EGGVP comments as regards the **EMA scientific recommendations** on delegated and implementing acts as part of the implementation of the new veterinary medicines Regulation 2019/6

Subject: **Necessary measures and practical arrangements for the Union database on veterinary medicinal products (Article 55(3))**

Preamble

On 27 February 2019 the European Commission sent a request to the European Medicines Agency (EMA) for scientific recommendations as regards the Union product database (UPD) and the technical and functional analysis necessary for its establishment.

The Committee for Medicinal Products for Veterinary Use (CVMP) adopted the scientific recommendation on 29 August 2019.

On 18 September 2019, the European Commission (DG Sante) contacted EGGVP with a kind request for written comments as regards the EMA advice, in the context of a targeted stakeholder consultation.

EGGVP highly values this consultation and the opportunity to share its views on this topic; we thank DG Sante for the initiative.

Introduction

Developing and establishing the new UPD within the short time-frame set by the new veterinary legislation will be a resource intensive challenge for both regulators and industry, but in the long-term bears the promise of significant simplification, transparency and reduction of administrative burden.

As a stakeholder association representing mainly small and medium sized enterprises, EGGVP appreciates the aim of the new regulation to reduce administrative burden for both, regulators and industry and suggests that, when designing the systems, emphasis is made on 5 key points:

PARTNERSHIP	▪ The new DB should be designed and work for all ▪ Interested Parties should be jointly participating in its functional design ▪ Partnership between all Agencies and MAHs is an essential success factor
USER-FRIENDLINESS	▪ Simple and cost effective IT solutions for the veterinary domain, appropriately adapted considering size and requirements ▪ Users can easily and effectively carry out the required tasks, while minimizing errors ▪ Connection to EMA Account Management in order to avoid multiple user registrations
EFFICIENCY	▪ Minimum data fields ▪ Extensive use of existing, quality-improved legacy data ▪ Inter connected to ensure a high re-usability of entered data (i.e. guarantees one single level of reporting sales, ESVAC, PhV DB, …) ▪ UPD should constantly synchronize with existing national DBs
DATA PROTECTION	▪ Sharing product data with the general public is appreciated, ▪ **but** sharing commercially confidential information is not. ▪ Multi-level user roles allow clear control over who sees what kind of information
PLACE IN IT LANDSCAPE	▪ Full compatibility of UPD with all relevant EU Telematics Projects ▪ Use of Master Data Services available at that time, at least RMS and OMS ▪ Possibility to use data to generate CESSP submissions

Considerable investments are foreseen in the next years and it is imperative that such investments are proportionate and manageable for all stakeholders. Especially taking into account the factuality of small European companies, where limited resources are more critical and the scale of benefits is not as obvious compared to the big pharma sector, high investment are questionable and need to be viewed critically.

EGGVP general comments

1- Transparency periods of protection of technical documentation

EGGVP welcomes the European Union's approach to facilitate exchange of information with the general public and therefore supports the establishment of the Union Product Database (UPD).

According to Art.40 of the new veterinary regulation, where the first marketing authorisation is granted for more than one animal species or a variation is extending the marketing authorisation to another species, the initial period of the protection shall be prolonged for a determined period for each additional target species, provided that, in the case of a variation, the application has been submitted at least three years before the expiration of the initial protection period.

Unfortunately, these provisions of the new veterinary regulation lack transparency for generic submissions, bringing the legal uncertainty for the Competent Authorities as well as the applicants, and adding unpredictability for generics in order to plan and perform their investments. The information on the submission for extension of the marketing authorisation shall be made publicly available, and as such the UPD shall guarantee transparency provisions by disclosing the information on the submission and subsequent extension of the protection periods.

It should be noted that the EMA Scientific recommendation on the revision of Annex II to the NVR (page 13) currently state that *" 9. Confirmation by applicant that all submitted data relevant to the quality, safety and efficacy of the veterinary medicinal product, including data publicly available, are not subject to protection of technical documentation should be provided in Part 1 of this annex. "*

It will not be possible for applicants to meet this requirement without the necessary guarantees that access to the relevant product data related to protection of technical documentation is made available to other marketing authorisation holders. Both, the regulators and the applicants, need transparent data provided by the UPD to avoid juridical consequences.

2- Use of existing functionalities and functionalities under development

On page 1 of its advice, EMA makes a general recommendation: *"The Agency, supported by the Expert Group, advises that the UPD concept should be built utilising existing functionalities and functionalities under development in the network, as far as possible".*

- With regards of the use of existing functionalities: today, every Member State has been using its own approach to develop its national database, therefore migrating this existing legacy data will be very resource consuming since every country will have to develop a specific tool for this purpose. Checking of legacy data would be very time consuming for all MAHs with no human resources dedicated to such projects, and should be avoided by all means.

The authorities are required to populate the UPD initially with their data. Presumably this requires a phased approach: CP -> DCP/MRP -> National. Additionally, the data format has to be established as soon as possible, since mapping of data fields and cleansing of legacy data will be crucial to functionality / usability of the product database by the time the new veterinary regulation becomes applicable. Since integration in PMS is a long term goal, specifications should be discussed as closely as possible with PMS team / representatives of the SPOR TF.

- With regards to the use of **functionalities under development**: It is of major concern that in the future the UPD and PMS will co-exist, which will need duplicated efforts from the industry/competent authorities to keep them updated and coordinated. At EGGVP we strongly plea that only one database should exist, and that PMS of SPOR should form a base of the future UPD. If combination of PMS and UPD in the mid to long term is the goal, the new database should be designed as close to PMS as possible, including the characteristics/specifications of the PMS of SPOR, in order to achieve a smooth transition later on.

  This will also impact **user access.** User roles of SPOR should be translated to the UPD. Users, who already have a specific role in SPOR, should be automatically assigned the same role in the product database without extensive authorisation process.

  The UPD should make full reference to as many master data services as possible at the time of go-live. Minimum requirement are RMS and OMS.

3- Minimum information and handling of variations

Article 55(2) lists the minimum information contained in the database. EMA main recommendations on page 2 suggest “to focus on the minimum viable product fulfilling only legislative requirements and those additional requirements that ensure legally required business processes can be operated effectively”.

While this is basically supported, more data than the minimum required by Art. 55 will be needed to handle variations in the way requested by the legislation. The industry supports and urges the development of a fully operative Product Database that allows implementing variations management in full along with all other legislative requirements.

Furthermore, management of variations not requiring assessment will require provision of documentation during the procedure. For these variations a mechanism to allow provision of documentation in the UPD should be considered.

EGGVP therefore recommends setting up UPD extending the minimum data sets as required by Art. 55 (i.e. adding new ones: number, scope, status, product change log, etc.) so as to allow handling variations in the way requested by the legislation. In addition, agreement should be reached about how any required supporting documentation can be provided after the change has been recorded in the database.

The implementing act on variations not requiring assessment should be usable entirely as from the date of application of the regulation, and the UPD specifications should allow a company to record all changes and upload all required supporting documentation. Restriction on these due to database limitations would increase administrative burden which would entail a serious regression away from one of the main objectives of the regulation, while it will generate a high level of uncertainty and unpredictability for industry as well as for regulators.

Furthermore, confidentiality levels have to be discussed for these (contents of variation, variation status), since this is sensitive commercial information for the industry.

EGGVP specific comments

In track changes (17 comments) - document enclosed *(available below)*

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 August 2019
EMA/392996/2019
Veterinary Medicines Division

Advice to the European Commission on the Union Product Database

Implementing measures under Article 55(3) Regulation (EU) 2019/6 on veterinary medicinal products as regards the Union product database and the technical and functional analysis necessary for its establishment

Background

According to Article 55(1) of Regulation (EU) 2019/6 ('NVR') the European Medicines Agency ('the Agency') shall establish and, in collaboration with Member States, maintain, a Union database on veterinary medicinal products ('UPD'). For this purpose, according to Article 55(3), the Commission is to adopt, by means of implementing acts, the necessary measures and practical arrangements relating to the electronic exchange mechanism and format, the functioning of the database, the detailed specifications of the information therein, contingency arrangements and, possibly, additional data.

On 27 February 2019, the European Commission requested the Agency to provide advice on the measures and arrangements required to deliver the technical and functional analysis allowing for the actual development of the UPD to be launched.

In this regard, the Agency agreed that an expert group should be constituted to provide advice to the Agency in relation to the measures above described.

Scope of the Union Product Database

The UPD, as described in the NVR, is understood to consist of several interacting IT (information technology) components, most already existing or under development in the network telematics landscape. In this case, most of the development work to be executed would be related to adding and linking functionalities of these components, rather than developing a new standalone IT system.

Commented [a1]: See EGGVP General comment #2

Recommendation: The Agency, supported by the Expert Group, advises that the UPD concept should be built utilising existing functionalities and functionalities under development in the network, as far as possible.

From an operational point of view the objectives of the UPD are:

- To be the common database to collect, store and provide information about veterinary medicinal products within scope of NVR to both individual users and other, centralised/NCA systems

- To use structured data and controlled vocabularies in the UPD; to foster the use of controlled vocabularies for improved data quality in the regulatory processes
- To be the common database to collect, store and provide information on availability of veterinary medicinal products (VMP)
- To allow integration of the UPD in the activities of the regulatory network
- To support electronic exchange of product data between competent authorities and the Agency

The system concept should be based on a vision (see Annex I). Due to the tight schedule driven by the implementation deadline laid down in the NVR, a stepwise approach is recommended.

