SPOR for VETERINARY

EU Network Data Board / SPOR Task Force
29, 30 June – 1 July 2016

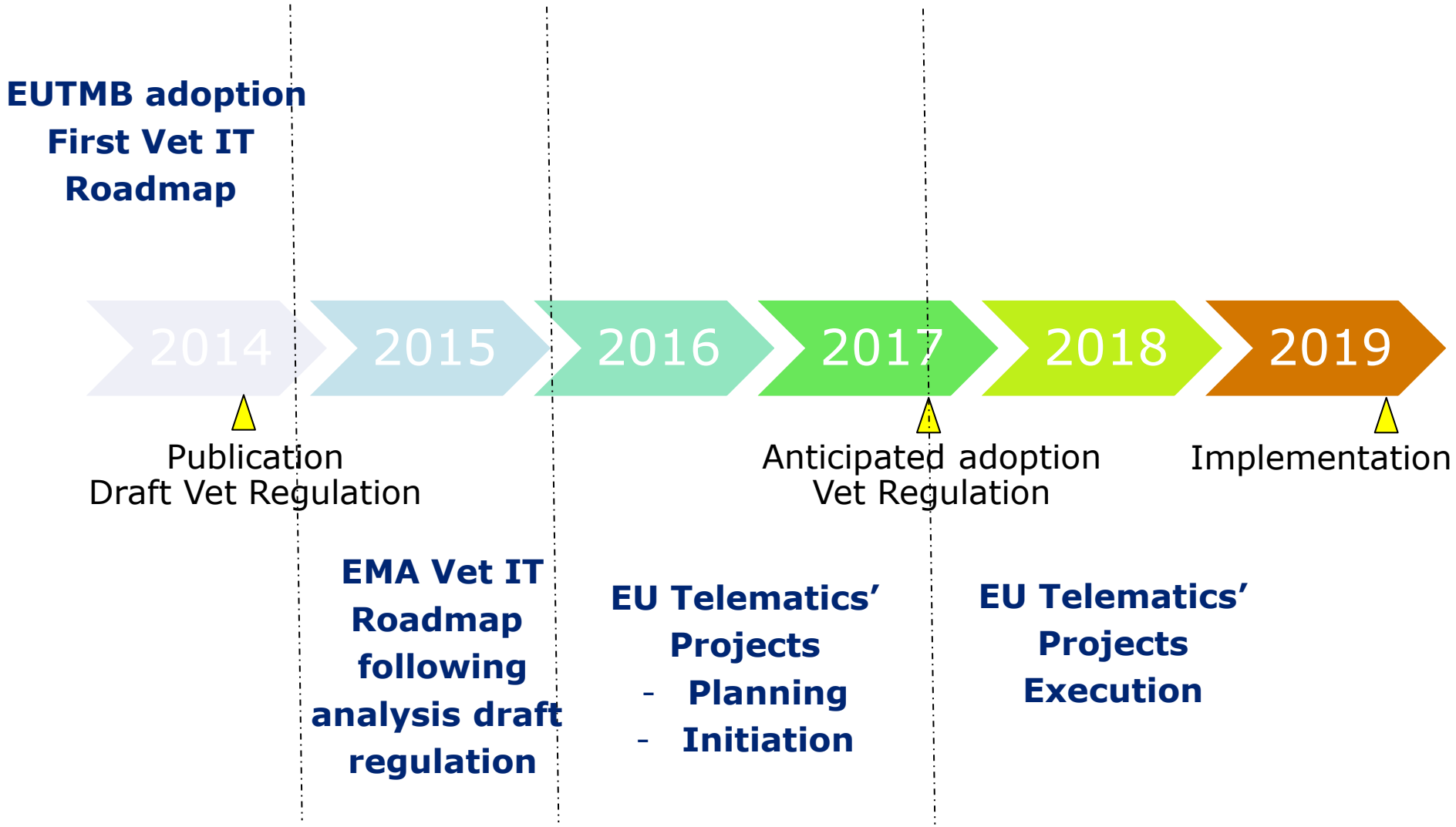
Presented by: Jos Olaerts
Veterinary Division

Content

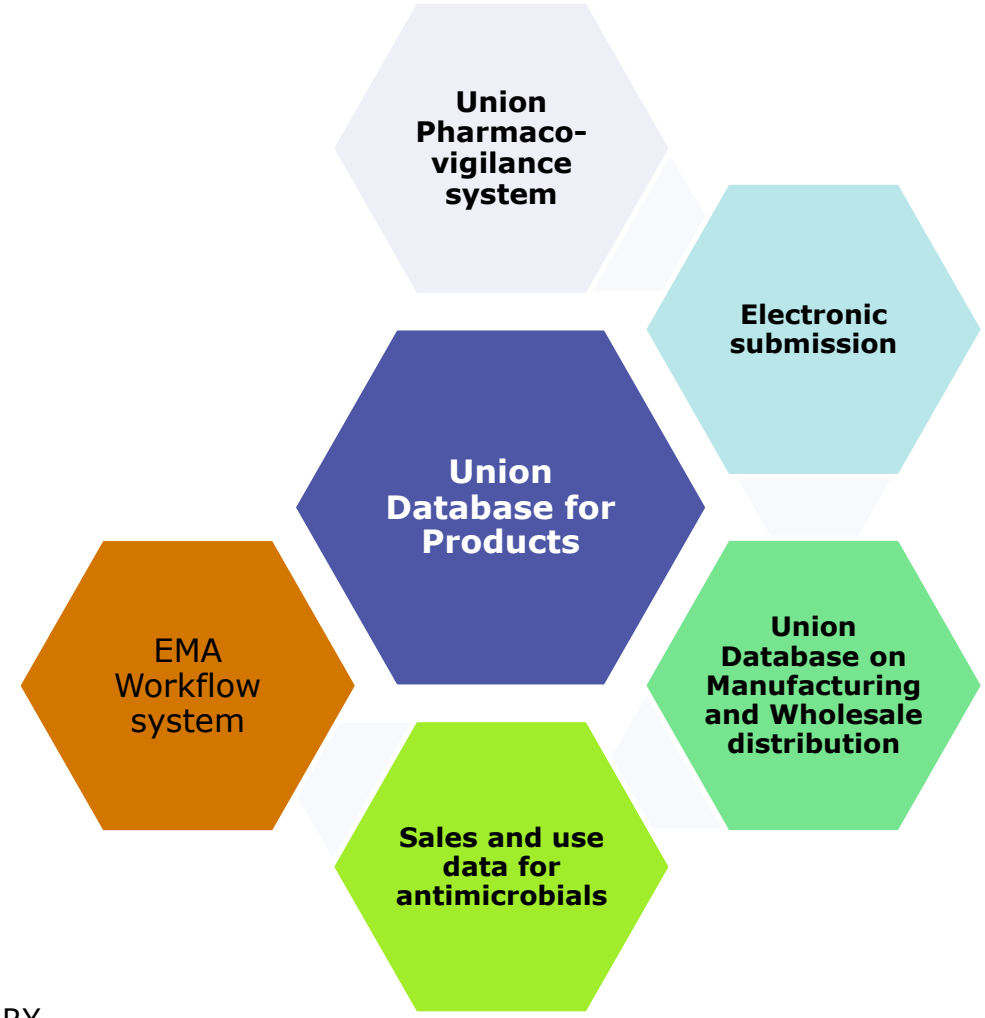
- Draft Veterinary regulation and SPOR
- Feedback from the Veterinary SPOR Webinar (22 June)
- Status of Veterinary SPOR and way forward

Draft Veterinary Regulation

- Published Sept 2014
- European Parlement: COM AGRI & ENVI adopted opinion/report
  - EP PLENARY on 10 March 2016 - mandate to enter into inter-institutional negotiations on VMPs
- Council discussions ongoing – slow
- Anticipated adoption – 2017?
- Anticipated implementation – 2019?


