EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance and product data

Future Legislation: pharmacovigilance

EMA Veterinary Medicines Info Day 16-17 March 2017, London

Presented by Jos Olaerts on 17 March 2017
European Medicines Agency - Veterinary Medicines Division

Overview

- Key PhV elements of draft legislation
- Anticipated impact on pharmacovigilance related systems
  - Focus on product data
- To do

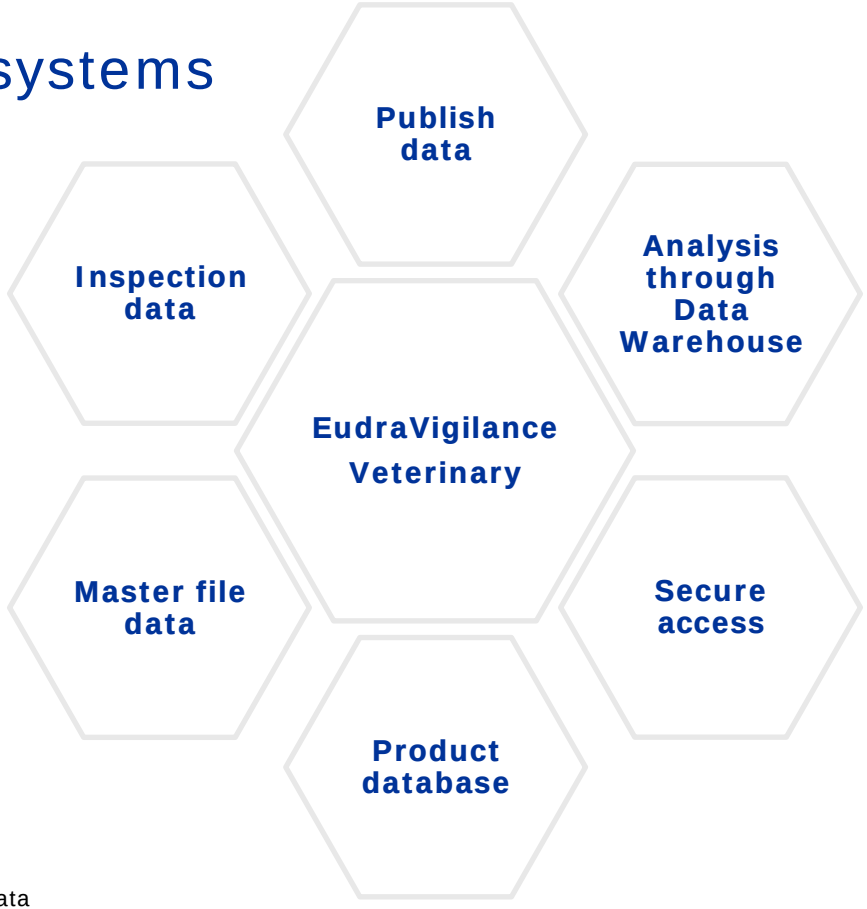
This presentation is based on draft legislation which may change further to amendments thereto, following discussions at the level of the European Parliament and the Council of the European Union.

- Maintain high standard of post-marketing surveillance
- Simplification
- Reduce administrative burden
- Address known current inadequacies
- Use technological progress

Key new elements

	Simplification	Reduce administrative burden	Address known issues	Use technological progress
Adverse event (no distinction serious/non-serious)	✓✓	✓✓	✓✓	✓✓
30 day reporting	✓✓	✓✓	✓	✓
Signal management to replace PSURs	✓✓	✓	✓	✓✓✓
Master file concept	✓	✓✓		✓
PhV Inspections		✓	✓	

