Implementation of the UPD / Architectural Advice considering the data feed process for human and veterinary synergies

15.10.2019

Who met?

- 2 hour meeting
- Telematics Enterprise Architecture Board
  - primary role is to provide strategic technical advice to the network
- Representatives of the SPOR PMS subgroup that have also worked on the TOM
  - Industry
  - EMA
  - NCAs
- 3 members of the NVR UPD expert group that worked on the UPD recommendation document to the Commission

Motivation

- The UPD concept paper was presented to the EC and will be the basis for the systems decisions which will happen in autumn 2020
  - UPD recommendation to EC: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/advice-european-commission-union-product-database_en.pdf
  - Next phases

    https://ec.europa.eu/food/sites/food/files/animals/docs/ah_vet-med_imp-reg-2019-06_mandate_art-55-3.pdf
  - EMA information

    https://www.ema.europa.eu/en/veterinary-regulatory/overview/implementation-new-veterinary-medicines-regulation

- Include TEAB expertise to define the architectural landscape of the UPD components
- Ensure synergies between the human and veterinary domain

Motivation

- This short workshop shall be a trigger to include TEAB's expertise and knowledge to support the fulfilment of "Phase 3" tasks (from UPD mandate from the Commission)
  - As is situation:
    - Establish a list of systems (registers or databases), which already exist, are in use or under development at Union level, or at network and/or national level as appropriate, for either veterinary medicinal products, or medicinal products for human use.
    - Assess which of those systems may serve as building blocks for the establishment of the Union database of veterinary medicinal products.
    - Provide the architectural blueprint for the medicinal products for human use operation, data exchanges and key functions (in form of use cases for EU-wide and national cases).
    - Elaborate a suitable blueprint for the system architecture and database design.
  - Future Architecture
    - Consider the file formats, indexing and search capabilities and the specifications of the information to be stored, updated and shared in the system.
    - Elaborate on the system security, performance, scalability, availability, reliability and maintainability.
    - Elaborate on the adequate state-of-the-art data exchange mechanisms and electronic formats, which should allow the product database sufficient compatibility, integration and inter-operability with existing national systems or data exports therefrom, as well as with other Union IT tools and databases, while ensuring compliance with international standards in force and recommended by international organisations, e.g. VICH, WHO, and OECD.

Key questions

What are the main questions (in this context)

- Establishing a digitalised data flow – what should the process to get the data into the UPD look like?
- Mapping requirements and IT components
- Avoiding human and veterinary silos
- Integration of national and centralised IT systems

Which are the options?

- Start from the scratch (“greenfield”) for VET
- Mix of re-using (like OMS, RMS, ..) and scratch
- Embedding and extending existing components (like OMS, RMS, PMS, CESP, Gateway, ...)

What are the consequences?

- Prioritisation of IT initiatives
- Resource allocation
- Impacts on the project plan / phased approach

Topics for today

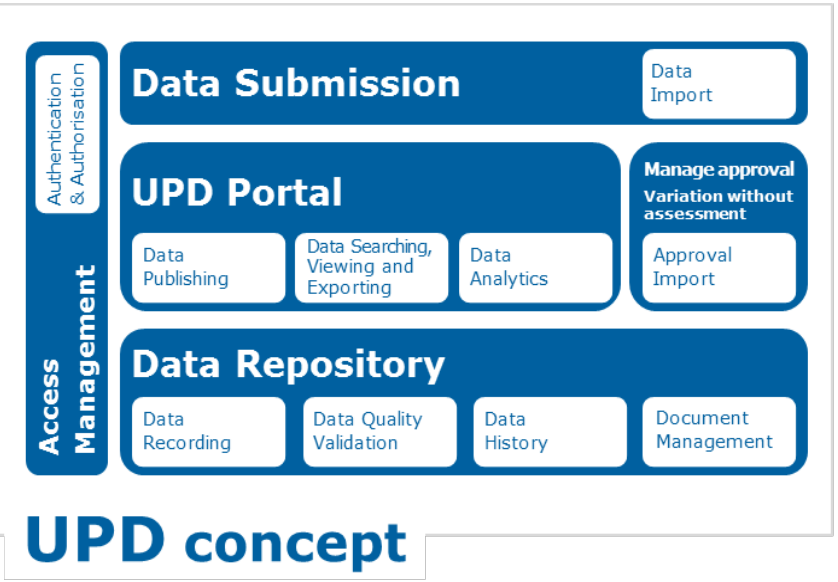
1. INPUT: UPD concept
   - High-level architectural components according to the recommendation

2. Discussion: Operational Data feeding process and data exchange standards
   - Applicants – NCA/EMA – UPD

3. Discussion: Mapping exercise to proposed IT components to be used for UPD

UPD concept

UPD concept as input



UPD concept

Access Management –
It ensures that controlled users have the appropriate access to the resources provided by the UPD.

