Use of Mod 3/SmPC**	**Use of Mod 3/SmPC**	**Use of Mod 3/SmPC**
Submission via xEVPRM	Submission via FHIR	Submission via FHIR	Submission via FHIR
xEVPRM database	Availability of API/EU IG/MDM hub	Basic technology solution (UI) to View/Edit/Create products	Needs of use case to support the change and development
	Business case available	**HMA/MB approval**	**HMA/MB approval**

4. PMS TOM next steps.pdf

Isabel Chicharo complemented the presentation stressing out that SPOR TF mission is to continue delivering the 2021 milestone, when companies should be able to submit data to PMS. Indifferently which of the both proposals will be chosen to be used for submitting data either TOM or the Minimum viable product, SPOR TF should cater for a flexible solution to accommodate one of them by providing the message, the data, and the guidance EU IG.

After lunch a discussion has taken place with regards to the TOM implementation. A common agreement to move forward and wish to continue delivering SPOR were expressed. Challenges related to technology, change management communication in continuing delivering TOM and how to maintain the high data quality through TOM from its inception were acknowledged.

As an answer to a question, EMA confirmed that currently the only **approved business case** for SPOR (and PMS) is Pharmacovigilance which has a legal mandate to implement IDMP. In time, benefits of TOM master data are able to support additional use cases like cross border, NVR, etc. **which will also need to be driven by business cases**. Nevertheless it is the perception of EMA and the SPOR TF members that the current data quality process is sufficient to fit the pharmacovigilance purposes; while other use cases may require additional quality checks stressing out the need to implement TOM.

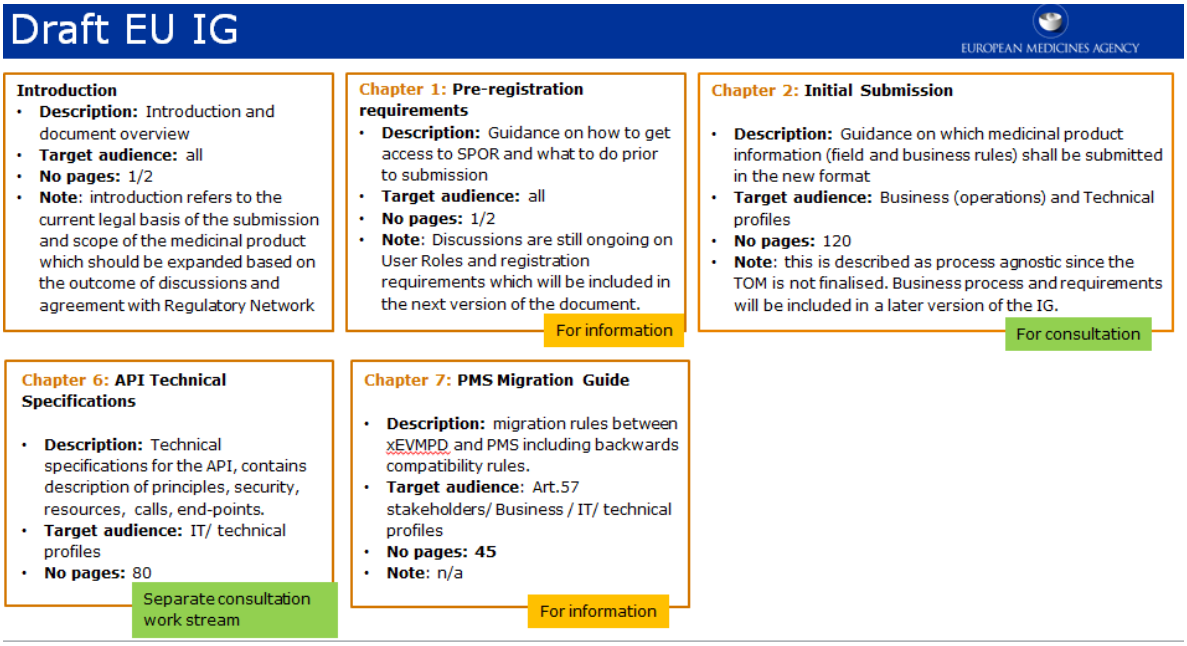
The discussion lead to the fact that current situation requires clarification on several aspects of TOM. It was proposed to nominate a number of NCAs and EMA business champions to create a business case that justifies the need to improve data quality by means of the TOM beyond pharmacovigilance data standard and to present it to relevant EU telematics governance route. Industry expressed interest in preparing supporting documentation for the TOM business case.