Thus, prioritisation of requirements will be essential to fulfil legal requirements but also to ensure that the system is fit for purpose. In the implementing act, it is recommended to mention that further releases would be necessary to fulfil the complete vision of the UPD.

Commented [a2]: See EGGVP general comment #3

Recommendation: The Agency, supported by the Expert Group, advises that the initial development should focus on the minimum viable product fulfilling only legislative requirements and those additional requirements that ensure legally required business processes can be operated effectively.

Legislative scope

In consequence, the following Articles of the NVR[1] constitute the basic scope (content not reproduced here):

- Recital 29 on access of the general public to information in the databases
- Recital 84 on information relating to authorisation of veterinary medicinal products in the Union
- Article 55 on the Union Product Database
- Article 56 on Access to the Union Product Database
- Article 58 on Responsibilities of the Marketing Authorisation Holder
- Article 61 on Variations that do not require assessment
- Article 67 on Measures to close procedures for variations requiring assessment
- Article 74 on connection of Pharmacovigilance Database with Product Database
- Article 102 on Parallel trade products
- Article 153 on Transitional measures regarding delegated and implementing acts
- Article 155 on Initial input to the product database by competent authorities
- Annex III on List of obligations referred to Article 136(1)

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]

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0006&rid=1

- 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 mandated in the NVR
  [light workflow management to be included only for variations not requiring assessment]

1. High-level requirements

1.1. Level 1 business processes

For the preparation of this document a compilation of level 1 (L1) business processes has been selected and represented through a series of diagrams. L1 models demonstrate the high level information flow regarding the processes, and their representation serves both to identify UPD needs and elicit requirements that will support the envisaged system concept.

In accordance with the content of the legislative text, five main groups of processes have been identified:

- BP1 - New Product Data
- BP2 - Post Authorisation Changes to Product Data
- BP3 - Access Management
- BP4 - Provide Data to the Public
- BP5 - Provide Data to Controlled Users

Commented [a3]: Consider including information on periods of protection of technical documentation – See EGGVP general comment #1

The **New Product Data** process allows a Competent Authority to introduce new products in the UPD. Different types of products can be inserted at this stage: authorised VMP, registered homeopathic VMP, VMP allowed for use in pets (Art. 5.6) and parallel traded products.

Post Authorisation Changes to Product Data are the processes through which it is possible to introduce a change in the data set of an authorised VMP that already exists in the UPD. Changes for product data are introduced after a variation with or without assessment, but also when additional post marketing authorisation data not linked to regulatory procedure is introduced by the Marketing Authorisation Holder (MAH) or Competent Authorities.

According to the NVR (Art. 61), all variations not requiring assessment are introduced in the UPD by industry and will have to be accepted or rejected by a competent authority. Many variations not requiring assessment will not change data in the UPD but these procedures will need to be logged for approval/rejection purposes to fulfil the legal requirement laid down in the NVR.

Different modalities of changes are possible, and can be introduced in parallel. They are represented in the three processes:

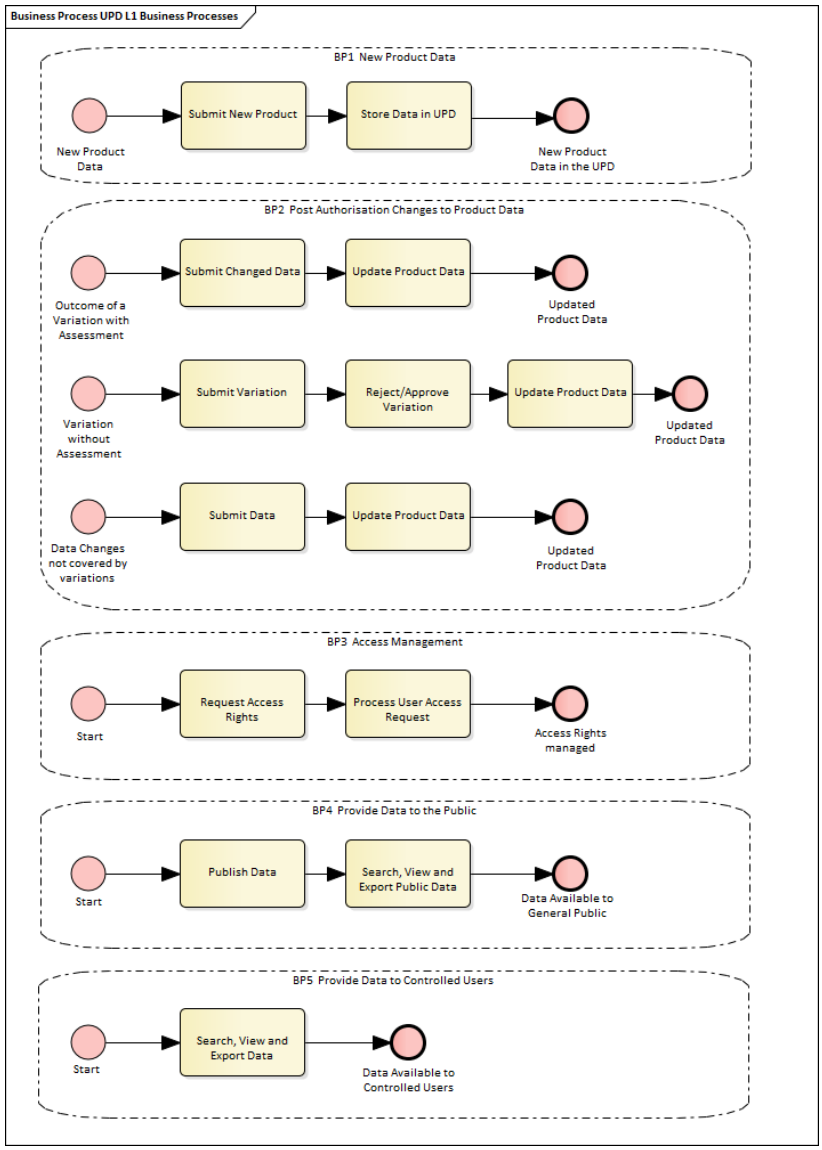
- Variations with assessment
- Variations that do not require assessment
- Data changes not covered by variations and/or regulatory processes: e. g. volume of sales, availability, marketing authorisation status, placement on the market

The **Access management** process allows the management of access rights of controlled users.

The **Provide data to the public** process allows making available regularly updated information that general public users would be able to search and view.

The **Provide data to controlled[2] users** process allows the different controlled users of the UPD to see information of the system depending on the permissions that have been granted to their profiles through the Access Policy.

The processes are described generally in the diagrams below.



[2] Please see glossary for definition of "controlled user"

A more extensive and detailed compilation of business processes will be carried out as the implementation of the UPD concept progresses, as part of the detailed analysis and design.

1.2. High-level business requirements

Recommendation: The Agency, supported by the Expert Group, advises that only 'Must' requirements are considered in the implementing act, with 'Should' and 'Could' requirements prioritised for further development of functionality after the UPD is established (see Annex on Vision for UPD).

Business requirement ID	Requirement name	Requirement description	MoSCoW[3]
BP1 – New Product Data			
BR-01-001	Create new product entry	Competent authorities can create new product entries following approval of a product (any type). These entries will contain legally required fields and additional fields required to fulfil the business processes covered in the UPD.	Must
BR-01-002	Create pending product entry	Competent authorities can create new product entries at the end of the assessment phase for MRP/DCP products to be authorised/not authorised in specific member states. This is needed to support variation procedures.	Should
BR-01-004	Identify existing identical parallel application	Competent authorities can identify applications which should be rejected because of the existence of a parallel pending application in another member state through a detailed search on a web interface and/or through an API.	Could
BR-01-005	Provide legacy product data for agreed data fields in UPD	Competent authorities shall be able to electronically submit legacy data in line with the legally required and agreed additional mandatory fields.	Must

[3] The acronym MoSCoW stands for 4 different categories of initiatives (here: requirements): must-haves, should-haves, could-haves, and will not have at this time.

