Veterinary and Substance, Product, Organisation and Referential (SPOR)

SPOR TF meeting 13 December 2016

Presented by: Jos Olaerts

Veterinary Division - EMA

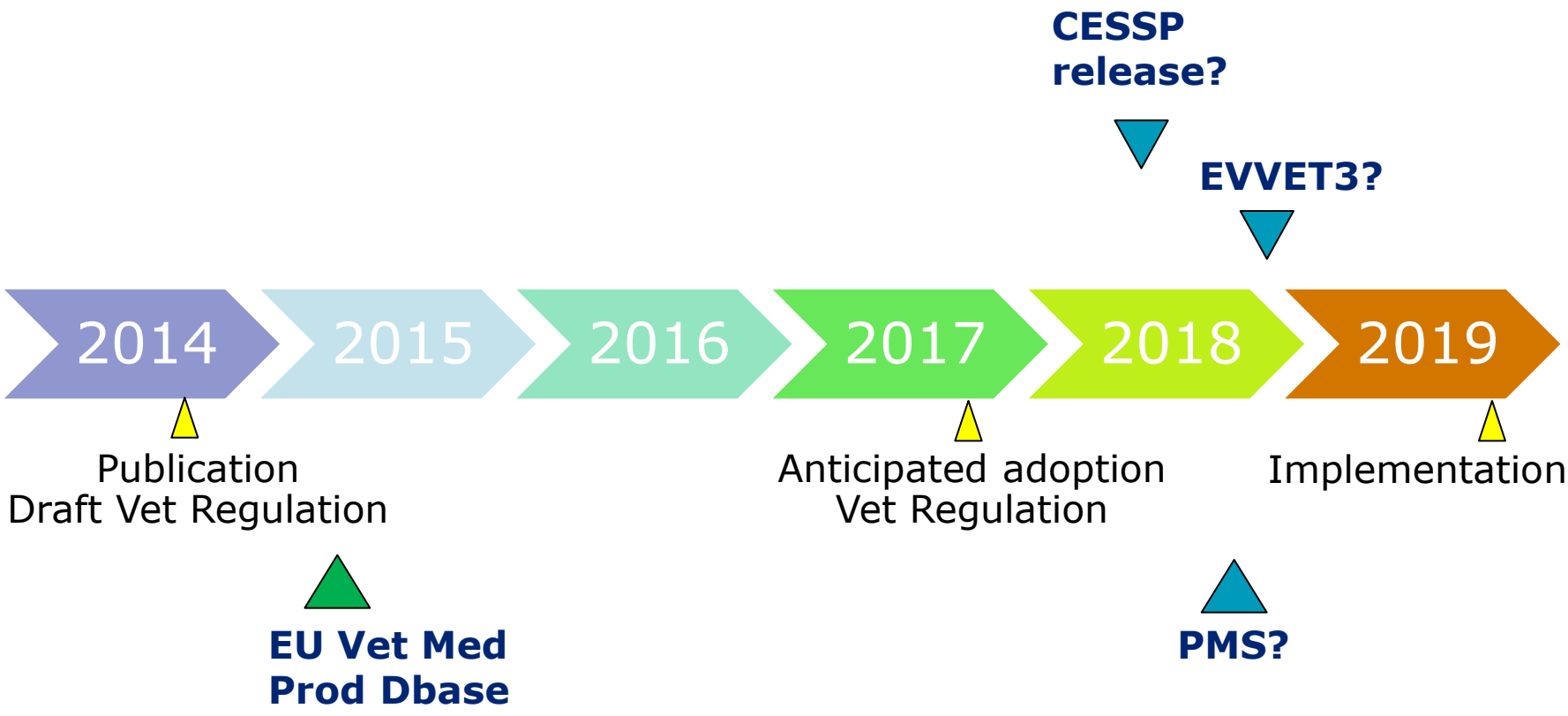
30’

Overview - drivers

Data and data-model

Operating model – Discussion

What to do for MS and Industry - Discussion


CESSP release?
EVVET3?
2014
2015
2016
2017
2018
2019
Publication Draft Vet Regulation
EU Vet Med Prod Dbase
Anticipated adoption Vet Regulation
PMS?
Implementation