Impact on PhV systems



EudraVigilance Veterinary

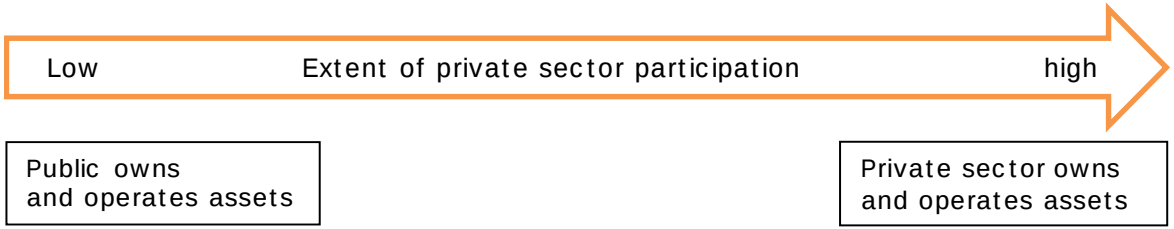
Compliance with international standards - VICH

Technology update and improve user experience

Improve access and publish data

EVVET3

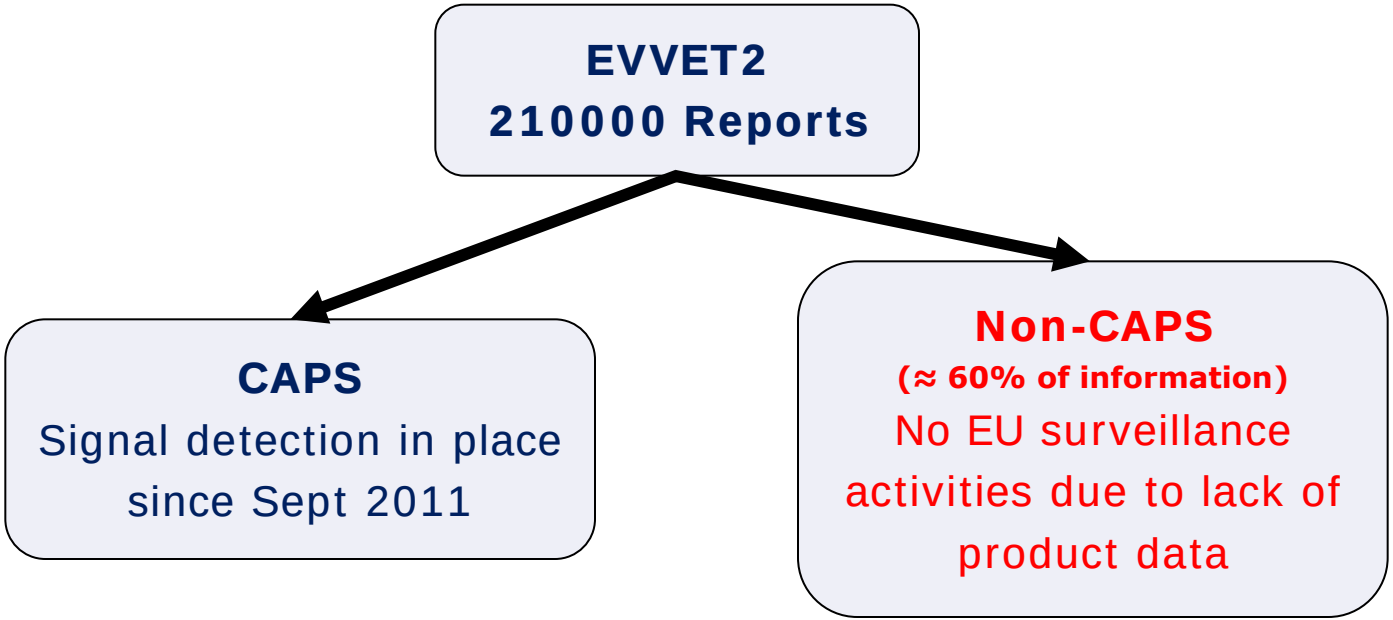
- Start of project - Gate 1 – end Q1
- Survey to IT Directors and Pharmacovigilance Working party
  - Great majority of Member States support the vision of a single EU Veterinary Pharmacovigilance system - some Member States still require complementary national systems
  - Majority of Member States support looking into potential models that allow for private/public partnership for development and/or operation