Business requirement ID	Requirement name	Requirement description	MoSCoW[3]
BR-01-006	Provide information on parallel traded products	Competent Authorities of the destination member state shall be able to electronically submit information on parallel traded products in the UPD, including legally required and any agreed additional mandatory fields.	Must
BR-01-007	Additional data fields necessary to fulfil the vision	The UPD database shall contain additional data fields to fulfil the product data requirements of other databases included in the NVR.	Could
BR-01-008	Use controlled vocabularies	The UPD shall use controlled vocabularies and organisation data.	Must
BR-01-009	Use harmonised product data after MRP/DCP	The UPD shall support consistent common data of product entries after MRP/DCP procedures (excl. legacy data).	Should
BR-01-010	Data validation	The system validates new product data against defined standards and business rules.	Must
BR-01-011	Update of Competent authority databases	After a change notification, competent authorities can apply the update to their own database, to help ensure data consistency in the regulatory network.	Must
BR-01-012	Assign unique product identifiers	The system assigns unique product identifiers to enable automatised data exchange between the UPD and other centralised or Competent authorities' databases.	Must
BR-01-013	Update of MAH databases	After a change notification, MAH can apply the update to their own database.	Should
BR-01-014	Obtain manufacturing site data	The system shall be able to obtain manufacturing site data from an external system.	Could

Commented [a4]: Suggest replacing by Should – the system should allow interconnectivity to ensure a high re-usability of entered data (and in line with BR-01-015 and BR-01-016)

Business requirement ID	Requirement name	Requirement description	MoSCoW[3]
BR-01-015	Provide data to PhV database	The system allows the PhV database to obtain the product data (incl. sales volumes) at pharmaceutical form level.	Should
BR-01-016	Provide data to Antimicrobials sales and consumption database	The system allows information on products to be available at package level to the antimicrobial sales and consumption database.	Should
BR-01-017	Identify existing identical product authorisation	Competent authorities can identify applications which should be rejected because of the existence of the same product in another member state through a detailed search on a web interface and/or through an API.	Should
BR-01-018	Bulk upload of legacy data	An environment for the testing of the bulk upload of legacy data should be available approx. 6 months before the implementation deadline.	Should
BP2 - Post Authorisation Changes to Product Data			
BR-02-001	Record variation not requiring assessment in UPD	Where a variation is included in the list established in accordance with Article 60(1), the marketing authorisation holder can record the change in the product database.	Must
BR-02-002	Provide product data for creating variation procedures	Marketing authorisation holders shall be able to select from authorised products and shall see the relevant master data that shall be changed, if applicable.	Should

Business requirement ID	Requirement name	Requirement description	MoSCoW[3]
BR-02-003	Acceptance or rejection of the variations not requiring assessment	Competent authorities 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.	Must
BR-02-004	Reporting on changes to dataset	Competent authorities can obtain report on the history of changes to the dataset in the UPD.	Should
BR-02-005	Reporting on changes to dataset	The MAH can obtain report on the history of changes to the dataset in the UPD.	Could
BR-02-006	Recording data change following variation requiring assessment / MA transfers	Competent authorities can update the product database following variations requiring assessment, where this affects the product data. This should include MA transfers.	Must
BR-02-007	Collection of sales volumes	MAH must be able to submit annual sales data at package level for authorised products on the market to fulfil their legal obligations.	Must
BR-02-008	Analysis of sales volumes	The system shall enable reporting on sales data for analysis.	Must
BR-02-009	Record availability information	The MAH or Competent authorities shall be able to update information about market availability of products.	Must
BR-02-010	Analysis of availability information	The system shall enable reporting on information about market availability of products.	Should
BR-02-011	Record authorisation status	The system shall allow changing of the marketing authorisation status of a product.	Must

Commented [a5]: Suggest replacing to Should – this is an important functionality for MAHs while aligned with BR-02-004

Business requirement ID	Requirement name	Requirement description	MoSCoW[3]
BR-02-012	Analysis of marketing authorisation status	The system shall enable reporting on information about marketing authorisation status of products.	Should
BR-02-013	Processing of parallel variations	The system shall support processing of parallel variations in the UPD.	Must
BR-02-014	Download of sales volumes	The system shall enable download of sales data for analysis outside the system, in accordance with access rights.	Should
BP3 - Access management			
BR-03-001	Public access	The general public can search and view non-restricted data.	Must
BR-03-002	MAH access	MAHs can access with read permission all information about their own products following secure authentication and authorisation, and write permissions to selected data to allow MAHs to fulfil their post-marketing obligations.	Must
BR-03-003	Competent authorities read access	Competent authorities can access (read) all information following secure authentication and authorisation.	Must
BR-03-004	Competent authorities write access	Competent authorities can access (write) the data they are responsible for following secure authentication and authorisation.	Must
BR-03-005	Access right delegation	MAHs can grant access to other users to manage product data on their behalf.	Should
BP4 - Provide data to the public			
BR-04-001	Export public data	A non-registered user can download the relevant search results from the public data in the UPD.	Should

Business requirement ID	Requirement name	Requirement description	MoSCoW[3]
BR-04-002	Subscription to change notifications	A non-controlled user can subscribe to changes in data they have access to.	Could
BP5 - Provide data to controlled users			
BR-05-001	Notification of changes to Competent authorities	Competent authorities shall be able to subscribe to receive notifications of any change done by MAH to the dataset under their responsibility.	Must
BR-05-002	Notification of changes to MAH	MAH shall be automatically notified of any change done by Competent authorities to the dataset under their responsibility (their products).	Must
BR-05-003	Search restricted data	A controlled user can search the restricted data in the UPD, according to their access rights.	Must
BR-05-004	Export restricted data	A controlled user can export the relevant search results in restricted data in the UPD, according to their access rights.	Should

1.3. High-level non-functional requirements

Non-functional requirements (NFR) considered essential are recommended based on the Agency's standard NFR catalogue. The following table provides the list of essential NFRs (all NFRs listed below are considered MUST requirements):

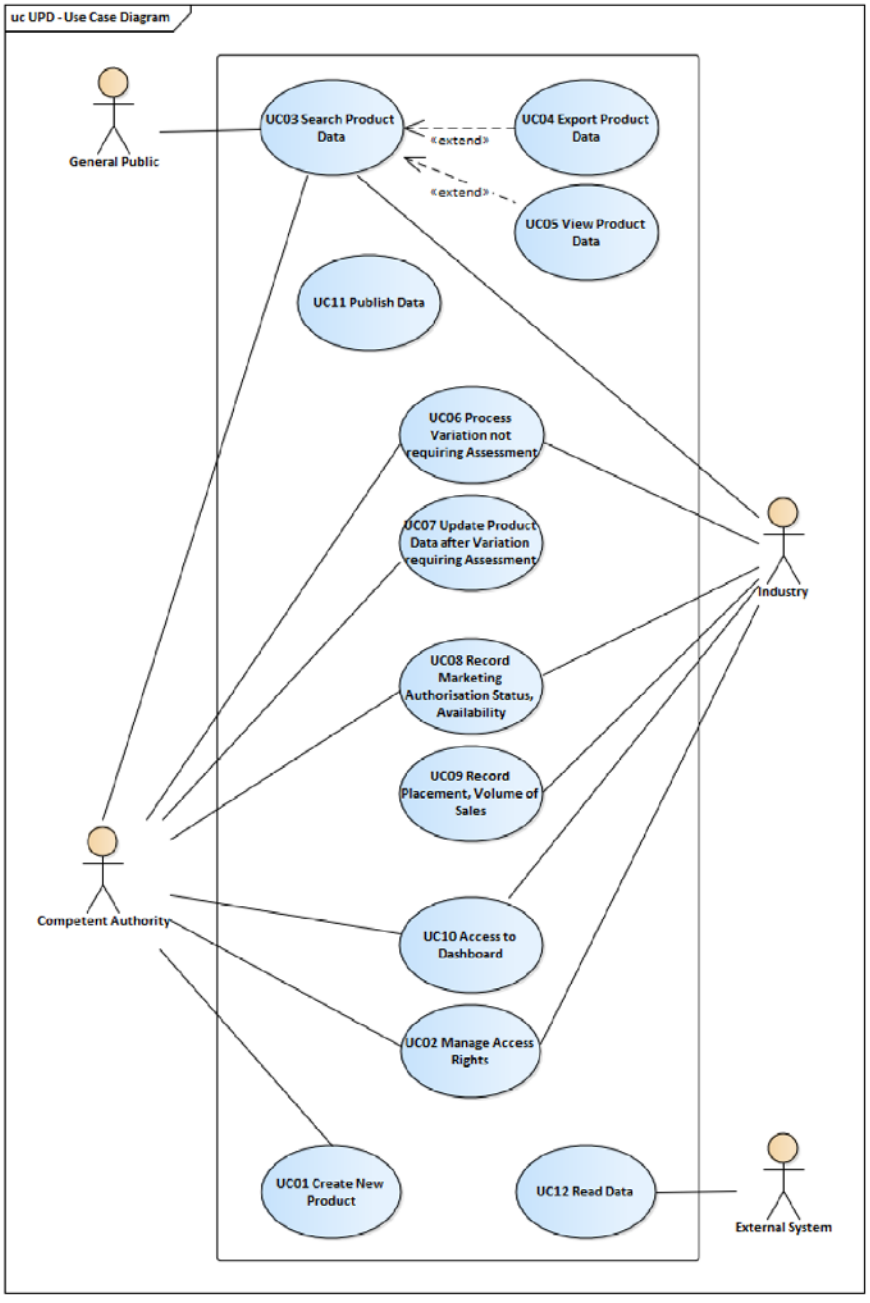
Req ID	Name	Description
NFR-01	Backup & Recovery - Data Store	The system shall ensure data recoverability.
NFR-02	Business Continuity - System Recovery Time	The system shall not be unavailable for longer than 24 hours within European working hours between 08:00 CET and 19:30 CET.
NFR-03	System integration	The system shall be interoperable with other existing or to-be-built systems that consume veterinary medicinal product information.

