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SCIENCE MEDICINES HEALTH

New veterinary regulation (NVR): impact on IT/Telematics

SPOR TF

04.12.2018

Goals of this presentation

- Provide high-level overview of requirements for IT systems arising from NVR
- Inform on current situation of Telematics IT systems landscape
- Inform of ongoing work of Vet expert group
- Next steps

IT systems/requirements arising from NVR

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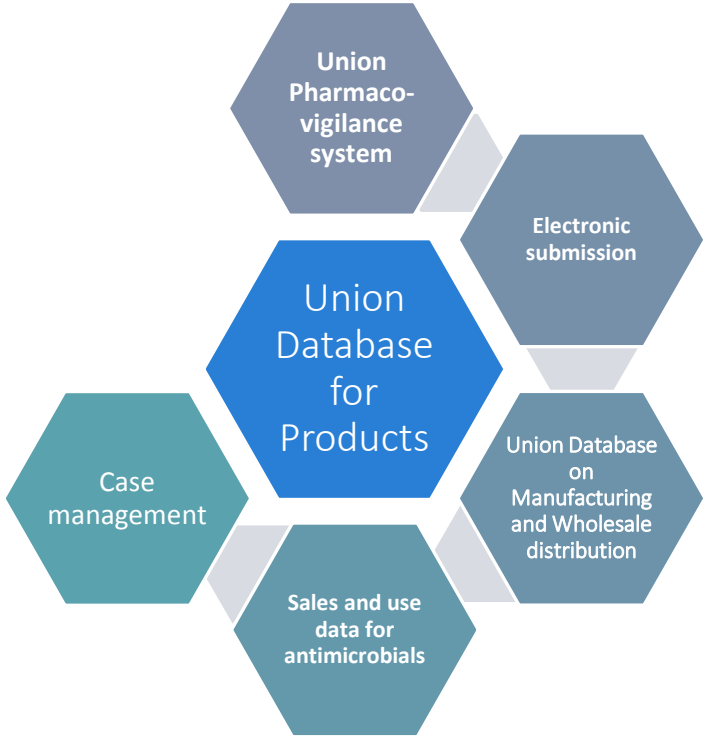
EU-level (EC/EMA)	Member States
EC MRL database (Interface with UPD - *to be developed/managed by EC*)	Individual websites: information on **online retailers** (deadline: by DoA)
EMA **- Union Product Database (UPD)** (To be adopted 12 months before DoA* so data can be submitted by CA** by DoA) **- Union database on pharmacovigilance** of veterinary medicinal products (to be established by DoA) **- Union database on manufacturing, import, and wholesale distribution** (to be established by DoA) - **Sales and use data for antimicrobials** (to be established by DoA)	Ensuring interoperability between the national and the EU databases.

Expectation is that specific requirements, formats, technical specifications of those IT systems / requirements should be detailed in the Delegated acts, Implementing acts, or other provision.

*DoA: Date of Application (3 years after entry into force) **CA: Competent Authorities

Union Database as cornerstone of veterinary data systems



Telematics AS-IS IT systems landscape (VET view)

