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SCIENCE MEDICINES HEALTH

Update on the New Veterinary Regulation

with a focus on the Union Product Database

SPOR Task Force – 16th October 2019

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The New Veterinary Regulation

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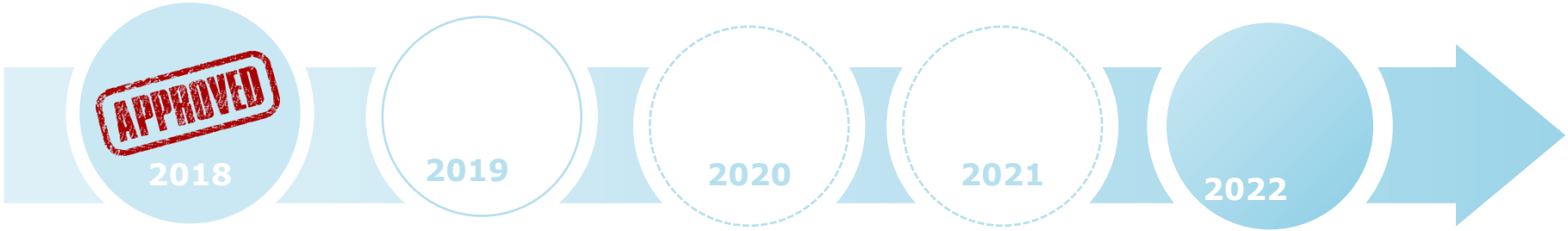
Regulation (EU) 2019/6

- Published on 7 January 2019; came into effect on 28 January 2019
- 3 years implementation period (applicable from 28 January 2022)
- Will modernise existing rules on authorisation and use of veterinary medicines in EU
- Contains new measures for increasing availability and safety of VMP and enhances EU action against antimicrobial resistance



EMA role in implementing the Regulation

EMA contributes to discussions on implementing and delegated acts, which the European Commission is preparing as part of the implementation of the Regulation. In particular, the Agency provides **scientific and technical recommendations** as and when requested by the European Commission.

EMA is also responsible for:

- revising its **procedures** and regulatory and scientific guidance documents, in line with the Regulation and its implementing and delegated acts;
- leading the implementation of IT systems required by the Regulation, including the **Union Product Database (UPD)**, which will provide information on all authorised veterinary medicines and their availability in EU Member States;
- implementing the outcomes of the implementing and delegated acts.

Timelines for the UPD

Specification of UPD- Implementing act 8/01/2019 – 27/01/2021

Phase I: Mandate Governance and Scope Definition 1/03/2019 – 31/08/2019

Phase II High level requirements (functional and non functional); high level architecture model; data fields, contingency arrangements;… 1/06/2019 – 31/08/2019

Presentation of Advice prepared by expert group on UPD

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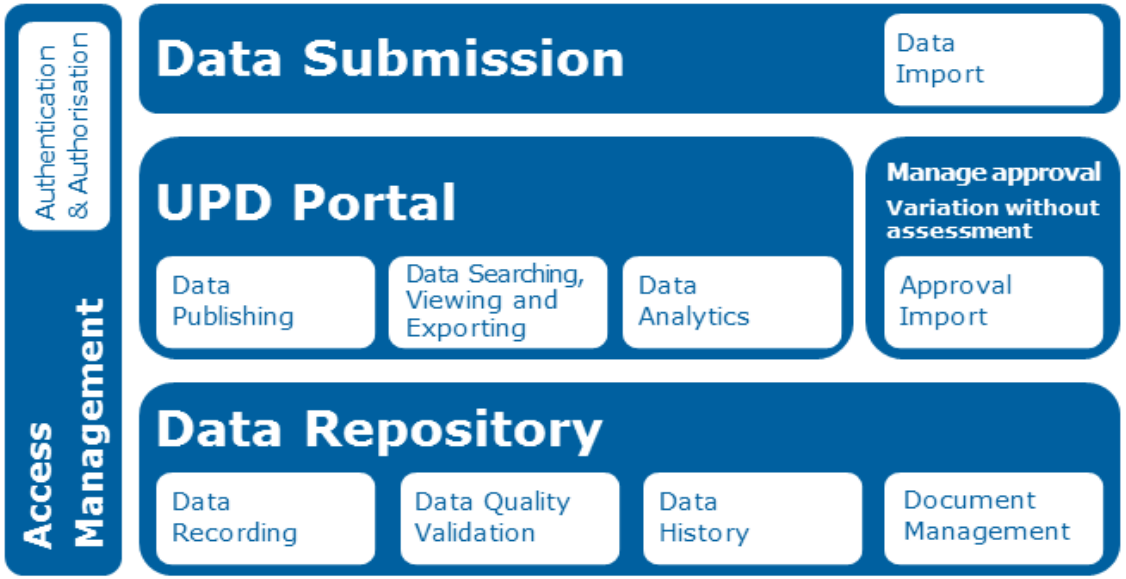
Definition and objectives of the UPD