EU IG updates

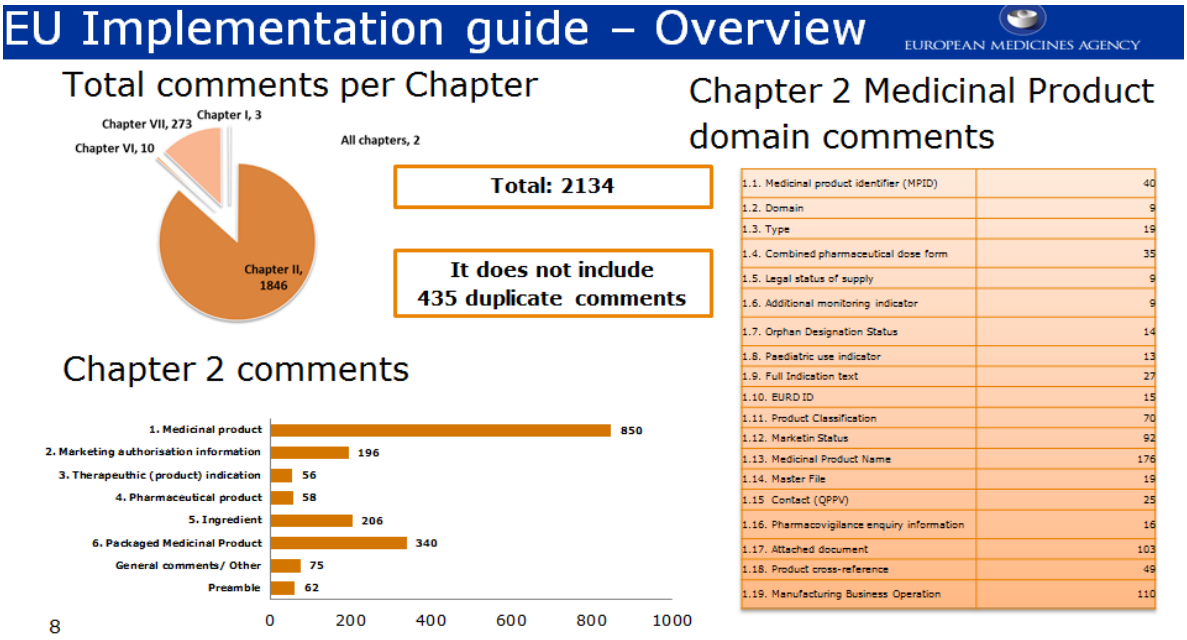
Carlos Aicardo Muñoz briefed SPOR TF on the EU IG progress for the submission of human medicinal products. In January 2019 it was launched the consultation on the EU IG draft v1 with expectations to be published in June 2019. Considering the high number of comments received during the consultation period the publishing date was postponed to October 2019.

It was reported that from the 8 chapters of the EU IG - chapter 1 (Pre-registration requirements), chapter 2 (Initial submission), chapter 6 (Technical specifications on structure and format) and chapter 7 (Migration guide) were circulated for consultation. Remaining chapters: 3 (Maintenance), 4 (Data quality), 5 (Data access/export) and 8 (Examples) are foreseen to be created, consulted and released in future versions.

Brief description and composition of the chapters included in the EU IG v1, as previously shared with the SPOR TF, were re-iterated in the presentation.



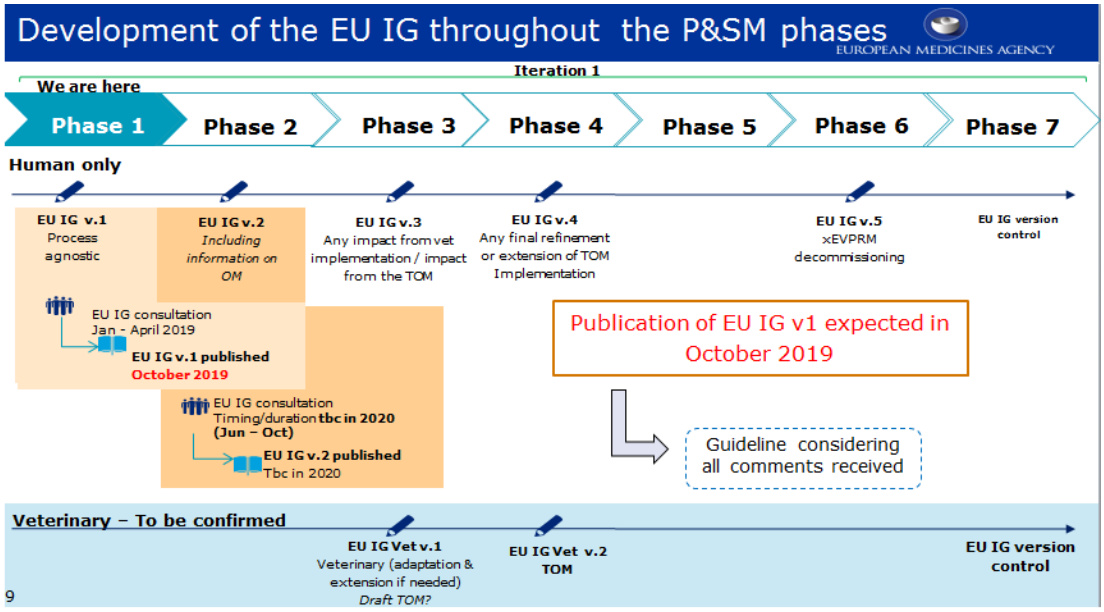
Carlos Aicardo Muñoz shared with the task force more details on the EU IG comments received during the consultation process. After the 1st consultation, February 2019, dedicated mainly to comments with technical impact, a number of 599 comments were collected. After the 2nd consultation, April 2019, a number of 1535 comments and additional 435 duplicated comments were received. A breakdown of the comments by the subject matter was indicated in the presentation:



It was reported that all the comments are planned to be addressed by section every week. Additionally, complex topics are envisaged to be discussed in the P-SG webinars. It was remarked that not all of the received comments may be resolved until the EU IG v1 publication date; however it's expected for the unsolved comments to be mentioned in the EU IG v1 as ongoing discussions.