EUTMB adoption
First Vet IT
Roadmap
2014
2015
2016
2017
2018
2019
Publication
Draft Vet Regulation
EMA Vet IT
Roadmap
following
analysis draft
regulation
EU Telematics'
Projects
- Planning
- Initiation
Anticipated adoption
Vet Regulation
EU Telematics'
Projects
Execution
Implementation

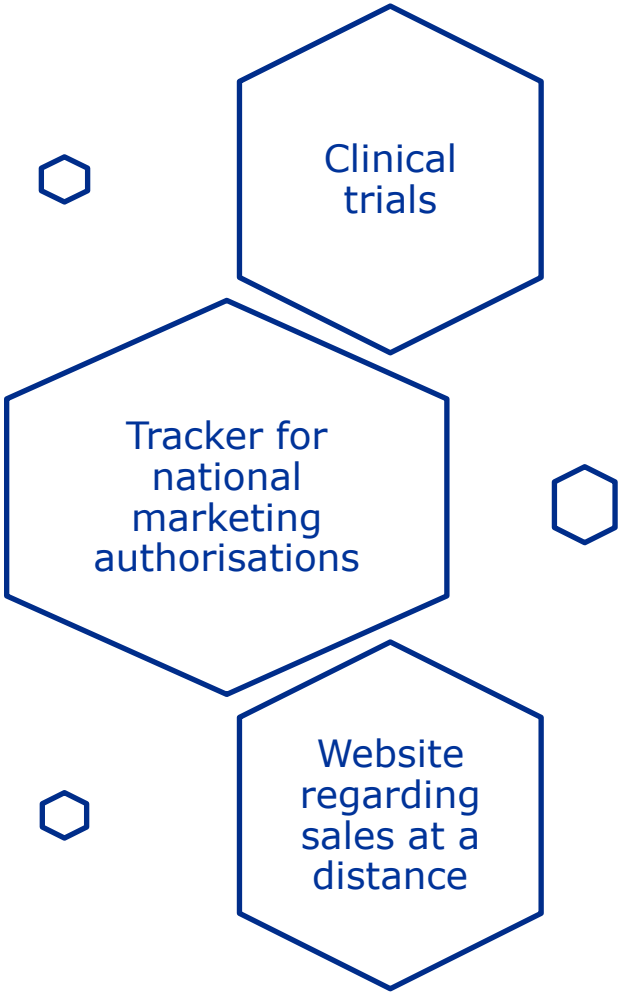
Main systems affected by legislation



5 distinct but interlinked Vet IT Data systems identified from requirement analysis of draft regulation

Systems	S	P	O	R
Product database	✔	✔	✔	✔
Pharmacovigilance	✔	✔	✔	✔
Certificates		✔	✔	✔
E-Submission	✔	✔	✔	✔
Sales and use of AB	✔	✔		

Non - EMA Data and System related topics



Product Database System (EMA Perspective)

2019

Integrate with GMP/Certificates database (Art. 51 (2a))

T EU VET MED PROD DATABASE (ex-Eudrapharm) development and integration with **SP**or

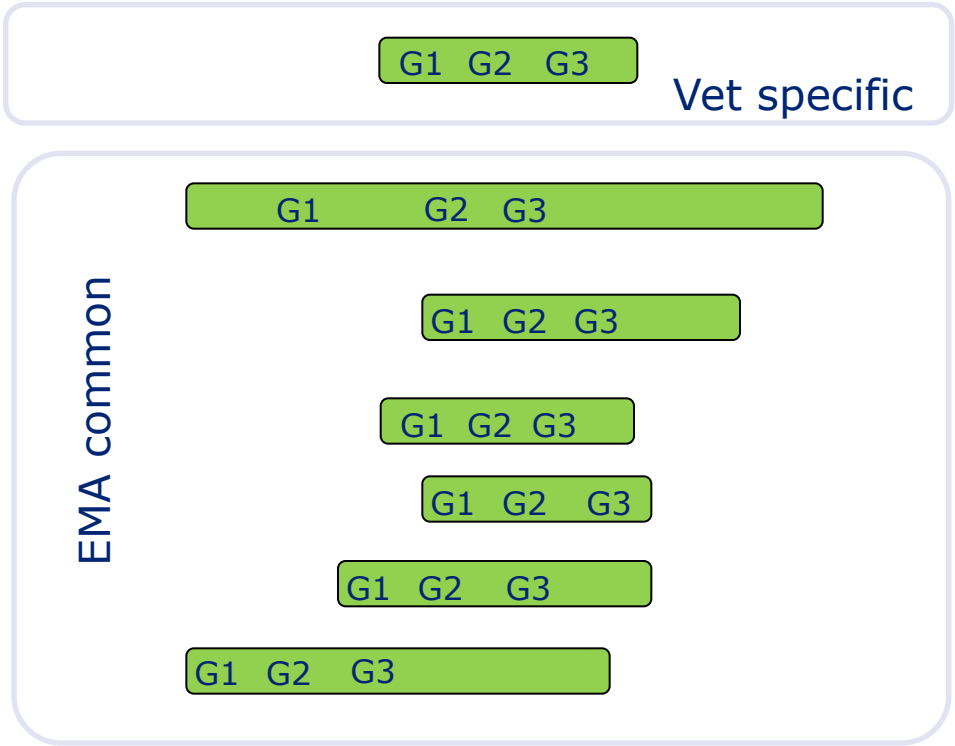
T Integrate with e-submission (including Art. 60 (1) direct MAH update of variation)

Integrate with sp**O**r

Integrate with spo**R**

Update of product index generation and recoding application *(as done for Art.57 human data)*