- **Recommendation**: UPD concept should be built utilising existing functionalities and functionalities under development in the network, as far as possible.
- To be the common database to collect, store and provide information about veterinary medicinal products within scope of NVR / information on availability of VMP
- To use structured data and controlled vocabularies in the UPD for improved data quality in the regulatory processes
- To allow integration of the UPD in the activities of the regulatory network
- To support electronic exchange of product data between NCAs and EMA


Access Management
Authentication & Authorisation
Data Submission
Data Import
UPD Portal
Data Publishing
Data Searching, Viewing and Exporting
Data Analytics
Manage approval
Variation without assessment
Approval Import
Data Repository
Data Recording
Data Quality Validation
Data History
Document Management

UPD concept

Out of scope

Pending veterinary products	• except those involved in MR/DC procedures that have reached the end of the assessment phase
Publication of decisions	• to grant, refuse, suspend, revoke or amend a marketing authorisation by way of a variation (Art. 5.3); • *[publication is under responsibility of the relevant competent authority]*
Publication of report or opinion	• following the withdrawal of applications (Art. 32); • *[publication is under responsibility of the relevant competent authority]*
Case management system	• for processing all regulatory activities • *[light workflow management to be included only for variations not requiring assessment]*

What has been done so far ?

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Development of :

1) High level business processes

2) High-level business requirements and non-functional requirements

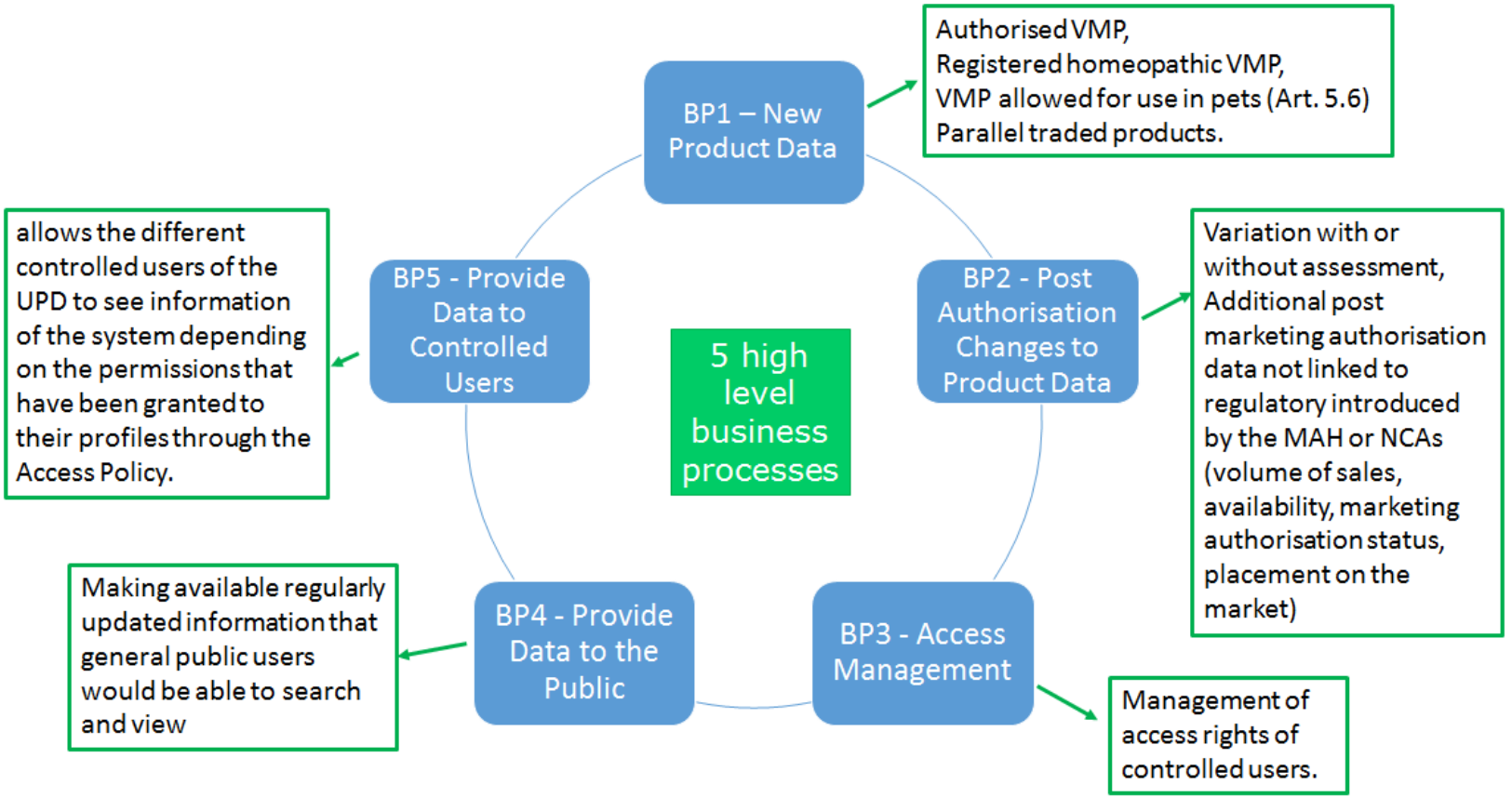
3) High-level use case model of the UPD concept, linked to Business processes