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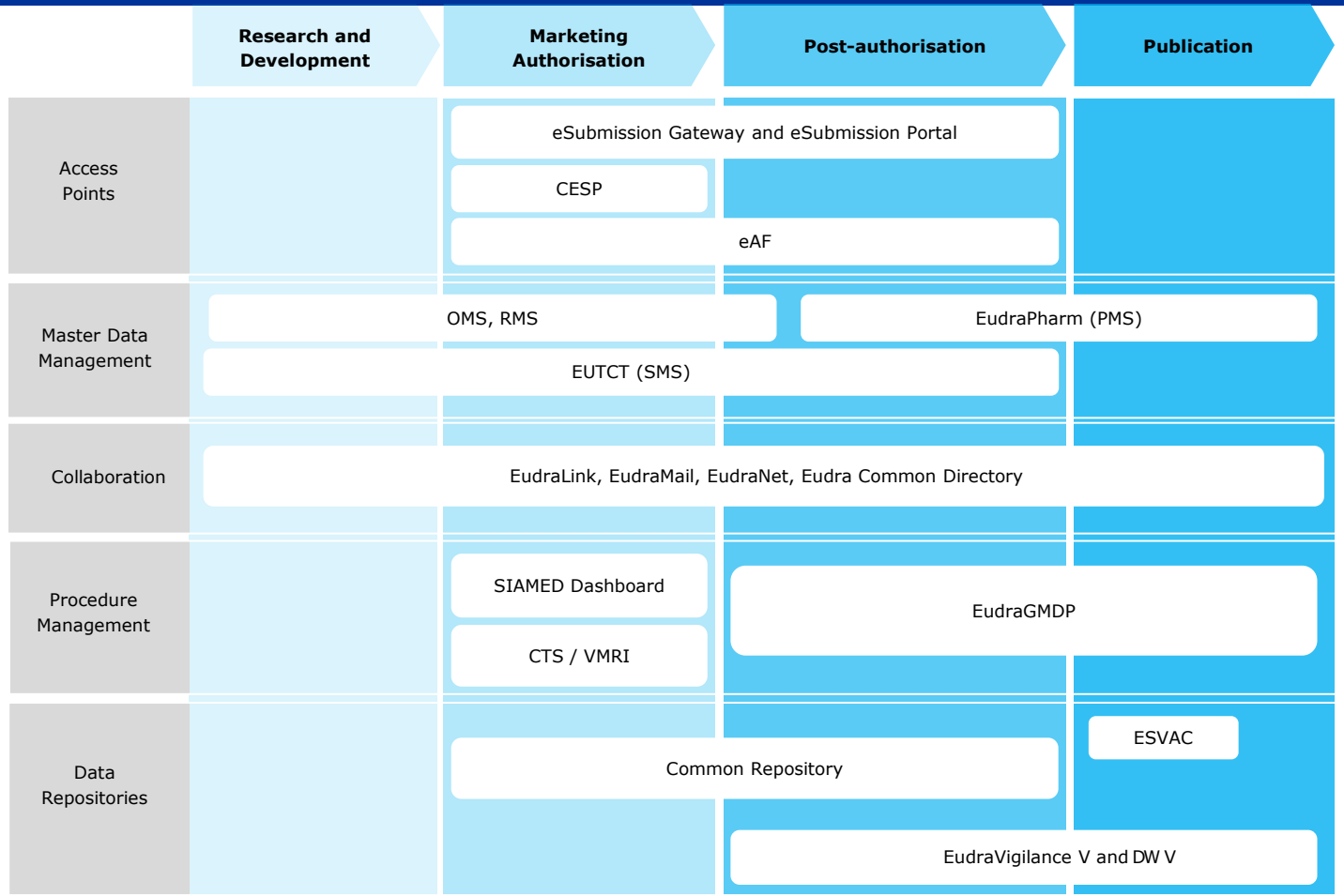

Impacted Telematics systems (goals)

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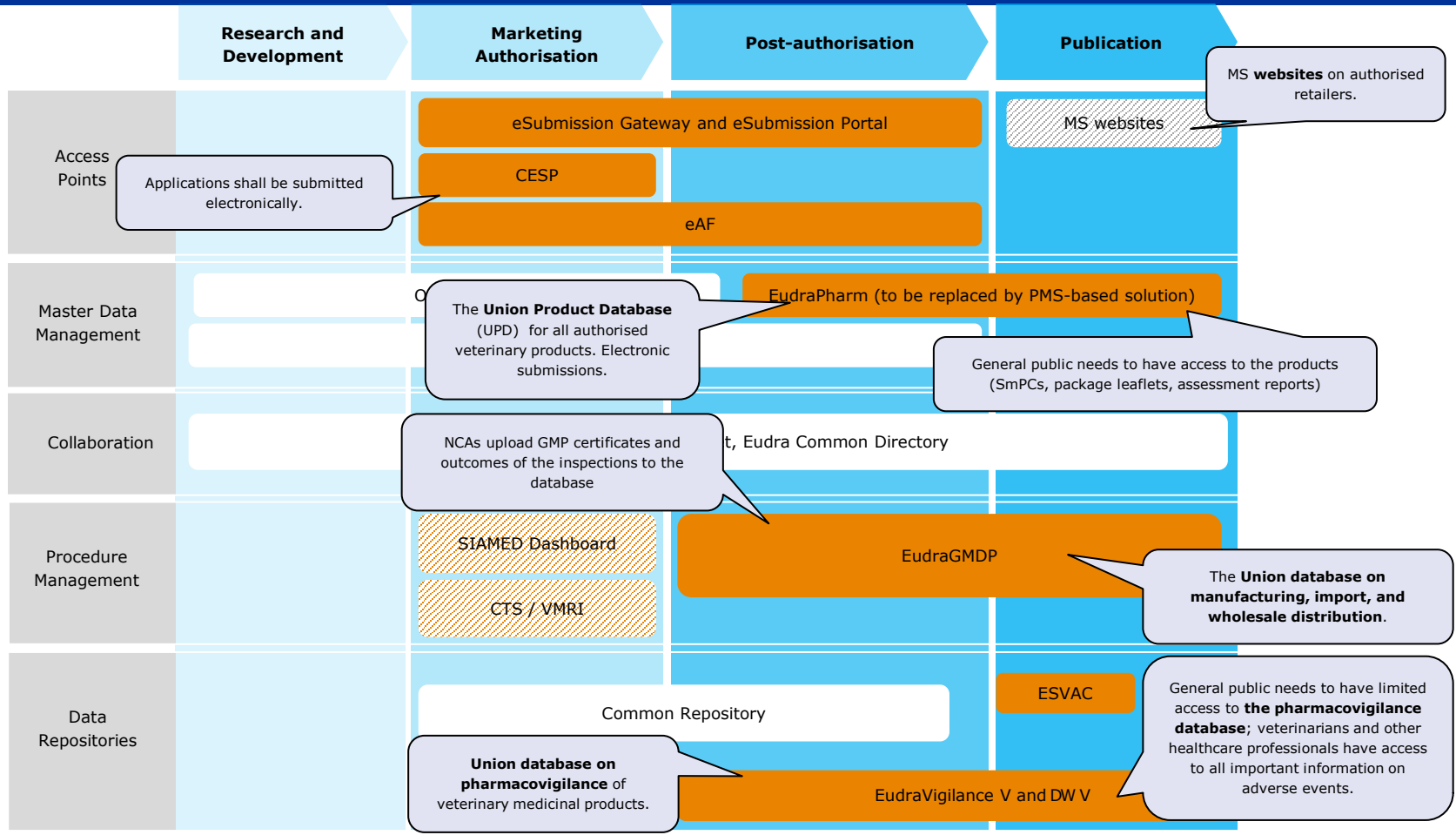