Data Submission –
New products and post authorisation changes to the products are submitted to the UPD through this module.

Data Repository –
It manages all the information that enters into the UPD through the following function groups: data recording, data quality validation, data history and document management.

UPD Portal –
The information will be exposed to the general public and controlled users through this component that will make certain features available to the user such as: searching and viewing information or data analytics reports.

Manage approval of a Variation without assessment
Through this component and according to the NVR (Art. 61), a competent authority will be able to accept or reject the variations not requiring assessment.

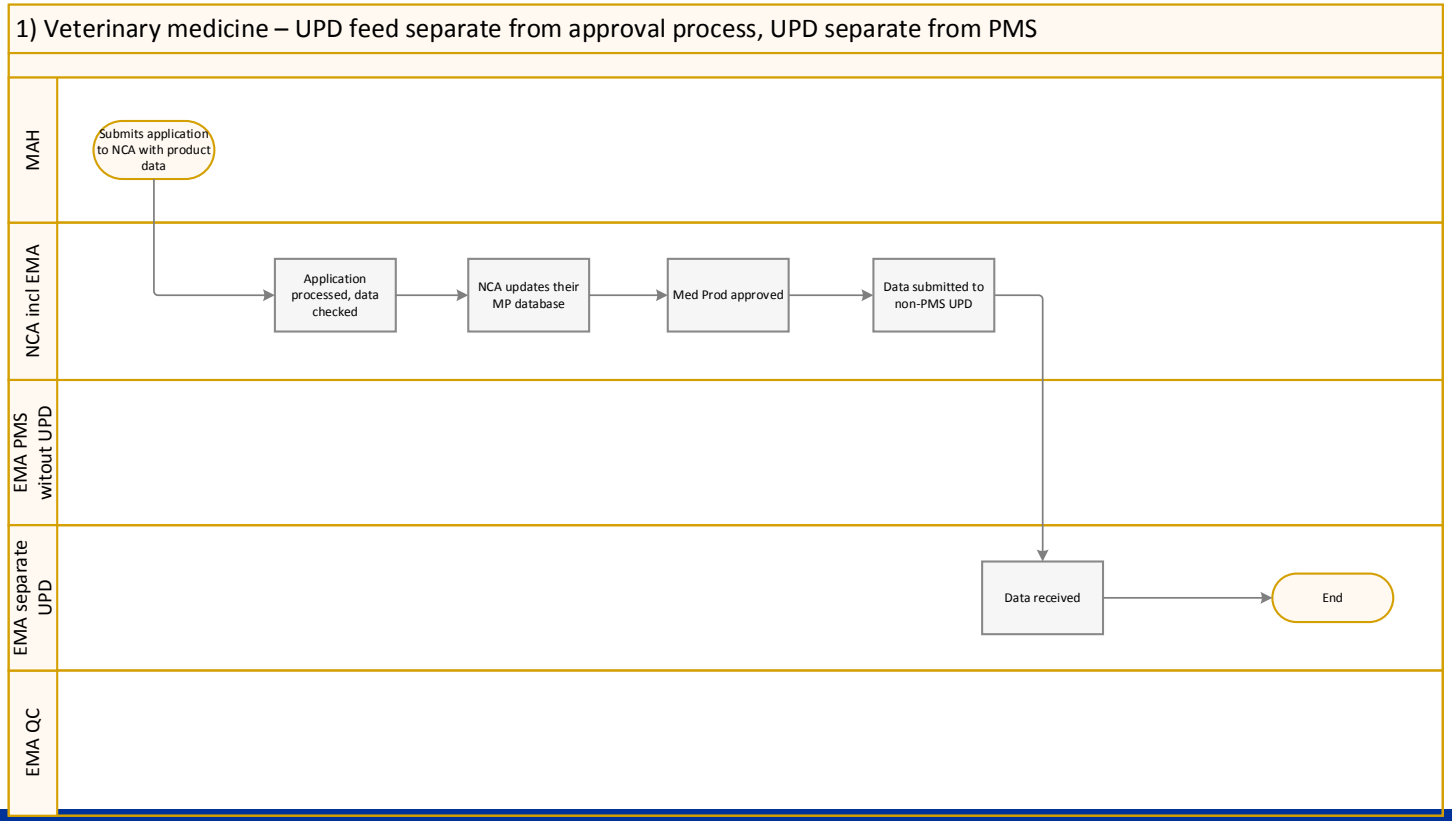
Recommendation: The Agency, supported by the Expert Group, advises that the UPD is understood as a system concept based on **a set of integrated system components** and not as development of a standalone, monolithic system.

