EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on the New Veterinary Regulation (NVR)

– with focus on the Union Product Database (UPD)

SPOR Task Force - 24 May 2019

Presented by Ivo Claassen

Agenda

1. Introduction: the NVR
2. The UPD expert working group
3. Potential impact on SPOR

1.Introduction: the NVR

The New Veterinary Regulation

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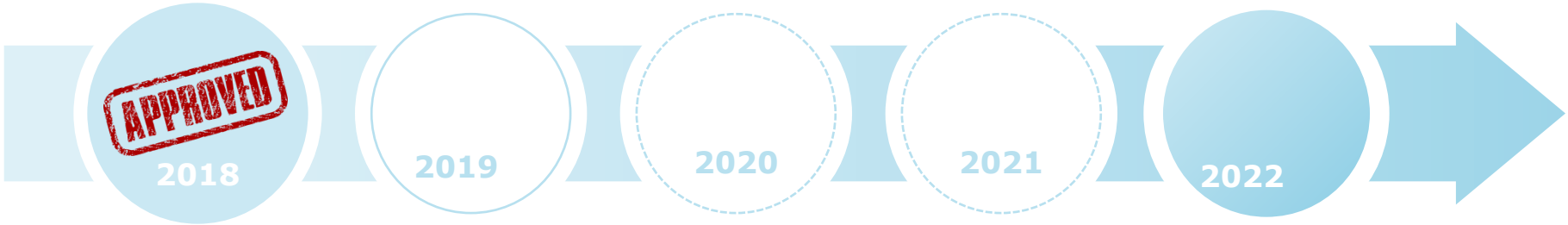
Regulation (EU) 2019/6

- published on 7 January 2019; came into effect on 28 January 2019
- 3 years implementation period (applicable from January 2022)
- 20 Implementing or Delegated Acts foreseen to be developed in implementation period



2019 brings many challenges

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First 7 mandates for recommendations/scientific advice from European Commission:

- Revision of Annex II (dossier requirements); esp. to introduce requirements for biologicals and novel therapies (due Aug 2019)
- Variations: list of variations not requiring assessment (due Aug 2019)
- Criteria for designating antimicrobials restricted to human use only (due Oct 2019)
- Collection of data on antimicrobial medicinal products used in animals (due Aug 2019)
- Pharmacovigilance: format and content of the Pharmacovigilance System Master File and its summary
- Good Pharmacovigilance Practice (to replace Volume 9B) (due June 2020)
- Specifications for Union Product Database (going beyond master data covered by SPOR) (due Aug 2019)

Up to 9 more mandates expected in May and June 2019, respectively

=> overlapping work on 16 mandates in 2019

Article 55(3) Implementing act

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- **Article 55 (3)**

Implementing act to define:

- the technical specifications of the product database including the electronic data exchange mechanism for exchanging with the existing national systems and the format for electronic submission
- the practical arrangements for the functioning of the product database, in particular to ensure protection of commercially confidential information and security of exchange of information
- detailed specifications of the information to be included, updated and shared in the product database and by whom
- contingency arrangements to be applied in case of unavailability of any of the functionalities of the product database
- where appropriate, data to be included in the product database in addition to the information referred to in paragraph 2 of this Article.

2. The Union Product Database (UPD) expert working group

Composition and organisation until 31/08/19

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- Mandate on Specifications for Union Product Database (UPD) received by the Agency
- The Agency considered that for the preparation of the advice an expert working group should be formed, pending establishment of a **formal governance structure in Autumn 2019**
- UPD expert working group includes:
  - 6 experts from NCAs (some are Members of EUNDB, SPOR TF, TOM facilitation group…): Georg Neuwirther (AT), Jeffrey Martin (SE), Paule Carnat-Gautier (FR), Ly Rootslane (EE), Jose Manuel Simarro (ES), Miriam Alexander-Katz (DE);
  - 2 EMA staff representing business: Jana Schalansky, Anne-Christine Lantin
  - 1 EMA staff members representing IT : Pekka Pulkkinen (Business Architect)
  - Oversight from the EC is provided: Giorgos Georgiannakis, Luben Goranov, Caroline Fabre
- Meetings
  - Expert group meets (virtually) every 2 weeks;
  - One physical meeting held in Paris on 13-14 May 2019
  - One physical meeting scheduled 6th June at EMA