ID and Access Management Project

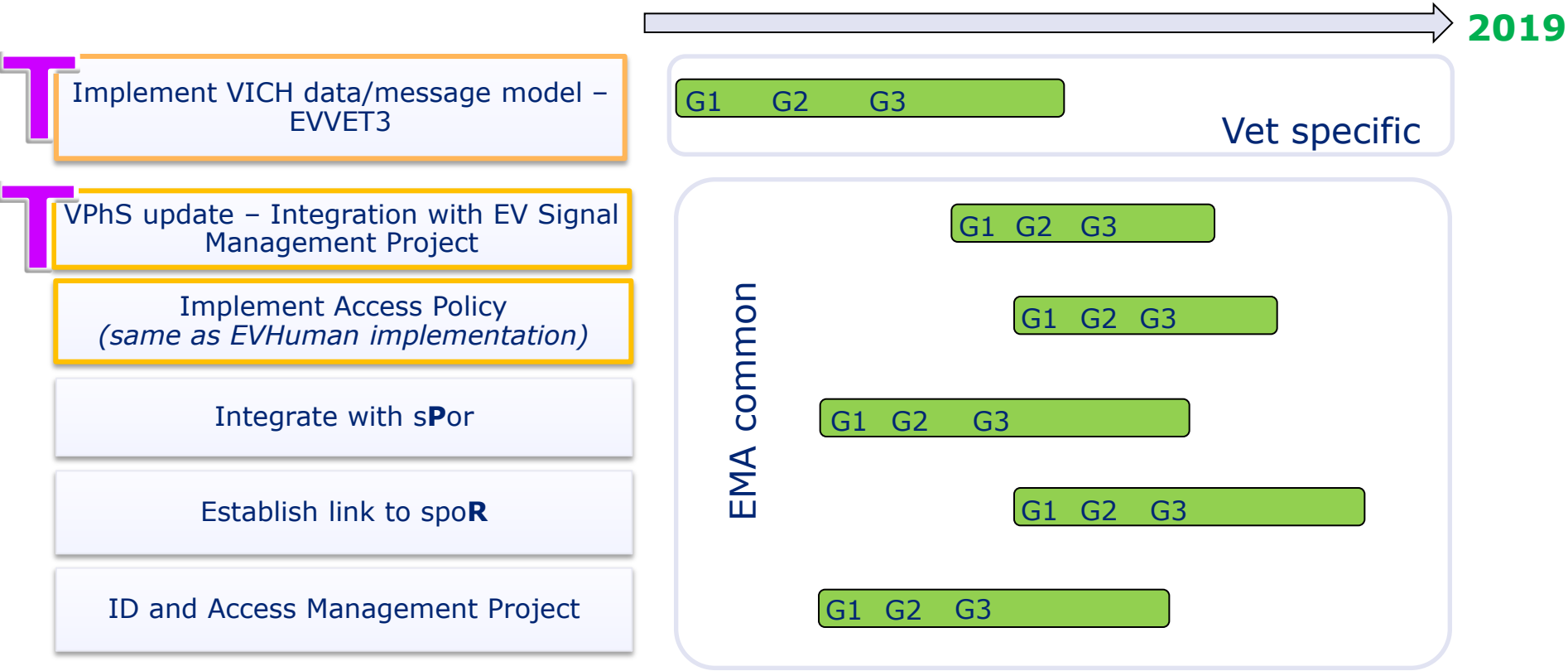


Caveat – Subject to outcome of co-decision procedure

T elematics projects

= Driven by legislation

Union Pharmacovigilance system



Caveat – Subject to outcome of co-decision procedure

Telematics projects

= Driven by legislation

Union Database on Manufacturing and Wholesale Distribution

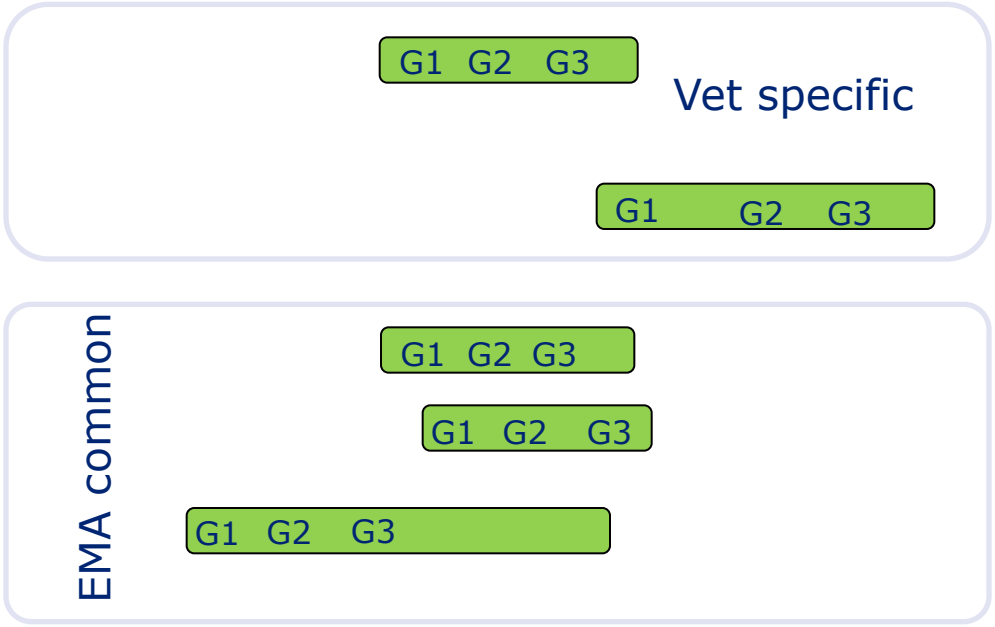
Integrate with Product database (Art. 51 (2a))

Allow export certificates uploads and publishing (Art. 103)

Integrate with sp**O**r

Integrate with spo**R**

ID and Access Management Project



Caveat – Subject to outcome of co-decision procedure

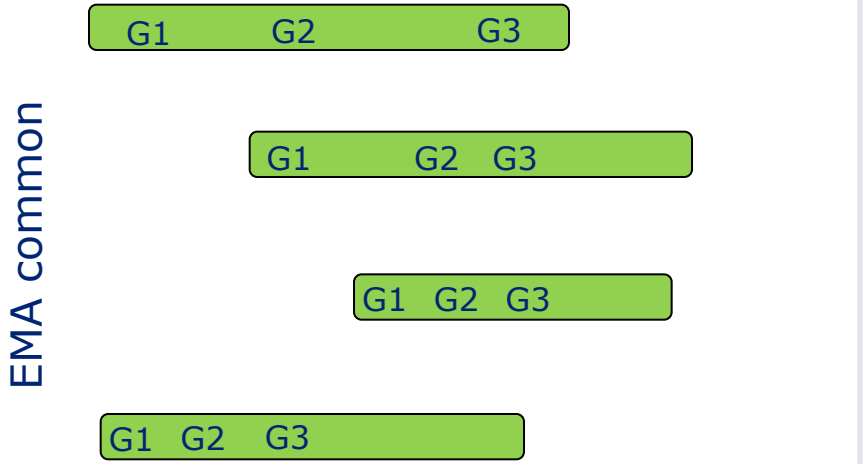
Telematics projects

= Driven by legislation

Electronic submission

2019

- CESSP: E-submission / gateway integration project (**SPOR** compatible)
- **Common repository (for vet applications)**
- Integration with SIAMED
- ID and Access Management Project

