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

20 October 2017, 9:00 to 16:00

**Co-chairs:** Isabel Chicharo (EMA), John Kiser (EFPIA)

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present</td>
<td>EUNDB: Thomas Balzer (Germany), Giovanni Ferretti (Italy), Andrea Johnson (United Kingdom), Jeffrey Martin (Sweden), Darko Krnić (Hungary), Ly Rootslane (Estonia), Antonio Blazquez (Spain), Aziz Diop (France), Georg Neuwirther (Austria), Hans-Joachim Bigalke (EDQM), Paule Carnat-Gautier (France), Luke Wakefield (United Kingdom), Edit Tóthné Hajdu (Hungary), Martha Schei Hynne (Norway).</td>
</tr>
<tr>
<td></td>
<td>NCA experts: Anja van Haren (Netherlands), Stina Wahlin (Sweden), Dubravka Sudić (Croatia), Fabio Macchiagodena (Italy), Triin Maesalu, Lionel Ridoux (France), Jose Manuel Simarro (Spain), Catherine Russell (United Kingdom), Christopher Jarivs (EDQM).</td>
</tr>
<tr>
<td></td>
<td>AnimalhealthEurope: Patrizia Oelker, Pauline Battaglia</td>
</tr>
<tr>
<td></td>
<td>EGGVP: Jaka Petrič</td>
</tr>
<tr>
<td></td>
<td>AESGP: Christoph Kox, Andrew Thornley, Andreas Franken</td>
</tr>
<tr>
<td></td>
<td>Medicines for Europe: Remco Munnik, Kelly Hnat, Anjana Pindoria</td>
</tr>
<tr>
<td></td>
<td>EFPIA: Neil Newman, Paul Mills, Joerg Stueben</td>
</tr>
<tr>
<td></td>
<td>EuropaBio: Laurent Desqueper</td>
</tr>
<tr>
<td></td>
<td>ECI-EEIG: Jean-Michel Cahen</td>
</tr>
<tr>
<td></td>
<td>Vaccines Europe: Edouard Michoud, Quentin Grignet</td>
</tr>
<tr>
<td></td>
<td>EBE: Gordon Topping, Herve Rique</td>
</tr>
<tr>
<td></td>
<td>ECHAMP: Isa Bünger.</td>
</tr>
<tr>
<td></td>
<td>Vendors/software providers: Andrew Marr, Barry Hammond, Markus Pfahlert, Rune Ringsholm Bergendorff, Susan Metz, Ursula Tschorn, David Scanlon, Bob Allkin, Christian Hay, Malin Jakobsson.</td>
</tr>
<tr>
<td></td>
<td>EMA: Francisco Penaranda, Paolo Alcini, Isabel Chicharo, Agnieszka Laka, Kepa Amuxastegi, Herman Diederik, Ilaria Del Seppia, Hanna Palyszka, Gabriel Boronat, Panagiotis Telonis, Marek Lehmann, Lantin Anne-Christine.</td>
</tr>
</tbody>
</table>

**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 from ECI-EEIG: Jean-Michel Cahen; AnimalhealthEurope: Stefan Barry (apologies), Pauline Battaglia; Medicines for Europe: Anjana Pindoria replacing Vito Strasberger; Aris Global: David Scanlon replacing Wim Cypers; NCA experts: Stina Wahlin replacing Louise Petré Linder. New observers for ECHAMP: Gunther Pfeifer (apologies) and Isa Bünger; Identifica: Vada Perkins (apologies) and the EMA re-joining member Ilaria Del Seppia were introduced to the SPOR Task Force team.

2. Governance & SPOR TF ToR

**Update on ongoing discussions:**

The meeting started with updates from June 2017 SPOR Task Force meeting on the Incident regarding the leak of information from a Task Force member before the EMA approval for publishing, which resulted in the cancelation of the membership.

Due to this incident, the EMA legal department was contacted to understand the implications and the processes with regards to termination and the Terms of References (ToR). The advice of the legal department was to clarify and segregate the roles of different groups within the Governance Model and make termination conditions explicit.

The Telematics Governance (EMA Management board, Telematics management board and IT directors) represents the network and the Agencies. The Data Integration Program reports to the Telematics Governance. SPOR TF is the only group reporting to the Data Integration Program.