4) Access policy : roles/permissions

5) High-level architecture model / high-level UPD conceptual data model

6) List of data fields : required in legislation and additional data fields required for functioning of processes/procedures

1) Development of the high level business processes



2) Development of the functional business requirements

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BP1 - New Product Data	
BR-01-001	Create new product entry
BR-01-002	Create pending product entry
BR-01-004	Identify existing identical parallel application
BR-01-005	Provide legacy product data for agreed data fields in UPD
BR-01-006	Provide information on parallel traded products
BR-01-007	Additional data fields necessary to fulfil the vision
BR-01-008	Use controlled vocabularies
BR-01-009	Use harmonised product data after MRP/DCP
BR-01-010	Data validation
BR-01-011	Update of Competent authority databases
BR-01-012	Assign unique product identifiers
BR-01-013	Update of MAH databases
BR-01-014	Obtain manufacturing site data
BR-01-015	Provide data to PhV database
BR-01-016	Provide data to Antimicrobials sales and consumption database
BR-01-017	Identify existing identical product authorisation
BR-01-018	Bulk upload of legacy data

BP2 - Post Authorisation Changes to Product Data	
BR-02-001	Record variation not requiring assessment in UPD
BR-02-002	Provide product data for creating variation procedures
BR-02-003	Acceptance or rejection of the variations not requiring assessment
BR-02-004	Reporting on changes to dataset
BR-02-005	Reporting on changes to dataset
BR-02-006	Recording data change following variation requiring assessment
BR-02-007	Collection of sales volumes
BR-02-008	Analysis of sales volumes
BR-02-009	Record availability information
BR-02-010	Analysis of availability information
BR-02-011	Record authorisation status
BR-02-012	Analysis of marketing authorisation status
BR-02-013	Processing of parallel variations
BR-02-0014	Download of sales volumes

BP3 - Access Management	
BR-03-001	Public access
BR-03-002	MAH access
BR-03-003	Competent authorities read access
BR-03-004	Competent authorities write access
BR-03-005	Access right delegation

BP4 - Provide Data to the Public	
BR-04-001	Export public data
BR-04-002	Subscription to change notifications

BP5 - Provide Data to Controlled Users	
BR-05-001	Notification of changes to Competent authorities
BR-05-002	Notification of changes to MAH
BR-05-003	Search restricted data
BR-05-004	Export restricted data