Mandate and objectives

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- **Phase 1**

1 Scope definition: - **short and long-term goals** of the UPD

- **Phase 2** - Use the outcome of Phase 1 to establish detailed requirements. 2

High-Level Functional Requirements
- functional requirements in the form of **use case headings** initially
- Provide the non-functional requirements and specifications
3 - Define the "**to be" business processes**

High-Level Architecture Model 4 5
- Provide a **high-level application architecture** view and **conceptual data model**.

Interoperability and Interface
4 - Describe the **interactions with all other relevant databases**
- Provide a high-level view of the **electronic data exchange mechanism** and the **format** for electronic submission 6

Contingency Arrangements under point (d) of Article 55(3)
- Review the best available **backup and contingency options**

Additional Information under point (e) of Article 55(3)
7 - Explore what **information in addition to the minimum required data** might safely be considered for inclusion in the product database coverage in view of its utility for ongoing operations

Deliverables and reference architecture method

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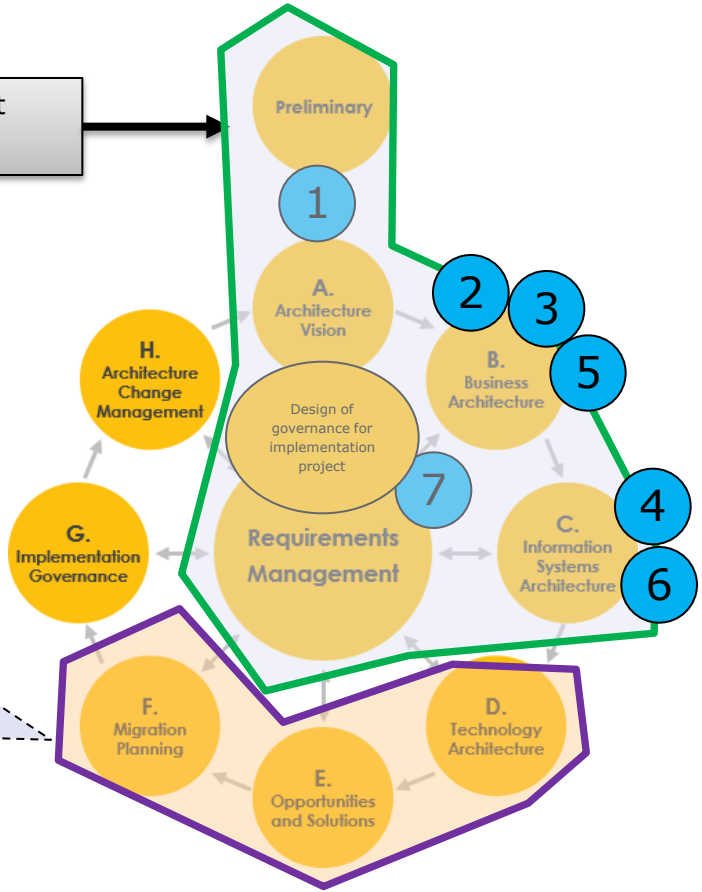
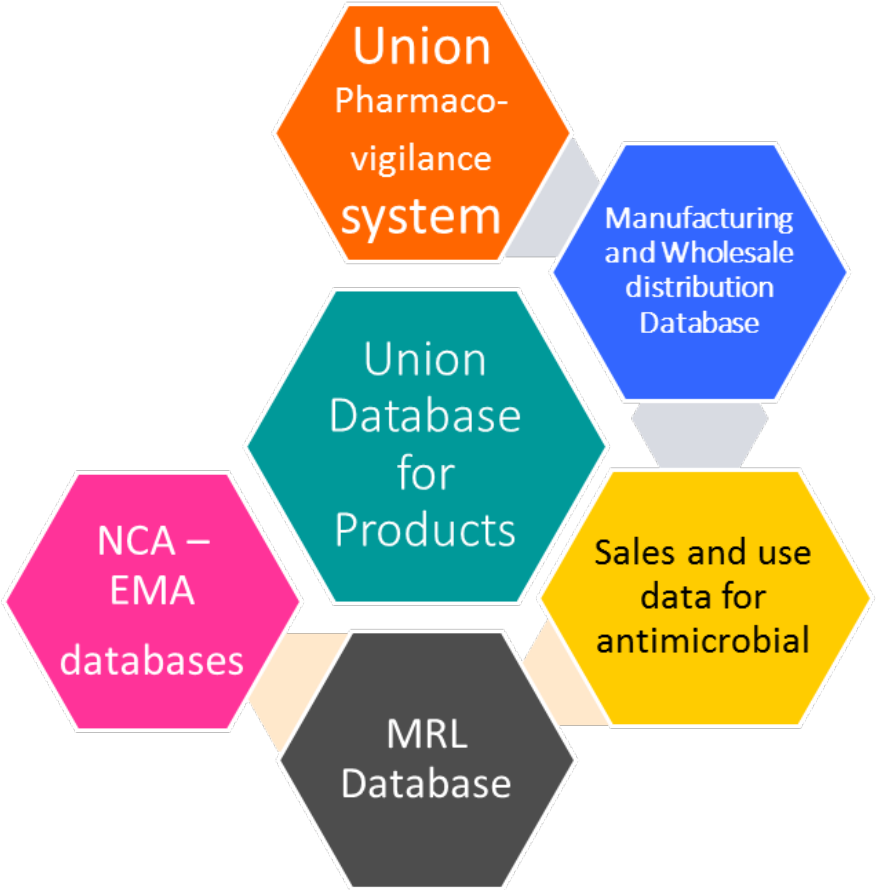
Delivered by the NVR – UPD expert group by 31 Aug

