EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Substance & **P**roduct Management Services (P&SMS) update

P&SMS SG workshop & SPOR Task Force meetings
19-22 June 2018

Content

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1. Summary

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- A combined SMS/PMS subgroup workshop was held on 19 and 20 June 2018. The objective of the workshop was to work together on the current key topics
- The SPOR TF meeting took place on 22 June 2018

- Good progress has been made in the following areas of the SPOR program:
  - PMS Iteration 1
  - PMS Target Operating Model
  - Legacy Data Validation
  - NCA Data Pilot
  - Submission of Veterinary legacy data by NCAs
  - EU SRS project request
  - ROG Type 1A simplification

- The following slides provide an overview of the above areas as well as a short description and the next steps

- The most notable next step is to define implementation plans for these and to align them with the overall PMS implementation plan

2. PMS Iteration 1 data fields

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- The scope of the PMS Iteration 1 has been fairly stable in terms of the number of fields. Specific fields such as manufacturers and shelf life have recently been made mandatory to support certain use cases

- The clarification as to which fields are mandatory, particularly for industry enrichment, cannot be completed before API consultation starts at the end of 2018. The finalisation of such rules will also continue developing until PMS API UAT which is planned for the end of 2019. In addition, it is acknowledged that the PMS API will evolve in each phase and therefore will be under change control

- Therefore it is necessary to describe the status of the work, how it will evolve and the associated risks

- Consideration should be taken about which interim format could be used to bring clarity around the Iteration 1 scope to stakeholders outside of the Task Force

3. PMS TOM vs legacy validation

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PMS TOM

- **How PMS data management fits into the Marketing Authorisation regulatory context:**
  - PMS TOM aims to optimise the exchange of *application* data between regulators and applicants and within the regulatory network
  - it is a mechanism to simplify regulatory submissions (1 message to many users/procedures)
  - It covers:
    - New Products
    - Variations/changes (such as renewals, transfers)
  - PMS TOM will bring a **gradual increase of data quality (DQ) by checking data within the scope of the procedure**

- **How PMS TOM supports Art 57 process**
  - PMS TOM does not exclude the need for enrichment by Industry and is not a precondition for it
  - PMS TOM brings efficiencies (1 submission to NCA & EMA) and allows Industry to perform the Art 57 enrichment

Legacy validation

- **Background:**
  - Product data quality means that product data has been reviewed/approved as needed and is the same across Industry; Regulators and EMA
  - Improved DQ is required to support certain use cases: regulatory efficiency, eHealth

- **Activities have been undertaken to substantially improve the DQ of products already in Art 57 database (i.e. legacy data)**
  - Legacy validation is **likely to be a set of activities outside/parallel to the regulatory context**
  - Legacy validation will be done in "data blocks" by NCAs

- **How legacy validation fits in with PMS TOM**
  - PMS TOM can be implemented even if no legacy validation has occurred
  - **PMS TOM may be used to improve the cleansing of data beyond the scope of the procedure but is not a process for complete legacy validation**

4. PMS TOM 1/2

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

- **PMS TOM should:**
  - be introduced in the short term without triggering big changes in the regulatory processes
  - be implemented in the human AND veterinary domains
  - support all procedure types (CP, MRP, DCP, NP)
  - allow the sharing of workload in the regulatory network and must consider specifics (such as MRP/DCP/Worksharing, etc.)
  - work with ~~a~~ minimum requirements for NCAs/EMA and applicants (keep it simple!)
  - support the re-use of data for PMS and NCA/EMA databases
  - re-use existing technology frameworks for implementation

- The design of PMS TOM is seen to meet the objectives as stated above and **will result in high quality of PMS data**. There is an overall agreement with what has been designed, enabling the work to move forward

4. PMS TOM 2/2

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- The team began looking at **solution requirements** for:
  - Initial preparation of the application
  - Tracking, locking data and work-sharing across NCAs
  - Issue resolution and how errors found in the submitted dataset would be resolved at different points in the process
    - These initial requirements will be further elaborated as part of the TOM workstream

- **Next steps:**
  - Establish plan and milestones for approval of PMS TOM through the relevant governing bodies (CMDx, HMA) in alignment with the other components of the SPOR PMS project
  - Obtain the approval by Q3 2018 as this is a critical component for the EU Implementation Guide consultation which begins at the end of 2018

5. Legacy validation i.e. Data Cleansing

- 'Data blocks' for cleansing
  - Breaking data cleansing into data 'blocks' will help bring NCAs on board without being overwhelmed by the volume of work
  - Use cases and other considerations will drive the fields to be included in each block of data for cleansing
  - Key elements have been identified for Block 1 – these are elements owned by the NCAs (MA#, Authorization Status, Procedure Number)
  - Data ownership for remaining elements still needs to be agreed
- The phase/block approach will bring challenges in the existing database. Further discussion is needed on how to handle these
- Requirements/recommendations for communication between NCAs and industry during the cleansing process have started to be planned