Data feeding process UPD

Data feeding into UPD

1. Options
    1. Separate regulatory and application process and data feeding process to UPD
    2. Integrate the application procedere and regulatory activities into the data feeding process to UPD

1) Separate Data Feeding Process



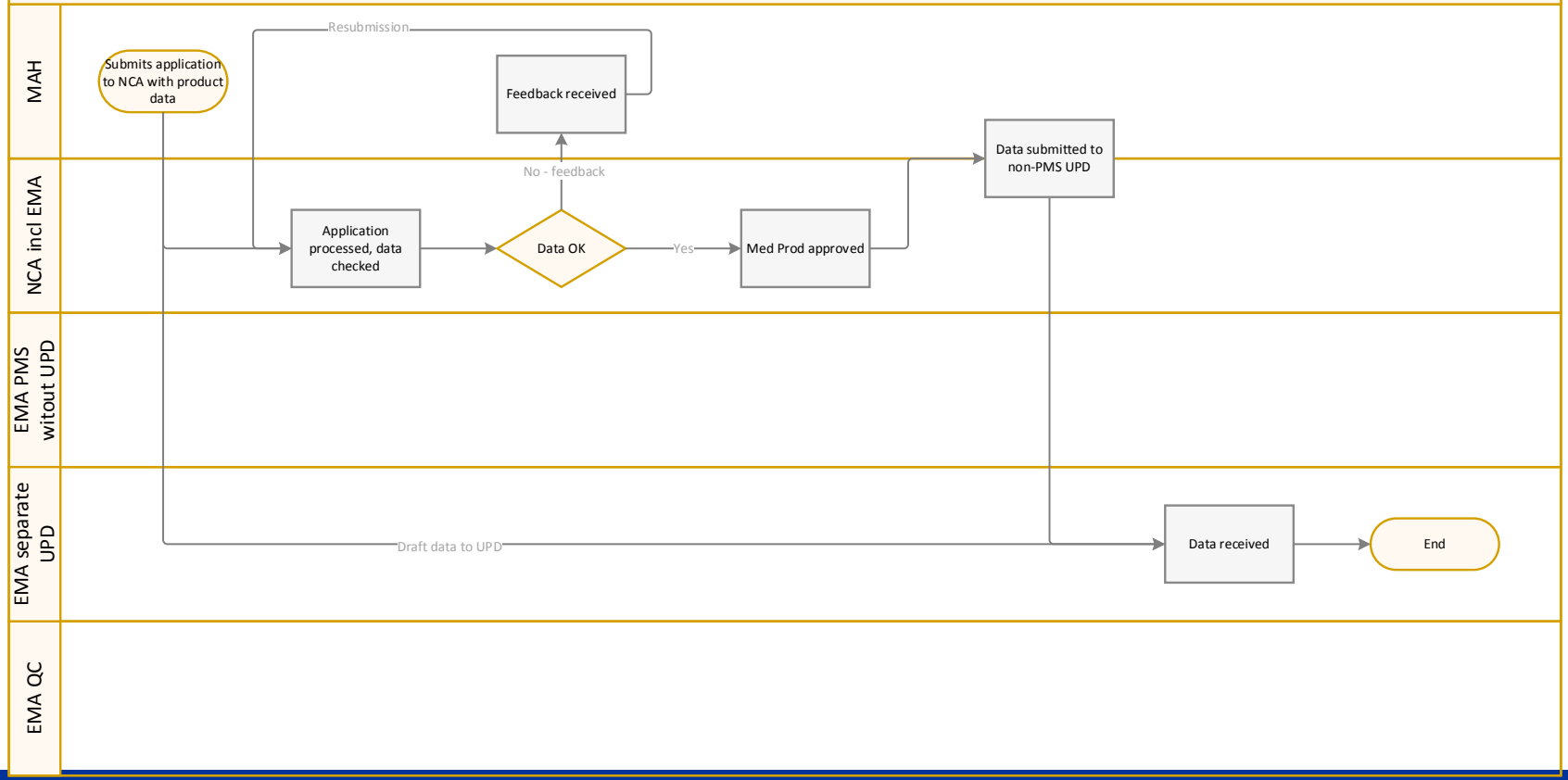
1) Separate Data Feeding Process

- Extra resources needed by NCA/EMA for this additional process after ending a regulatory procedure
- NCAs will need a UPD-compatible database
- NCA databases and UPD might have different data quality standards; therefore "mapping on the fly"
- More complexity due to different "modus operandi" for variation without assessments

- In short term: might be easier for the NVR project management to roll-out in the network

2) Integration application procedure and regulatory activities with the data feeding process

2) Veterinary medicine – separate UPD (not PMS-based) but with an integrated process



2) Integration application procedure and regulatory activities with the data feeding process

- May need more communication within the Regulatory Network

- Minimal extra resources needed by NCA/EMA since submission is part of the normal regulatory procedure
- "Application forms" in place and can be extended to CARRY THE DATA
- No mandatory need that EMA and NCA databases have the same data standards or structures at the same time
- Ensures data consistency between MAHs, NCAs and UPD
- Synergies with human domain possible

UPD option for data repository

Alternatives for UPD data repository

1. A new product database
2. Existing EudraPharm-based Veterinary Medicinal Product Database
3. Using PMS as starting point

1. New database

- Building from zero – expensive and time consuming
- Integration with S, O and R must be built
- Potentially new database structure to deal with
- Potentially meaning joint NCAs and Industry would have two different data structures to deal with
- Silos – no human-veterinary synergies

- No restrictions due to existing systems
- Does not impact human PMS phases

2. Existing EudraPharm-based Veterinary Medicinal Product Database

- Built on old technology (> 10 years old)
- Not user friendly. Not available for smartphone/tablet use.
- No mandatory use of S, O and R master data which is crucial for quality control and searchability