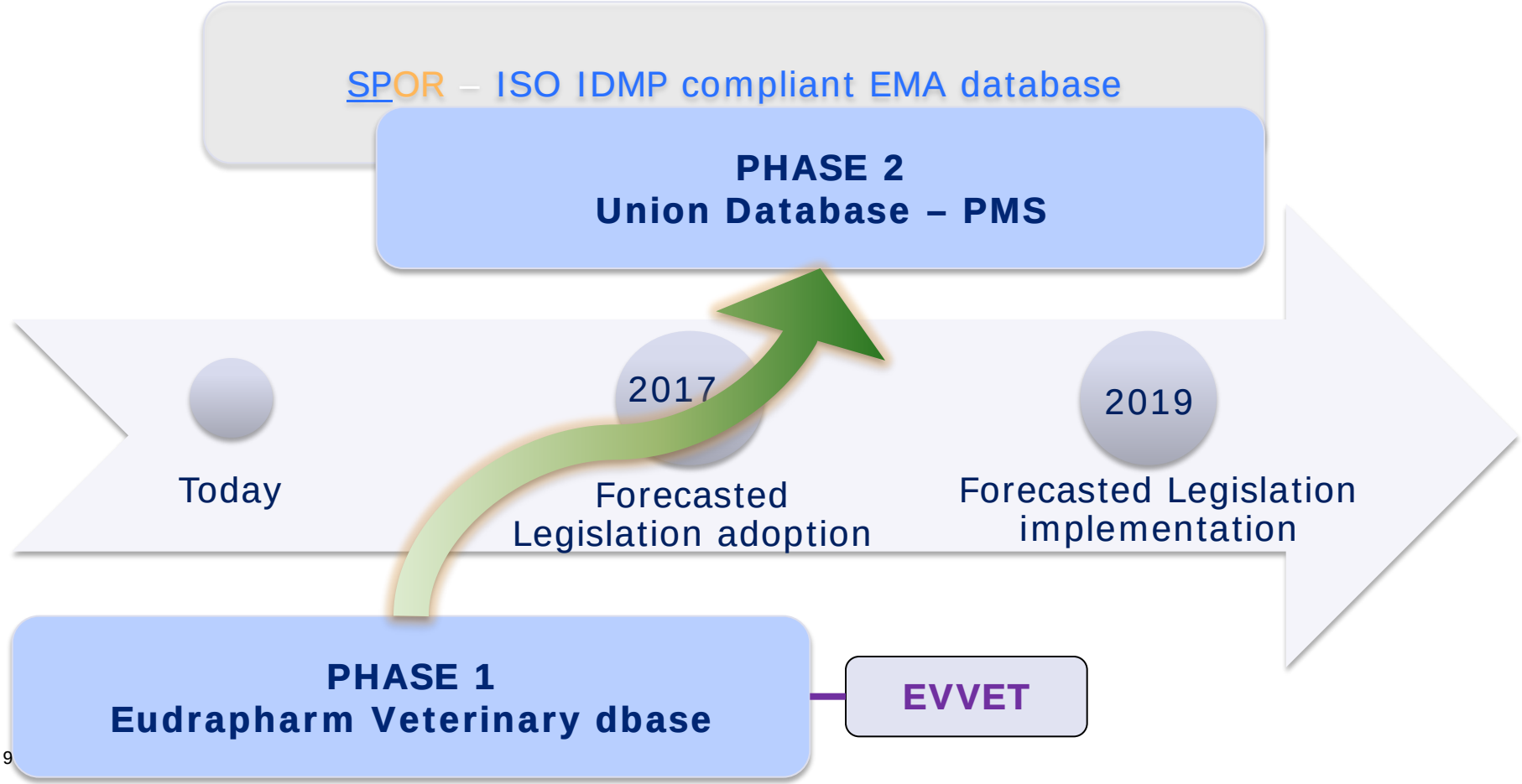


EVVET2 to 3

- Consultative Group for Veterinary Medicinal Product Data Systems (CGVPS)
  - Day to day operational issues / bugs
  - @ start of EVVET3 project
    - Revisit of 2010 - 9 Business use cases + anticipated legislation related changes
      - Access to the data
      - Master file
      - Link to PhV inspections
      - Analysis and publication of data
      - PRODUCT DATA