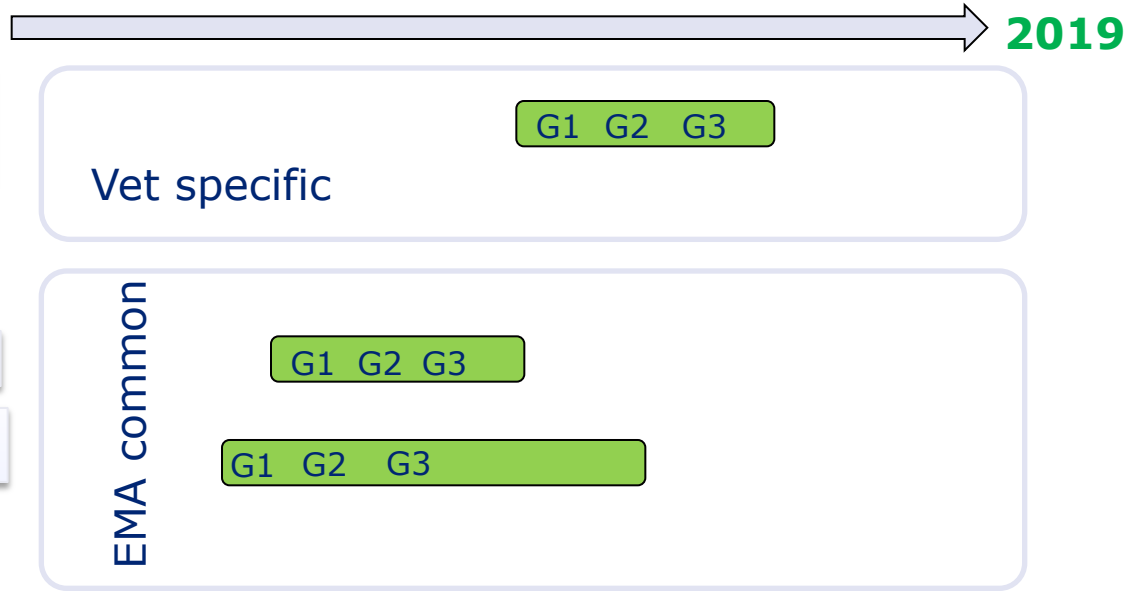


Caveat – Subject to outcome of co-decision procedure

Telematics projects

= Driven by legislation

System for the supervision of use and sales of antimicrobials

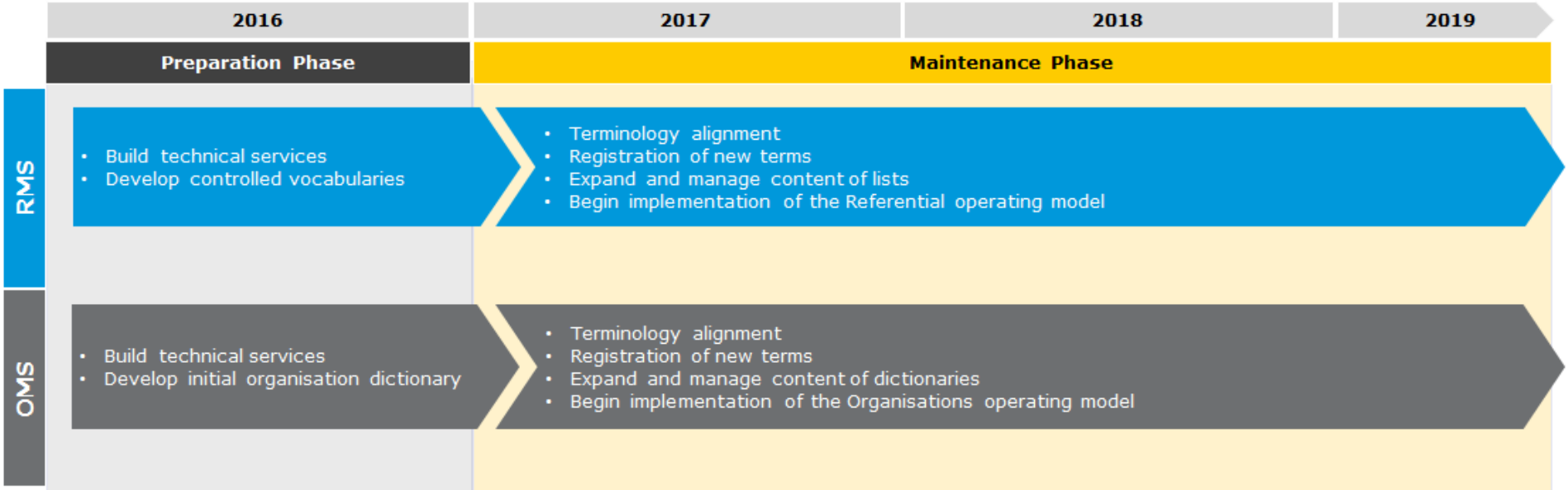


Caveat – Subject to outcome of co-decision procedure

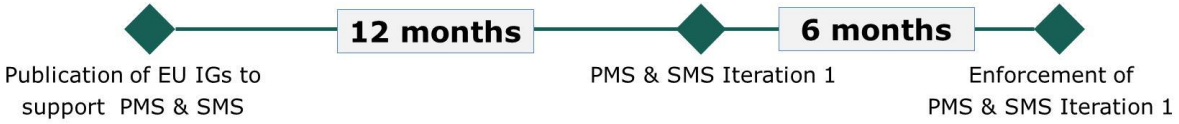
Feedback from the Veterinary SPOR Webinar (22 June)

High level programme timelines

- The focus for 2016 is on implementation of Referentials and Organisations



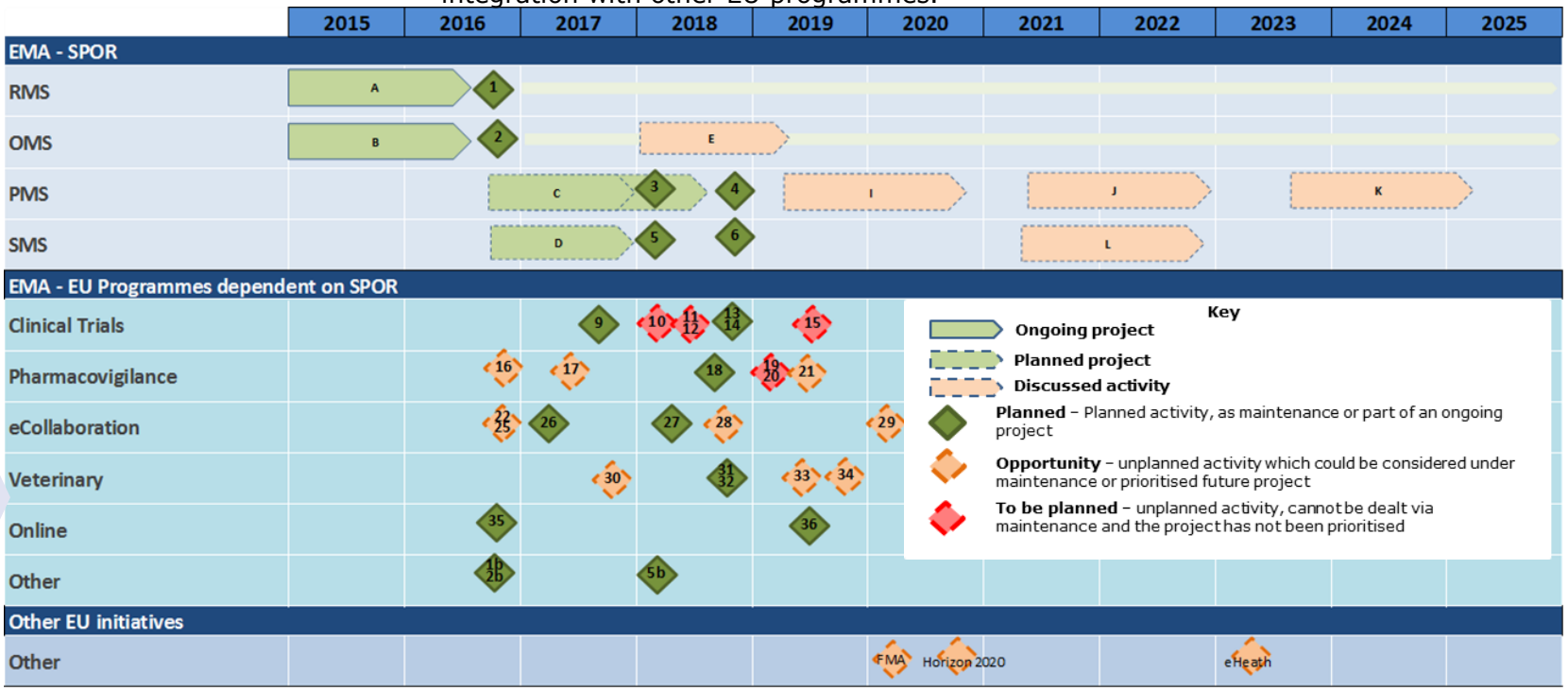
- Referentials and Organisations will lay the data foundations for Products & Substances

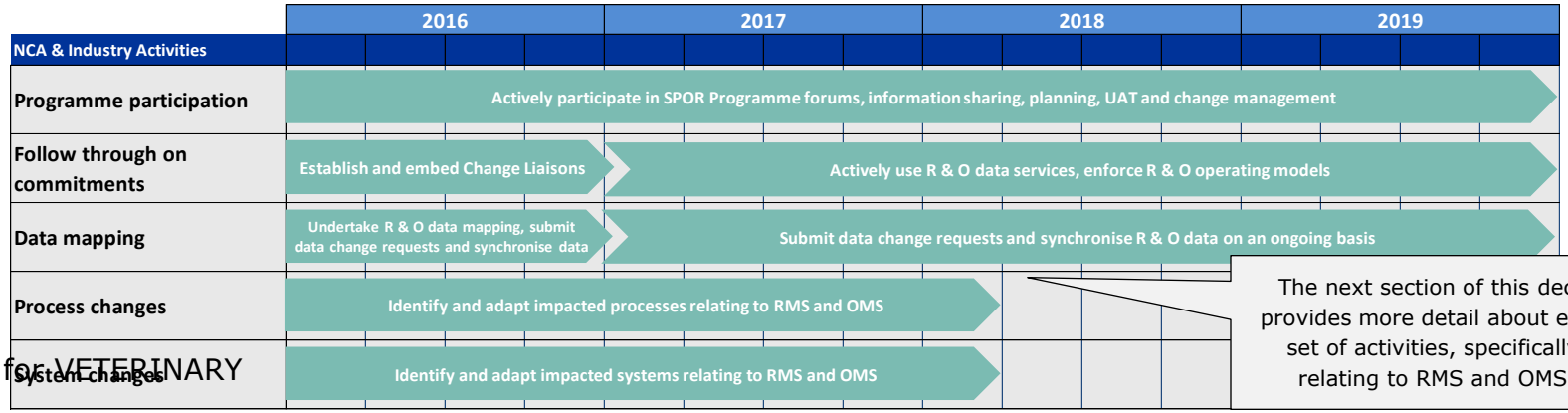


Roll out plan

Ongoing conversations with other programmes. Benefits will be released incrementally through each iteration within SPOR and through integration with other EU programmes.