- No place for many NVR mandatory data fields
  - SmPC, assessment report, manufacturing sites…
- No support for submission of variations not to be assessed
- Much development would be needed
- Existing data comes from few (6?) NCAs and therefore represent only a fraction of the total products. Several of these NCAs did only a one-off feed (e.g. SE). All would need to resubmit data

- Already up and running

3. UPD based on PMS

- **Need to decide how much of PMS structure to use**
  - possible decrease in mandatory fields
  - some different business rules
- **Development would be needed to support variations without assessment**
  - cannot be part of PMS master data system

- **PMS is already under development and further development is planned**
  - costs will be shared between human and vet
  - most can be reused with limited additional costs
  - faster time to production since the development is already well under way
  - Already integrated into the Telematics landscape
- **Integration with S, O and R already in place**
- **Common human and veterinary structure**
  - Project and development synergies
- **Joint human and veterinary Agencies and Industry do not want to deal with two different databases with two different structures**
- **Some veterinary extensions already designed and in place**
  - based to some extent on early versions of NVR
  - these need to be checked with the NVR to see if they fulfil the needs

Core questions in context of UPD

1. Utilising RMS?
2. Utilising OMS?
3. Utilising SMS?
4. Utilising PMS?
    1. Use EudraPharm or?
    2. Develop a new product database?
5. Utilising CESP delivery?
6. Utilising CESP Dataset Management?
7. Utilising EMA Gateway?
8. Fostering the single submission portal as stated in the eSubmission Roadmap?

Conclusions:

- TEAB to give an advice about EudraPharm
    - Can we minmize the options for UPD data rep.?
- Suggesting a core group providing a document with **recommandations** (via consulting TEAB experts, UPD expert group, SPOR experts, VET Expert Group)
- Possible actions:
    - TEAB: collect feedback from SPOR taskforce
- Think about the telematics strategy
- Shall we inform the programme manager about this meeting and think if we utilise our expertise?