Current 2-speed surveillance system in the EU for VMPs




SPOR – ISO IDMP compliant EMA database
PHASE 2
Union Database – PMS
Today
2017
Forecasted
Legislation adoption
2019
Forecasted Legislation
implementation
PHASE 1
Eudrapharm Veterinary dbase
EVVET

Sms	• Substance data management system
Pms	• Product data management system
Oms	• Organisational data management system
Rms	• Reference data management system
CESSP	• Common European Single Submission Portal

PRODUCT DATABASES AT NATIONAL LEVEL

EUROPEAN MEDICINES AGENCY

Separate Vet Agencies

Integrated database

Germany

Separate database

Croatia, Cyprus, Czech Republic, France, Hungary, Italy, Latvia, Lithuania, Malta, Portugal, Romania, Slovakia and UK

Joint Agencies

Integrated database

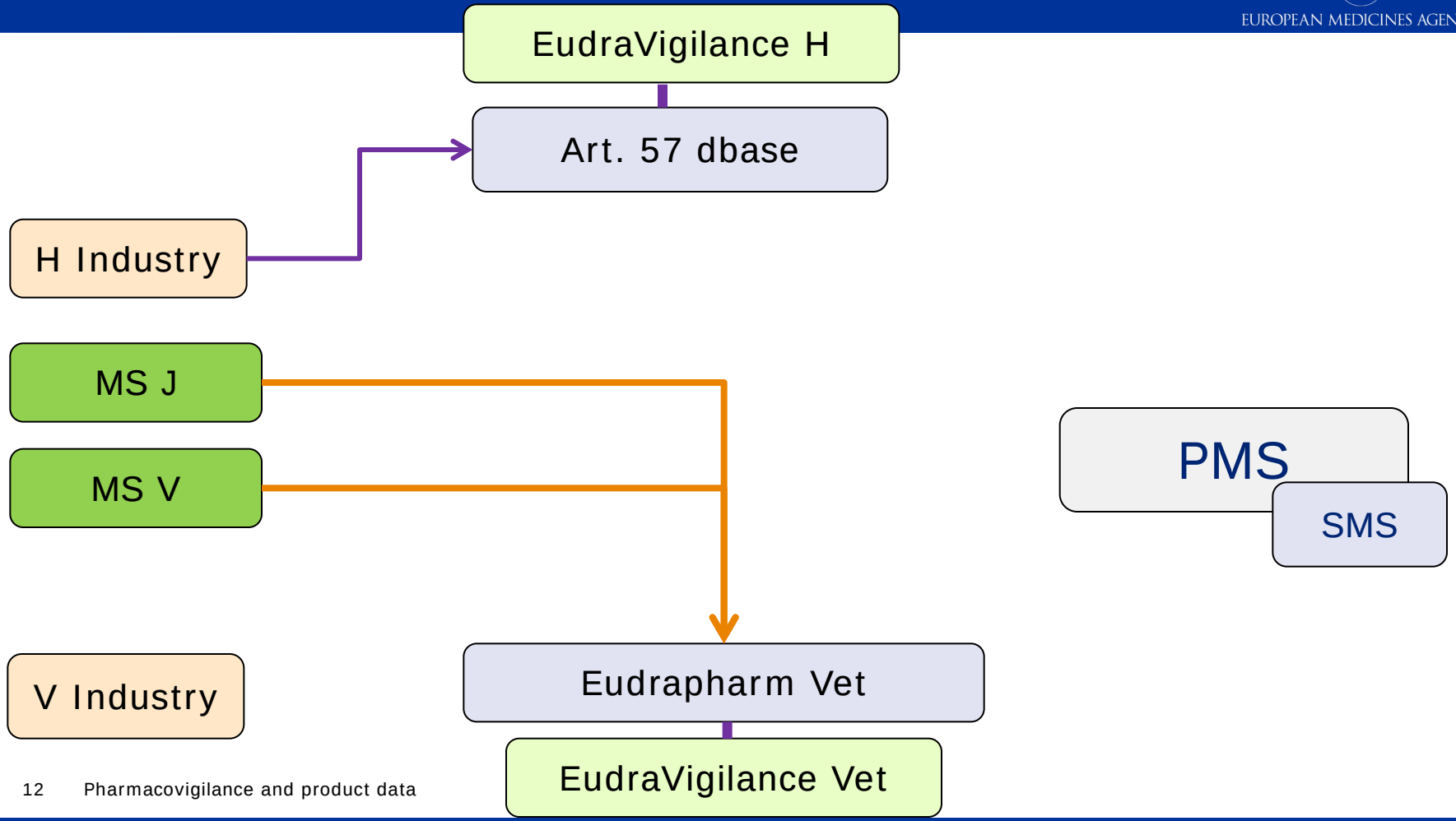
Austria, Belgium*, Denmark, Estonia, Finland, Ireland**, Liechtenstein, Netherlands, Norway and Sweden