This roll-out plan demonstrates the drivers behind the timing of SPOR implementation activities. It also sets out critical supporting activities required from NCAs and Industry, specifically relating to **RMS and OMS**





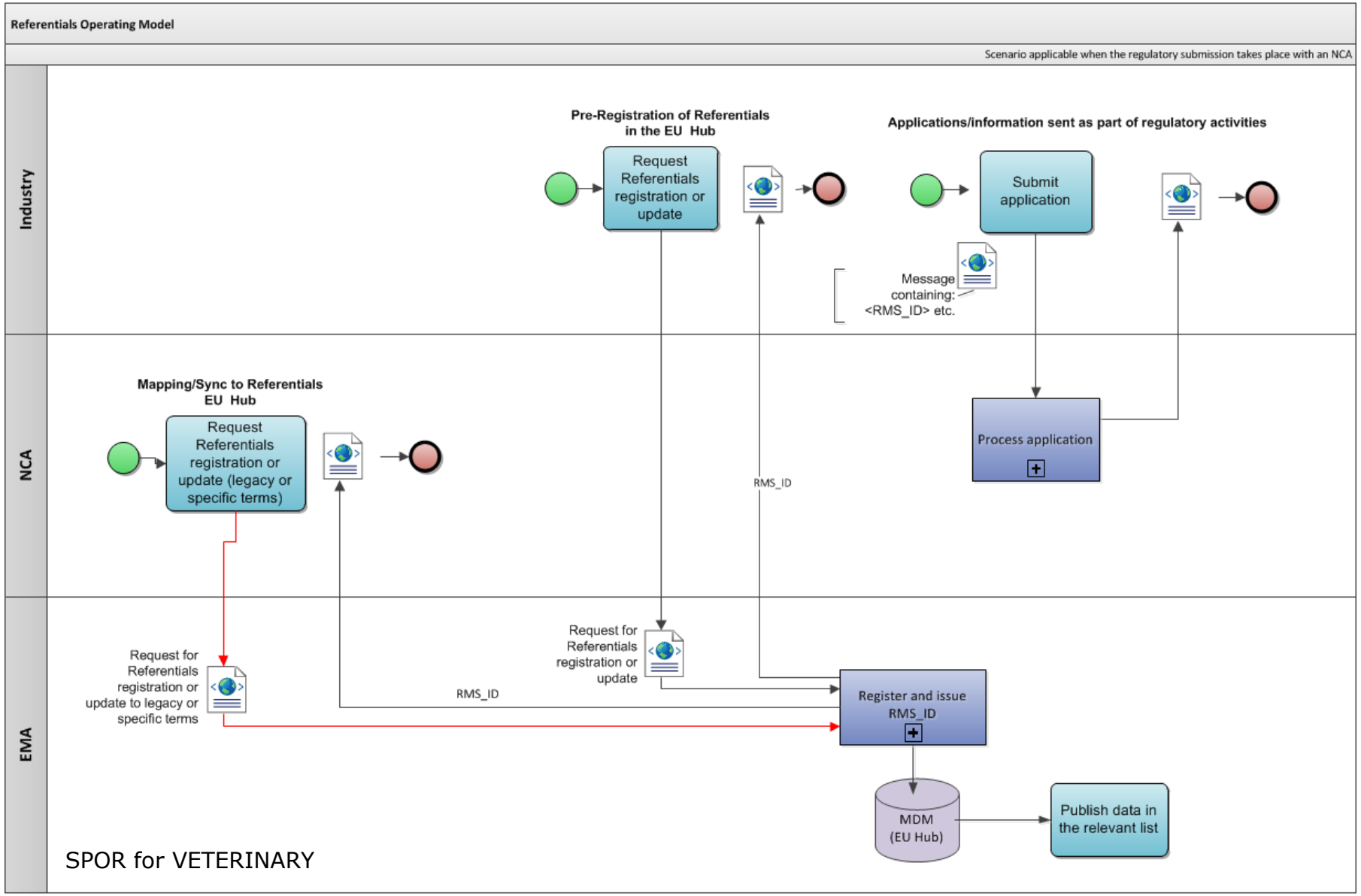
The next section of this deck provides more detail about each set of activities, specifically relating to RMS and OMS

SPOR for VETERINARY

EMA will act as the broker

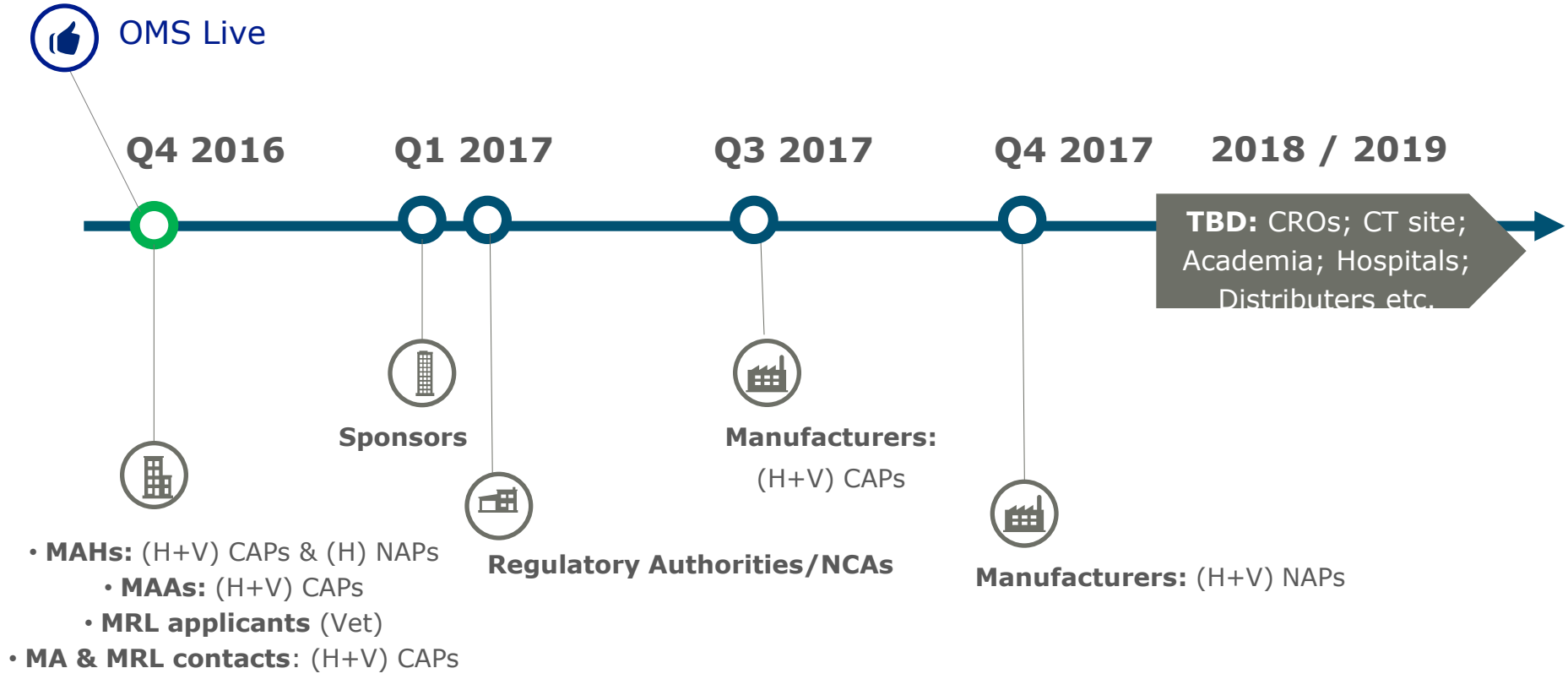
- EMA will provide referential data services to EU network
  - Referentials data maintained by EMA Data Stewards and available in structured format
- EMA will host reference lists from different maintenance organisations (WHO, EDQM, MSSO, BFARM, etc)
  - EDQM: maintenance organisation for ISO IDMP 11239 (ph. forms, units of presentation, routes of administration, packaging)
  - BFARM: maintenance organisation for Units of Measurement (ISO IDMP 11240)
- EMA will be a maintenance organisation for new lists where no maintenance organisation exists
- Common process which requires industry and other parties to request term registration before regulatory submission
- Translations done by NCAs
- All organisations need to register legacy & specific terms with EMA
- This model provides for a global forum, but this aspect is yet to be discussed