Req ID	Name	Description
NFR-04	User authentication	The system shall require the controlled user to login with their credentials for every session.
NFR-05	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.
NFR-06	Enforce controlled access	The system shall limit access to the types of information and functions that controlled users are permitted to exercise. The proposed access control mechanism shall conform to the security classification of the data expose and follow the Agency's security requirements, ensuring the segregation of responsibilities and to restrict access to data.
NFR-07	Scan uploaded documents for viruses/malware	The systems shall scan every document for viruses and shall prohibit the upload of documents with viruses or malware.
NFR-08	System security	Exposed system components shall be protected against known vulnerabilities.
NFR-09	Programming interface(s)	The system shall have application programming interface(s) able to transfer and exchange data with the software used by industry and national competent authorities.
NFR-10	Graphical user interfaces	The system shall include graphical user interfaces providing direct access to users in accordance with their access rights.
NFR-11	Responsive design	The system's graphical interface for the general public shall support responsive design.
NFR-12	Legal requirements	The system shall comply with general legislative requirements, e. g. EU DPR, Accessibility.
NFR-13	Audit trail and traceability	The system shall enable operators to monitor the system and ensure action accountability.
NFR-14	Persistent URLs	The system shall enable links to products and documents to remain stable regardless of the version.

It should be remarked that this NFRs compilation shall be completed when addressing the detailed analysis of the UPD system. Having a more detailed list of NFRs will help ensuring a proper functioning and evolution of the envisaged UPD system. To achieve this, the aforementioned requirements shall be further developed, including others such as usability, maintainability and compatibility.

1.4. High-level use case model of the UPD concept

This section introduces a number of essential Use Cases supported by relevant IT components, which have been identified and defined to support the establishment of the UPD concept.


uc UPD - Use Case Diagram
General Public
UC03 Search Product Data
«extend»
UC04 Export Product Data
«extend»
UC05 View Product Data
UC11 Publish Data
UC06 Process Variation not requiring Assessment
UC07 Update Product Data after Variation requiring Assessment
Industry
UC08 Record Marketing Authorisation Status, Availability
UC09 Record Placement, Volume of Sales
Competent Authority
UC10 Access to Dashboard
UC02 Manage Access Rights
UC01 Create New Product
UC12 Read Data
External System

The main actors that will interact within the UPD concept are described below:

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

In the use case model diagram, the main goals of system-user interactions are represented. The use cases are intended to represent the long-term use of the UPD and therefore exclude the one-time loading of legacy data. The use case model and use cases will be further elaborated in later phases, when addressing the detailed analysis and design of the different functionalities included in the UPD system concept.

A description of each of the use cases represented in the diagram is presented in the following table:

Use Case	Short Description	Business Process	Actor
UC01 Create new product	This use case describes how Competent authorities can securely create new product entries in the UPD based on electronically submitted data and approval information. *This use case does not support legacy data creation.*	New Product Data	Competent Authority
UC02 Manage access rights	This use case describes the process of assigning access rights to users.	Access Management	Competent Authority; Industry
UC03 Search product data	This use case describes how users can search information on the UPD to obtain results according to their access rights.	Provide Data to the Public Provide Data to Controlled Users	Competent Authority; Industry; General public
UC04 Export product data	This use case describes how users can export product data in defined formats according to their access rights.	Provide Data to the Public Provide Data to Controlled Users	Competent Authority; Industry; General public

Use Case	Short Description	Business Process	Actor
UC05 View product data	This use case describes how a user can view search results in the UPD according to their access rights.	Provide Data to the Public Provide Data to Controlled Users	Competent Authority; Industry; General public
UC06 Process variation not requiring assessment	This use case describes how a variation without assessment is managed in the UPD.	Post-authorisation changes to product data	Competent Authority; Industry
UC07 Update product data after variation requiring assessment	This use case describes how a change to product data following a variation with assessment is recorded in the UPD.	Post-Authorisation Changes to Product Data	Competent Authority
UC08 Record marketing authorisation status, availability	This use case describes how a controlled user can update the marketing authorisation status and the availability information of a veterinary medicinal product in the UPD.	Post-Authorisation Changes to Product Data	Competent Authority; Industry
UC09 Record placement on the market, volume of sales	This use case describes how a controlled user can update information on the placement on the market and the volume of sales of a veterinary medicinal product in the UPD.	Post-Authorisation Changes to Product Data	Industry
UC10 Access to dashboard	This use case describes how a controlled user can access reports including restricted data generated in the UPD, according to their access rights.	Provide Data to Controlled Users	Competent Authority; Industry
UC11 Publish Data	This use case describes how non-restricted data from UPD is published.	Provide Data to the Public	System (UPD)
UC12 Read Data	This use case describes how external systems can read the information from the UPD, according to access rights.	Post-Authorisation Changes to Product Data	External Systems

1.5. Access policy: roles/permissions matrix

Article 56 Access to the product database

1) The competent authorities, the Agency and the Commission shall have full access to the information in the product database.

2) *Marketing authorisation holders shall have full access to the information in the product database as regards their marketing authorisations.*

3) *The general public shall have access to information in the product database, without the possibility to change the information therein, as regards the list of the veterinary medicinal products, the summary of product characteristics, package leaflets and, after the deletion of any commercially confidential information by the competent authority, assessment reports.*

The above legislative requirement has been translated into a high-level roles-permissions-matrix, taking into consideration also the business requirements listed above under section 1.1.

Permissions	Agency / Commission	National Competent Authorities	Industry[4]	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		

Note: Roles can be performed either by a human user or by a system.

Recommendation: The Agency, supported by the Expert Group, advises that a detailed access policy is developed and maintained by the Agency in collaboration with the Member States and Industry through an established governance model, and adopted by its Management Board. The initial version should be drafted and made available following the adoption of the implementing act. This aims to ensure that the different access levels for different actors are established adequately to ensure the functioning of the UPD processes, while protecting commercially confidential information and personal data, also taking into consideration the final technical specifications of the UPD system concept.

2. High-level architecture model

2.1. High-level application overview

This section introduces a high-level application architecture envisioned to fulfil the requirements previously described.

Recommendation: The Agency, supported by the Expert Group, advises that the UPD is understood as a system concept based on a set of integrated system components and not as development of a standalone, monolithic system.

[4] Based on actor definition in use case model

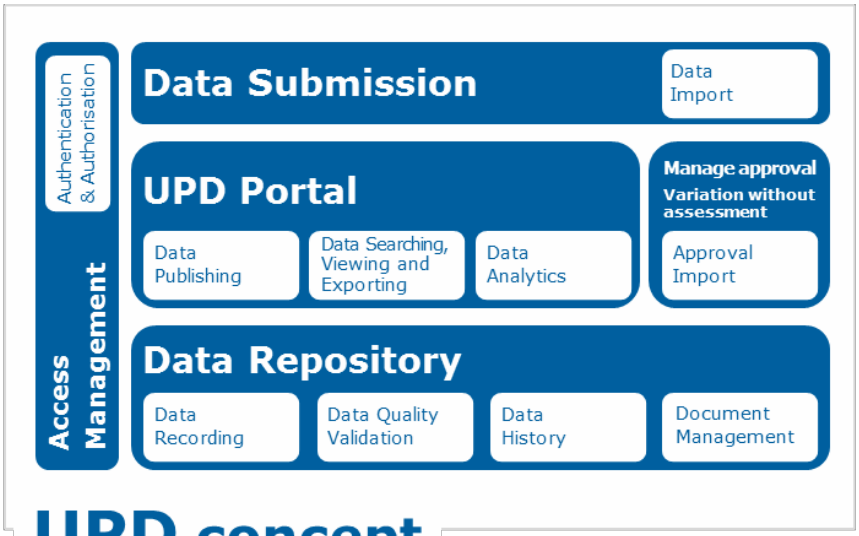
Commented [a6]: Delegation is important for many companies for which MAs are managed by several legal entities

Commented [a7]: Somehow we should use this to make publication of final product texts mandatory. This will allow easier review after MA / Var

The UPD is envisioned to be built as a set of interrelated components that will allow a holistic management of the information that will be stored in the system. In addition, this information will be made available to the general public as long as restricted data has been protected. Considering the required functionalities, five components have been identified:

- **Access Management** – It ensures that controlled users have the appropriate access to the resources provided by the UPD.
- **Data Submission** – New products and post authorisation changes to the products are submitted to the UPD through this module.
- **Data Repository** – It manages all the information that enters into the UPD through the following function groups: data recording, data quality validation, data history and document management.
- **UPD Portal** – The information will be exposed to the general public and controlled users through this component that will make certain features available to the user such as: searching and viewing information or data analytics reports.
- **Manage approval of a Variation without assessment** – Through this component and according to the NVR (Art. 61), a competent authority will be able to accept or reject the variations not requiring assessment.

Commented [a8]: Portal should also function as graphical user interface for data entry into manufacture and wholesale distribution DB. See section 2.4 below for further details.