The ToR will be updated by creating a new section for the:

- mandate and roles for the S & P sub-groups,
- a formal role for the NCA change liaisons and the Industry Change liaisons,
- a new group called Testers with a balanced nomination process for the participants in the testing of the system.

**Segregation of roles:**

SPOR TF maintains a similar mandate. Addressed points were the sharing of the information. By joining SPOR TF or PMS Sub-group a member has access to the early information when is still being in the discussion phase. All the information exchanged within SPOR TF or a PMS Sub-group related to planning, development and implementation is confidential. The change liaisons only, have the role to publish and cascade the information externally. If a member has different roles including the role of the change liaison, his/her responsibility is to understand how to segregate and how to share the information.

For the Demos, UAT and Testing purposes the advice from the legal department was to create a Tester group with a nomination process to access the software and different versions. All access to Demos, UAT and Testing information is also strictly confidential.

Changes to the new version of the ToR are the introduction of the nomination process and particularly the replacement and termination procedures. Additional proposal, still under discussion, was to reduce the number of members per association.

Francisco Penaranda concluded the topic by highlighting the reasons for the changes in ToR and stressed out on the confidentiality of the information. One of the reasons being that the information discussed
within SPOR TF meetings is only about planning, development and implementation which further has to be communicated to and agreed by the Telematics Governance.

John Kiser requested clarification about information such as minutes and meeting documents which will not go through the Change liaisons but EMA will maintain the logistics.

**ACTIONS:** A draft Word document to be prepared together with the EMA legal department describing the confidentiality of the information, segregation of roles and nomination processes for different groups. The information will be revised by the Telematics Governance and the revised version will be presented to the SPOR Task Force members.

**Impact on meeting dates:**
The 2018 IDMP/SPOR TF face to face meeting dates:
- 23 March 2018
- 22 June 2018 (potential changes or restrictions to be communicated).

Due to EMA relocation, the 19 October 2018 meeting is cancelled.

---

### 3. OMS integration with eAF

Agnieszka Laka provided the SPOR Task Force with the RMS / OMS & eAF Milestones for Industry change liaisons and also updated the Task Force group about the changes that will take place starting with 15 December 2017.

Key milestone until the mid of December is the eAF integration with OMS - a trigger to start the on boarding of Industry for SPOR.

Changes that will take place from mid-December:
- Industry can start requesting Referential terms and updates via the RMS portal. SPOR user role is required.
- Industry can start requesting Organisation and updates to Organisation data for MAHs, MAAs, MRLs applicants via the OMS portal. SPOR user role is required.
- January - Industry will start requesting Substances via EMA Service Desk portal (SPOR role is NOT required). Industry will be requested to use EMA Service Desk to request Substances instead using the mdms@ema.europa.eu.

A mandatory use of the OMS process regarding data pre-registration will be introduced later. A transition period is foreseen and all the specific changes will be communicated.

Hanna Palyszka communicated that the new OMS will be integrated in all 4 forms (MAA Vets, MAA Humans, Renewal and Variation) for all address fields in the eAF release v1.22.0.0, which will go live on 15th of December 2017. User Acceptance Testing (UAT) for the next release of the eAF, v1.22 introducing the OMS integration, will start on 13th of November 2017 with industry and on 23rd of November 2017 with NCAs. Both, NCAs and Industry are encouraged to register and take part in the UAT to ensure that the functionalities are user friendly and work as expected. For the registration Users will send an email to eSubProgOfficer@ema.europa.eu.

All the 4 forms (MAA Vets, MAA Humans, Renewal and Variation) are going to be changed in terms of integration with OMS and picking up information about the Organisational addresses from OMS.

The use of OMS in the eAF will be initially optional. Both, the search by the organisation option as well as introducing the data manually will be available; however, the applicants are strongly advised to perform a search by the organisation in the form in order to familiarise themselves with process and the use of OMS.

A process to record companies in OMS is in place for the cases when the company name is not found through the search. With regards to addresses:
- If the address is not found it is possible to clear the address and provide the details using free text fields as previously
- If the address/location is not found, the user is advised to follow the new OMS process to add new organisations
- If the address/location is not correct, the user is advised to follow the new OMS process to modify organisation/location data by logging a change request via EMA Service desk portal.

Summary of the eAF - OMS form, was presented also showing how to perform:
- Search by address: By pressing the 'Find address' button a new Form opens where the Local ID/Organisation ID can be chosen. Insert the Local ID/Organisation ID
- Search by Organisation name and the Country.