Conclusions

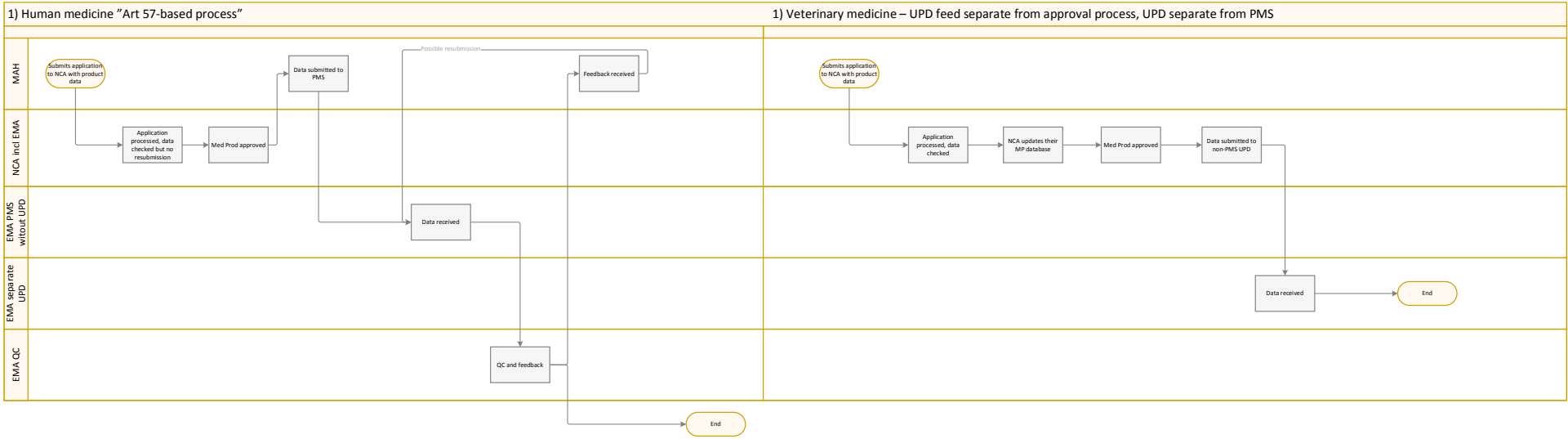
- Needs to get a group under the UPD project together to describe the different strategic alternatives
  - Make recommendations for the points on the previous slide
  - Give strategic guidance to the NVR project groups
    - to support the product owners especially when defining the NVR vision
  - Look at what needs to be done for the different alternatives
  - Look at the process to feed the data
    - What tools are needed and how to get there
- Need to look at resource competition for EMA projects
  - human PMS vs UPD
- Ideas to have synergies between human and vet

Conclusions

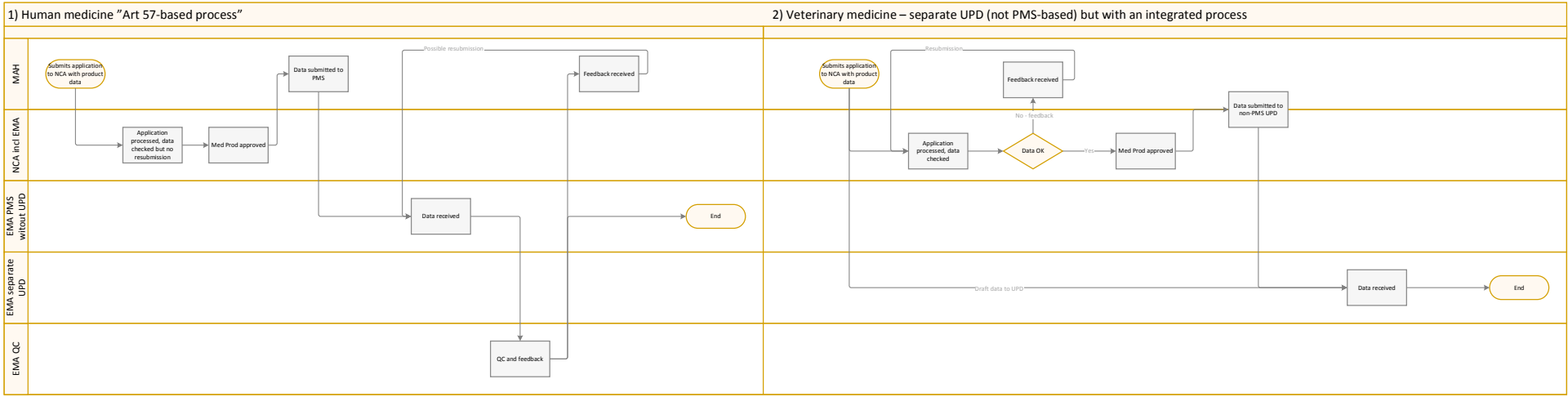
- small group that needs to consult with
  - EMA Telematics strategy
  - Telematics Enterprise Architecture Board
  - Vet Expert Group from the PMS
  - SPOR experts – all four elements