RMS data flow - regulatory context

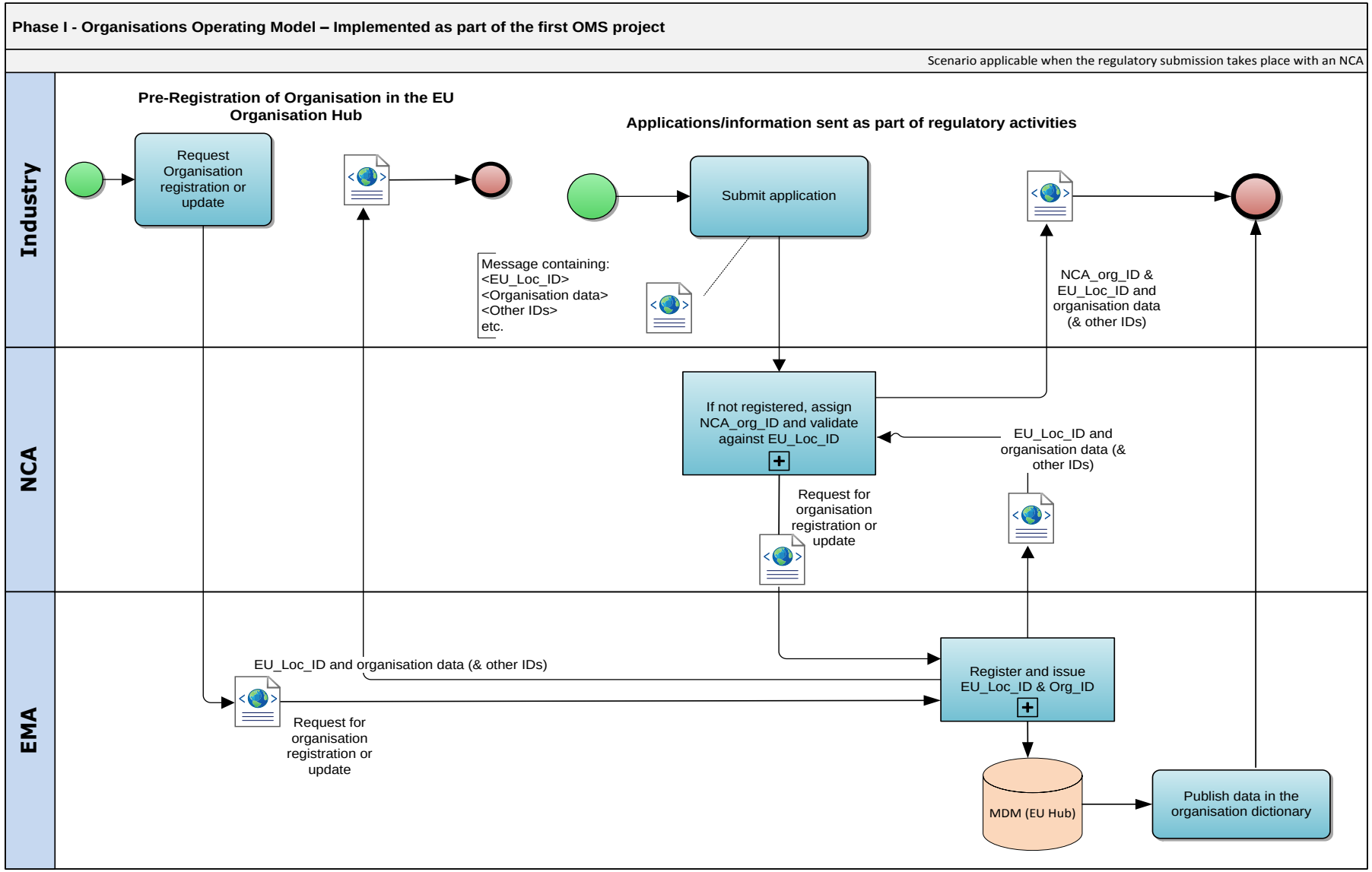


SPOR for VETERINARY

OMS dictionary at go live and how it will be expanded with organisations data



OMS Operating Model – Phase I



Update on the UAT activities

- High level UAT approach drafted and agreed with SPOR Task Force. It envisages wide stakeholder participation
- Appointment of testers almost completed
- Following stakeholder groups are represented:
  - Industry provided a list of testers representing Industry and Vendors
  - NCAs list of testers has been collated
  - Veterinary Industry and Vendors are not yet represented
- Next steps:
  - Plan TCs/Webinars to on-board all testers
  - Review of Test Cases and UAT plan
  - Confirm UAT dates

EU VET MED PROD DATABASE (Eudrapharm Vet)	UNION DATABASE (revised legislation)
Released in February 2015 To be live until 2020->?	Available from 2018 ? Integration of veterinary medicines within ongoing EU Telematics project on SPOR
Part of database system feeding product data into EVVET allowing DWH analysis	SPOR (ISO-IDMP) compliant system
Objective: **EU wide Signal detection** for all EU veterinary medicinal products.	Objective: serving all requirements identified by legislation
Direct submission by Member States	Direct submission by Member States for the legacy data Integrated with other systems, e.g. Electronic submission by MAHs allowing direct data input by MAH for e.g. new applications or variations.

First business objective: allowing signal management at EU level

(Requested by HMA/ESS by letter to ExDir EMA in 2013)

Discrepancy between EU surveillance level for Veterinary CAPs (periodic signal detection in place) and non CAPs (no EU wide analysis possible, because of lack of product data to cross link with adverse event data).

Specifically affecting smaller Member States who only have access to limited local adverse event data.

Required data: National Product Data **AS APPROVED – NO NEED FOR PRIOR STANDARDISATION** – Signal detection runs 95% on the basis of VEDDRA coding within the adverse events.

