PMS Workshop

20-21 March Summary

WS Agenda Topics

- EU IG plan & structure (EMA)
- Data flow - TOM & transition (EMA)
- Validation data sources (EMA)
- Migration; validation & enrichment strategy (Ind)
- Backwards Compatibility IDMP-to-XEVMPD (Ind)
- PMS TOM (NCAs)
- Approval process & risks/impacts
- Validation of Legacy Data (NCAs)
- Data Standardisation (NCAs)
- Data Pilot (NCAs)
- DQ assurance in TOM (Ind)

EU IG Plan/Structure

- See ‘04b. EU IG Plan Overview.pptx’ and ‘PMS - EU IG Plan (Human).xls‘
- Review of the overall plan
  - Version 1 will address primarily the art 57→PMS mapping and migration, including feedback loop, and backwards compatibility
  - Drafting to begin in June 2018
  - To be processes will be tackled in version 2 of the guideline
  - Change in process for referentials & organizations
  - Amend convention on MA# for article 57 to align with the local practices Q1 2019

EU IG Plan/Structure: Discussion

- Authoring of IG initial version
  - Agency is driving the drafting of the guidance
  - Initial version will be EMA business & IT
  - Maintenance of documents also will be led by EMA
- Version 2 will need involvement of NCAs – Q4 2018
  - Action: prepare requirements for NCA resource requirements & approve via EUNDB
- Process to amend documents and release new versions – EMA to lead
- RACI matrix in IG Plan spreadsheet

EMA Data migration: Key overview points

- Transition period where xEVMPD and PMS messages will be accessed by agency
- Two-way flow of data will be required to support existing integrations/uses
  - ART 57 ←→PMS and vice versa
- Key message: only one message type will be accepted per organization.
  - This will be at the sender level, not MAH level.
- New web interface is intended be available at the beginning of the transition period. This will be CESSP – still need to confirm the plan for CESSP as this is a key dependency.
- Note: Migration timeline is human only, not vet

EMA Data Migration: Discussion

- Confirmation of timelines will be iterative
  - Due to complexity and dependencies, EMA will be able to confirm each phase/year
  - Discussion of lead time requirements for industry to be prepared
  - Action item: industry & vendors prepare a boilerplate timeline to demonstrate critical path work to implement a change in vendor package →industry implementation etc
    - Understand per phase of the EMA implementation what are the dependencies
    - Include preparation of composition for products

EMA Data Migration: Discussion

- Discussion of FHIR
  - Concerns about maturity and fit for purpose
  - EMA is working to develop draft messaging based on what is available

  - Phase 2 has a dependency on this being delivered.
  - As EMA delivers the API specification they will fine tune the messaging specification
  - TOM finalization is a dependency for the messaging business requirements

Industry: Migration validation and strategy; backwards & forwards compatibility

- Discussion of questions industry still has regarding the strategy
  - Ability to generate IDs
  - Limitations in migration to new formats per outcome of recent industry data pilot
  - How enrichment will be managed & the forward/backward compatibility, MAH switchover to PMS submission etc.
  - NCA validation process
  - For compatibility activities
    - What are use cases?
    - How long will this be in place?
    - Technical & continuation of data integrity questions discussed
- Action: Industry collate detailed list of questions/concerns to bring to PMS teleconferences for discussion
- EMA has already considered many of the items which were raised
- Some of these were discussed during the meeting; a follow-up discussion in greater detail is to be planned (action item EMA)
- Currently there is not a common base of understanding for all team members, these actions will support establishing a baseline to support ability of industry & NCAs to best contribute

Legacy Data Validation

- Review of challenges of NCA validation of legacy data due to varying existing forms of data, eg strength representations
  - Difficult to identify that a product is really the same in multiple countries
- Challenges/questions regarding the assignment of PhPIDs discussed
- NCAs plan to complete a data pilot to fully understand challenges and build understanding of the standards and how they apply to varying types of products (simple to massively complex)
  - Will include IDMP SMEs and industry input as well
- Details regarding how legacy data validation will be done still need to be worked out
- Full legacy data validation by NCAs is unrealistic. The NCA team is beginning to identify strategies (eg validating blocks of data) A key input to this will be prioritized business cases for use of legacy data to drive the prioritization of fields
  - Action item: This is to be discussed at EUNDB
  - To be further discussed during NCA meeting in April
- 'Starter' validation of MA numbers is being planned to encourage NCAs

TOM discussion

- Review of current draft of TOM process for new MAs & variations
- TOM is becoming mature with assigned analysis items to sort out remaining questions/complexities. Addressing these is not considered a prereq to obtaining approval of the TOM
  - Industry involvement in some of the remaining items esp thos

- Current model addresses control of approved data through submission to PMS via CESP (CESSP?)
- TOM as designed should not add much effort to NCAs. Key is getting all remaining NCAs on CESP
- Question raised re whether CESP or some more persistent solution should be used to manage the data during review process
- CESP functional requirements will increase complexity of the solution
- CESP is a critical path item for implementation of the TOM
- TOM approval process: preparations
  - Document benefits, resource requirements etc
  - Approval by: Telematics governance including HMA / CMDh/CMDv

DQ assurance in TOM

- Industry tasked with defining the technical requirements for communicating changes related to data quality review
- TOM obviates a feedback process like 3rd ack as the data quality will be addressed during the normal submission review process
- DQ feedback during legacy validation process is important
  - Requirements will be based on the detailed process for legacy validation
  - This topic will be re-introduced as soon as the legacy validation process is defined

ROG

- Key proposals presented to HMA in March meeting
  - Type 1a variation optimization
  - CESP infrastructure in place in all member states
  - Electronic SmPC (to be further discussed)
    - Would result in additional fields such as shelf life & storage conditions
    - Action: industry to discuss and make recommendation
- Discussion of ‘mandatory’ use of CESP
  - Calling CESP ‘mandatory’ restricted by lack of legislation
  - Establishing CESP as means for submission and review will essentially establish it as ‘mandatory’ for both MAHs and NCAs
  - Additional legal discussion to be had on this
- Awaiting approval from HMA for Type 1a optimization by 30 March
- Following approval ROG work will begin, initiating work by involved parties
- Next ROG meeting 16 May

Iteration 1: Review of EMA activities

- EMA presented work in progress document showing database cardinality for fields included in current LDM by category (EMA, eAF, CESP, Art 57, Vet
- Actions
  - Align table format for review of fields (Marek/Remco)
  - Make changes as suggested during discussion
  - Reconcile Art 57 column to ensure accuracy to current requirements
  - Following completion, review with EUNDB & regulatory network
  - Input from NCA data pilot as available
  - Make changes to this document to reflect accurate alignment with eAF and CESP mid April (Remco)
  - Review/compare existing It 1 spreadsheet with the db report list to ensure completeness
  - Identify what is technical and what is legal conformance criteria
- This is a technical document, need to complete a business requirements document around the data fields/entities and business use of each in order to feed into these specifications.
- Business requirements need to be completed by the PMS team: define each entity for initial registration, maintenance activities, and validation of legacy data

Vet

- Include vet in NCA pilot
- Presentation to EUNDB Thursday
- Some agencies use single DB for human & vet – prefer to make changes only once
- EudraPharm – analysis necessary to determine best path forward
- Determine how Vet will fit into the TOM
- Would like to understand scope of Iteration 1 as soon as possible