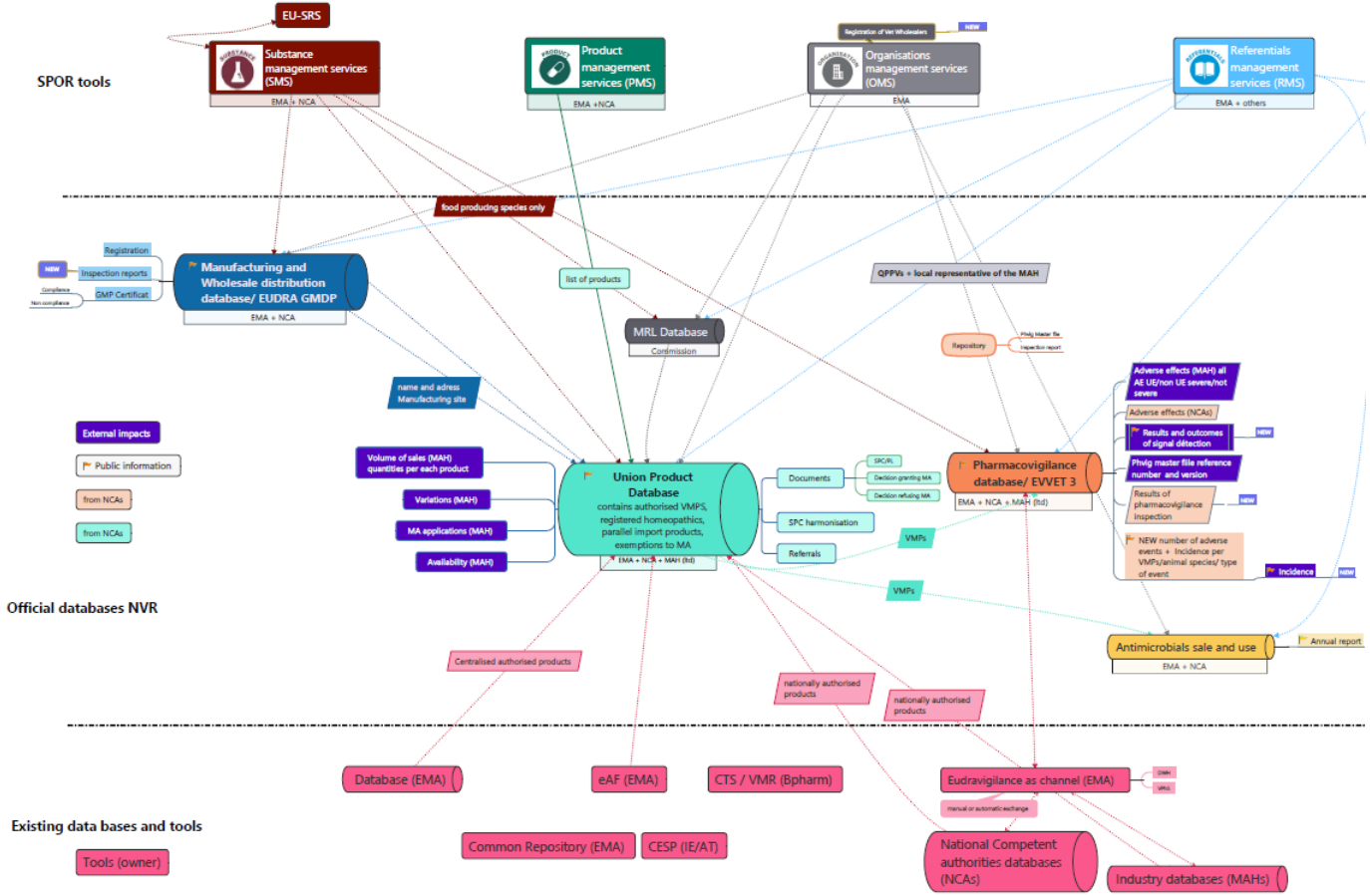


- Technology decisions, transition and implementation planning requested by end of 2019, but to be considered / confirmed