Main drivers for VET SPOR implementation

CESSP

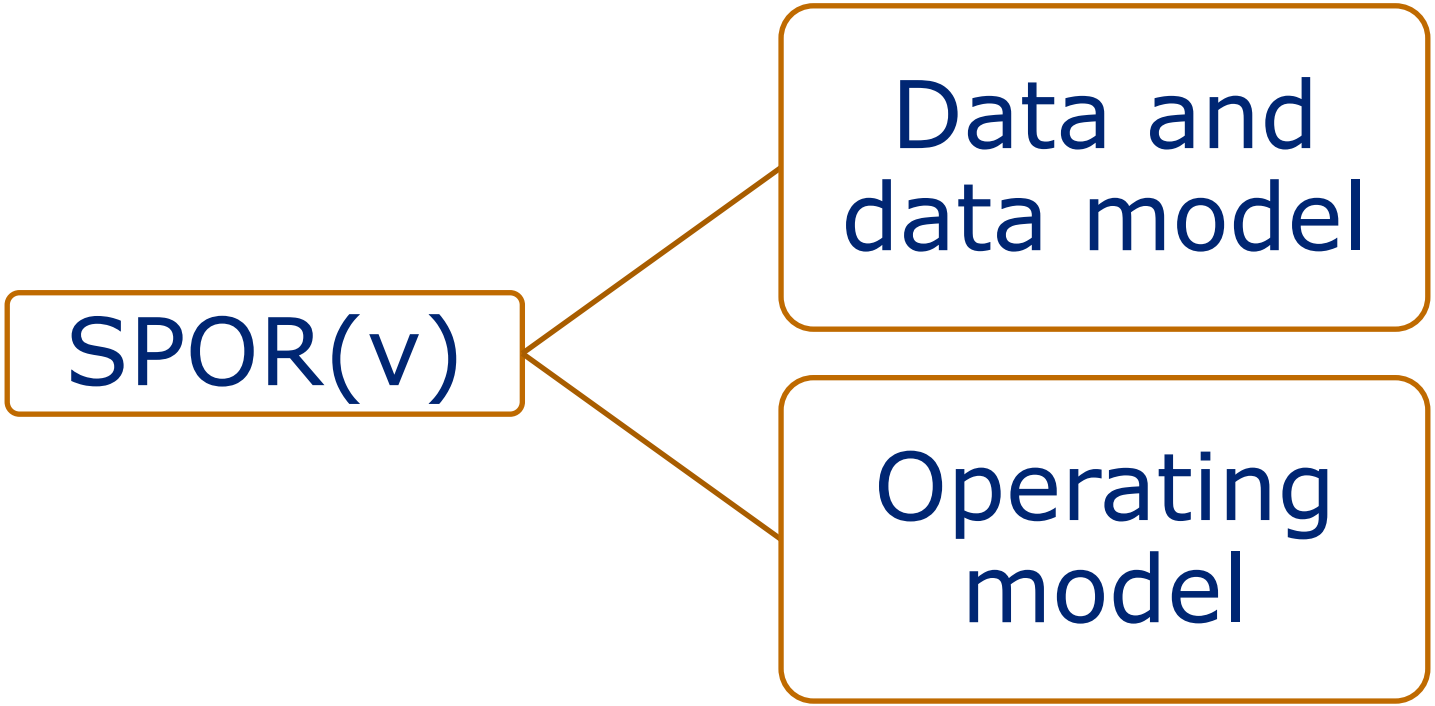
- Allowing SPOR compliant submission of new applications for CAPS and Non-CAPS
- Allowing SPOR compliant submission of **MRL applications**
- Allowing SPOR compliant submission of variations

