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PMS TOM

Enabling business cases of PMS by enabling high data quality

SPOR TF, Georg Neuwirther, 04.12.2018

Foreword

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- This presentation was given at the EU Telematics Management Board Meeting (8/11/2018)

Setting the scene

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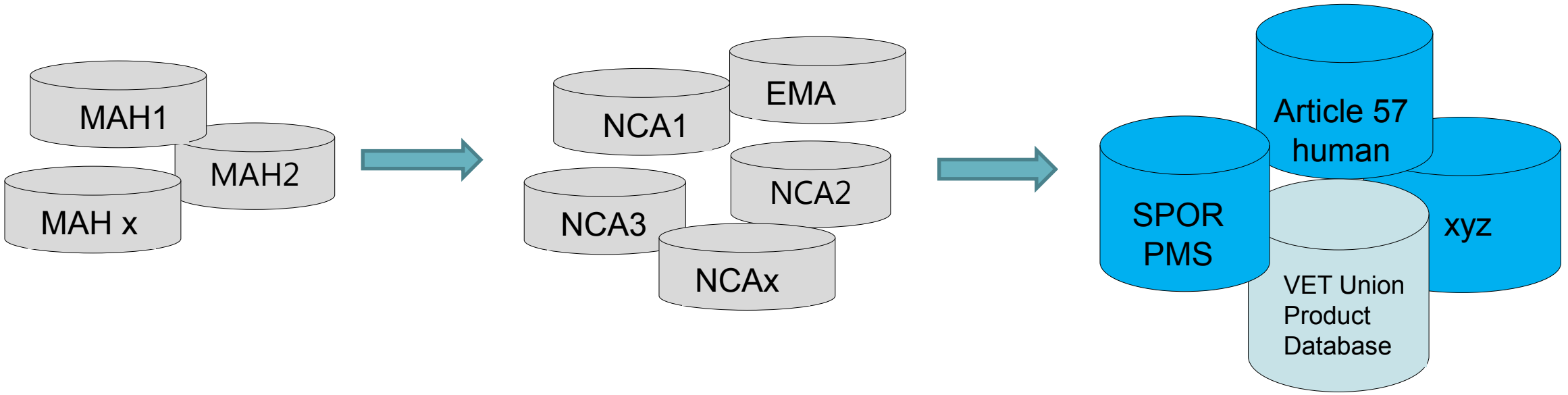
Industry databases

NCAs/EMA databases

Centralised Databases (Telematics)



Make sure that data in national and central databases are **consistent**

Minimise **additional administrative burden** to keep data synchronised

Enable **automatisation** of data exchange

Needs: What and why

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- A **process** to create/update medicinal products in centralised databases needs to be established
  - for PMS and for the upcoming VET Union Product Database
  - to minimise the administrative burden for keeping data consistent in centralised and national databases
- **Lessons learned** from Article 57 (human) and EudraPharm Human/Vet should be considered

→ These needs led to intensive discussions in the "SPOR taskforce" and the "PMS subgroup" about solutions resulting in a suggestion for a target operating model (PMS TOM)

→ New opportunities and standards are now available to support the needs

- e.g. OMS, RMS, IDMP standard, FHIR, EU Implementation guide (in progress)

PMS - Target Operating Model (TOM)

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TOM is a **business process model** to ensure **data quality and consistency** and to optimise the **exchange of application data** between regulators and applicants.

- → **Minimize administrative burden**
  - → Re-use the same data for regulatory activities AND centralised databases (PMS, …)
  - → Abandon separate Article 57 data feeds
  - → Improve electronic data exchange in the network (CTS, national databases, etc.)
- → **Integrate SPOR**
- → **Ensure** that centralised and NCA/EMA databases have consistent data

Timeline

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- Triggered by discussions in the SPOR Taskforce and PMS subgroup the need for PMS TOM was identified
- Business experts from human and veterinary domain from AT, DE, ES, EE, FR, NO, NL, SE have so far worked on the PMS TOM (financed by these NCAs)
- Industry representatives have also contributed
- EMA's feedback for CAPs is now included in version 0.7.8

Excerpt timeline:

Initiated by the PMS subgroup	May 2017
@EUNDB and SPOR Taskforce	19-20 October 2017
@ITDIR meeting	17 November 2017
@SPOR taskforce	23 March 2018
"… the maturity of TOM is good enough to start the discussion on the other Telematics groups and CMDh/CMDv … "	
@P&SMS SG workshop & SPOR Task Force	19-22 June 2018
@EUNDB	21 June 2018
@CMDh	26 September 2018
@CMDv	8 November 2018
@EUTMB	8 November 2018
@IT directors meeting	22 November 2018