2) High-level non-functional requirements

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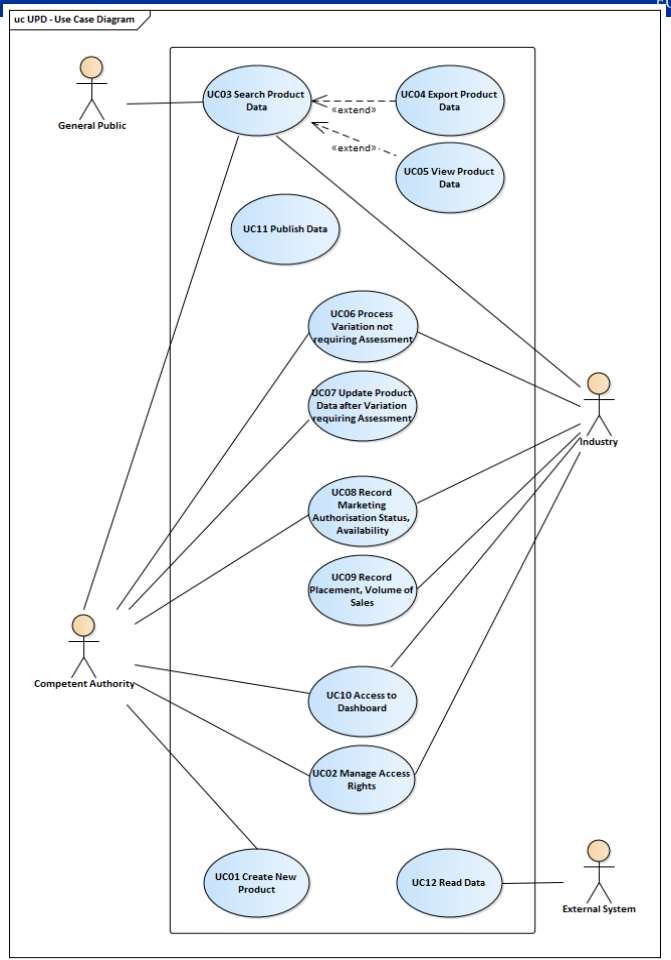
Req ID	Name	Description
NFR_1	Backup & Recovery - Data Store	The system shall ensure data recoverability.
NFR_2	Business Continuity - System Recovery Time	The system shall not be unavailable for longer than 24 hours within European working hours between 08:00 CET and 19:30 CET.
NFR_3	System integration	The system shall be interoperable with other existing or to-be-built systems that consume veterinary medicinal product information.
NFR_4	User authentication	The system shall require the controlled user to login with their credentials for every session.
NFR_5	Secure communications	The system's communications channels shall be securely encrypted. Applicable security protocols and connectivity rules shall be based on non-proprietary open standards.

3) Identification of use cases of the UPD

Actors	Description
General Public	Any user (controlled or not) who accesses/views the publicly available information web portal without logging in.
Competent Authority	A controlled user, at the Agency, the European Commission or a National Competent Authority level.
Industry	A controlled user at pharmaceutical industry level.
External System	Any telematics system or systems belonging to the Agency, a National Competent Authority or industry, which will interact with the UPD.