More detailed information on the EU IG consultation phase including main issues affecting the guidelines and proposed timelines were shared in the presentation slides.

For the submission of the veterinary medicinal products a veterinary specific EU IG is anticipated to be created. A timeline diagram foreseen to represent the development of both EU IG for human and veterinary products, in parallel to PMS and SMS phases, were shared with the SPOR TF:



During the meeting it was noted that initially the EU IG v1 was envisaged to be process agnostic; however, for the EU IG v2, it was expressed the intention to be process gnostic. It was also acknowledge that many elements of EU IG v2 will dependent on the selected operating model.

ACTIONS:

- Communication with stakeholders and more details on the EU IG v2 as being process gnostic.
- Additional communication on the change between the EU IG v1 expected for June 2019 and the EU IG v1 extended to October 2019 considering the comments addressed.

4. EU IG_2.pdf

5. Programme updates

Olivier Simoen, the SPOR project manager, presented updates on both S&PMS project plan and its progress.

S&PMS project has been split in 7 phases which are foreseen to be delivered during the period 2019-2023. Every phase is planned for a length from 6 to 9 months and consists of several work packages of 3-4 months that can each go live during that period. For every work package a User Acceptance Test (UAT) can be organised. Every work package consists out of a number of agile sprints.

Olivier Simoen highlighted to the SPOR TF the importance of having defined clear objectives and requirements for each phase and work package before starting any development.

An overview of the objectives for each of the 7 phases of the S&PMS was shared with the SPOR TF:

Phase 1:

- Limited Human product data from Art. 57 available in S&PMS – Phase 1A
- Sourcing Product and Substance data from Siamed II (CAP management system) to be available in S&PMS
- Sourcing substance data from EV Human and EUTCT Human and Veterinary to be available in SMS. End of 1st package of Phase 1 envisaged having a core SMS data
- Functionality to manage substance data in SMS by EMA
- Functionality to feedback data from SMS to EV and EUTCT with improved data
- API to provide access to the data in S&PMS for EMA-internal systems.

  Additionally, it was mentioned that the 2019 versions of the S&PMS API need to be generic as no specific requirements are available. Testing of the initial (i.e. 2019) versions of SMS, PMS and the S&PMS API will be performed during 2019 via EMA-internal systems.

Phase 2:

- SMS web portal (UI) to provide access to substance data in S&PMS to NCAs, CESSP and other consumers
- Remaining Human prod data from Art 57 available in S&PMS

- Functionality to manage product data in PMS by EMA (and NCA if agreed)
- API to provide access to the data in S&PMS to NCAs, CESSP and other consumers.

Phase 3:

- Veterinary product data from EudraVigilance available in PMS
- Integration with EU-SRS (TBD the NVR requirements and timelines; this is likely to change the scope of the phases as listed in the presentation).

Phase 4:

- Provision of human and veterinary product data into PMS via the FHIR message by both MAHs and NCAs.

  Phase 4 is expected to go live in Q4 of the 2021 and is envisaged to be the starting point when the current provision of product data would be redirected into S&PMS. In this phase it is foreseen to have only one entry point for the product data via a FHIR message which is a HL7 standard of the data provision of the ISO IDMP. The provision of product data via FHIR message is expected to take place gradually with the deadline projected in phase 6.

Phase 5:

- PMS UI for Industry/NCAs (optional) in the context of CESP.

Phase 6:

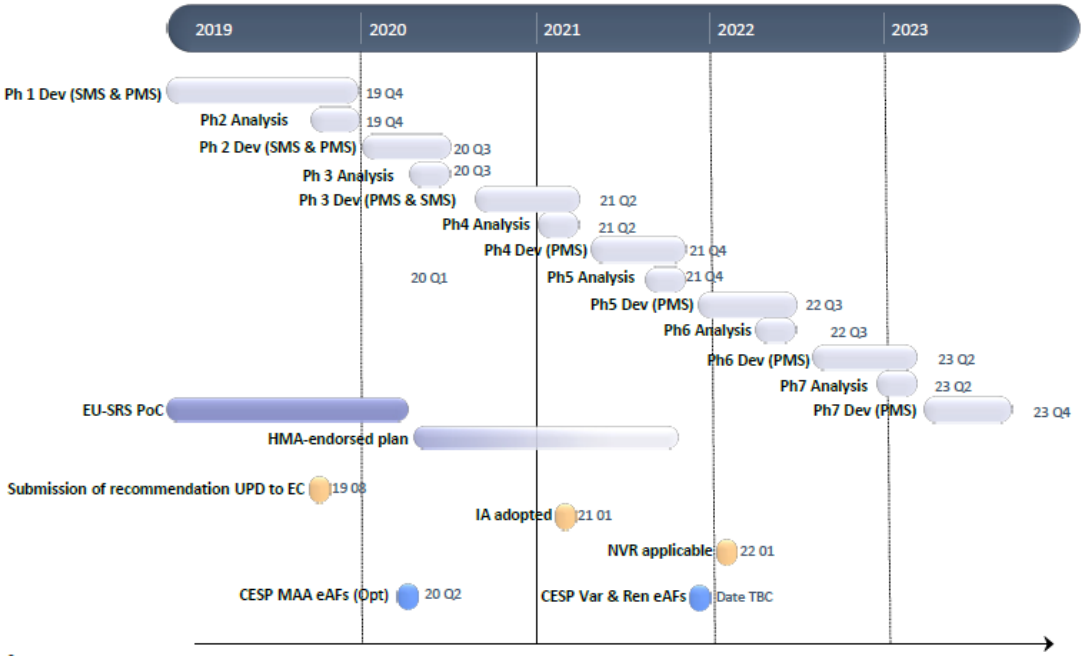
- (TBD: Implementation for Veterinary legislation and improvements for Vet TOM).