UPD at the cornerstone of IT systems

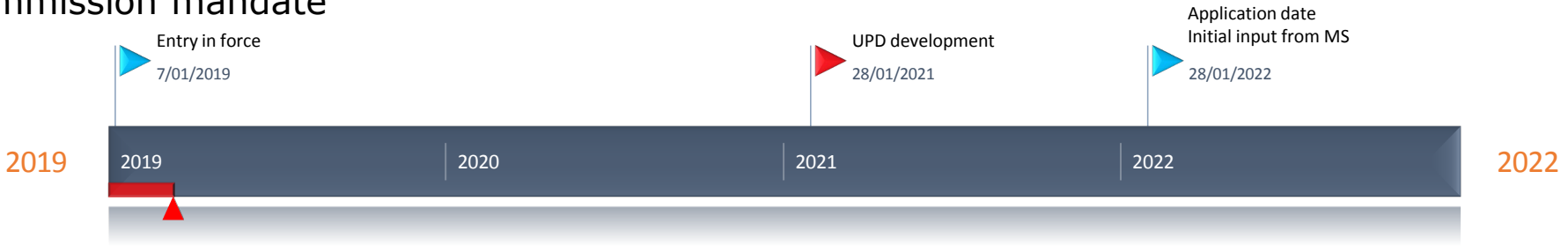


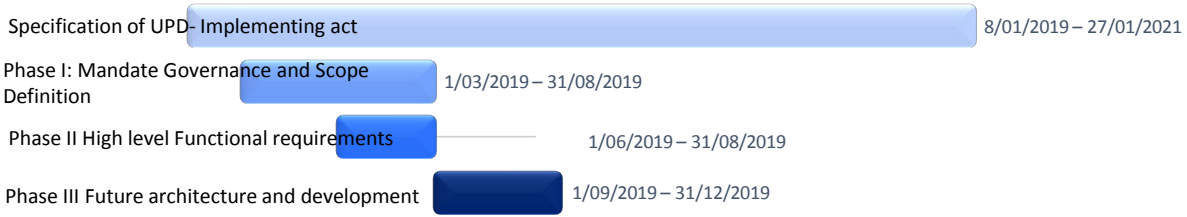
Possible interactions with SPOR and other IT systems