6. NCA Data Pilot

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- NCAs are conducting a Data Pilot with the goal to **further understand IDMP and PMS Iteration 1 implications**

- **Deliverables:**
  - Products in an Excel sheet format
  - A short report detailing issues and solutions
  - Presentations to PMS sub-group, EUNDB, SPOR Task Force

- **Participants:**
  - Led by NoMA and SE MPA
  - FR – ANMV (vet), EE, AT, ES, DE – BfArM, DE – PEI, NL, EMA
  - Consultations with industry stakeholders

- **Progress to date:**
  - Excel template and instructions ready; Confluence space available for document sharing
  - AT, NO, SE, ES, DE-PEI, EE, FR – ANMV (veterinary) have delivered a few products each, others are working on them

- **Next steps:**
  - Meetings scheduled for September and November
  - Conclusion estimated before EU Implementation Guide (IG) consultation in Q4

7. Submission of legacy data by Vet NCAs

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- **NCAs should send legacy data to populate PMS**, therefore no migration from EudraPharm to PMS will be required
  - Until PMS is operational, Eudrapharm will still be in use and NCAs should continue sending data to support Vet Pharmacovigilance

- The **minimum set of core mandatory fields for legacy data** to be submitted to PMS has been identified
  - Work is still ongoing to identify how exactly to populate each field
  - NCAs have been advised to **start mapping R, O** & **S for these fields** in local databases
  - More fields can be submitted if they are available + SmPC
  - Other essential data (QPPV, Master file, sales related information) to be submitted later
  - This set of data is a draft work until implementation act of the New Veterinary Regulation (NVR) is endorsed. The Task Force that will be created to implement the NVR should take these proposals into account

- For new data, more mandatory fields should be expected, but no more than are currently required from eAF

8. EU SRS update

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- **Endorsement** was reached on the **strategic direction** for EU-SRS to support the SPOR landscape in Europe from the substance perspective
  - **Scope** is agreed as described in Option 4:
    - Minimal fields (signature fields) for Human and Veterinary (with Veterinary being addressed by combined agencies initially)
    - Focus of EU-SRS is on Structurally Diverse substances

- **Endorsement** was reached on the strategic role of the **Substance Validation Group**
  - phased participation will be agreed individually and confirmed at HMA II in Vienna in November 2018

- Decision to **use and adapt G-SRS** (system developed by FDA in collaboration with several European experts) as a basis and adapt to European requirements (EU-SRS) **to be confirmed** at HMA II Vienna in November 2018

- **Next steps:**
  - Working with stakeholders and partners (Network, EMA, FDA, Industry)
    - Investigate whether we can use experience gained in Europe (DE, et al)
    - Prepare for hand-over of system to EMA at suitable time
  - Discuss funding (direct and in kind)
  - Prepare project initiation:
    - Finalise architecture assessment (with EMA)
    - Align with development plans FDA
    - Start setting up Substance Validation Group, including Terms of Reference, call for participation & onboarding – to allow for data cleansing approach
  - Formalise all arrangements at HMA II in November in 2018

9. ROG - Type IA simplification update

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HMA endorsed:

- Using **SPOR database and PMS TOM to automate some Type IA changes**
  - Further clarification on the process and consultation is needed with ROG, SPOR, CMDx etc.

- Inclusion of **manufacturer's data + role in SPOR database**
  - This is perceived as the "mandate" for SPOR to make Manufacturer + role **mandatory** (includes manufacturer of Active substance/excipients and Finished product) for Human only
  - The implications for Vet products as per NVR is still to be clarified

- **Optimise specific CEP updates**
  - Although there was explicit reference to SPOR it is still perceived as a "mandate" to be considered in SPOR as **optional**