Separate database

Luxembourg, Poland, Slovenia and Spain

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

** Integrated for references and substances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Art. 57 dbase
H Industry
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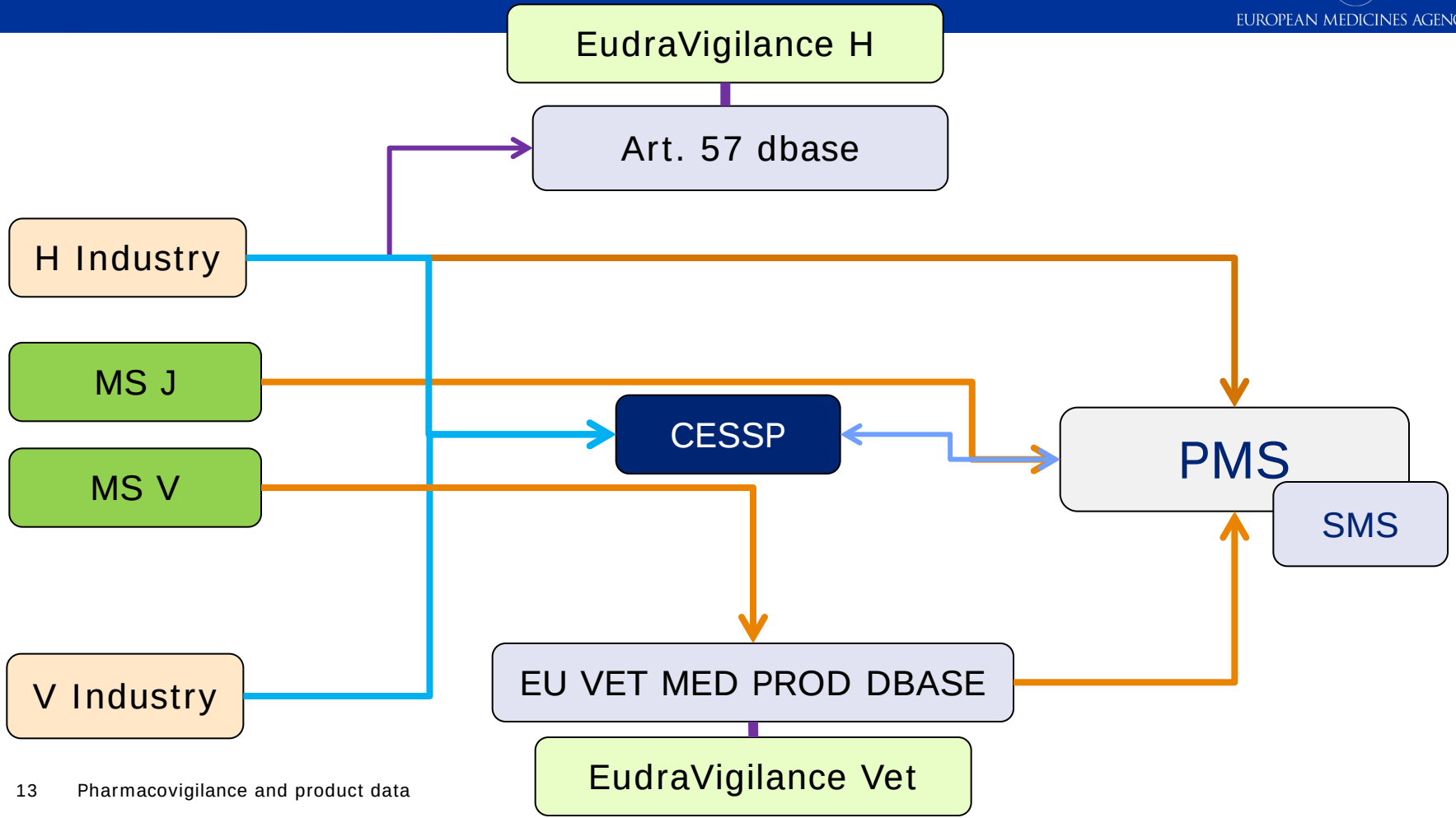
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