Timelines

Commission mandate





Phase I : Mandate Governance and Scope Definition

Phase II :

- High-Level Functional Requirements
- High-Level Architecture Model
- Interoperability and Interfaces
- Contingency Arrangements under point (d) of Article 55(3)
- Additional Information under point (e) of Article 55(3)

What has been done so far?

Union product database art 55 – scope as defined in NVR

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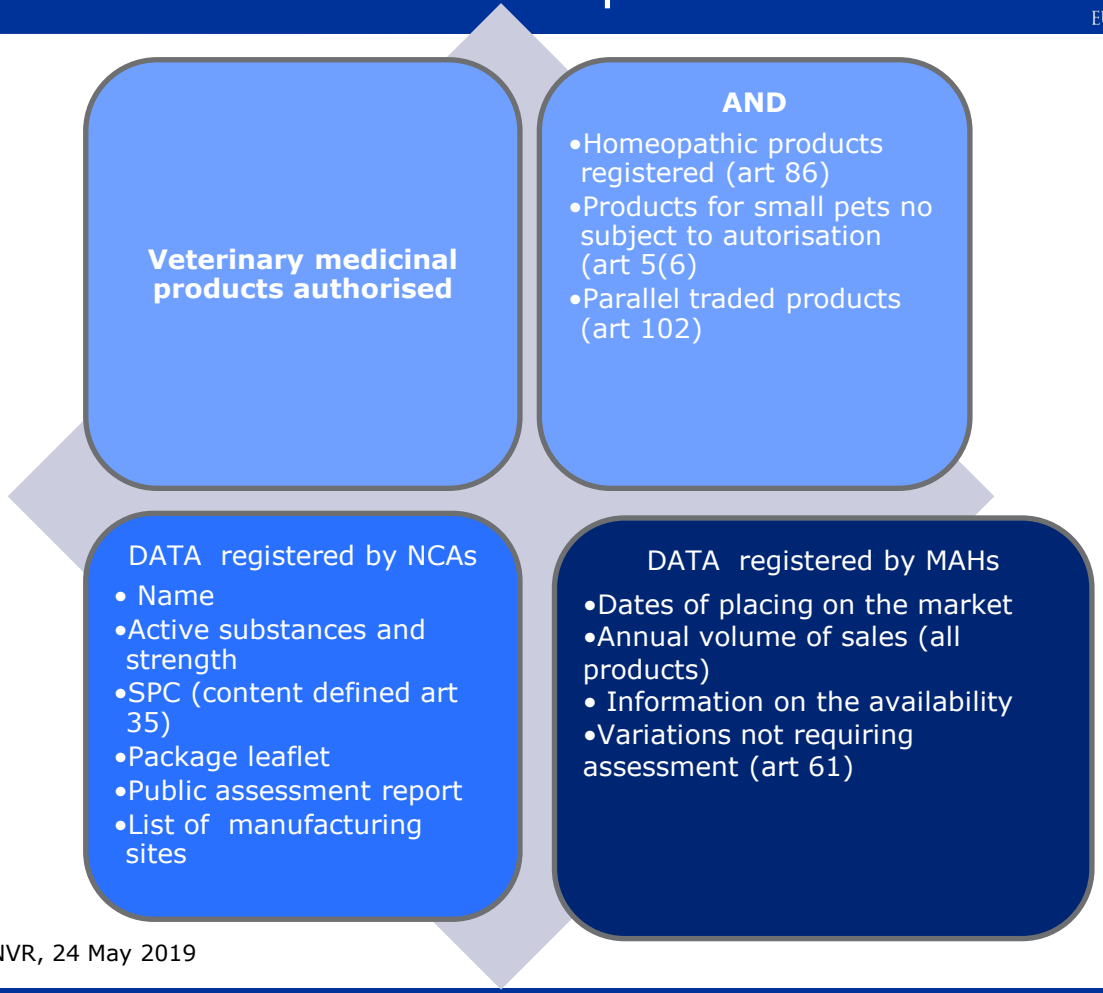