EVVET

- Use P
- Use S
- Use R

EVDAS

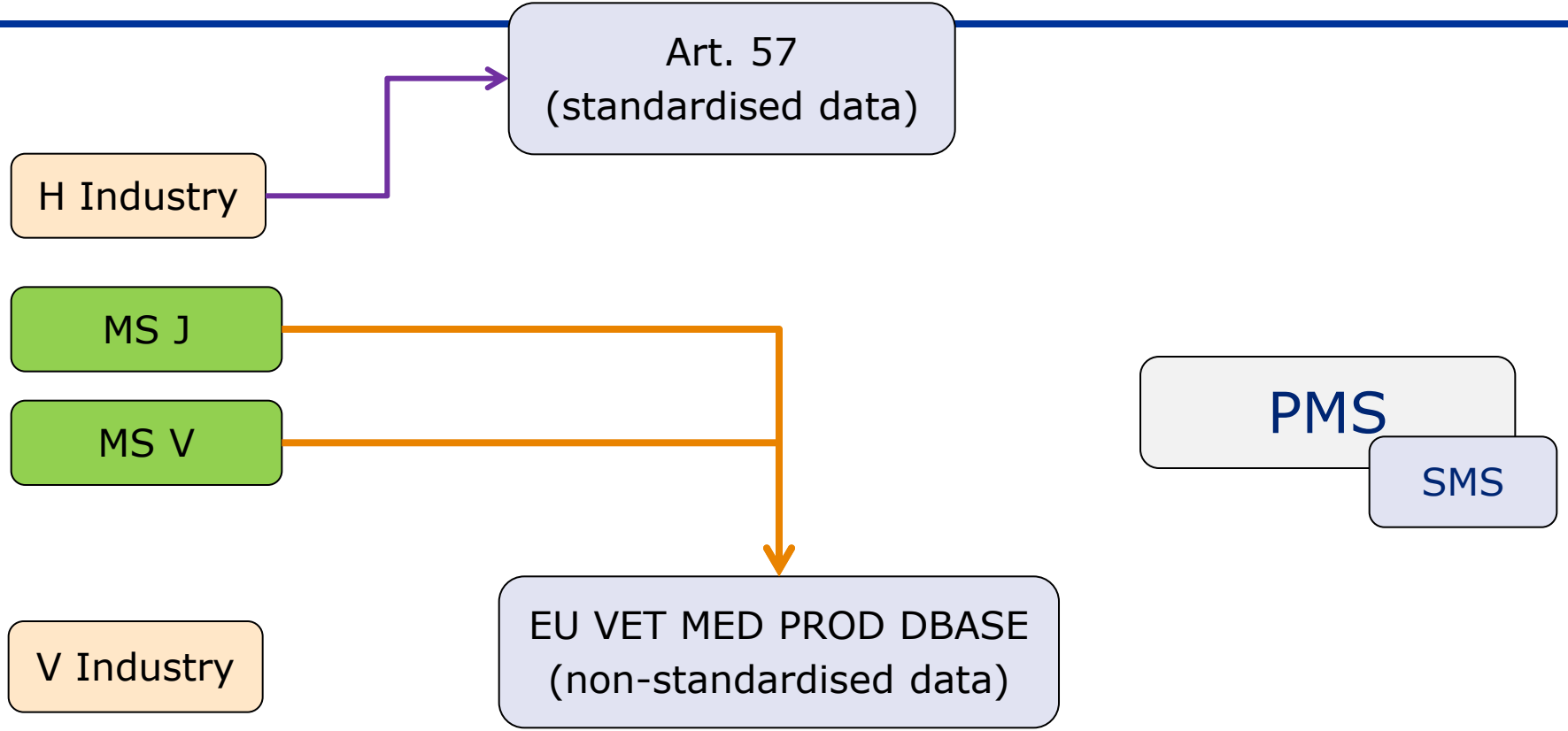
- Use P
- Use S
- Use R

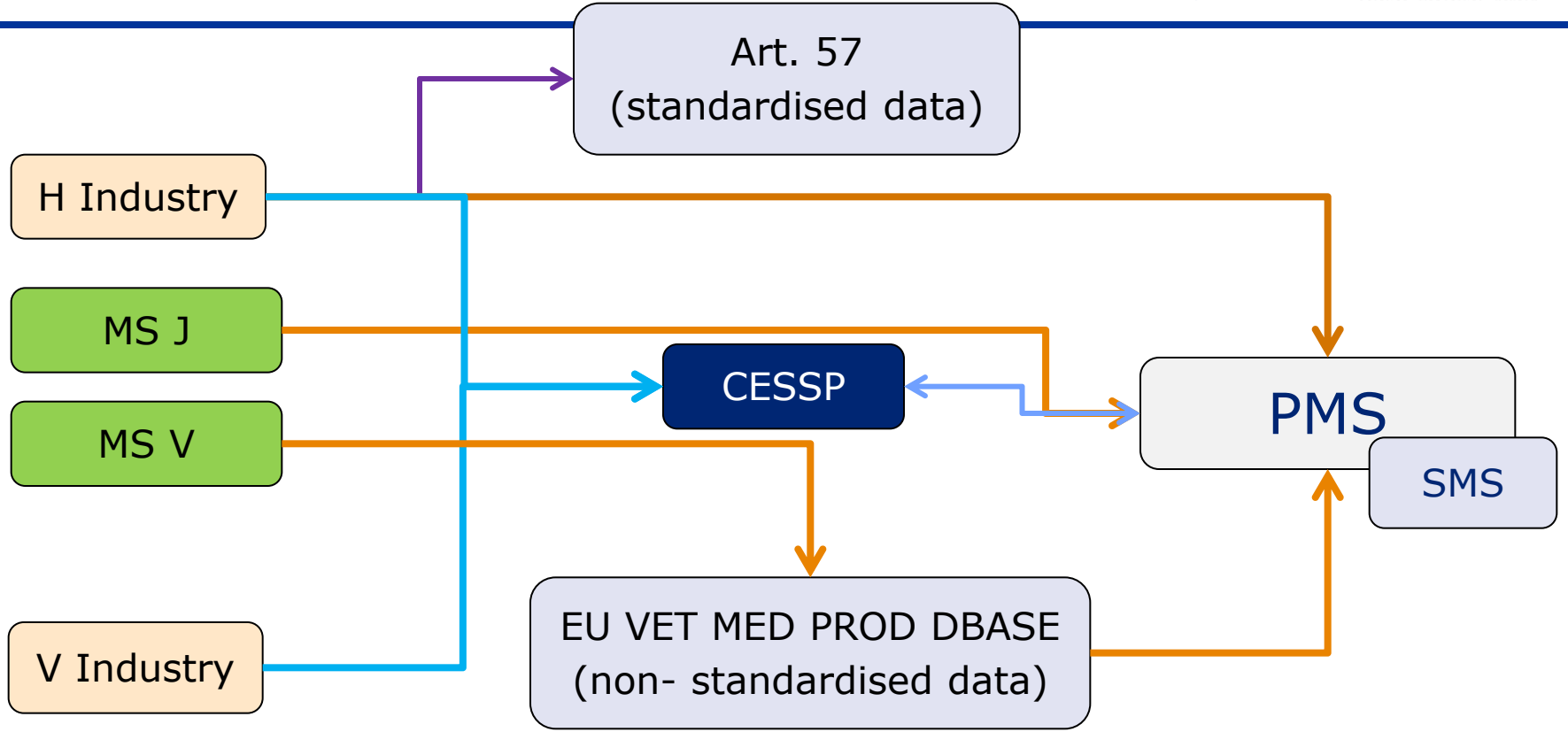

SPOR(v)
Data and data model
Operating model

Data and Data model

S & P	• Use case analysis – ISO IDMP/SPOR iteration 1 (to be finalised) • Data model – Species / ATCVet / Route of admin • Immunologicals
O	• O from CAPs and MRL applications in OMS • Waiting for sufficient data load in EU Vet Med Prod dbase
R	• Species list • MRL related lists