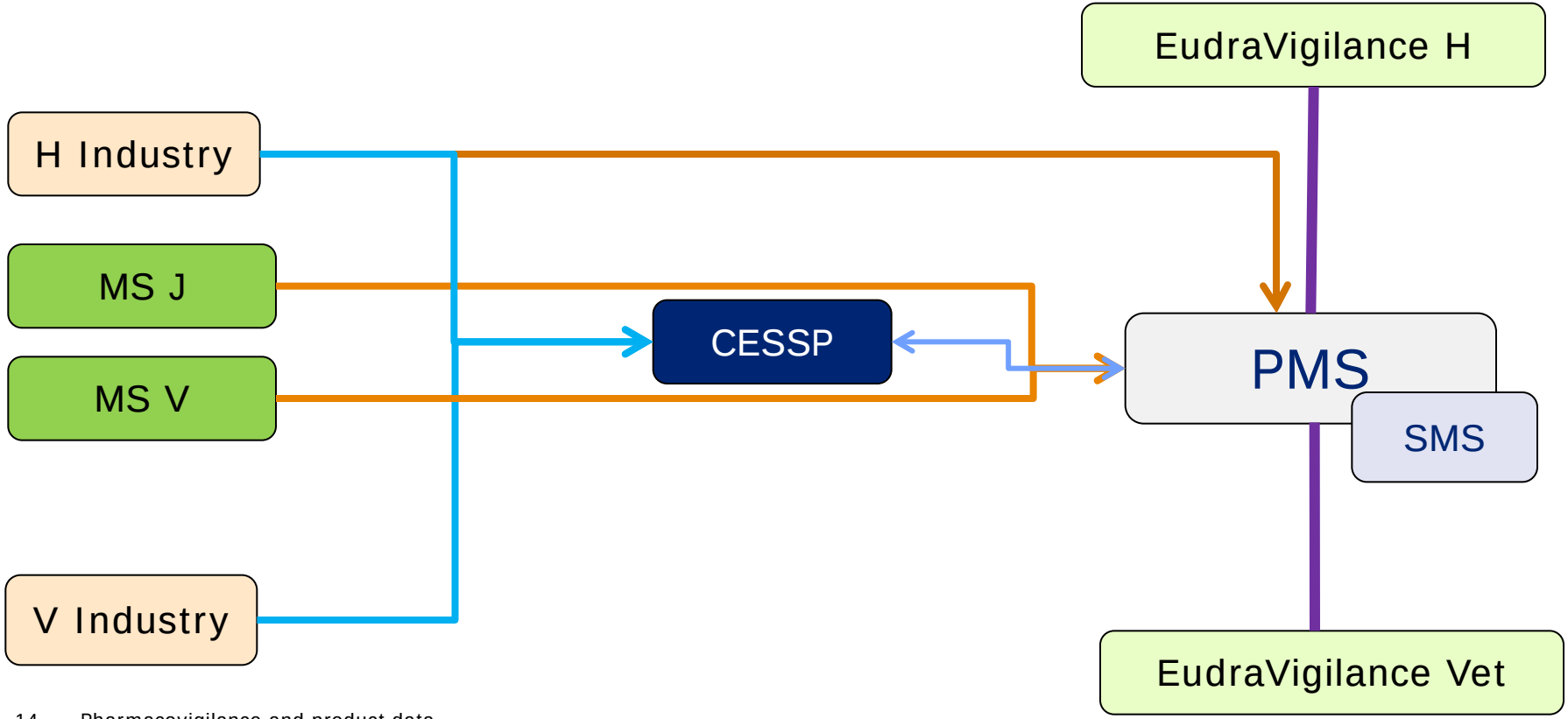
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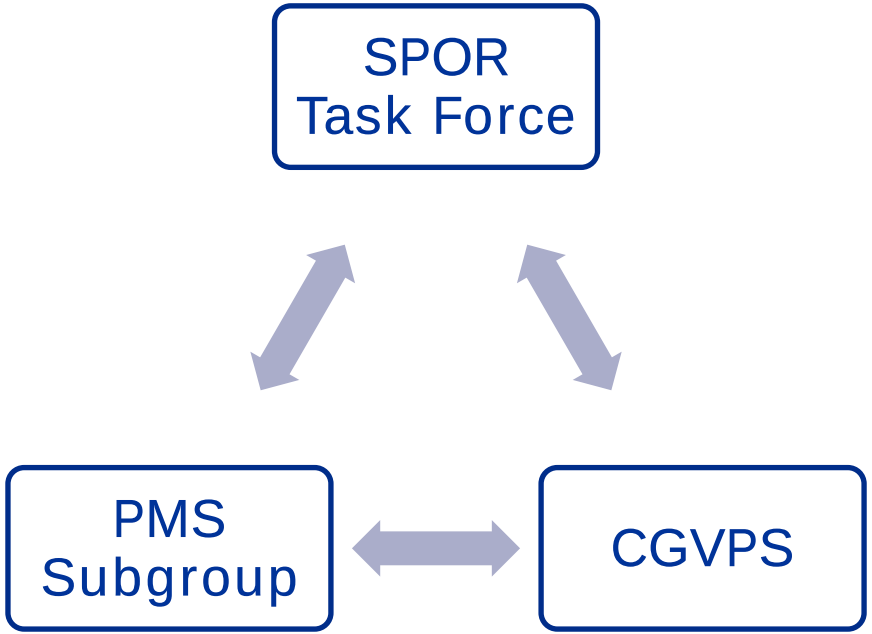
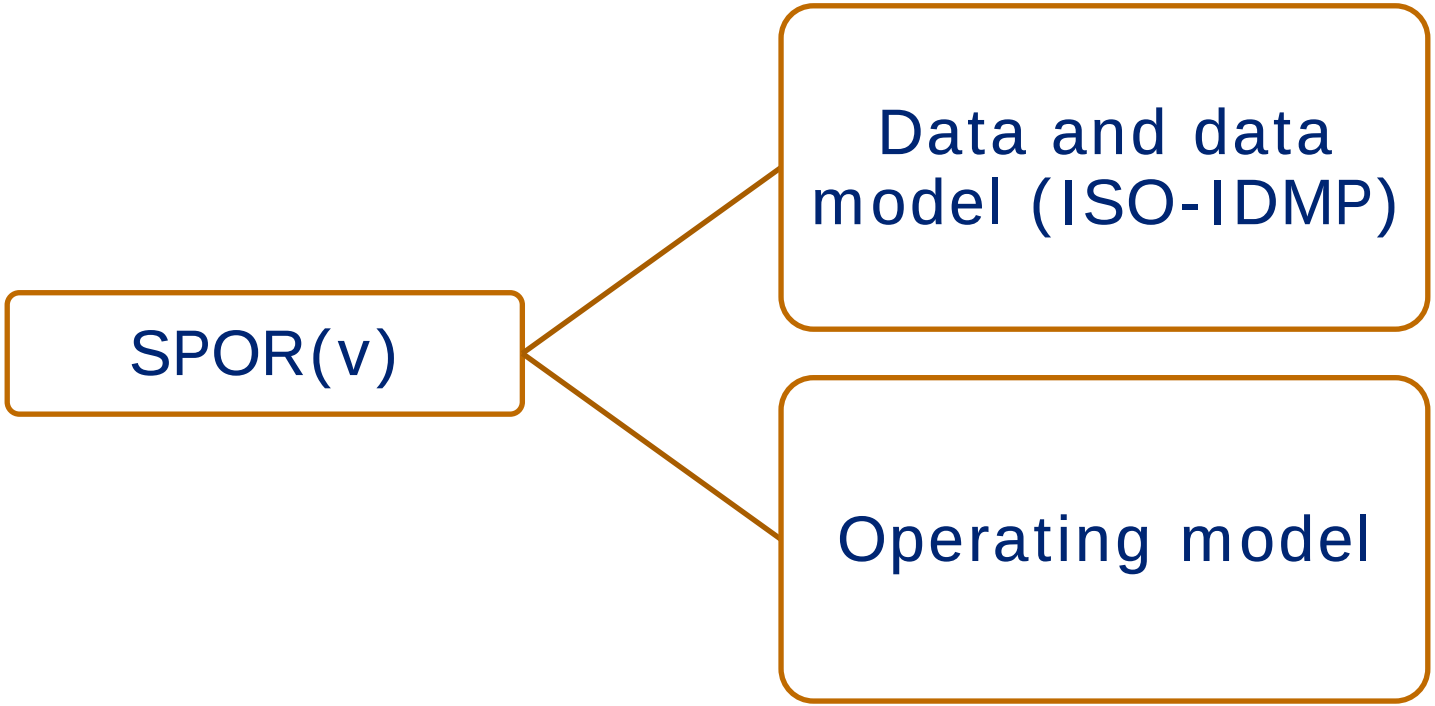
PMS - Governance