Phase 7:

- Provision of product-related data to DWH, Doc repository, SAS…

More details on the timeline for the whole project were shared:

Timeline 7 phases S&PMS:



Access to PMS data for both Test and Production environments is envisaged to be granted in early stages of the development. More details on the business rules on how to convert Art. 57 to PMS can be found in the Chapter 7 of the EU IG.

In conclusion, it was communicated the adverse impact of relocation on the resources allocated to deliver planned work packages; nevertheless the implementation of S&PMS continues.

Additional clarification on the timelines

A number of SPOR TF members raised a potential inconsistency on the timelines between previous slide of this document, which contains different phases of the project compared, and the following slide related to the TOM and EU IG publication of v2.

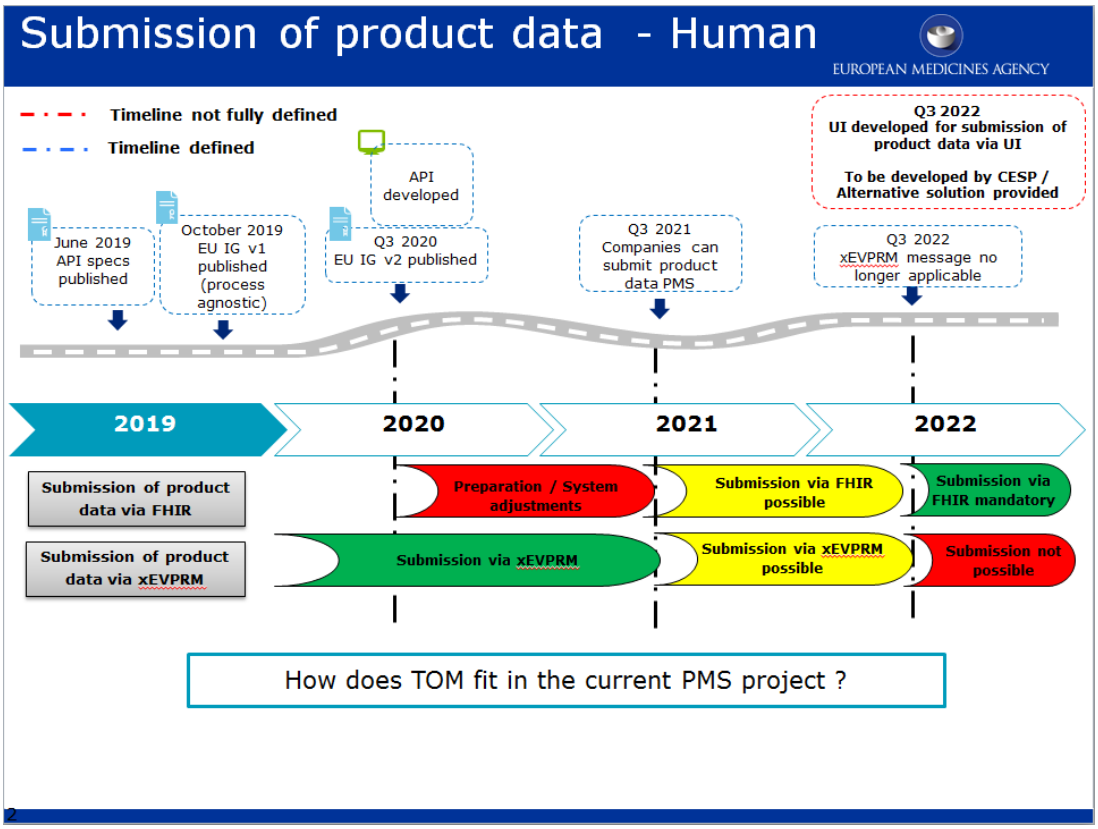
Previous communicated project timelines:

- PMS Ph2 (API) Q3 2020
- PMS Ph3 (vet) Q2 2021
- PMS Ph4 Q4 21
- PMS Ph6 Q2 2023.

Previous communicated EU IG driven timelines:

- Publication of version 2 of EU IG planned in Q3, 2020
- Start submission using FHIR Q3 2021
- Only FHIR acceptable, xEVPRM message is no longer applicable Q3 2022.

After publication of v2 of EU IG, one year will be allowed to Industry to start submitting product data in FHIR and another year to enforce the use of FHIR. After that, the submission from xEVPRM will no longer be applicable. Decommission of the xEVPRM is envisaged to start after Q3 2022.



Clarification main timelines:

In the past because the timelines aligned better we had aligned the start of FHIR submission with Phase 4 and the decommissioning of xEVPRM with phase 6.

Despite the re-planning of phase 1 scope, we can still follow the original plan for product submission because the building blocks are in place earlier than phases 4 and 6.

The determining factor to start the product submission preparation is the availability of the API Specification and the EU IG both of which will be finalised in Q3 2020.