Working on PMS TOM includes

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- **Group data elements**
  - to allow to define responsibilities for creating, updating and approving data elements
- **Define a TOM process flow**
  - to have a common approach how to process data fields
  - and to identify regulatory impacts
- **Define integration of OMS, RMS, SMS and PMS, Union Product DB**
  - Define how to create and update medicinal products in PMS and the VET Union Product DB
- **Intensive collaboration**
  - with regulatory bodies and stakeholders to agree on concepts, guidance and implementation plans

1- PMS TOM - Data Groups

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- **EU Phase data group**
  - Created by applicant, approved by e.g. RMS (e.g. active substance, dosage form, strength)
- **National Phase data group**
  - Created by applicant, approved by RMS/CMS (national particulars, e.g. name, legal basis for the supply)
- **NCA/EMA data group**
  - added by NCAs or EMA (e.g. Date of approval, MA number)
- **MAH data group**
  - added by MAH after approval, no regulator validation (e.g. sales start, risk of shortage – Art 57 extra data)
- **Additional data group(s)**
  - added e.g. by EMA (e.g. EURD list information)

2 - Process Flow

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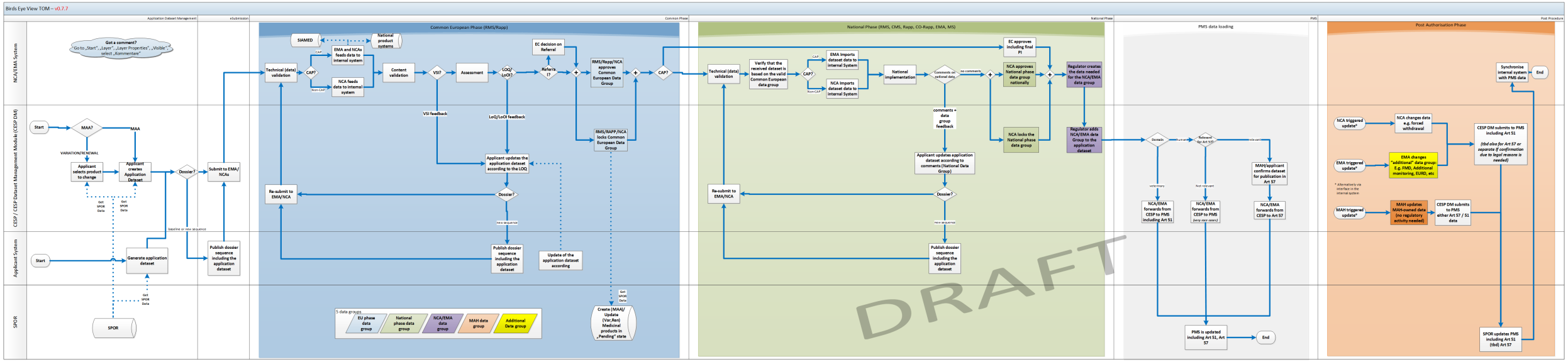

Create or update and submit an application dataset (MAA, Variation, Renewal)

- Utilizes OMS, SMS, RMS **and PMS**

Agree on common data group

- **Process is similar but if needed an updated dataset has to be submitted**
- Approval of data group by the RMS (tbc)
- Lock data group for further usage

Agree on *national specific data group Create Approval Data Group*

- **Process is similar but if needed an updated dataset has to be submitted**
- Approval of national data group by the specific regulator
- Create approval data by regulator
- Lock data group for further usage