SMS & PMS development phases

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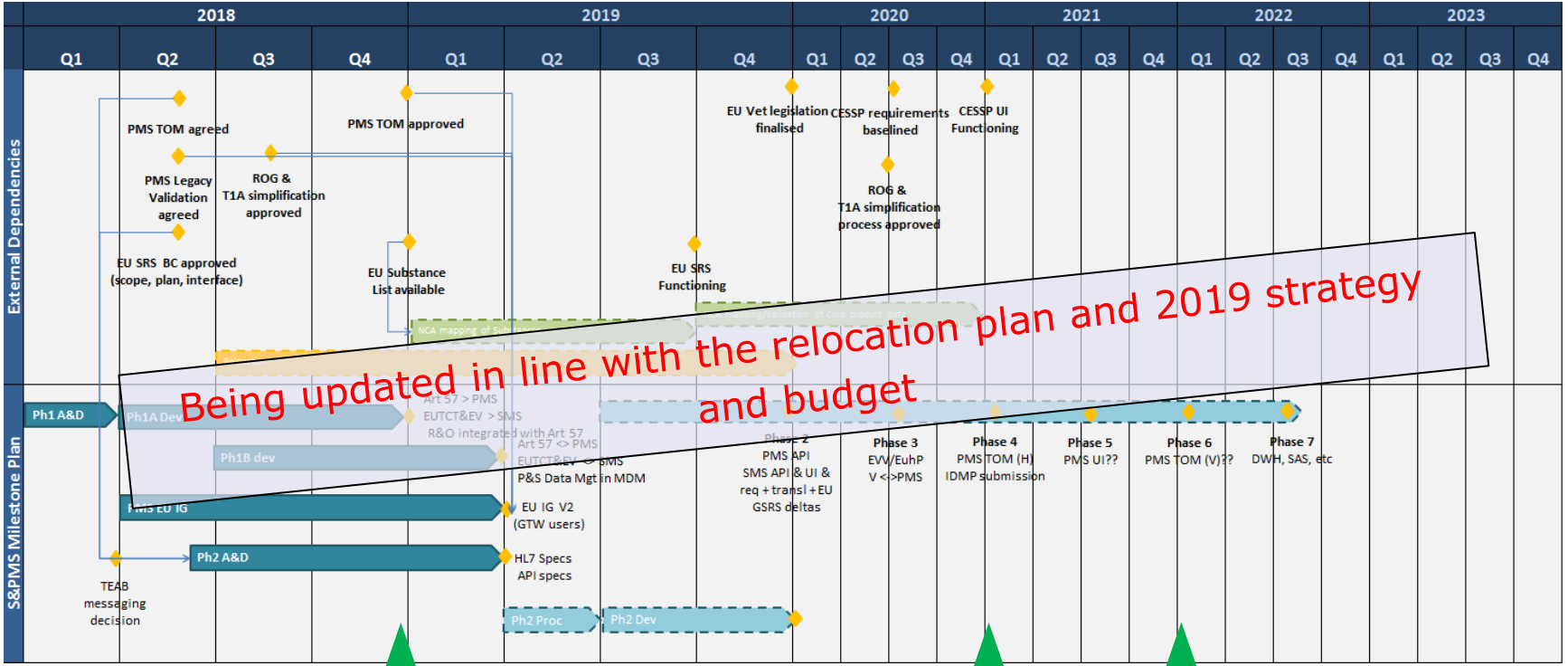

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Variations not requiring assessment