- If the EU IG covers a process similar to the one used today for art 57 (FHIR + mod 3 + after approval + QA by EMA) **we will start the submission in Q3 2021 and make FHIR mandatory in Q3 2022.**
- If the EU IG covers a new process (any form of new TOM) we *may consider* if additional functionality is needed that justifies linking the start of submission to Phase 4 (or later, depending on the nature of this additional functionality) and making FHIR mandatory one year later.

ACTIONS:

- Align the S&PMS Project timelines to match the timeline presented under this topic.
- Share more information about timelines for each phase; suggested to publish current timelines on the SPOR homepage.

5.1. SPOR Pgm Updates.pdf

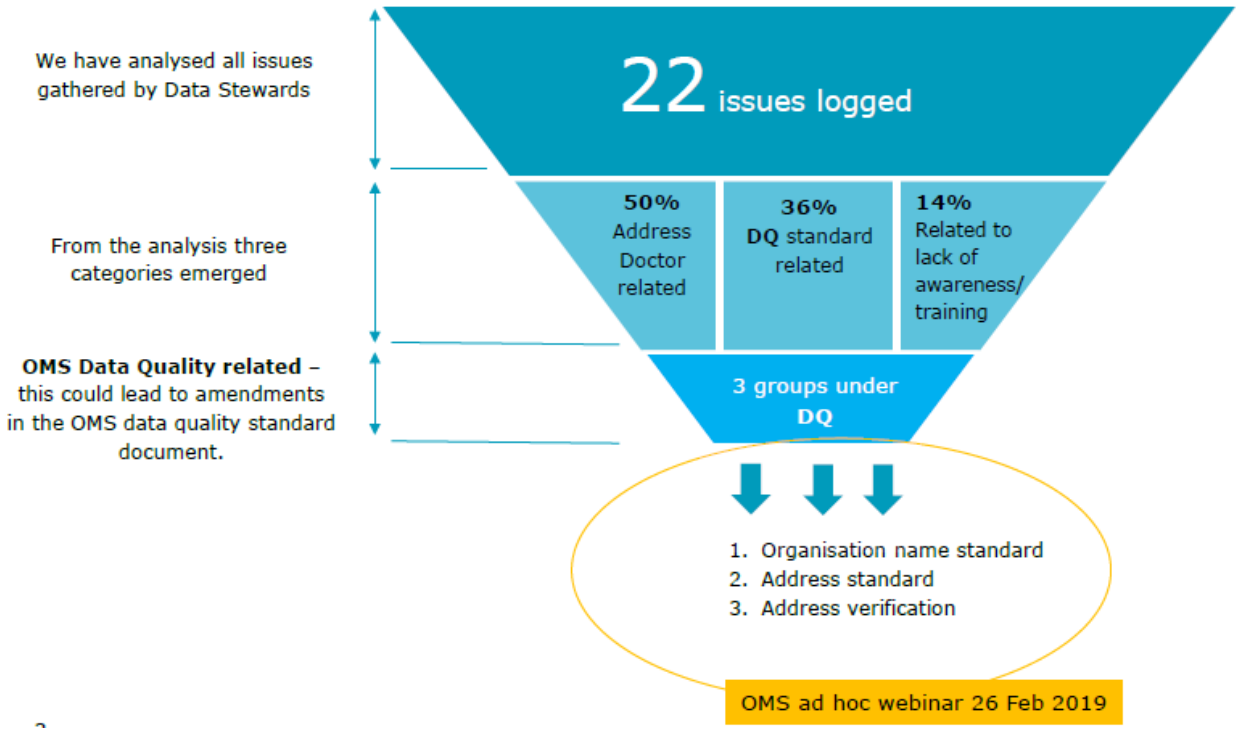
RMS and OMS data services update

Agnieszka Laka presented a brief update on both RMS and OMS usage and integration, key user group (KUG) and highlighted the OMS data quality related issues. The outcome of the ad-hoc OMS webinar and the upcoming engagement activities were also shared with the SPOR TF members.

The user on-boarding continues and reached the number of 1009 industry super users and 519 industry users registered; additionally 20 organisations (NCAs and industry) have access to SPOR API.

It was reported that since 15 December 2017 over 3500 change requests were received in OMS and 298 in RMS since June 2017. The eAF uses RMS and OMS data; the EV user registration process uses OMS data and IRIS portal uses both RMS and OMS. For the RMS and OMS KUG priority is given to operational RMS and OMS Service Level Agreement (SLA), mastering of manufacturers, SPOR API and PMS EU IG work-streams.

The OMS data quality related issues were shared with the SPOR TF; 22 types of issues were reported:



Agnieszka Laka reported that an ad hoc webinar took place on February 2019 to address the OMS issues. Positive comments and feedback were received from participants, though no concrete decisions were taken. Outcome of the webinar is documented and expected to be shared with the SPOR TF.

Upcoming engagement activities reported:

- EMA in the business continuity plan (BCP) - engagement activities have not stopped
- SPOR API v2 + EU IG consultations - excellent stakeholder engagement

    - Draft SPOR API v.2 publication planned in June 2019
    - Publication of EU IG v1 expected in October 2019
- Working with Telematics Secretariat to seek opportunities to bring relevant SPOR updates to Telematics groups
- Upcoming SMS related webinar (timing TBC)
- Updates to SPOR change liaisons around the key project milestones
- Communication campaign to improve the awareness of the OMS data quality standard.