IT to IT one to one Teleconference meetings

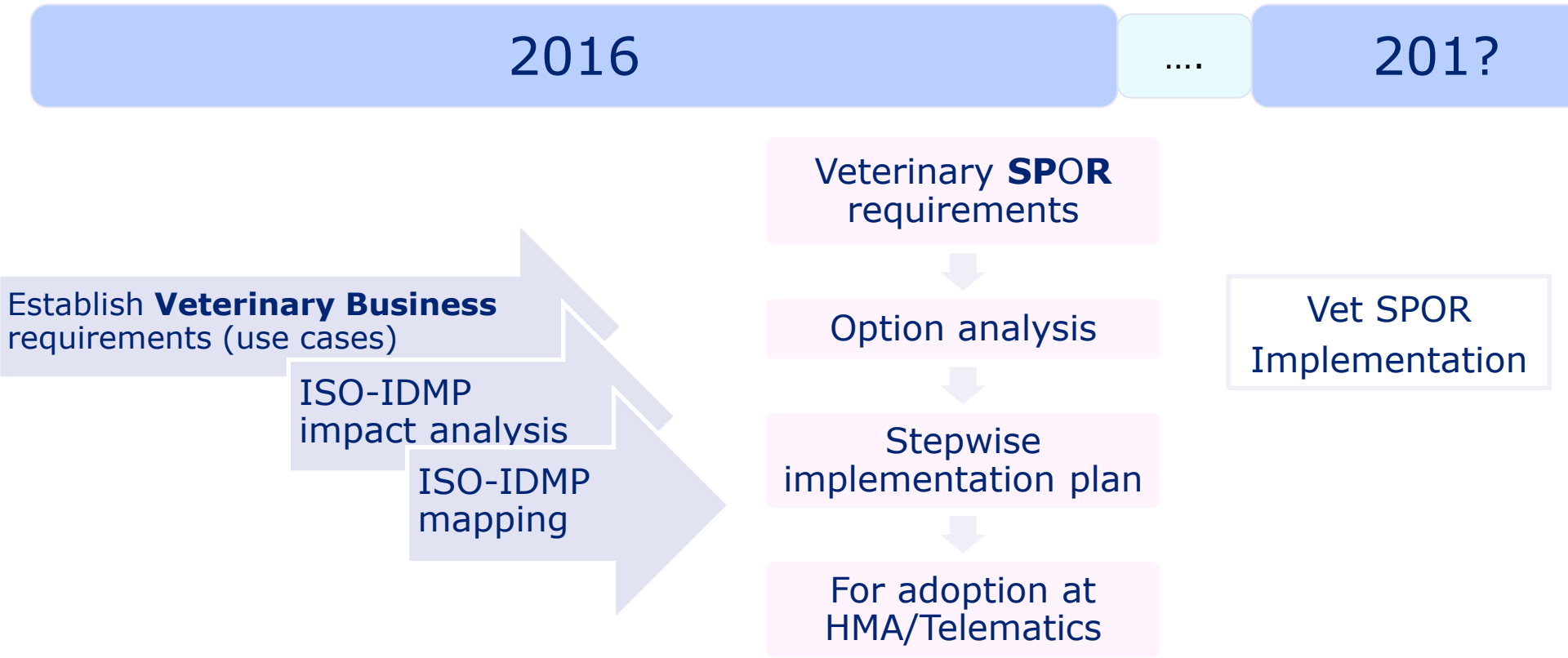
- Meetings have taken place with Finland, Sweden, The Netherlands, Portugal, Slovenia, Latvia, Lithuania, Cyprus, Spain, Belgium and Estonia. (Czech Republic – ongoing exchange in writing).
- Spain finished Gateway testing and sent first product batch for compatibility check (3079/3087 loaded).
- Czech Republic finished gateway testing
- Sweden going into test phase
- All remaining Member States invited for June-July meetings.

French software found useful by Swedish and Spanish authorities to extract data and create the XML message

Number of products in EUVetMedProd per Member State

STATUS	Country Name	Number of products
UP TO DATE	United Kingdom	914
	Ireland	1181
	France	2712
NOT UP TO DATE	Finland	400
	Latvia	1129
Old data removed on request, resubmission pending	The Netherlands	1121
	Italy	1559

Work done within the CGVPS



Veterinary **SP**o**R** requirements

- Mapping of 90 data fields (ISO-IDMP to Eudrapharm) ongoing
- Use case analysis to identify role of each data field
- Use case analysis to clarify and confirm the type of **referential lists** required for each data field (as defined by use case analysis) (allowing stepwise implementation)
- Agreement to be reached by all Member States (within Telematics/HMA?, role ESS?)

PMS Iteration 1 data fields

PMS Iteration 1 now has 80 data elements. This is due to the new model presented in ISO where the marketing status date has been made explicit as two separate fields (whilst before it was 1 field containing two pieces of information for Stop/Start date). The content doesn't change; it is only the model design that has been amended.

Medicinal Product
MPID
Combined Pharmaceutical Dose Form
IMPID Corss-Reference
Additional monitoring indicator
Orphan Designation Status
Name (Med.Product)
Invented Name Part
Scientific Name Part
Strength Name Part
Pharmaceutical Dose Form Part
Formulation Part
Intended Use Part
Target Population Part
Container or Pack Part
Device Name Part
Trademark or Company Name Part
Time/Period Part
Flavour Part
Classification System
Classification System Value
Version Date
Version Identifier
Document Type
Document Identifier
Regulated Document
Document Effective Date
Country
Language

Marketing Authorisation
Marketing Authorisation Number
Country
Legal Status of Supply
Authorisation Status
Authorisation Status Date
Date of First Authorisation
Procedure Identifier/Number (e.g. MRP number)
Procedure Type (e.g. MRP/DCP)
Country (national authorisation)
Marketing Authorization Number (national authorisation)

Organisation (e.g. MAH, QPPV, PSMFL)
Identifier
Role
Location Address
Location Role
Entity Identifier (according to Role e.g. PSMF ID)

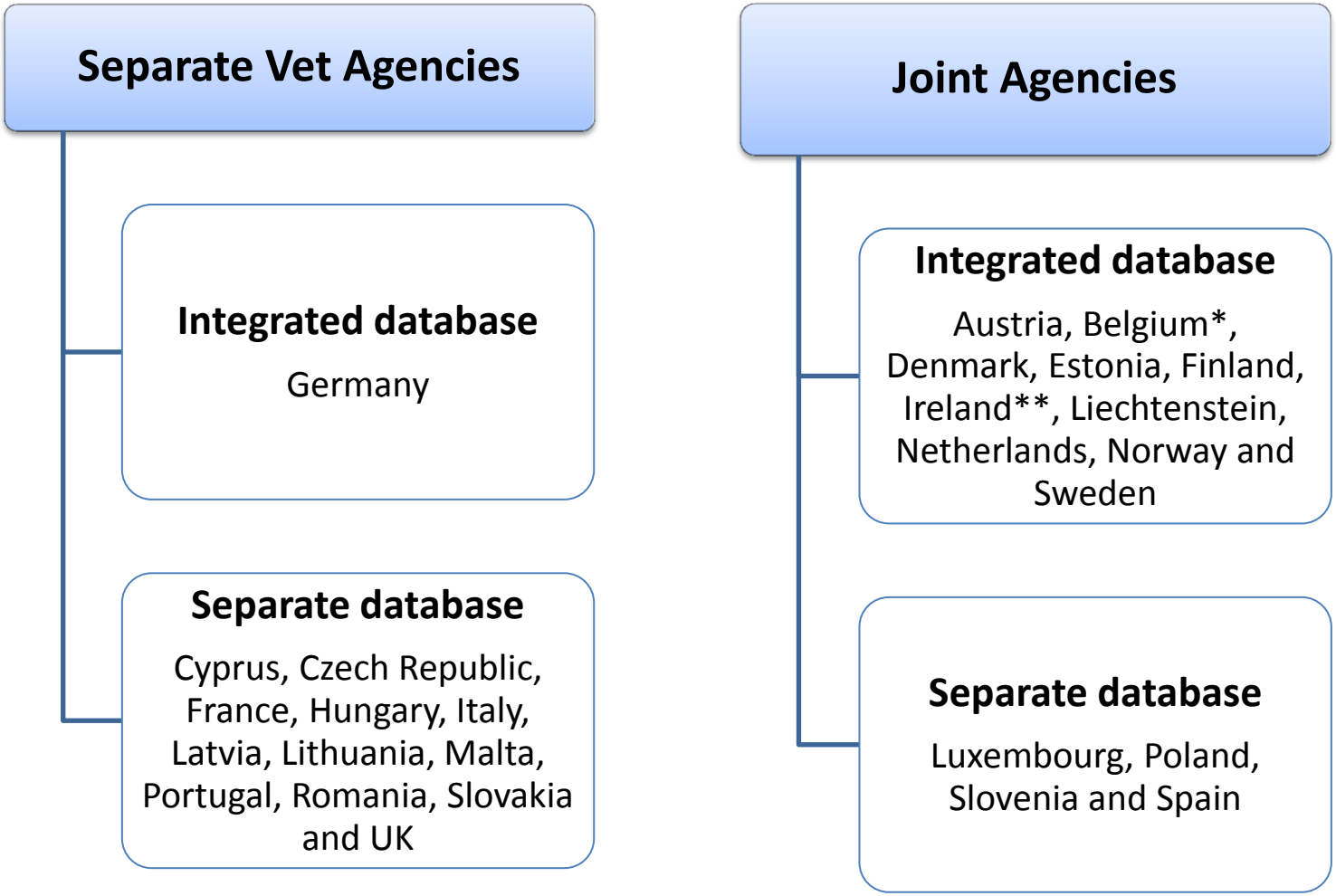
Marketing information
Country
Marketing Status
Marketing Start Date
Marketing Stop Date
Risk of shortage supply
Risk of shortage supply comment