The search will result in a list of Address records – where the right address can be chosen. Data should be revised and either can be locked and proceed with the application form or if address is incorrect, according to OMS process a change request should be logged via EMA Service Desk.

For the change of address, a second option along with the OMS process is the manual data entry of the address by using the 'Clear address'. This option is for the transition period only and the change of the address should follow the OMS process eventually.

To conclude with the eAF and OMS updates - all the SPOR TF members were invited to participate in the UAT which is seen as a way to exercise with the new forms and help the users familiarise themselves with the new changes.

Questions:

Q1: Is there any process in place to be followed in order to reduce address duplicates for addresses in different languages?
- Kepa explained how the addresses in multiple languages are managed in OMS. eAF shows the versions of the addresses, some of them can be in different languages. Each address record has a language code at the beginning of the address data. Hence, an address which has records in different languages with different language code should not be considered as duplicate.

Q2 was related to the search of an Organisation by the ID.
- The Identity and access manager has been designed to enter the full Organisation ID number in order to find the organisation. If the Organisation ID is not fully entered the result won’t be correct.

It is foreseen for December that the content of the OMS dictionary for the MAH will be completed for all Human Products and for veterinary CAP products.

Q3: For the AF, is there a button to export the MetaData before being locked? Will the data for the Organisation be in the Export file?
- Not if the data are entered manually.

Q4: How long will the UAT last?
- 1 week for Industry and 1 week for NCA to test the feedback.

Q5: How long the manual data entry period will last?
- There is no date established yet to switch to the mandatory use of the OMS process but it is foreseen to be confirmed in no less than six months. The date will be communicated.

4. OMS & RMS Industry on-boarding

Kepa Amutxastegi introduced the milestones for the RMS&OMS – Industry on-boarding to SPOR, the OMS Content Plan Q3 2017 – 2018 and how the content is managed. An emphasis was made on the eAF integration with OMS, particularly on the new user roles and the user registration process in SPOR.

Key updates:
• For 15 December 2017 is planned for Industry on-boarding to SPOR to be aligned with eAF / OMS integration.
• OMS & RMS release 2.2 is live and it introduces additional improvements on the functionality on the content management of both domains.
  o RMS: The subscription capability has been improved; work in progress for the implementation of data loads from EDQM.
  o OMS: export of the different contents is available such as content of the dictionary, content for the search results etc. With regards to the WebPortal functionality for the change request process the work is in progress.
• Final OMS & RMS release 2.3 is planned for early December and integration with eAF applies to all the eAF application forms. Once the revised eAF forms are published, they can be used by the Industry. To use the OMS process, Industry will use OMS to register and obtain a SPOR role.
  There are 2 types of user roles proposed: Industry Super User role and Industry User role.
• The first user to be registered in SPOR will be granted Industry Super User access rights assigned to a specific organisation. The Super User will have the responsibility for the user management, grant or revoke access, within the same organisation. EMA will register the Super Users following the request from Industry submitted via the EMA Service Desk portal. Industry is encouraged to start registering their Super Users and Users in December and commence using both RMS and OMS.
• Different user registration scenarios for users were presented.
  The communication with the SPOR team continues via the mdms@ema.europa.eu.
• With regards of the content for the OMS, as a starting point EMA is working on increasing the content for the MAH for the human side used in National (inc MRP, DCP and NAP) and Centrally authorised products as well as MAH used in veterinary CAP products.
  Update for vet non-CAPs will follow. EMA to progress on that topic and should have a more concrete plan for the next Taskforce in March.
  Available tools for both OMS and RMS to access the content are the WebPortal and the Application Programming Interface (API), both available in production.
  As for the Industry proposal to have a non-production environment to support their own development solutions – discussions are still taking place. The final outcome will be communicated.
• For the SLA for OMS and RMS, as starting point are proposed:
  o OMS SLA – up to 5 days for change requests.
  o RMS SLA – Validation within 2-5 days and Approval up to 1-2 months.
• The feedback received during the UAT was taken into consideration, currently work is in progress for the enhancement of the data management functionality within the EMA Master Data Management tool.

**ACTIONS:** EMA was requested to provide a document with clear instructions on the user management, how accounts should be managed and how the roles can be allocated including activation/deactivation of the accounts.