4) Access policy : roles/permissions

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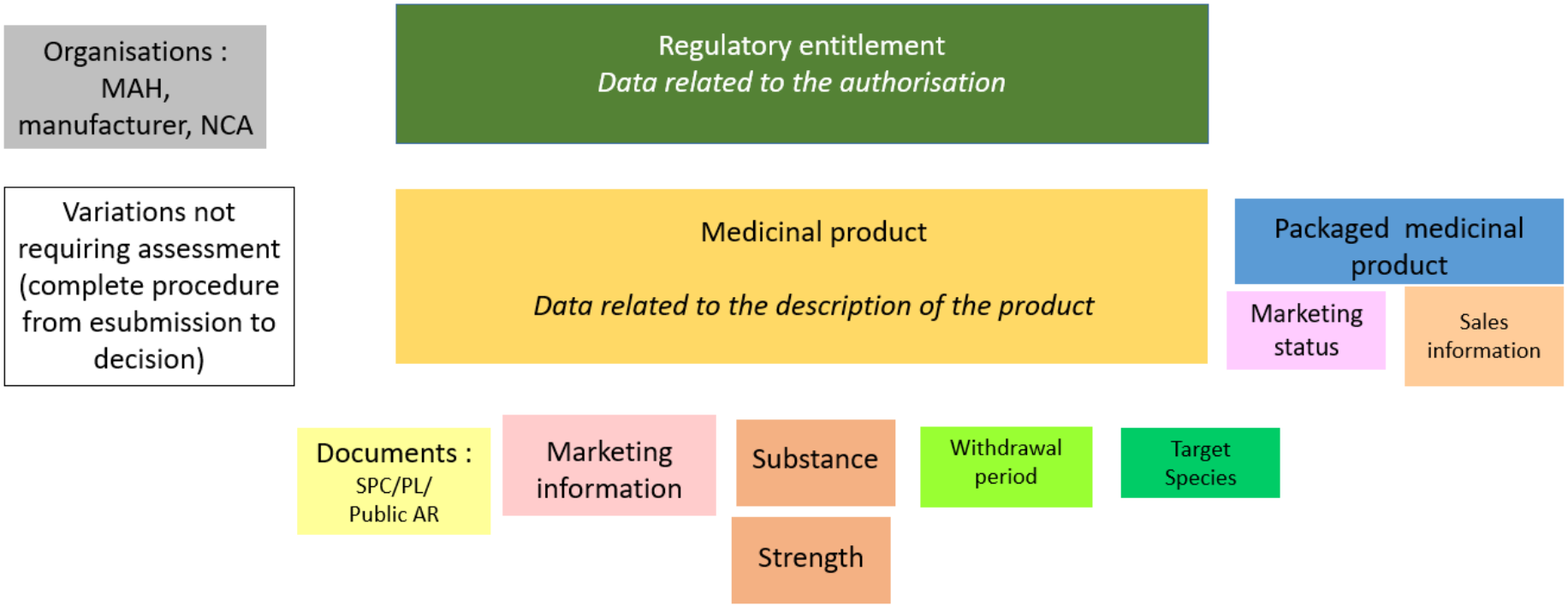
Permissions	Agency / Commission	National Competent Authorities	Industry	General Public
View public UPD information	X	X	X	X
View restricted UPD information	X	X	X	
Create new product	X	X		
Submit variation without assessment			X	
Approve variation without assessment	X	X		
Update product data after variation with assessment	X	X		
Record availability, marketing authorisation status	X	X	X	
Record placement on the market, volume of sales			X	
Record information on parallel traded products, registered homeopathic veterinary medicines and veterinary medicines allowed for use in pets		X		

5) Development of a high level UPD Conceptual data model



6) List of data fields

Category of products

- Authorised VMPs
- Registered homeopathics products
- VMP allowed for small pets (art. 5.6)
- Parallel traded products

Common data set

For all products

Specific data fields required per category of product

Medicinal product data

Procedural information for initial autorisation

Procedural information for post-authorisation changes

Other topics included in the Advice to the Commission

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- Interoperability and interface
- Data exchange mechanism and format for electronic submission
- Contingency arrangements, including proposal for phasing of initial data entry

Out of scope of the UPD expert group mandate

Some adjustment to the UPD requirements will undoubtedly need to be done when the requirements for the above systems are known but work on these has not started yet.

Status update / Next steps (1/3)

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- Advice published on Commission website
- the Commission will draft the implementing act and further consultation periods are foreseen (organised by the Commission);
- The Agency intends to initiate the NVR-UPD development project in agile methodology in early 2020, in collaboration with the member states.
- Governance structure approved, nomination still to be reviewed
- NVR-UPD Project Group and Key User Group(s) to work on:
  - Detailing business requirements
  - Discuss future architecture and development of the UPD concept, interconnection, data exchange and key functions
    - Input to the EU Telematics Enterprise Architecture Board
  - Detailing data specification
  - Defining legacy data to be provided for the initial input
- First meeting NVR UPD Project Group: Mon 28 Oct.

Status update / Next steps (2/3)

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- EU Telematics governance:
  - 15 Oct: TEAB: Start discussion on the architecture for UPD
  - 02 Dec: TEAB: Agree on the architecture for UPD
  - 29 Oct: IT DEC Presentation UPD project
  - [07 Nov? Date TBC]: EUTMB: Presentation UPD business case

Status update / Next steps (3/3)