UPD concept

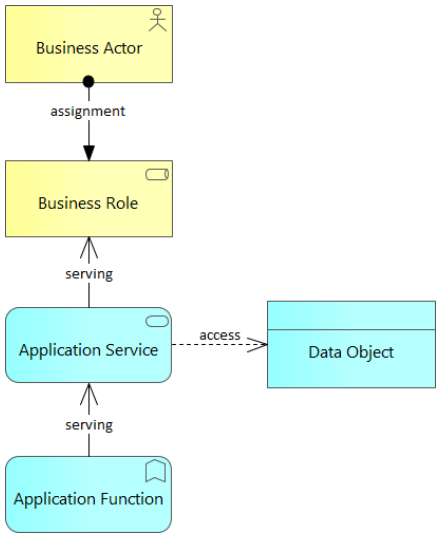
The UPD concept further elaborated below, using a high-level solution architecture *functional* view. To achieve this, a set of standard Archimate 3.0[5] Enterprise Architecture elements have been selected for use in the model, as follows:

Element	Description

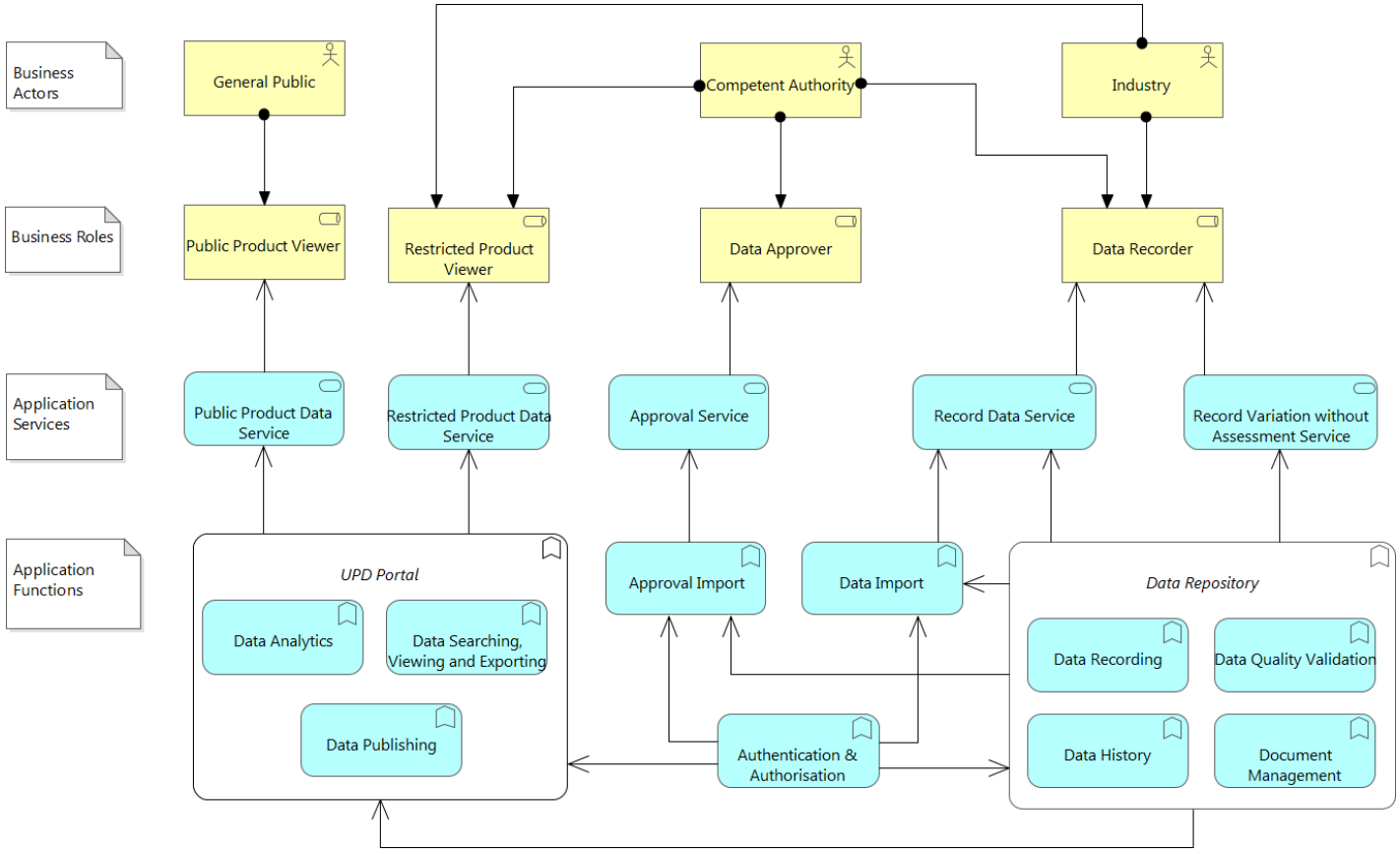
[5] Archimate specification: https://pubs.opengroup.org/architecture/archimate3-doc/

Element	Description
	A *Business Actor* is a business entity that is capable of performing a behaviour. It could be an end user, an organisation or a system. A *Business Actor* may be assigned to one or more *Business Roles*. It can then perform the behaviour to which these *Business Roles* are assigned.
	A *Business Role* is the responsibility for performing a specific behaviour, to which an actor can be assigned. A *Business Actor* that is assigned to a *Business Role* is responsible for carrying out the corresponding behaviour. A *Business Role* may be served by one or more *Application Services*.
	An *Application Service* is an externally visible unit of behaviour, provided by one or more *Application Functions*, exposed through interfaces, meaningful to the environment and having business relevance. The *Application Service* element provides a way to explicitly describe the functionality to be shared and made available to the environment. This functionality serves one or more *Business Roles*.
	An *Application Function* describes the behaviour to fulfil one or more *Application Services*. An *Application Function* describes an application behaviour that could be exposed externally through one or more services. An *Application Function* abstracts from the implementation, only the necessary behaviour is specified.

The relationships between the architecture meta-model elements are defined as follows:



The figure below depicts a preliminary and high-level UPD solution architecture functional view, intended to support the recommendations given in this document; and subject to change during the detailed analysis and design:



The elements that comprise the UPD solution architecture functional view are described below:

Business 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 National Competent Authority level.
Industry	A controlled user at pharmaceutical industry level.

Business Roles	Description
Public Product Viewer	Enables the access to public product information
Restricted Product Viewer	Enables the access to restricted product information
Data Recorder	Role to submit or change product data, as well as post-authorisation changes to specific sub-sets of data, according to access rights.
Data Approver	Enables competent authorities to accept/reject variations without assessment

Application Services	Description
Public Product Data Service	Service responsible for managing the search and view functionalities for public product information
Restricted Product Data Service	Service responsible for managing the search, view and dashboard functionalities relating to restricted product information

Record Data Service	Service responsible for managing the following changes related to:
	• Product data
	  o New product requests
	  o Record variation with assessment (change product data requests)
	• Specific sets of data related to Marketing authorisation status, Availability, Placement on the market, or Volume of sales
	These changes are consolidated immediately.

Record variation without assessment service	Service responsible for managing the changes that are not consolidated immediately, i.e. variations without assessment. These changes require approval before their consolidation in the UPD and imply that some sort of data versioning must exist in the UPD.
Approval Service	Service responsible for managing the changes that have not been consolidated yet.

Application Services	Description
Application Functions	Description
Data repository	
Data Recording	Manages the capability of recording data, including versioning
Data Quality Validation	Manages the validation and quality checks on data prior any consolidation in the database
Data History	Manages the audit trail and traceability of data changes
Document Management	Manages the storage and access to documents
UPD Portal	
Data Searching, Viewing and Exporting	Manages the capability of data search, view and export
Data Publishing	Manages the publishing of data to be accessed by general public
Data Analytics	Manages the capability of data analytics and reports
Data submission	
Data Import	Manages the requests of data submission (e.g. new products, variations, changes on products, etc.)
Manage approval of variations without assessment	
Approval Import	Manages the coordination of activities relating to certain business needs (i.e. approval of variation without assessment prior to consolidation in the database)
Access Management	
Authentication and Authorisation	Manages the access control to data and/or functionalities, enforcing that the user has the proper permits to do so

Commented [a9]: Should be the same as used for other EMA services to reduce number of portals to register for- see EGGVP general comment #2

In order to ensure the suitability of this architecture and illustrate traceability to the use cases, the table below provides the mapping of the use cases to the application services suggested to implement the functionality foreseen to be required by the use case:

Use Case	Mapping to Application Service(s)
UC01 Create new product	Record Data Service
UC02 Manage access rights	Restricted Product Data Service
UC03 Search product data	Public Product Data Service Restricted Product Data Service
UC04 Export product data	Public Product Data Service Restricted Product Data Service

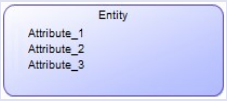
Use Case	Mapping to Application Service(s)
UC05 View product data	Public Product Data Service Restricted Product Data Service
UC06 Process variation not requiring assessment	Record Variation without Assessment Service Approval Service
UC07 Update product data after variation requiring assessment	Record Data Service
UC08 Record marketing authorisation status, availability	Record Data Service
UC09 Record placement on the market, volume of sales	Record Data Service
UC10 Access to dashboard	Restricted Product Data Service
UC11 Publish Data	Public Product Data Service
UC12 Read Data	Public Product Data Service Restricted Product Data Service

2.2. Conceptual data model

This section introduces the high-level conceptual data model, including:

- Entities, with a description of the meaning
- Fields of the entities
- Relationships between entities

The conceptual data model has been developed using Barker's[6] notation, which uses the following rules:

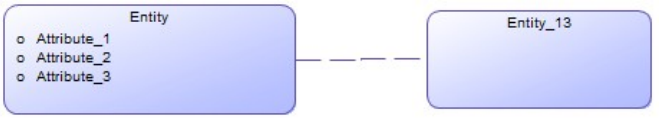
Conceptual data model Barker's notation rules
The main element is an **Entity**, which is represented by a rounded corner rectangle: 
The entity contains **attributes** that describe the characteristics of a particular entity instance: 

[6] Barker's conceptual data model notation: https://www.vertabelo.com/blog/technical-articles/barkers-erd-notation

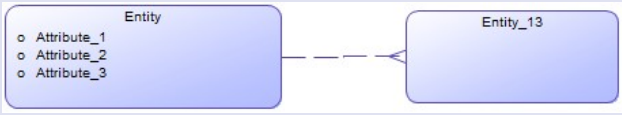
Conceptual data model Barker's notation rules

Entities relate to each other with **relationships**, showing information of the following perspectives:

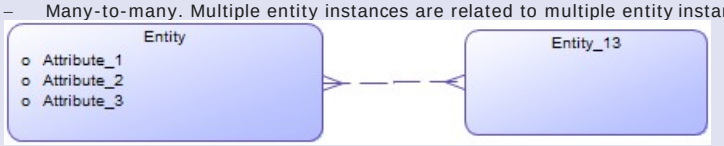
- Optionality:
  - Mandatory, which is represented by a straight line.
  - Optional, which is represented by a dashed line
- Degree:
  - One-to-one. Each entity instance is related to just one entity instance:



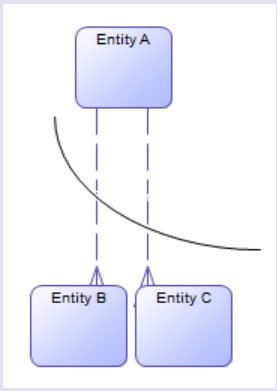
  - One-to-many. One-to-Many Relationship (1:M). Each entity instance is related to multiple entity instances:



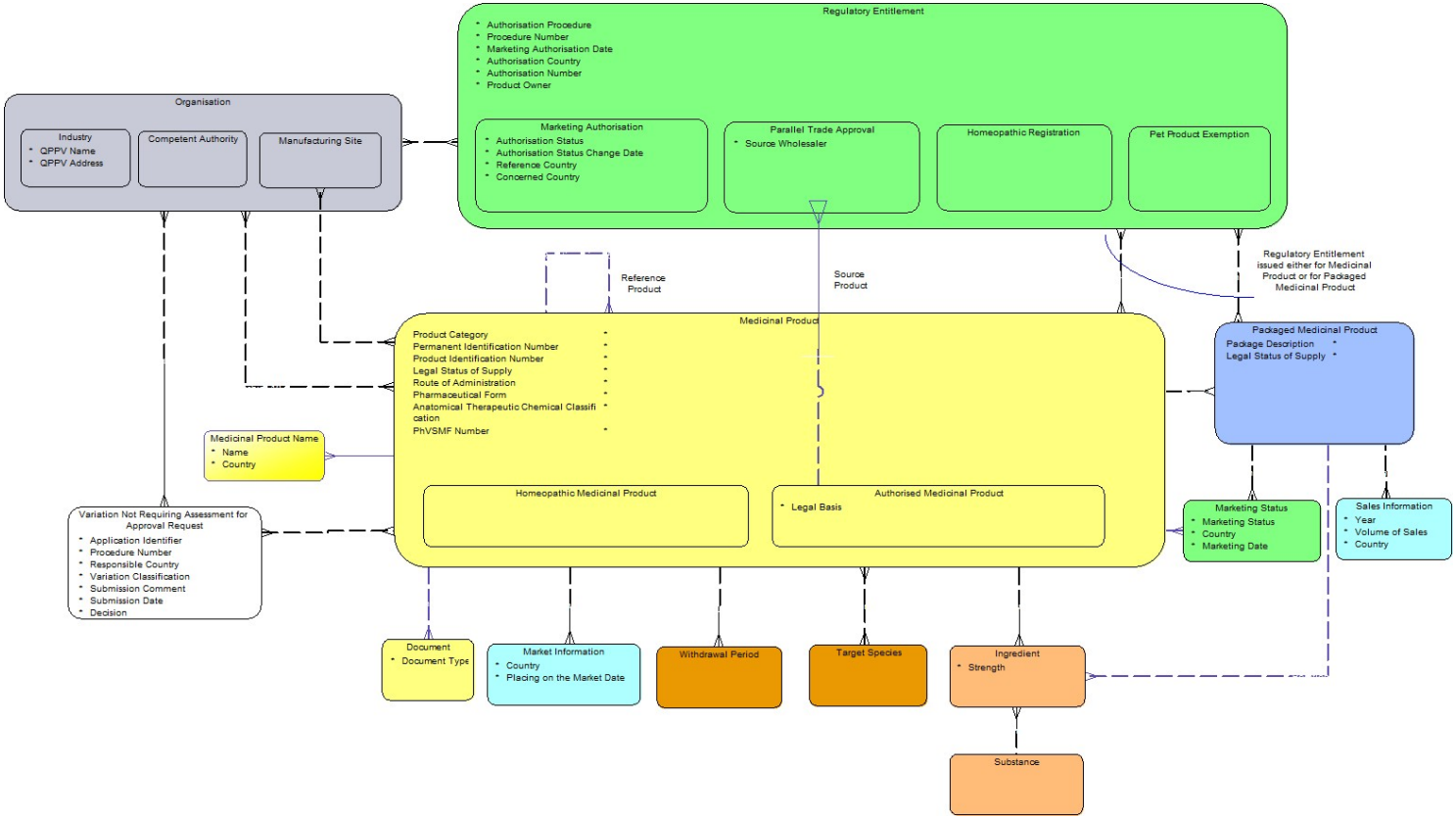
  - Many-to-many. Multiple entity instances are related to multiple entity instances:



An entity has "exclusive or" relationships where it is related to two or more other entities, but only one relationship can exist for a specific entity occurrence.



The picture below shows a preliminary high-level UPD conceptual data model, intended to support the recommendations given in this document; and subject to change during detailed analysis and design:



The table below describes the entities of the conceptual data model:

Entity name	Description
Organisation	A representation of a legal entity (e.g. a business, government department, regulatory body).
Manufacturing Site	A place where a manufacturer produces veterinary medicinal products.
Competent Authority	A body that carries out regulatory activities relating to medicines, including the processing of marketing authorisations, the monitoring of side effects, inspections, quality testing and monitoring the use of medicines
Industry	An organisation within the pharmaceutical industry that is not a National Competent Authority.
Regulatory Entitlement	An entitlement granted by a Competent Authority or the European Commission to a Pharmaceutical Company to undertake a certain activity or acquire a given right in regards to a pharmaceutical product in a given jurisdiction. Examples are Marketing Authorisation, limited market classification, etc.
Marketing Authorisation	Authorisation issued from a Competent Authority or the European Commission that a Veterinary Medicinal Product may be placed on the market.
Homeopathic Registration	Registration to market within the Union of a veterinary homeopathic medicinal product according to the procedure described in Chapter V of NVR.
Parallel Trade approval	Approval of veterinary medicinal product to be parallel traded. The veterinary medicinal product obtained from a Member State ('source Member State') and distributed in another Member State ('destination Member State'), which shares a common origin with a veterinary medicinal product already authorised in the destination Member State. Synonymous to parallel import.
Pet Product Exemption	Marketing Authorisation exemption for veterinary medicinal products intended for animals which are exclusively kept as pets (Art. 5(6) NVR).
Medicinal Product	Article 4 (1) NVR: "Any substance or combination of substances which fulfils at least one of the following conditions: • it is presented as having properties for treating or preventing disease in animals; • its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; • its purpose is to be used in animals with a view to making a medical diagnosis; • its purpose is to be used for euthanasia of animals"
Medicinal Product Name	Name as authorized by the Competent Authority or the European Commission.

Entity name	Description
Packaged Medicinal Product	Medicinal Product in a container being part of a package, representing the entirety that has been packaged for sale or supply.
Authorised Medicinal Product	Proprietary Medicinal Product for veterinary use intended to be placed on the market or industrially manufactured Medicinal Products, the marketing of which has been authorised by a Competent Authority or the European Commission.
Homeopathic Medicinal Product	Homeopathic veterinary medicinal product means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States.
Ingredient	Material used in the preparation of a medicinal product.
Substance	Matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical.
Target Species	Species for which the veterinary medicinal product is intended for as described in the product information. This is not a category of taxonomic classification, ranking below a genus or subgenus and consisting of related organisms capable of interbreeding.
Withdrawal Period	The period necessary between the last administration of the veterinary medicinal product to animals, and the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits for active substances laid down pursuant to Regulation (EEC) No 2377/90.
Document	Refers to documents that provide additional information of a certain veterinary medicinal product
Marketing Status	The marketing status describes when a medicinal product is available on the market (placed in the market) or the date as of which it is no longer available which is considered the date of the last release into the distribution chain.
Market Information	Aggregated relevant information per country, such as date of first placing on the market
Sales Information	Volume of sales per country and year of a certain veterinary medicinal product
Variation Not Requiring Assessment for Approval Request	Hosts information elements that need an approval of the competent authorities prior to the consolidation in the UPD database.