SPOR(v)
Data and data model (ISO-IDMP)
Operating model

Use Case Analysis

- To cover current veterinary regulatory activities and anticipated new regulatory activities under the revised legislation.
  - Initial approach – focus on minimum requirements in terms of data fields and standardisation.
- Keep use cases at high level, no ambition at this stage to establish an exhaustive list (legislation not adopted yet)
  - However: ensure coverage of all distinct and specific veterinary regulatory activities (to ensure to identify all required data elements at least once)

To be considered:

- Pharmacovigilance data to be exchanged by VICH XML message standard (VICH GL30, 35, 42)
  - Preparedness of local systems / support that EVVET3 includes all necessary requirements to serve as single EU PhV system.
- There will only be 1 EU XML message standard (human and vet) to exchange product data – driven by CESSP
  - Member States and Industry to support in identifying the essential veterinary specific data fields and standardisation level.
  - Member States and Industry to follow-up and prepare for compatibility of local systems to CESSP – PMS (ISO-IDMP standard)

Conclusions and to do

	To do	MS / Industry
EVVET3 – Project to be initiated	Participate in CGVPhS (Consultative Group for Veterinary Pharmacovigilance Systems)	MS + Industry
Eudrapharm Vet	Transfer Product data	MS
PMS - SMS	Participate in CGVPS / PMS Subgroup/ SMS Subgroup/ SPOR Taskforce	MS + Industry
	Map local systems to Referentials, Organisational data	MS + Industry

Thank you for your attention

Further information

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