Operating model


Art. 57
(standardised data)
H Industry
MS J
MS V
PMS
SMS
EU VET MED PROD DBASE
(non-standardised data)
V Industry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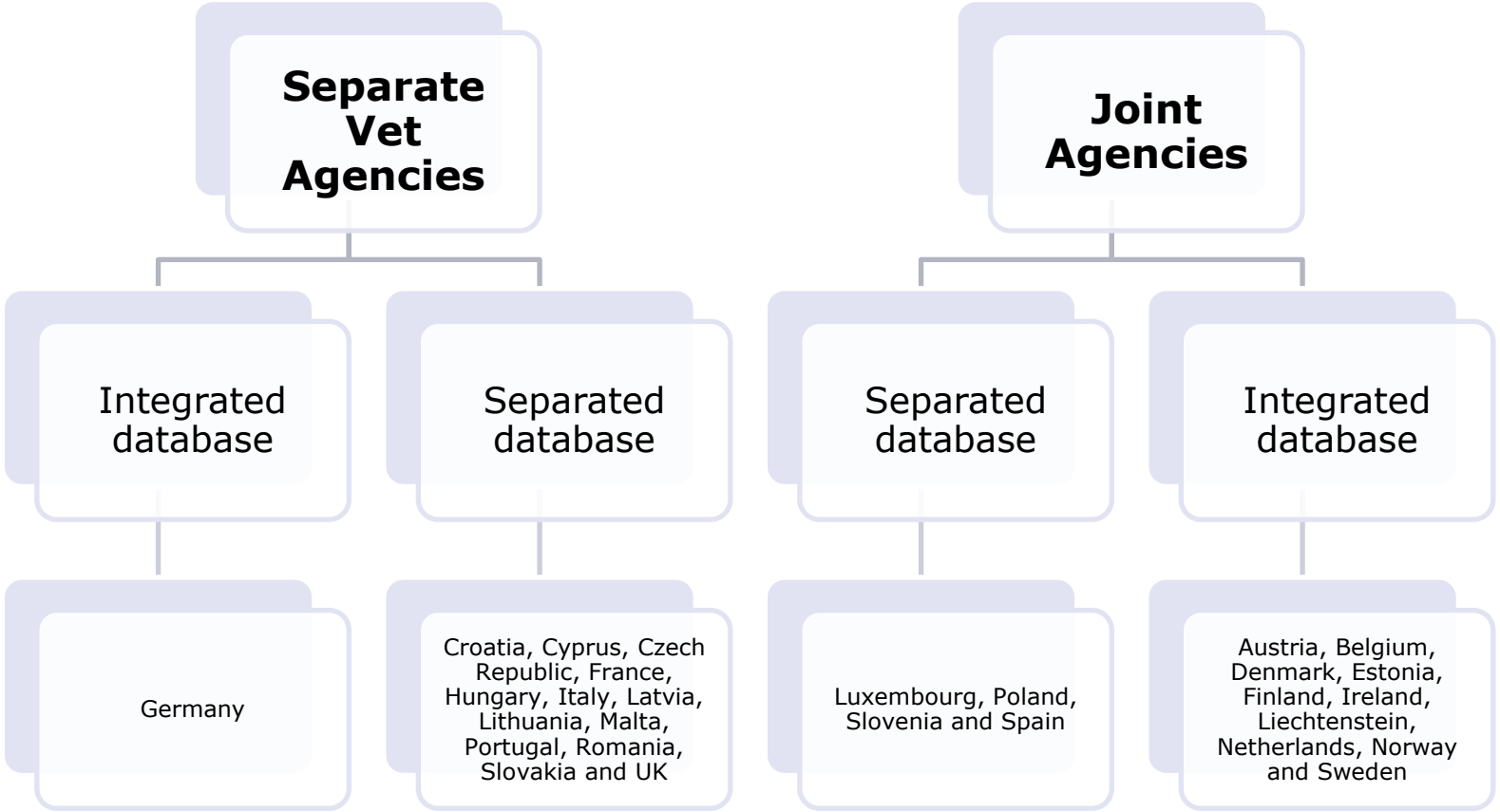
Separate Vet Agencies
Integrated database
Germany
Separated database
Croatia, Cyprus, Czech Republic, France, Hungary, Italy, Latvia, Lithuania, Malta, Portugal, Romania, Slovakia and UK
Joint Agencies
Separated database
Luxembourg, Poland, Slovenia and Spain
Integrated database
Austria, Belgium, Denmark, Estonia, Finland, Ireland, Liechtenstein, Netherlands, Norway and Sweden

Operating model - questions

- Which operating model?
- How much mapping will be required, by whom, and how to organise mapping from EU Vet Med Prod Dbase to PMS?
- How to ensure that CESSP will be able to consume adequate EU VMP data when going live for variation applications?
- Vet Industry to complete missing data while using CESSP?
- Applications through CESSP will produce SPOR compliant data - hence is it uberhaubt possible for e.g. Vet Agencies to remain non-SPOR compliant? Which operating model allows the best use of centralised systems reducing local system requirements for Vet Agencies to a minimum?

Member States – to do

- Initiate mapping to R
- Participate to the CGVPS discussions – process and operating model

Industry– to do

- Initiate mapping to R
- Participate to the CGVPS discussions – process and operating model

PMS - Governance