Indication
Indication Text
Indication as "Disease/ Symptom/ Procedure"
Co-Morbidity
Intended Effect

Pharmaceutical Products
Administrable Dose Form
Unit of Presentation
Route of Administration
PhPID Identifier Sets
Device Type (combined medical device ATMP)
Device Trade Name (combined medical device ATMP)

Ingredient
Ingredient Role
Substance
Specified Substance
Confidentiality Indicator
Strength Range (Presentation)
Strength Range (Concentration)
Reference Strength Substance
Reference Strength Specified Substance
Reference Strength Range

Package description
PCID
Package Description
Package Item (Container) Type
Package Item (Container) Quantity
Material
Component Type
Component Material
Manufactured Dose Form
Unit of Presentation
Manufactured Item Quantity
Device Type
Device Trade Name



No info from Bulgaria, Croatia, Greece and Iceland

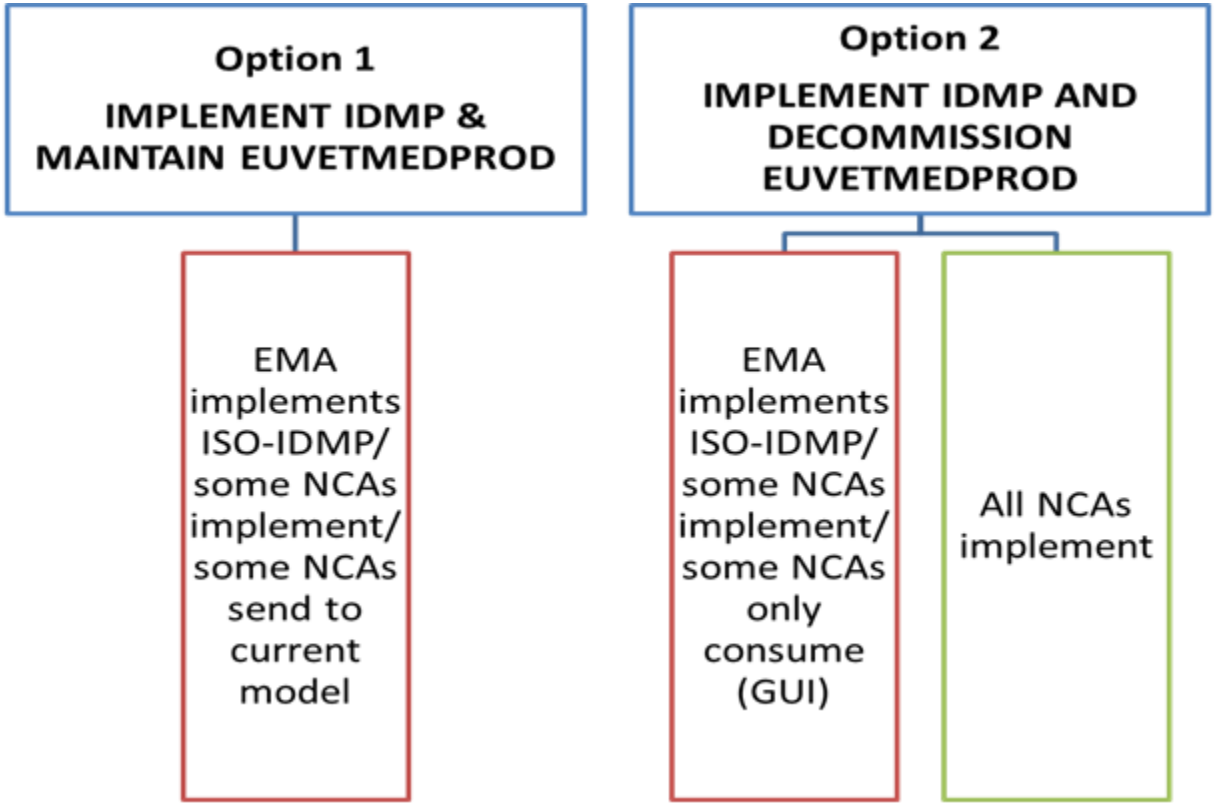
* It is one ICT system, for both domains, which are separate.

** Integrated for references and substances

Option analysis

- Given: S&P will also cater for VMPs in the EU
  - Allowing common product data message, data model and standardisation
  - Allowing joint Agencies to operate with only one system
- Which Member States will be able to comply with the data-model and within which timeframe?
- Maintain EU Vet Med Prod Dbase alongside S&P?
- Dedicated meeting for veterinary stakeholders in September?

Option analysis - *DRAFT*



Next for Vet

- Member States to provide Vet product data by end 2016 to allow signal detection.
- R and O ongoing – UAT with vet participation
- Participate and follow-up on Use case analysis and option analysis
- September Change liaison face to face meeting – 1 dedicated Veterinary meeting day
- Plan for Member States to endorse stepwise implementation plan for P based on option analysis

Annex

- Draft Veterinary regulation analysis

Draft regulation –Union Product Database (Art. 51)

- Shall be set up and maintained by the Agency
- To contain information on:
  - VMPs authorised within the EU (including homeopathics (Art. 88 (2)))
  - + SPC, Package leaflet, list of sites where each product is manufactured
- Within 12 months, Agency provides format and currently foreseen that **NCAs submit data** *(Vet Specific) (Implementing acts?)*
- Agency + MSs and Commission draw up functional specifications
- Access policy defined by Art. 52 (similar as current legislation)
- MAHs to record directly certain variations (Art. 60 (1)) *(NEW and Vet Specific)*
- MAHs to record dates when product is placed on market (Art. 53)
- QPPV to include reference number of the PhV Masterfile. (+ info on QPVV?) *(similar than Human)*

Draft regulation – Pharmacovigilance

- **Union pharmacovigilance system (Art. 73**)
  - Shall be set up by MSs, Commission and the Agency and MAHs
  - NCAs, Agency and MAHs make available to healthcare professionals and animal holders different means of reporting to them.
- **Union pharmacovigilance database (Art. 74)**
  - Shall be set up and maintained by the Agency
- Access policy (Art. 75) (*similar than current system*)
  - + information on the process and outcome of the signal management referred to in Art 81 *(NEW)*
- Results of the pharmacovigilance inspections shall be collected in the pharmacovigilance database (Art. 128 (3)) *(NEW and VET Specific)*
- Master File Related requirement – see product database

Draft Regulation - Database on manufacturing authorisations (Art. 94)

- A Union database on manufacturing, import and wholesale distribution shall be set up and maintained by the Agency ('manufacturing and wholesale distribution database')

  Must record the following authorisations and certificates:
  - Manufacturing authorisations (Art. 94)
  - Wholesale Distribution authorisations (Art. 105)
  - GMP certificates (Art. 127(2))
  - Certificates of manufacturing authorisations (Art. 103) *(NEW and VET Specific)*

"together with information on the veterinary medicinal products covered by the authorisations." *(NEW and VET Specific)*

- Access policy (Art. 95) – *(similar to current situation)*
- Integration with product database – see product database (Art. 51 (2b)) *(NEW and Vet Specific)*

Draft regulation – Electronic Submission

Explicit:

- Applications shall be submitted electronically. For applications submitted in accordance with the centralised marketing authorisation procedure, the formats made available by the Agency shall be used. (Art. 6(3))
- Direct submission of variations by MAHs to the product database (Art. 60(1))

Implicit:

- eSubmission *should* be integrated with SPOR and the workflow