Re-use application data for feeding product data into

- PMS
- Art 57
- Union Product Database
- and perhaps additional repositories

Additional data feed by MAHs

Additional data feed by regulators

Pattern to ensure data quality and consistency

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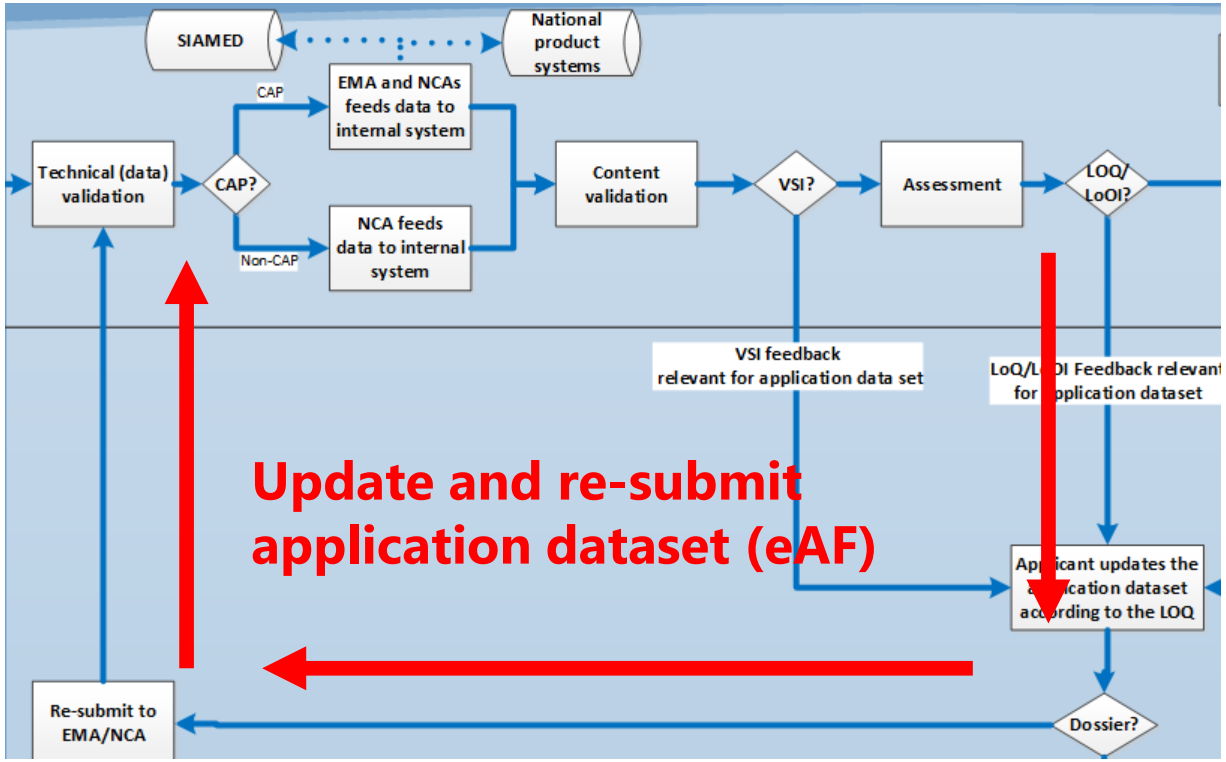
- **During the procedure in cases of changed application data an updated application dataset will be re-submitted to regulators (*mandatory*)**
  - mainly due to updated information from the applicant (e.g. additional batch releaser)
  - if needed also triggered by NCAs/EMA (VSI, validation issues, LoQ, comments, ..)
  - **Open topic:** how often should the re-submission happen within a phase?



- **During the national phase re-submissions are very unlikely**
  - Would be handled by variation procedures in most cases

TOM: Factsheet

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- **The TOM process flow is based on current regulatory practices in terms of data submissions:**
  - no major changes foreseen except the proposed mandatory re-submission of updated data
- **This model pattern is applicable for all procedure types**
  - NP, CAPs, DCP/MRP human and vet
- **No need that all NCAs/EMA are fully compliant to IDMP at the same time**
  - the TOM is being designed so that it would work even if the NCA/EMA is not **IDMP** compatible internally

Action

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- We kindly ask the EUTMB to support the implementation of the basic principles of the PMS TOM in the development of PMS (SPOR programme)
  - **Re-use of application data** (eAF) for regulatory activities AND for data feeds into centralised databases (like PMS)
  - Make **update** and **re-submission** of application data (eAF) **mandatory**
    - Consultation foreseen with scientific committees (CMDv, CMDh, CHMP, CVMP) prior making this mandatory

Status

Status / 04.12.2018

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- The group latest meeting was in Vienna in November to update the TOM process flow and to document requirements for PMS and CESP development.
  - Synergies with the upcoming project CESSP Phase 2 (variations and renewals) were identified
  - Industry participants gave positive feedback about the concept and are involved in the requirements task.
- Further meetings with the group are planned for 2019 and also for presenting the updated process to the full PMS group and the SPOR TF.
  - Requirements and open topics for PMS and CESP based on the TOM were gathered and will soon be ready to share them with PMS subgroup.
- It is suggested that EMA colleagues will occasionally participate in upcoming TOM meetings or in specific focus meetings as follow-ups.
- It is important to also include EC and/or implementation groups to discuss how the TOM would work to be able to meet the upcoming veterinary legislation (NVR) requirements

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- At the November HMA meeting in Vienna the need of high data quality in PMS was pronounced.
- Discussion is ongoing with EMA IT Management and SPOR programme management about how to progress to implement the TOM stepwise, but more details are needed before this can be decided.

→ Major concern: It is crucial that the PMS project don't take internal decisions just to meet the current SPOR project timetable without considering the TOM concept.

Please contact us for further questions:
georg.neuwirther@ages.at