**Questions:**
Q1: How the population of the manufacturers will be prioritised?
- Data were taken from EudraGMDP and loaded into OMS. It includes manufacturers for centrally authorised product and Nationally Authorised products. Data was also loaded from an EMA corporate system so as a result it is possible to indicate if the organisations relate to CAPs or not. First the data related to CAPs will be consolidated followed with the data related to NAPs.

Q2: Is there a quality data check performed?
- Yes. There is a check by the technical capability of the EMA mastering tool (address doctor), followed by a number of manual checks on data quality.

Q3: For the GMP certificate validation, if a site does no longer have a validation, does that mean that it will not show on OMS once it was taken off the source location?
- In the OMS there are 2 statuses for the Organisations: active and inactive. Once the Organisation site is published the default status is set to active. If the site is no longer in operation, EMA has to be informed and the record will be inactivated (not deleted). The site can still be published and available to support regulatory activities with the inactive status.
Q4: Are there any SLA for the stipulation of the inactive status?
- The standard SLAs apply as for the change requests which will need to be submitted for the inactivation of a site, location or entire organisation.

Q5: Are any clarifications on how to correctly write the addresses in order to keep consistency with the system?
- There is a data quality standard published on the OMS containing different rules on verification of the data and validate it. It’s a life document and it is continuously updated.

Q6: For the OMS and also in the AF, is there any information which the NCA will consume this data from which date onwards? When exactly the data is being processed by the NCA or by EMA?
- Action point for the Telematics board to bring clarity on this.

5. Outcome of P&SMS workshop

Jeffrey Martin started the discussion with a recap for the progress made within the NCA meetings on PMS highlighting that considerable attention was paid to the validation process of the art 57 PMS data. Agencies participating in the meetings were from Sweden, Ireland, Austria, Estonia, Norway, Germany and The Netherlands.

The objectives of these meetings were to:
- analyse the real data and identify potential challenges in using IDMP
- deliver a proposal for TOM for validation of new products and variations
- build a process for the validation of the art57 legacy data.

In order to analyse data a comparison was performed between medicinal products from Estonia and Sweden as countries involved in cross-border e-prescription project being joined by Austria, Norway and Germany. The outcome has shown differences in data presentation such as different ATC codes, procedure numbers, strength expressed in different ways etc. Not having the same structure of data for the products creates difficulties in identifying 'same' products in cross-border situations. Additionally, a survey performed on the NCA databases content has shown missing data or data available in a non-structured way.

The data analysis implies the need to standardize the definition of a medicinal product, need to have clear rules on how strength and ingredients are expressed also need for an European implementation guide written with detailed semantic description of data and data fields content.

It was mentioned that main priorities are to understand what attributes are needed for the PMS in order to support the art57. Additionally, the data analysis shown that for Pharmaceutical Product the current substance list in EUTCT is not of sufficient quality for use in IDMP and PMS, there being lots of duplicated substances with different IDs, substances not clearly defined etc.

The draft TOM for new products was shared with the SPOR Task Force. No pre-registration of product information is needed in the new version and 5 data groups are expected to be identified for different phases in the process.

In terms of data validation, it was mentioned that NCAs don’t have all the data to be validated in Iteration 1, hence there is a need to establish pre-requisites for validation.

The conclusions highlighted the collaboration with CMDh / CHMP and CMDv / CVMP as being essential to agree the regulatory process.

Further meetings to discuss TOM for New products and Variations, Validation process and Standardization of data are planned in November with NCA and December with EMA.

**ACTIONS:** A summary for the TOM to be performed and cascaded to the Telematics group for mid of December.
6. P&SMS Phase 1 updates

Isabel Chicharo presented the updates for the P&SMS Phase 1 and the progress made by the subgroups since June 2017.

Isabel started by briefing the SPOR Task Force on the scope of the SMS for Phase 1 and Phase 2, what are the expectations in terms of data quality, a recap of the business process for SMS in Phase 1 and the key points for the progress on discussion on the SMS Data Logical Model.

**SMS Phase 1 – end 2018:**

*In the scope:* As a foundation for the Phase 1 is the migration of the four different sources for Substance into one common repository which will serve as basis for the synchronisation with the GSRS. Having one system to manage the data also creates some process efficiencies internally for the EMA. The data will continue to be managed as it is now, by following a request process with a minimum validation performed according to certain scientific criteria but not according to ISO IDMP. Additional functionalities are translations and synonyms. The updated data in the new solution will be fed back to the consuming systems xevmpd and EUTCT for those NCAs already consuming data from EUTCT.