5.3. R&O data services update.pdf

KUG – Industry

Patrick Middag shared the industry position on the OMS KUG. It was acknowledged the amount of work required to continue delivering OMS; nevertheless it was expressed that the KUG should not become a helpdesk but aim to triage and prioritise issues and come forward with developing proposals for resolution.

It was highlighted the importance of good OMS data quality to enable successful PMS (feasibility, credibility of program) and it was expressed the willingness of industry group to play a leading role and to interact with EMA SPOR data governance.

Additionally, industry reported the interest in better understanding the current EMA MDM governance process, impact on manufacturers' data quality and the implications if not engaging now in the OMS data quality process. Last but not least, it was expressed the importance for industry of establishing a collaboration model with clear roles and responsibilities.

5.4 SPOR TF 24-05-19 KUG topic.p

6. SMS Update

Jaume Gonzalez Nogueras, the new SMS Business Lead, presented updates and the SMS plan for 2019-2021.

Since mid-2018, EMA Service Desk portal has been used by MAHs and Orphan Designation Applicants to request both new substance data and changes to existing substance data. Sponsors of Clinical Trials are also expected to use EMA Service Desk portal for development substances once SMS Phase I goes live. This temporary process will continue until the SMS web portal is expected to go live, Q3 2020.

Once SMS replaces EUTCT in phase 2, SMS change requests are expected to be submitted through the SMS portal. NCAs and Industry will access substance related data through the SPOR portal, while other users using substance list from EUTCT will continue to have access to substance data through the backward compatible API.

Additional details on the timelines were presented to the SPOR TF members.

- Phase I goes live in mid-2019 with data management capabilities to search/create/update data available to SPOR data stewards.
- Phase II is expected to be delivered in Q3 2020 with SMS web user interface (UI), API and additional capabilities such as nullification and merging of substances.
- Phase III is planned for Q2 2021 when the EU-SRS & SMS synchronisation is expected to take place.

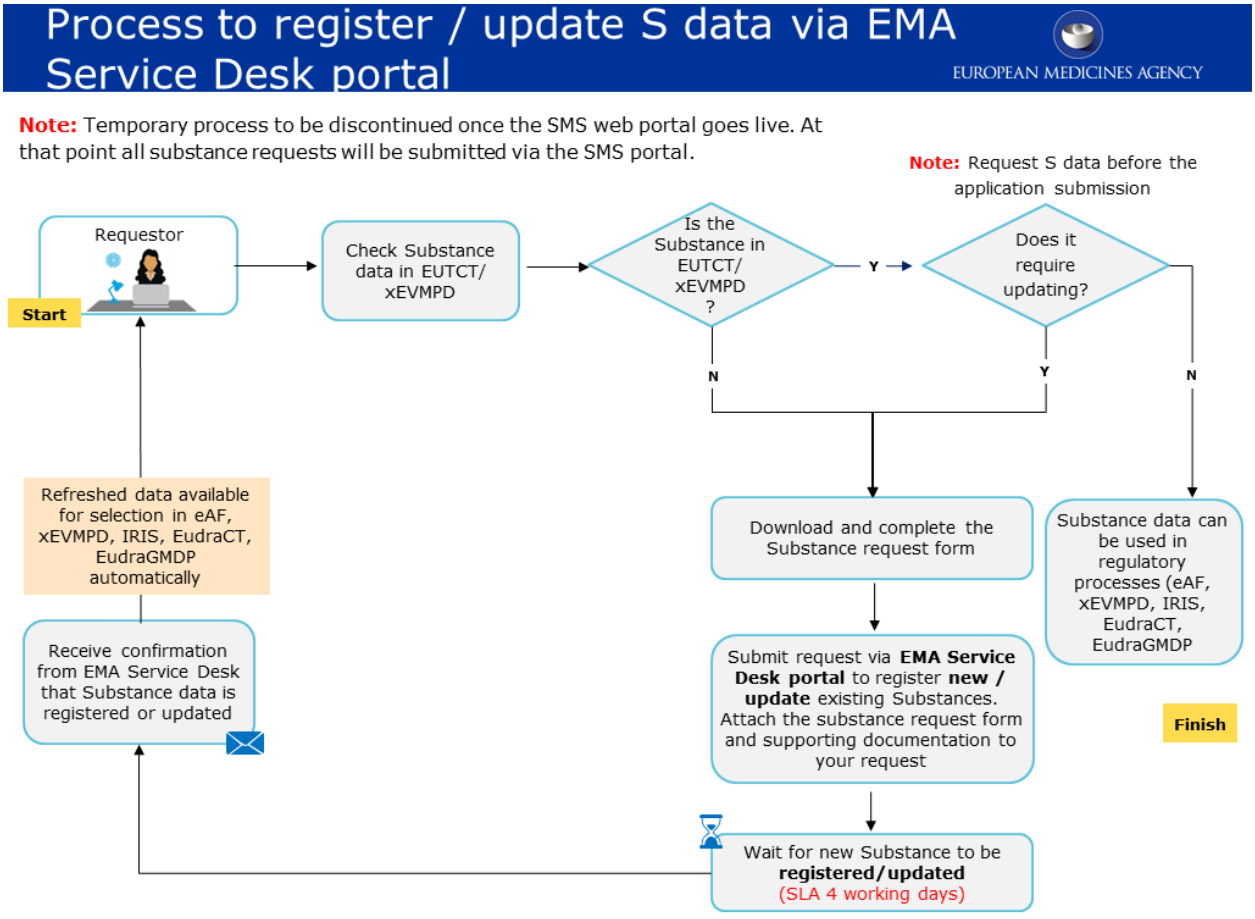
The SMS Business Lead introduced the temporary process to register and/or update substance data via EMA Service Desk portal to the SPOR TF. The above mentioned process is not new but it is expected to be extended to registration of development substances as of SMS phase I.