2.3. Data fields

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		

Data field	Description	Format
Source Wholesaler	Wholesaler who is providing the parallel traded product in the source Member State	controlled lists

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
Procedural information for initial authorisation		
Authorisation procedure type	EU regulatory authorisation procedure type	controlled lists
Procedure number	Procedure number for initial procedure	free text

[7] The name of the QPPV and number of the PhV system master file are laid down as a legal requirement for the Pharmacovigilance database in the NVR, not as a legal requirement for the UPD. However, from an information point of view, this data belongs at the product level and it may be more appropriate to store it in the UPD than in the pharmacovigilance system.

Data field	Description	Format
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

2.3.3. Data fields not included in recommendation

The Agency, in collaboration with the Expert Group, considered further data fields which were agreed to be excluded from this advice document, i.e. are not recommended for inclusion in the implementing act. A rationale for this is provided for reference.

Data field	Description	Rationale for exclusion
Domain	A field to distinguish between human and veterinary medicines	A distinction between different medicinal products is included in the medicinal product entity. If a standalone system were built, the distinction would not be necessary. If integration into a joint human/veterinary data repository (under development) is chosen, the distinction would be present at the level of the joint system.
Excipients	List of excipients	While considered potentially useful, the listing of excipients should be left for further discussion and possible addition at a later stage, as no clear business need was identified.
Other fields	Any other fields that may arise from secondary legislation to be adopted or guidance to be developed	The rationale for exclusion arises from two perspectives: 1. List of variations not requiring assessment: The related implementing act is not final and therefore there is no certainty on the complete, final list of fields that could be considered. Where those variations do not change any of the fields listed in sections 2.3.1 and 2.3.2, the UPD system concept still allows recording and approval of these variations, even if no data changes are consolidated into the data repository. Therefore, not all variations without assessment have to be transposed into a data field in the UPD. 2. Data fields that may become required at a later stage, from secondary legislation or guidance, could be prioritised for inclusion after the initial go live of the UPD system. (see Annex I: Vision)

Commented [a10]: From our point of view, this is an unjustified simplification because excipients are part of the VMP and many variations not requiring assessment deal with changes related to the excipients. Should be moved to 2.3.2

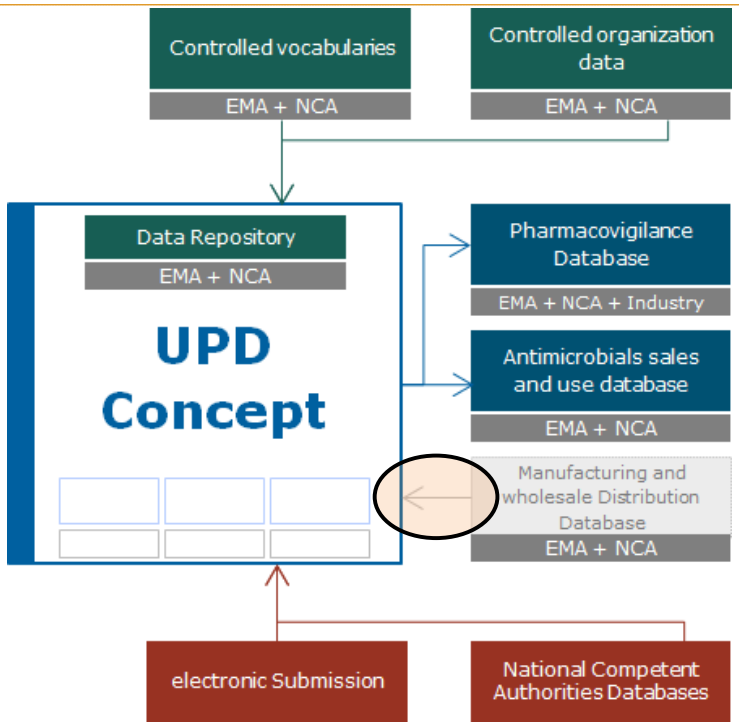
2.4. Interoperability and interface

The UPD is the cornerstone of several databases described by the NVR which are already existing or being developed in the network. To ensure interoperability and interfaces between these databases, the structure of data should be harmonized between the different systems using the same referentials.

As such, information about veterinary medicinal products should be registered in the UPD as the master data repository and not registered/duplicated in other databases, such as the pharmacovigilance database or the database for the sales and use of antimicrobials in the EU.

The interrelations are as follows, but not limited to: The submission of volume of sales is mandatory in the UPD and registered on an (at least) annual frequency by the MAH. The volume of sales will be used

by the pharmacovigilance database for the calculation of incidence and may be considered by member states in the collection of data related to the consumption of antimicrobials. UPD should consume data from other existing databases or IT tools to avoid duplication of data. Information about manufacturers requested in the UPD should be linked to the manufacturer and wholesale database.



Commented [a11]: The link between UPD and MWDD is acceptable in that direction, provided that the UPD portal can function as a GUI for the MWDD data entry. Otherwise, the link should be bidirectional to add manufacturers not already listed in the MWDD by electronic submission without pre-registering them. However, it is acknowledged that this is a critical process for data quality in the MWDD. So the GUI role of the UPD portal should be emphasized. #singledataentry

Veterinary medicinal products for food-producing species can only be authorised once an assessment of the maximum residue limits ('MRLs') of the substance in the relevant foodstuff is concluded. Information from the MRL database might be considered during the assessment of the safety of the product to define the withdrawal period, which is set at product level. Consequently, as the withdrawal period is linked to the product, but the MRL is only linked to a specific (group of) substance(s), a link between the two databases is not considered valuable.

2.5. Data exchange mechanism and format for electronic submission

The data exchange mechanism and format for electronic submission should follow recognised international standards for the exchange of medicinal product information wherever possible. Which standards and the exact details will depend on which systems will be used to support the UPD and the data feed process into the UPD. This will be done in Phase 3 when the actual project is defined and when it will be decided which components of existing and under development systems will be used when building the UPD. The exchange format should use structured data and avoid the use of unstructured content wherever possible.

The UPD will expose service oriented Application Programming Interface (API) able to transfer and exchange data with the software used by industry and national competent authorities. The data exchanged by the API will be in a semi-structured (XML or JSON) format defined according to detailed information models based on the UPD conceptual data model described in Section 2.2. Unstructured documents will be exchanged via API in a binary format (recommended PDF).

3. Contingency arrangements

Within the context of contingency arrangements under Article 55(3)(d) the Agency was requested to review the best available backup and contingency options, both within the Agency and in the wider context, to ensure the continuity of data entry, as well as updating and sharing in case of functionality failures.

The Agency acknowledges the timelines set in Article 155 NVR with regard to initial input to the product database by competent authorities. However, in order to ensure the continuity of data entry - the Agency, supported by the Expert Group, recommends - as a contingency measure - a phasing on the initial product data submission as follows:

Commented [a12]: This simplification of the development process is fully supported.

1. Authorised veterinary medicines by 28 January 2022; this is understood to include data on parallel traded products, as well as homeopathic veterinary medicinal products that are authorised as veterinary medicines in the member states
2. Registered homeopathic veterinary medicinal products by 2024
3. Veterinary medicines for use in animals exclusively kept as pets, and exempt from authorisation according to Article 5(6) by 2026.

The rationale for this proposed phasing is as follows:

Items 2 and 3 require more preparatory work by the member states, and more discussions on the details, e. g. which data fields would be agreed to be mandatory. A phasing would thus alleviate the pressure on the initial implementation period for the UPD. It is noted that in many Member States the information for points 2 and 3 above is not easily available and will take time to gather. The application of phasing would allow for a detailed assessment of the objectives for providing the information and implementation of the functionality required to make the relevant information accessible to all users of the UPD.

The recommendation takes into account that numerous activities provided for in the NVR, e.g. variations not requiring assessment, as well as the NVR's objectives, e.g. providing data on availability and sales/use, depend on the UPD's availability from Day 1 of the application of the NVR. It is agreed that the UPD needs to be functional as of that date at the latest to allow meeting these obligations. As such activities requiring the availability of a UPD do not apply to the products described under 2 and 3 (e. g. the products under 3 shall not include antimicrobials as the marketing authorisation exemption could only apply to products not subject to a veterinary prescription, while VMPs containing antimicrobials are subject to veterinary prescription – Article 34 (1) c), the above approach is considered possible both in terms of legal compliance with the letter and compliance with the spirit of Regulation 2019/6.

In relation to contingency arrangements for potential functionality failures during the ongoing operation of the UPD, at the current high-level, it appears that the use cases describing the functionality of the UPD do not demand a 100% up-time and the huge expense that would entail; for example, the UPD is not envisaged as being used for live support to e-prescription systems.

Commented [a13]: Supported in principle, but the down-time should be monitored and also acceptance criteria should be defined beforehand to measure the performance of the system against these.

However, since many regulatory activities will be highly dependent on the UPD being in operation, suitable Service Level Agreements (SLAs) will need to be in place when the system goes into production. For later guidance developed on specific processes (e. g. the submission of annual volume of sales), which will introduce deadlines, the detailed guidance proposed above should take this into account.

It is recommended that detailed guidance on critical back-up and business continuity processes is developed in collaboration with Member States and industry before the initial go-live of the UPD. Additional contingency and back-up processes need to be aligned with the systems and processes implemented, as well as their more detailed NFRs to be developed / agreed, and are therefore dependent on the detailed design of the UPD.