For the data quality the status-quo is maintained. The substances are managed as per current process i.e. when requesting a new substance, EMA inserts the new substance, adds synonyms and translations. All the requests for the Industry business process will be logged via the EMA Service Desk portal which replaces the requests via email. The request content will be a free text with the option to request many substances. Each logged call will be processed individually. The EMA Service Desk portal accommodates the exchange of messages between EMA stewards and the requestors in case of un-clarity of the request.

*Not in the scope:*

- GSRS synchronisation, which falls under the Phase 2.
- Deprecation of data for the de-duplication of records, on assumption that when the Expert Group – the substance validation group - is setup while creating the initial list, the group will perform the de-duplication of data.

**SMS Phase 2:**

A SPOR portal will be available for requesting new or updated substances. Functionalities for data export including translation will be available for the NCAs. One of the key points is the processing of the GSRS messages to keep the data synchronised.

**SMS Logical Data Model**

*Iteration 1:* the SMS Logical Data Model will contain all the data elements from the XEVMPD and EUTCT. The Data Model contains few elements not described in ISO IDMP which support the compatibility with the existing systems. SMS Data Model contains the mandatory elements of ISO IDMP, it doesn't contain all the ISO elements. The whole ISO IDMP for managing the substances is followed in the GSRS solution when SMS contains the minimum information needed to distinguish very similar substances. Some conditional fields may be introduced in order to help distinguish the substances when the distinction can’t be made from the name of the substance.

*Iteration 1, Phase 1 in 2018:* Implementation as a starting point only the content from existing systems XEVMPD and EUTCT.

After discussion it became clear that the members of the SPOR TF do not have the necessary knowledge in most cases to carry out the required review tasks. It was proposed that they will look for appropriate experts in their companies. The review and discussion with these experts is envisioned to take place in a one or two day face to face meeting in London – if it can be organised - or in various online sessions.

**ACTIONS:** The Draft Logical Data Model to be shared for review and comments with the SPOR TF group.
EMA to create expert profile with skills requested to understand and collaborate for the SMS Data Logical Model.
Industry takes the action to nominate the experts.

Questions:
Q1: Is the Scope of the Logical Data Model going to continue into the Phase 2?
The Logical Data Model contains proposal for the elements, critical in the ISO IDMP. The border lines between the phases are under discussion.

Q2: The Logical Data Model requires a different set of skills in order to be understood and explained further.
-Suggestion for Industry to find competent users with competent skills to understand and explain the Logical Data Model.
Skills required to understand and comment the Data Model (Logical Data Model for relational databases) are the data architect skills along with the expertise on a domain in the IDMP for the business prospective. Best team composition to review the Data Model would have a business user with IDMP knowledge and data architect.
Suggested timeline for nominating such users was few weeks followed by webinars on the Logical Data Model.

Q3: Are there more information regarding the Logical Data Model?
-There is a version of the Logical Data Model having more description but it can’t be shared and published due to copyright.

Q4: When the Logical Data Model will start to be implemented?
-In 2018 after finalising the Phase 1 analysis.

Target Operating Model

Substances – SMS Phase 2:
1\* step of the SMS process is the request of the substances via the SMS portal. It will be followed by an Initial validation and assignment of a provisional SMS ID. Additional collection of documents will be requested and forwarded to the substance validation group to assess the final substance data according the ISO IDMP in the GSRS. It will be followed by an additional step of Global alignment, meaning that a global ID for that substance will be assigned. Under discussion are the supporting documentation required for the assessment of the substances.
This process will run in parallel with the Initial MAA. The Industry can start the MAA with a provisional substance ID, however GSRS and Global alignment will need to be finalised before day 180 (in case of a CAP) when the draft opinion of the product is discussed.
Additional discussions are required to clarify how the Global alignment will work and how to deal in case of rejections.
The points above reflect the proposals of the substance group. However, to date there is no formal approval, neither for building a EU_GSRS nor for setting up a substance validation group

Products:
It was mentioned that few Controlled vocabularies for the Products were revised. Registration of the products will take place after their approval. On the Veterinary side for products there are expected differences in cases where the regulation require new (pending) applications to be checked.
Additional concerns were expressed on the reason for expiration and on the identification of different practices with regards to transfers and renewals. During the migration the priority will be to ensure the right granularity of the terms in RMS; the naming convention will be agreed after consulting the regulatory experts.
For the Medicinal Product record status it was identified the need to flag that the information of a product record is of a good quality. Under discussion remains whether the flags should be placed at the record level, at the element or attribute level.