Directly recorded in the database

List of variations not requiring assessment

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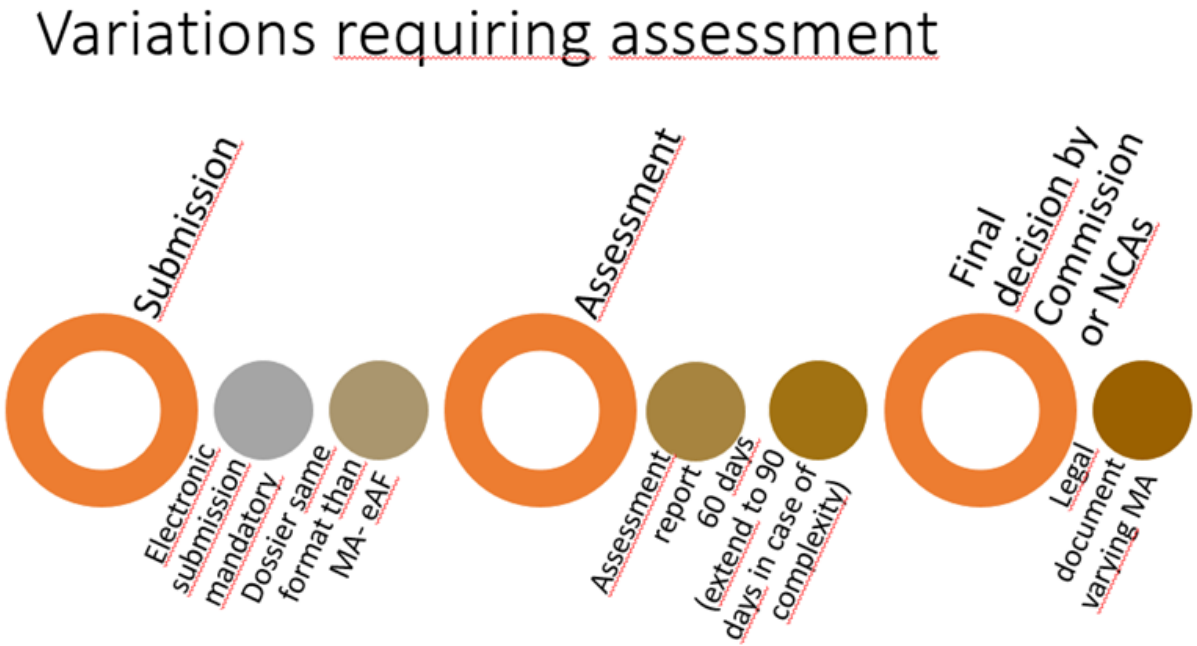
To be prepared 12 months before entry in application

- Impact IT :
  - MAH to access the product database
  - Update of product information by MAH
  - Information of NCAs
  - Variation can be approved/rejected by NCA
  - Update of product information by NCA
  - and also update of eAF, CTS

→ - Product database should be ready for these procedures in due time
- All VMPs registered in the database (impact on NCAs/EMA)
- All other IT tools ready (impact on Telematics Strategy)



Variation requiring assessment = all the variations not listed

Ongoing work of the Vet expert group

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- The group has identified limited number of mandatory fields that will need to be transmitted for all nationally authorised product data into the Union product database.
- Draft "to-do" leaflet for NCAs to help them fulfilling their legal obligations.
- The final document should be transmitted for consideration to the officially mandated expert group that will be working on the product data requirements.
- Colleagues part of the Data Pilot working group lead by a few NCAs will review at a next meeting of the group the mandatory fields identified for Vet product data and specific issues arising.

Nber.	Actions related to Union Product Database	Proposed Deadline	status
1	**Identify** nationally authorised products that will need to be sent to the Union product database	Now- end 2019	
2	Check that all mandatory fields* identified in the table below are available, and check when fields should have reference terms, whether this is the case for your products	Now – end 2019	
3	**Map** the reference terms	End 2020	
4	Prepare a sample of product data in collaboration with data pilot working group	Now - end 2020	
5	Send product data to Union Product Database – *further details will be communicated on how this process should be done, once further clarifications on technical issues and Business processes (Target operating Model) will be known*	By DoA	

Next steps

- Final adoption of NVR (expected by 15.12.18)
- The Commission will organise a meeting with Member States to discuss the plan for implementation of the new veterinary regulation. The meeting is expected to take place immediately after sign-off of the regulation
- The Commission will establish the governance for the Union product database and will oversee its development until delivery. The database, once established, will be operated/maintained by the EMA.
- The governance is not yet fully developed but the aim is that it will not be complex in order to ensure that it will have the ability to make quick decisions and to keep stakeholders informed without any delay.
- Clarification on the mandate of the TFCIVR* and the role of HMA and EMA shall be provided

*Task Force on the coordination of the implementation of the New vet regulation

Thank you for your attention

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