High-level requirements

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Example of format/content:

Business process reference	Business requirement ID	Requirement name	Requirement description	Business rationale	MOSCOW	Main actors	IN or OUT of UPD scope	Notes/questions
BP2-001	BR-02-001	Submission of variation	Where a variation is included in the list established in accordance with Article 60(1), the marketing authorisation holder shall record the change including, as applicable, the summary of product characteristics, labelling or package leaflet in languages referred to in Article 7, in the product database within 30 days following the implementation of that variation.	Art 61(1)	Must			
BP2-001	BR-02-003	Acceptance or rejection of the variation	The competent authority of the reference Member State or, in the case of variation to the terms of a national marketing authorisation, the competent authority of the relevant Member State, or the Commission, as applicable, shall inform the marketing authorisation holder and the competent authorities in the relevant Member States as to whether the variation is approved or rejected by recording that information in the product database.	Art 61(3)	Must			
BP2-001	BR-02-004	Reporting on variations	The MAH or NCA can obtain a report on the history of the non-assessed variations that have been managed in the UPD.	Organisation	Should			

- Requirements under consideration by expert group (content/prioritisation)
- Resulting list informs other deliverables to be provided by 31 August
- List will be reviewed to identify elements that should go into the recommendation on the text of the implementing act to be adopted by end of January 2021
- Balance between identified requirements/minimum viable product/flexibility in changing requirements over next 2-3 years
- About 15 business requirements identified, being refined over next meetings
- Status: we are on track to deliver outputs by end of August 2019.

3.Potential impact on SPOR

Strategic options

A) Using SPOR to support the implementation of the NVR

SPOR is a framework for the network. It's a concept that aims to harmonise collaboration in the regulatory network by using aligned processes, standards, terminology, etc. EMA and NCAs have been working on this for many years.

B) Using a different approach - to be suggested by relevant groups of the telematics governance

First thoughts about using SPOR

- Substances, Organisation and Referential Management Services to be considered for use as input for the UPD
- For the Product Management Service, it is yet to be decided if will be used for UPD
- Additional functionality may be required
- High level processes
  - 5 business processes Level 1 identified by UPD expert group
- The UPD needs to be operational

(submission of the existing products) by Q1-Q4 2021

- We have seen in the SPOR roadmap that Vet phase is included –

Synergies with NVR possible?

Level	ID	Name
L0		Union Product Database
L1	**BP1**	**New product**
L2	BP1-001	New authorised products
L2	BP1-002	New registered product
L2	BP1-003	New Art. 5.6 product (pets)
L2	BP1-004	New parallel trade product
L2	BP1-005	Initial upload of legacy data
L1	**BP2**	**Post authorisation changes**
L2	BP2-001	Variations not requiring assessment
L2	BP2-002	Variations requiring assessment
	BP2-003	Annual volume of sales
	BP2-004	Product availability information
	BP2-005	Authorisation status update
L1	**BP3**	**Access control**
L2	BP3-001	Public access
L2	BP3-002	MAH (and affiliates) access
L2	BP3-003	Regulator access
L1	**BP4**	**Data exchange with other database systems**
L2	BP4-001	Data exchange with NCA product databases
L2	BP4-002	Data exchange with Manufacturing and Wholesale Distribution database
L2	BP4-003	Data exchange with ESVAC database
L2	BP4-004	Data exchange with Union Pharmacovigilance Database
L2	BP4-005	Data exchange with MRL database
L2	BP4-006	Data exchange with other stakeholders databases
L1	**BP5**	**Publish data**
L2	BP5-1	Identify and correct data quality issues

Any questions?