PMS Logical Data Model
The Draft Logical Model follows most of the ISO IDMP specifications.
Iteration 1 will comprise the data elements from XEVMPD, new data elements from VETS and new proposed data elements to support the Art. 57.
The analysis and design for the Data Model are still in progress and new fields and relationships have to be identified in order to cover prioritised use cases such as eAF/CESSP. New business rules will be defined in order to specify which fields will be mandatory to support the Art. 57 vs other use cases. The current TOM discussions indicate that there will be a single data set with all the information required for the different regulatory process. On these premises, the Iteration 1 will be expanded. Implementation guides will be created once the API are finalised.

After discussion it became clear that the members of the SPOR TF do not have the necessary knowledge in most cases to carry out the required review tasks. It was proposed that they will look for appropriate experts in their companies. The review and discussion with these experts is envisioned to take place in a one or two day face to face meeting in London – if it can be organised - or in various online sessions.

**ACTIONS:**
The Draft Logical Data Model to be shared for review and comments with the SPOR TF group.
EMA to create expert profile with skills requested to understand and collaborate for the PMS Data Logical Model.
Industry takes the action to nominate the experts.

**Questions:**
Q1: What is the timeline to finalising the Logical Data Model?
- EMA wants to have a stable version to support Art 57 migration and Phase 1 by end of 2017. The final LDM that will be used to exchange information between EMA, NCAs and Industry will be discussed in 2018 and will be finalised at the end of Phase 2 after API UAT.

**PHPID**
Isabel Chicharo highlighted the business need for the PMS to identify “similar” products and the need to map/ ensure consistency of data across similar products to generate PHPID. Additional concerns were expressed on the lifecycle management of the substances and dosage forms when these get deprecated or updated. It is necessary to find a reliable way of generating the PHPID for substances, dosage forms and strength. A number of ways to generate the PHPID were presented with a call for a decision to be taken on which ID to use, ways of standardising data and the linkage to the NCA legacy data validation. The generation of the PHPID is in the scope of the Iteration 1, however is not foreseen for the Phase1.

**Veterinary**
The speaker shared the vision for the Veterinary legacy data emphasising the mandate for the legacy data to be transmitted by NCA to Eudrapharm/PMS and the strategies on the data transmission such as migration to PMS or resubmission.

For the new applications for the Marketing Authorisation or the product changes such as variation and renewal, PMS collects the new/updated product data submitted by Industry via eAF/CESSP. For the assessment and validation of the product information the responsibility falls under NCA with EMA acting as custodian. No intention was expressed for the Industry to backfill details on already approved products.

7. **Industry Data Pilot**

Laurent Desqueper introduced the Objectives for the Migration Data Pilot and constrains of the migration from XEVMPD to IDMP.
It was mentioned that the set of data used in 2015 was reused as examples in order to identify the need for any clarification and implementation guides.
Initially the information for pilot products was collected in an Excel spreadsheet as-is in XEVMPD and migrated manually to IDMP as-is, followed with the enrichment with the expected elements in IDMP. As a final part, the data was checked to ensure the backwards compatibility with the XEVMPD by checking the IDMP data and understand if it contains any differences comparing to the initial XEVMPD data.

As an outcome of the Data Pilot the Industry/Vendor analysis identified major limitations to migration from XEVMPD to SPOR and for the backwards compatibility, mainly due to the differences between SmPC and Module 3 which serve as ground for the data entry for the 2 systems. Additional examples were provided supporting the backward compatibility issues. Concerns were expressed for the transition time mainly with regards to the maintenance of data in both XEVMPD and IDMP, duration of the transition and the impact it will have on EMA, NCA and Industry.