Backup

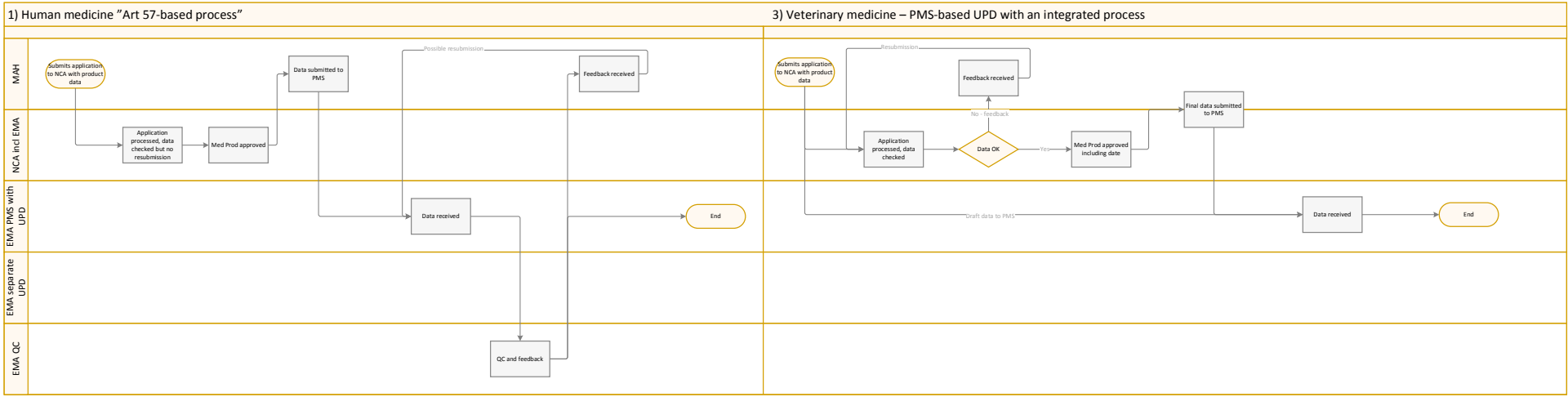
1) Human – ”Art 57 process, Vet not integrated, UPD not in PMS



2) Human – ”Art 57-process, Vet integrated process, UPD not using PMS

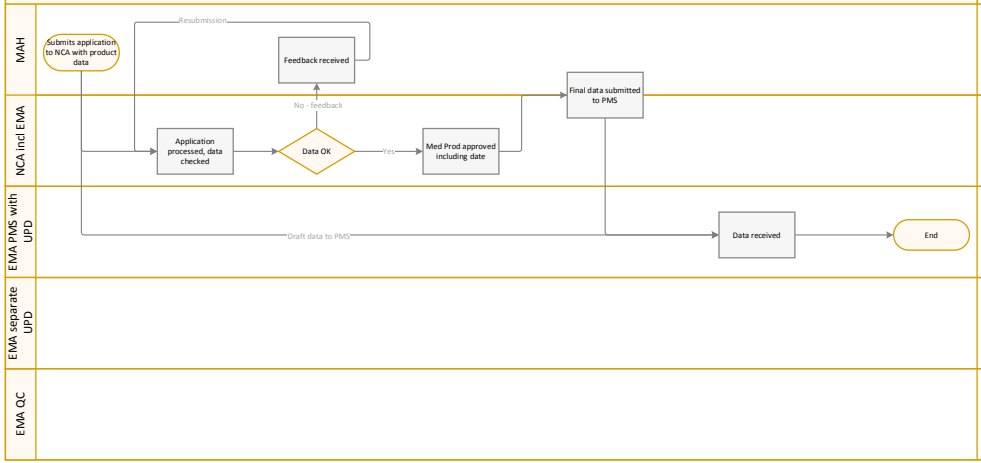


3) Human – ”Art 57-process, Vet integrated process, UPD using PMS



4) Data feed integrated with the regulatory process for both human and veterinary products, UPD in PMS

2) Human medicine – integrated data feed process



3) Veterinary medicine – PMS-based UPD with an integrated process