After SMS Phase I goes live, instead of creating development substances directly in xEVMPD, sponsors of clinical trials (CT) are expected to request them in advance through the EMA Service Desk portal. This process applies when requested to submit a clinical trial application or an Investigational Medicinal Product. The following additional information is expected to be attached in the service desk requests:

- Completed Substance request form (excel template)
- Supporting documentation for the substance (e.g. SmPC or Investigators' Brochure).

The form will be available in several locations: as knowledge based articles (KBA) in EMA Service Desk, in the Orphan Designation section of the EMA website, and in the EUTCT portal.

It was highlighted that the SLA to process the above mentioned substance requests is 4 days. Users are encouraged to take the SLA into consideration when planning the submission of their applications.



The SMS Business Lead concluded the presentation by highlighting the main changes for XEVMPD/EudraCT users:

- The distinction between "approved substance" and "development substance" does not exist in ISO 11238
- The purpose is to use the same substance ID across the whole lifecycle of medicinal product: orphan designation (if applicable), clinical trials, marketing authorisation and pharmacovigilance
- No more development substances will be created in SMS
- All new substances created in SMS will be synchronised to XEVMPD as "approved substances" (including substances for clinical trials)
- If an update is requested to a "development substance", a new approved substance will be created instead.
- Privacy settings will be in place in SMS to prevent the publication of confidential information (e.g. chemical names or molecular formula) in XEVMPD/EudraCT.

6. SMS Update.pdf

7. EU-SRS Update

Frits Stulp presented to the SPOR TF members the EU-SRS updates. The EU-SRS Proof of Concept (PoC) hosted by BfArM, was presented and approved in the HMA meeting held in February 2019 in Timisoara, Romania.

It was reported that the assessment from PoC is expected to be reported to the HMA by February 2020 indicating the suitability of EU-SRS for management of substances in EU and requesting enabling the decision for next steps (e.g. use as-is, adapt).

Deliverables in the context of the PoC were shared with the SPOR TF members:

- An installed Substance Validation Group (SVG) based on committed resources from NCA's
- Cleansed substance data according to IDMP (for selected substance categories):
    - Human and Veterinary substances
    - Classes: Chemicals, Proteins, Polymers, Herbals, Vaccines (based on available SVG capacity)
- Description of EU-SRS system: system documentation and user requirements
- Assessment of system suitability for Europe and associated way forward:
    - Evaluated SVG processes and supportive documents
    - EU-SRS system evaluation
    - Advice on next steps to HMA, February 2020.

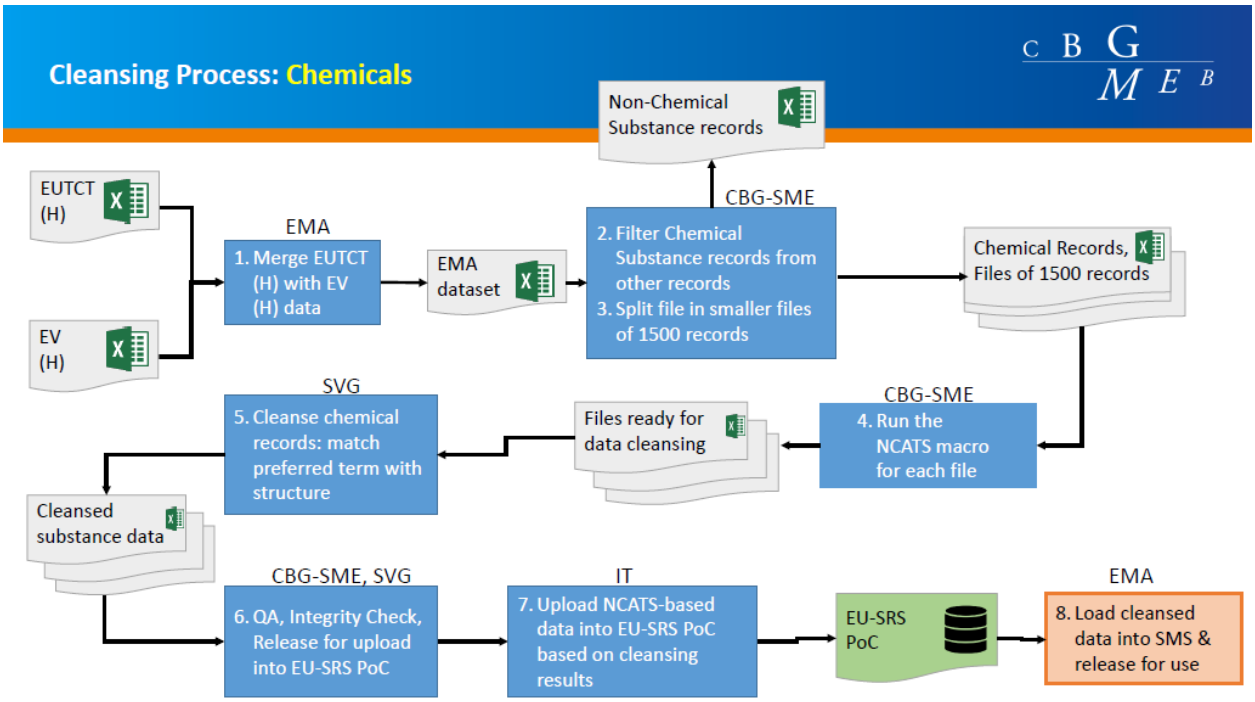
Frits Stulp presented the EU-SRS project plan. After the HMA approval the on-boarding of the SVG members has started. The list of the SVG members has been successfully completed and consists of 12 members. Additional meetings for the SVG project team kick-off took place on 13th to 15th May in Utrecht when the PoC has also initiated. More details on the project initiation were shared with the SPOR TF.