The migration and enrichment strategy was also briefly discussed. Due to the new approach of splitting the project into phases it is not advisable to simply compare the data model as-is it the one to-be, there will be different "versions" of the data model/data and transformations:

- **Phase 1** - migration from Art 57 into PMS & backwards compatibility: XEVMPD data will be transformed very little and the underlying information e.g. composition relies on the same data standards eg SmPC instead of Mod 3.
- **Phase 2** - PMS API: data is exposed as migrated (limited transformation) to support Industry data validation and/or enrichment as well as NCA data validation according to a new set of rules. EMA does not envisage that it will be possible to transform xEVMPD data into IDMP in one go or without external manual intervention.
- **Phase 4** - TOM and NCA validation: data is expected to change according to the new rules e.g. composition will be over-written to reflect Mod 3. Industry will not be expected to provide data with different definitions and granularity to two different EMA systems (EVMPD and PMS) at the same time. It will be one or the other (via messaging or UI). Backwards compatibility may be possible for individual data elements which are basically identical in EVMPD and IDMP but in certain areas it will be necessary to revisit whether/how legacy systems will use newly transformed data. The concerns come from how such data will be used if it relies on different granularity.

Assuming that the upgrade will be challenging, it was expressed the need to understand business cases behind the data compatibility and the scope of the data elements needed for the backwards compatibility. Additional information for the Marketing Authorisation elements, Packaging, Pharmaceutical Product, Ingredients, Therapeutic Indications, Organisations including a number of questions raised during the Pilot were presented with the aim to understand the pros/cons and to support decisions for the transition from XEVMPD to SPOR. The transition will take place from technical point of view followed by the enrichment with the content in the latest stages.

To summarise on the presentation outcome it was expressed the need to understand the limitations for the migration and the need for guidance and clarification on a number of IDMP data elements.

### 8. IRISS – IDMP/SPOR survey

Andrew Marr presented the results of the Survey that IRISS conducted with Industry after the June 2017 announcement of the possible delay for the implementation of the IDMP SPOR due to economic, resource and political issues. In total 35 companies participated in the survey. The scope of the survey was to identify the status on the IDMP/SPOR progress and address the issues of various companies having ongoing IDMP/SPOR Projects. Key issues were expressed: the lack of clarity on the timing for different phases of the IDMP/SPOR; increased concerns among the management of different companies on the continuity of implementation of IDMP/SPOR; availability of the PMS; evidences on deliverables; final guidelines on requirements specifications and solutions from vendors. The outcome showed mixed opinions on whether companies wish to continue to progress on IDMP/SPOR. EMA was requested to consider a number of actions which Industry believes are necessary to reinforce the interest of companies in investing in IDMP/SPOR.
As an outcome from the survey, John Kiser presented the Industry communication needs for companies to stay engaged such as the target for 2017 and an overall implementation timeline. Additional requests were for the EMA to prepare clear guidelines on the expectation from the Industry on the transition, clear instructions for iterations and implementation roadmap.

A number of actions that Industry and NCA could progress during the EMA move were also presented.

Francisco Penaranda encouraged all the Task Force members to work together on further steps of the IDMP/SPOR implementation. A common agreement was expressed on the benefits of communication of the achievements and deliverables.

**9. Communication & training update**

Gabriel Boronat shared the updates on SPOR training activities highlighting that priorities for SPOR training development are focussed to support users on-boarding for OMS and RMS, to use RMS as replacement for EUTCT and for the integration with eAF. It was also shared the training approach and how the curriculum supports the key stakeholders training needs. Training material will consist of a mixture of documents, videos and PowerPoint presentations, webinars will continue for the change liaisons. Notifications about the training material will be fully available via SPOR website, via Industry and NCAs change liaisons.

There were presented the key milestones for the RMS and OMS and the upcoming communications and events in order to help start industry on-boarding to SPOR and also to prepare for the integration of eAF with OMS.

The release 2.2 notes for the RMS&OMS are published on the SPOR portal. The release 2.3 is scheduled for the first week of December. A dedicated communication outlining the type of changes and improvements for the release will be in place. EMA data stewards are working on expanding the OMS dictionary. The information about the status of the OMS dictionary will be shared in each meeting of the Task Force. Weekly meeting are scheduled with eSubmission for draft communication plan preparation.

A number of webinars are scheduled for November and December in form of a Q&A for the on boarding industry and the registration process.

**10 A.O.B**

As reference point for the EU IDMP/SPOR TF actions log were taken the requirements from Industry presented in the slides for the Industry communication needs.

Due to the foreseen challenges of the EMA relocation and the current workload the focus for 2017 falls on the integration with the eAF. It was also emphasized the need to improve communication in terms of the work plan for the next years, expectations from the Industry and keep Veterinary stakeholders up to date.

A common agreement was to collaborate and create documentation on the achievements of the SPOR TF. The draft will be circulated and the final version will be published on the EMA website.