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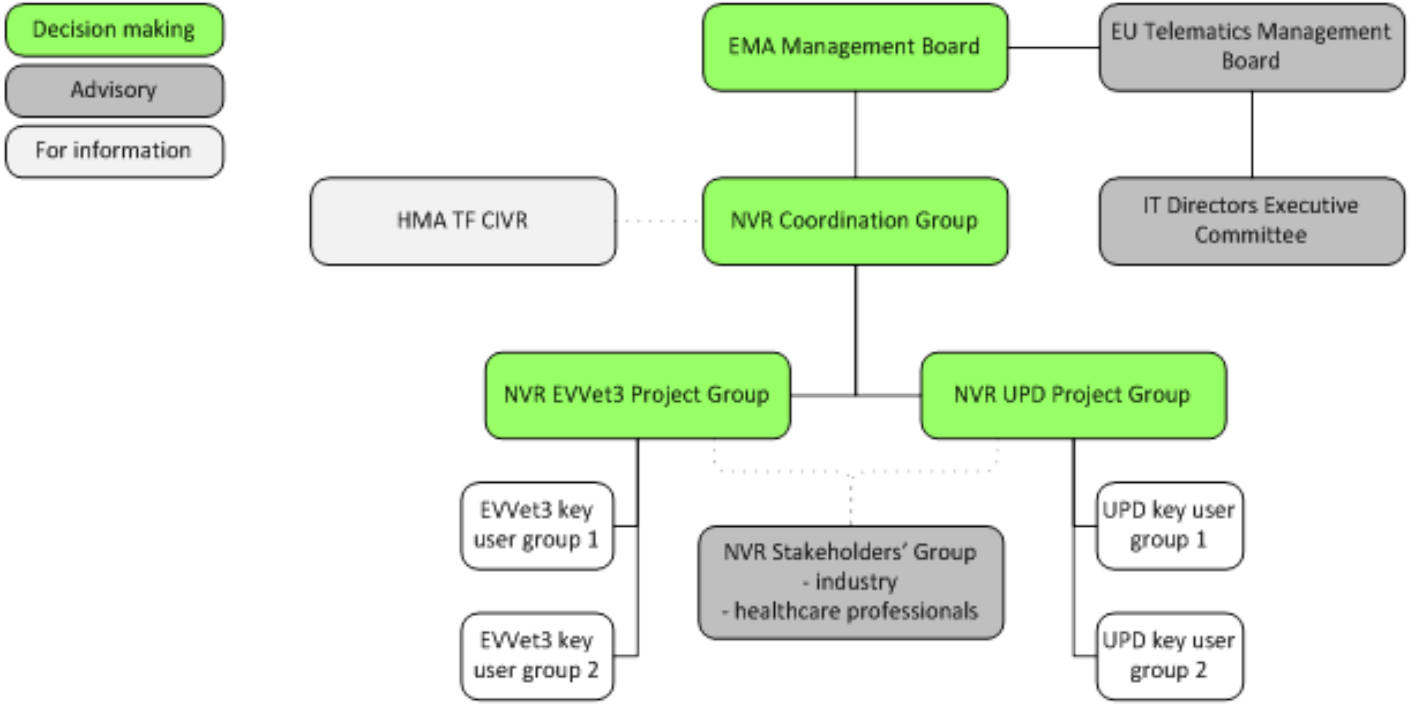
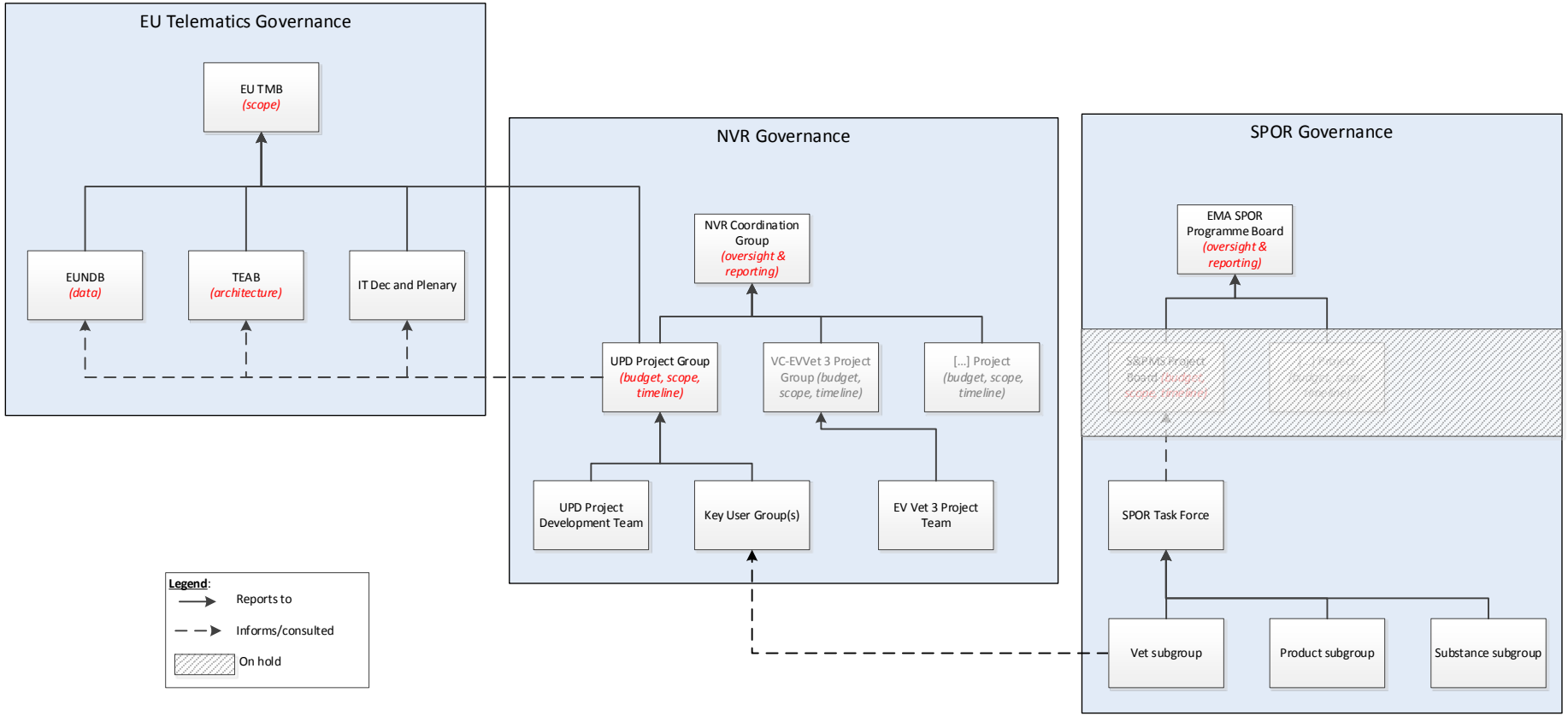
- Start implementation: Jan 2020
  - As per request EC: "the Agency will adopt agile methodology for the development of the UPD", "Application of this agile methodology is envisaged from January 2020 "
    - Challenge: The requirements will only be final and stable once the IA has been completed, in Dec 2020.
    - Therefore: Starting to develop in Jan 20 the requirements that will be known in Dec 20, is development at risk. However, the timeline in the regulation does not leave any choice.
    - Partial risk mitigation: Start with the development of the "certain" components
      - TBD with the NVR UP Project Group
- 20-22:
  - Agile development of the requirements in the product backlog, as prioritised by the NVR UPD Project Group and / or Key User Groups:
    - Sprints of (e.g.) 15 days, delivering testable cumulative functionality
- 28 Jan 22: Initial input to the product database by competent authorities completed (Reg 2019/6: Art 155)
  - Test system available some time before then