10. P&SMS Plan

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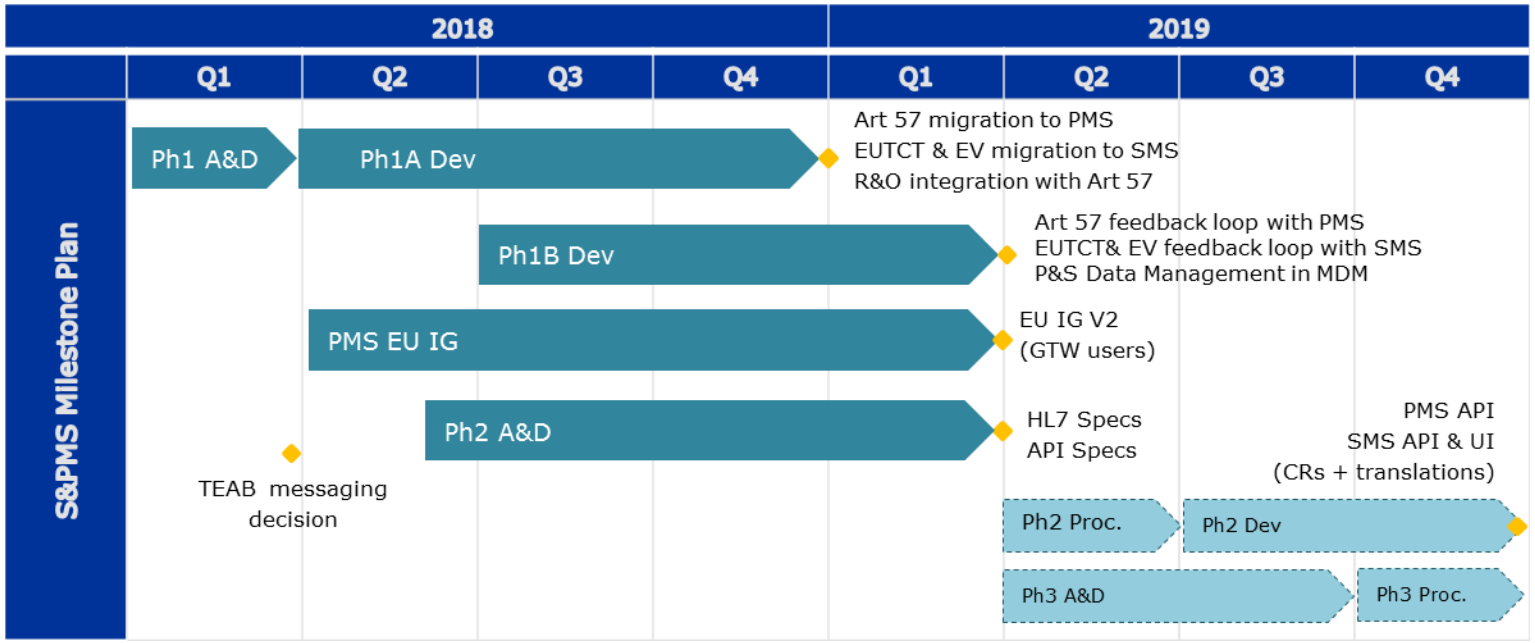

PMS EU IG

- Mapping Art 57-PMS work has started and is ongoing, completion is planned for >Q3
- EU IG fields/business rules (word doc) planned for consultation > Q4

Phase 1

- Ph1 Analysis & Design (ETLs and Data management functionality) complete
- Ph1A (migration) design work started
- Ph1B procurement underway & work (Data management functionality & feedback to EV) planned to start in Q3
- Progress as per plan so far but high risk profile due to EMA BCP/relocation

Phase 2

- Ph2 A&D (API specification) started, planned completion is end Q3 and will feed into EU IG, consultation planned for Q1, 2019
- Ph2 Procurement planned for EMA relocation period

10. P&SMS Plan

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Iteration 1

- No visibility of EMA relocation impact in the long term (after Ph1) plan yet
- SMS changes: Agreement with EU SRS that full synchronisation is not possible by Ph2 and therefore to be moved to a new Ph3. In the meantime manual periodic synchronisation will take place
- PMS phases are placeholders that represent an agreed strategy and an indicative scope/effort. There is some flexibility to adjust scope providing effort is equivalent
- Activities such as NCA validation, TOM implementation and EU SRS implementation need to be detailed and considered alongside those of PMS

11. Telematics strategy 2020-2025

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- The current Telematics Strategy & Roadmap came to an end in 2017 but was extended to 2018 and 2019
- **S&PMS implementation continues, delivering incrementally in phases**

- The Network is in need of a new Telematics strategy, beyond 2019, to ensure that the vision for information management and technology is clearly described and appropriately represents the Network's business needs
- Think-tank workshop took place in November 2017 identifying the following **business objectives**:
  - Better and more efficient regulatory decision-making in the Network
  - Facilitation of research and development in Europe
  - Building of trust by empowering patients, animal owners and health care professionals
- Output: **Concept Paper for Telematics strategy 2025**
  - **SPOR is listed as a key component to support the Network strategic objectives**

- **Next Steps:**
  - Concept Paper submitted to the EU TMB on 23 May for adoption
  - Pending EU TMB's approval the Concept Paper will be presented for endorsement to the HMA in July
  - Pending HMA's approval, a written procedure will be initiated in July to get it endorsed by the EMA MB
  - Work on developing the Telematics strategy begins early Autumn 2018; and
  - Telematics strategy 2025 is expected to be ready by the end of 2019

12. Key messages

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- RMS & OMS: Data is now gradually being integrated into processes and activities relevant for marketing authorisation
- PMS & SMS: Significant progress has been made over the past few months regarding scope, processes and strategy for data quality improvements
- SPOR has been given the highest priority in terms of BCP planning. SPOR was also identified as a key component to support the Network strategic objectives
- The concrete impacts of the relocation are still unknown, and delays could be expected but, given the network support, SPOR implementation is expected to continue pragmatically and steadily

Thank you for your attention

Further information

Please send any queries regarding the IDMP/SPOR to:
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