The execution of the PoC is envisaged to take place until the end of 2019. An evaluation of the SVG processes is foreseen for early 2020 followed by a meeting at the HMA to request advice on next steps.

Details on the data cleansing were highlighted to the SPOR TF. The data cleansing is expected to start with authorized substances only; development/investigational substances being out of scope. It will be continued with substances used in human products (veterinary-only records are out of scope) and followed by the substances used in medicinal products. It was noted, that in this moment in time, the focus falls on the human products data cleansing only.

The data cleansing was agreed among the SVG members to be performed class-by-class starting with chemicals. Other substance classes will follow later.

The agreed cleansing process for chemicals was shared with the SPOR TF:



Main focus of the EU-SRS PoC in the upcoming period falls on both activities: completing sourcing project team members and finalizing detailed description of data cleansing plan for chemicals. The estimated start for data cleansing of chemicals is planned for 10th of June 2019. Regular meetings with SVG members are foreseen to take place, and next face to face meeting planned for 2nd to 4th September 2019.

In conclusion of the presentation, Frits shared details on both the governance and the communication with the stakeholders for the EU-SRS PoC.

7. EU-SRS Update -SPOR-TF-WoHS.pdf

8. NCA Points

Martha Schei Hynne presented updates and progress made on the IDMP Data Pilot, findings and proposals. The Data Pilot started with the goal to understand the ISO IDMP standard and PMS Iteration 1 implications. During the Data Pilot it was addressed to find ways on providing good data quality in PMS ensuring consistency between similar and identical products, also possibly to generate useful PhPID and to reuse data for several purposes.

The work has been performed by the NCA members (SE, NO, ES, EE, AT, DE, FR vet) and by EMA. A number of around 50 products were described in a spreadsheet in IDMP format followed by a consultation where additional questions were addressed. The Data Pilot group provided input for the EU IG by publishing, in an informal manner, a number of issues versus solutions/don't know answer to address more complex areas of the ISO IDMP standard. These areas included pharmaceutical products, rules to express the composition, marketing authorisation section etc.

During the Data Pilot work a number of findings were identified:

- When users are allowed to add IDMP information with no clear rules or description to follow, similar products look very different
- It is not possible to find one pattern that fit all types of products
- The pharmaceutical products are a new concept that requires additional knowledge
- IDMP allows very detailed information, especially for packaging (containers, components, devices)
- For procedure and application: IDMP is not clear enough to be able to fill in the data
- For ingredients and strength is still unclear how to proceed with products not authorized according to IDMP/QRD.

To address the above mentioned concerns a number of proposals were made:

- Different patterns for different products must be described clearly in EU IG, possibly added in an annex
- Level of detail needs to be decided and confirmed
- Have in place a controlled enrichment process, when no data should be added to PMS unless clear patterns and rules are described
- Provide training on IDMP in the context of SPOR and on the EU IG for NCA, EMA and Industry.

8. Data pilot_Spor task force.pdf

9. Industry Points

Laurent Desqueper shared with the SPOR TF the industry points for the KUG, PMS TOM, EU IG, EU-SRS PoC and IDMP/SPOR Program highlighting industry expectations related to each of the mentioned topics. Industry confirmed being supportive and willing to continue the SPOR implementation.

To complement the topic from industry, Patrizia Oelker shared the priorities for the veterinary side to be addressed by date of application (DoA) of NVR – 28.01.2022.


9. SPOR TF 24-05-19 Industry Points.pdf


9. AhE and EGGVP - SPOR TF 24 May 201

10. AOB

Laurent Desqueper concluded the meeting by re-iterating a number of conclusions for the following topics:

NVR

- Impact on SPOR – NCA approach that UPD relies on PMS but could be another option
- Requirements by August 2019; Implementation decision by end 2019 – MVP

PMS TOM

- Walk-through 3 implementation options, where 2 seem very close; 1 the fall-back
- Need to develop a business case by October-November 2019
- Industry is committed
- Need lead from NCA side to present to HMA for adoption
- Funding to be looked at from Horizon 2020, Telematics or even Industry
- Next step to be discussed at co-chairs teleconference

PMS EU IG

- Many comments received – working towards addressing comments (PMS SG) for publication in October 2019

Programme Update

- Timelines shifted to Q4 2021 – Q2 2023 (request to publish as-is)
- Possibility to see KUG led by Industry – still need to work on practicalities

SMS/EU-SRS

- Information on progress
- Action on substance confidentiality on SMS side
- EU-SRS PoC to provide update/progress through SMS

Others

- Date for next SPOR TF to be established.