Governance for the development of the UPD



UPD Governance – SPOR Governance



What member States can already start doing

- 1) **Identify** nationally authorised products that will need to be sent to the Union product database (Authorised veterinary medicinal products; Registered homeopathic products; Veterinary medicinal products intended for animals which are exclusively kept as pets; Parallel traded products)
- 2) Now that Advice on UPD published, Check that the fields identified in the Data fields section are available for your products, and check when fields should have reference terms, whether this is the case for your products
- 3) **Map** the reference terms
- *Final goal: Send relevant product data to Union Product Database by date of application (DoA) of the NVR*
- Note: Once the development project on the NVR-UPD will be established and launched, more practical details will be communicated, for instance whether a testing environment will be available beforehand for MS to test sending data, whether all categories of products will need to be sent at the same time or whether there might be some stepwise approach, and most importantly what will be exactly the mandatory fields to be provided for legacy data.

Why mapping is critical?

1. Mapping is a **pre-condition** for NCAs which use or plan to **use SPOR through a system/data integration**
2. EU **harmonised** vocabularies and **comprehensive** organisations dictionary **depend on NCAs completing their mapping**
3. **Products and Substances cannot be implemented** in the Network without harmonised vocabularies and organisations

Data mapping process

Data mapping *- is the process of matching data objects between two (or more) distinct sets of data*

1. **Know your data & Determine Mapping approach**
2. **Map (or Match) data**
3. **Transform & Enrich data**
4. **Submit changes/ updates**
5. **Determine Synchronisation approach**

Thank you for your attention!

Annex – Data fields required in legislation

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2.3.1. Data fields required in legislation

The data fields listed below are considered to fulfil the basic legal requirements of the NVR.

Data field	Description	Format
All products		
Category of product	Distinction between authorised VMP, registered homeopathic VMP, VMP allowed for pets, parallel traded product	controlled lists
Product name	Name as authorised in the MS or by the Commission. The name could include the invented name, pharmaceutical form and the strength description *[full presentation name as approved in the MS]*	free text
Active substance	Name of active substance	controlled lists
Strength (composition)	Content of active substances in a veterinary medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the pharmaceutical form	structured data
	Composition of immunological veterinary medicinal products	Free text when structured data is not possible
Manufacturing sites	List of manufacturing sites	controlled lists
Date of placing on the market in the Union	Date when the product was first sold on the market in any member state	date
Documents	Documents to be attached to product record, incl. selection of type (SPC, package leaflet, public assessment report, etc.)	controlled lists plus uploaded documents
Product owner	Marketing authorisation holder, holder of small pet products exemption, holder of homeopathic registration or wholesaler who owns the parallel trade approval	controlled lists
For authorised veterinary medicinal products only		
Availability status	Marketing status: product available on the market per member state	controlled lists
Date of availability status	Date of marketing status	date
Authorisation status	Product authorised, suspended, revoked or withdrawn	controlled lists
Date of authorisation status change	Date of authorisation status change	date
Annual Volume of sales	Annual volume of sales	structured data
For parallel traded products only		
Source Wholesaler	Wholesaler who is providing the parallel traded product in the source Member State	controlled lists

Annex – Additional Data fields

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2.3.2. Additional data fields required for functioning of processes/procedures

The additional data fields listed below are considered essential to support the operation of the business processes arising from the NVR.

Data field	Description	Format
Permanent identification number	UPD unique identification number	structured data
Product identification number	Product unique identification number for same products across countries *[to enable grouping of MRP/DCP products and products that underwent SPC harmonisation]*	structured data
Route of administration	Routes and methods of administration	controlled lists
Pharmaceutical form	Pharmaceutical dose form	controlled lists
Target species	Target species	controlled lists
ATC Vet Code	Anatomical Therapeutic Chemical classification system – Veterinary	controlled lists
Withdrawal period	Withdrawal period per species and per tissue *(for medicines for food-producing species only)*	free text
PhVSMF number[7]	Reference number of PhV system master file	free text
QPPV name[7]	Name of the QPPV	free text
QPPV localisation[7]	Address and country where the QQPV is located	Structured data
Package description	Pack sizes	free text
Legal status of supply	Legal status for supply (e.g. over the counter, prescription only, etc.)	controlled lists

Data field	Description	Format
Procedural information for initial authorisation		
Authorisation procedure type	EU regulatory authorisation procedure type	controlled lists
Procedure number	Procedure number for initial procedure	free text
Marketing authorisation date	Date on which the first marketing authorisation was granted	date
Authorisation country	Country in which the authorisation was granted (incl. European Union)	controlled lists
Reference member state	Country name *only if authorisation type is MR/DC*	controlled lists
Concerned member state	Country name *only if authorisation type is MR/DC*	controlled lists
Legal basis	Legal basis of product authorisation, incl. e. g. limited market and exceptional circumstances.	controlled lists
Authorisation number	Marketing authorisation number, homeopathic registration number, declaration numbers for MA exemptions, parallel trade approval number	free text
Reference product	ID of authorised reference product if legal basis = generic, hybrid, biosimilar, informed consent or parallel traded product the reference product in the country of destination	identifier
Source product	ID for the reference product in the source country for parallel traded products	identifier
Procedural information for post-authorisation changes *(multiples, for – at least – every variation not requiring assessment)*		
Application identifier	Identifier generated by submission system	structured data
Procedure number	Centralised, mutual recognition or national procedure ID	free text
Responsible authority	Country name	controlled lists
Variation classification code	Variation classification	controlled lists
Submission comment	Comment from product owner as part of the submission	free text
Date of submission	Date generated by submission system	date
Decision	Approve or reject	controlled lists
Date of decision	Date of decision, generated by UPD	date