As such, it would be possible to describe, in the guidance proposed to be developed above, a non-electronic submission of information (or submission via email) in case of reporting deadlines during a complete system failure, or, for example, a switch to a web interface provided for smaller NCAs and companies, in case of a gateway failure. As described above, as this depends on the final technical specifications of the UPD, and a certain degree of flexibility is advisable, it is suggested to introduce such arrangements in the form of guidance when the detailed design of the UPD system concept is available.

Commented [a14]: We can submit via Eudralink, CESP or e-mail, but non-electronic submission is NOT acceptable. We should try to eliminate all national requirements that require non-electronic submissions with the introduction of the NVR.
In addition, it is not a suitable solution for the problem: when there is a deadline to be met and there is all of the sudden a complete system failure, how shall the documents be submitted in time non-electronically? MAHs are prepared for e submission and changing it probably takes too long.

4. Recommended guidance to be developed

The Agency, supported by the Expert Group, advises that supporting guidance to the legislative acts is developed in the following areas:

1. Access policy as described in section 1.5
2. Guidance on contingency arrangements in case of system failure, as described in section 3.
3. Guidance on the principles and approach for managing the regulatory process in case of parallel variations submitted for a veterinary medicinal product.

5. Open issues to be resolved

- Mandatory data fields to be defined in detail as a matter of priority (for import of legacy products, but also new product data entries)
- Responsibilities for parallel traded products: how is compliance of MAH to report sales volumes at country level ensured?; will additional responsibilities, currently not foreseen in legislation, be placed on wholesale distributors? This could have an impact on the complexity of access management.
- Collection of volume of sales will be consumed both for pharmacovigilance and antimicrobials purposes, and the requirements may be different (they come from different users for the same product). As far as possible, it should be aligned to reduce development effort.

Commented [a15]: Mandatory data fields should be defined as closely to SPOR data fields as possible to facilitate data usability (or exchange) – see EGGVP general comment #2

Commented [a16]: Data exchange and connectivity between NVR databases should be a basic design principle for all NVR DBs

Annex I: Vision for UPD system concept

It is acknowledged that the recommendations above are intended to only advise on the technical specifications of the UPD, based on the legislative requirements, to inform the drafting of the related implementing act. A wider vision of the UPD system concept is provided for further context.

Introduction

The Regulation 2019/06 on veterinary medicines aims to increase the availability of veterinary medicines, reduce bureaucracy and administrative burden, improve the single market, and provide a set of tools to reduce the risk of antimicrobial resistance arising from the use of antimicrobials in veterinary medicines.

The Union Product Database will contribute in these goals by:

- Improving transparency of veterinary medicinal products approved for use in the EU
- Supporting harmonisation of product information
- Implementing a reliable tool that veterinary practitioners can use to elaborate treatment options, also in case of unavailability of a specific product in a particular Member State
- Providing a self-service access for industry for certain activities and enabling to manage variations that do not require assessment
- Providing functionality to perform data analytics and provide reporting that supports regulatory processes outside the remit of the UPD

The UPD is considered as a legal concept and consists of the building blocks provided by the competent authorities.

The key success factors to reach the above mentioned goals:

- Available financial and human resources for all building block providers
- Simple and effective decision making
- Phased delivery of the system functionality / data
- Agreed operating model
- Change management activities (targeting industry, competent authorities, general public)

Commented [a17]: EGGVP accepts that this is necessary, but this needs to be closely monitored to avoid undesirable delays or halting at a semi-functional system.

Motivation

Currently the veterinary medicines domain in the European Union faces a number of key difficulties. These, in no particular order, are:

- There is no single source of information on all veterinary medicines approved for marketing in any or all EU Member States. This creates a lack of comprehensive information to support the single market, and, for example the use of the prescription cascade – if information on which products are approved in other Member States is not accessible, treatment alternatives cannot be fully elaborated.
- The current tool (EudraPharm) is considered technologically outdated and does not conform to current best practice in terms of structured data formats. It is therefore not fulfilling the essential business requirements demanded of a central product database. This was identified as one of the main root causes for the lack of commitment of Member States to submit their national product

data into this early central database and also why it is believed to be unsuitable to build upon when creating the UPD.

- There is no interoperability between a database holding master product data and other national and EU telematics systems that should ideally consume this product data; this means that stakeholders often have to enter the same information into several systems. The fact that many of these systems allow the use of free text for descriptions means that establishing links between the data is, at best, a laborious manual process, and creates a risk of disharmonised information in individual systems.
- In addition, the public has no direct access to centralised 'single source' information on veterinary medicinal products at all.

In addition, the new legislative framework for veterinary medicines in the EU sets out a number of functional requirements for a union product database, which are currently not covered by existing systems.

Guiding Principles for delivery

1. The UPD system concept must be developed in alignment with the legal requirements arising from the NVR, the supporting implementing act on its technical specifications, as well as any other legal requirements (such as EU GDPR and accessibility requirements).
2. Where possible and feasible to achieve the required functionalities, the UPD system concept will be developed using existing system components or system components currently under development in the EU telematics network.
3. The UPD system concept must be developed avoiding duplication of data across systems to ensure that there is a single source for each type of information.
4. A phased approach for the development of the UPD system concept shall initially prioritise legislative compliance functionalities and such functionality that enables this legislation compliance in the resulting business processes; thereafter, prioritisation of functionality (incl. further data fields) in collaboration with the Member States shall move the UPD system concept towards a single submission delivery system concept, based on a Target Operating Model to be agreed between HMA/EU Telematics and the Agency Management Board.

It is noted that the incremental release of functionality described above is heavily dependent on adequate prioritisation of budget and resources, both at Agency and Member State level.

Out of scope

While the objectives, as described in the introduction, include making available a system that is ready for integration with other system, the development of any other NVR systems or functionality requirements within those systems, e. g. to make the consumption of product data possible, remain out of scope of the UPD system concept. This includes, but is not limited to:

- Pharmacovigilance database and related business processes
- Database for collection of sales and use data for antimicrobials
- Manufacturer and Wholesale Distributor database

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.

Annex II: Proposed delivery methodology

In light of the very short timeframes for implementation and budget/resource constraints, as well as based on recent experience with the implementation of IT systems arising from the human pharmacovigilance and clinical trials legislations, it is proposed that the Agency will adopt agile methodology for the development of the UPD.

The rationale for this is twofold:

1. The UPD will likely conceptually be a system integrating components already existing or under development in the network telematics landscape, with only a limited set of functionalities (UPD portal) potentially to be developed separately. In this case, the development work to be executed is mainly related to adding and linking functionality rather than developing a new standalone IT system. For this, agile methodology will allow adequate sequencing as other systems/components become available as well as managing the interdependencies in an efficient manner.
2. Agile methodology will allow the prioritisation of functionality/requirements as the implementation project progresses, and as such allows for the Agency, in collaboration with the member states (see proposed governance structure in Annex III) to ensure that a minimum viable product will be achieved within the short timelines available.

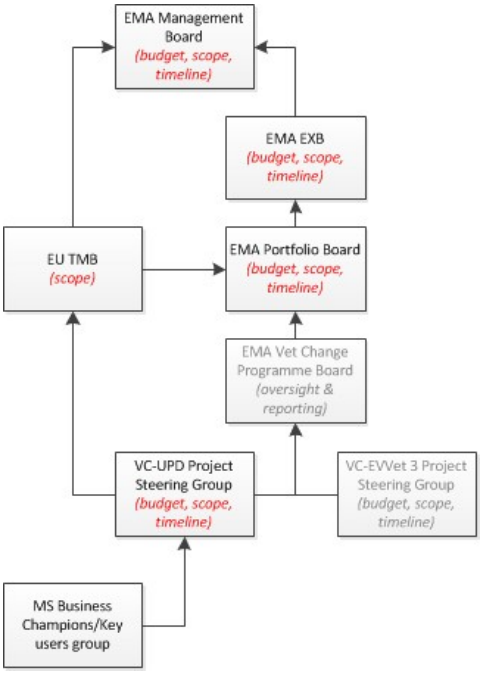
Application of this agile methodology is envisaged from January 2020 following establishment of the governance structure described in Annex III and subsequent formal initiation of the project within the governance structure of the Agency.

Annex III: Proposed governance structure

Full project governance in keeping with the Telematics principles is recommended to be established in autumn 2019 and to be used during implementation. The Agency notes the strong dependency on approval/allocation of adequate funds and resources for the development phases.

The following principles were applied:

- The proposed structure is based on experience with/lessons learnt from previous projects, such as the implementation of the Clinical Trials legislation.
- The structure is embedded in both the Telematics and Agency portfolio governance structures.
- Strong representation of Member States is proposed to facilitate collaborative decision making.
- The proposed structure will require significant resource allocation from several Member States.



Roles:

EMA Management Board

- Overall Agency portfolio responsibility

EU TMB

- To approve scoping (e. g. in semi-annual plans) proposed by Steering Group to inform decisions by Agency Portfolio Board, and defend in Management Board
- Industry review/input is considered to be facilitated here in the joint meetings

It is strongly recommended to review membership and add a further member for veterinary medicines to reflect the priority of NVR in the portfolio over coming years.

EMA Vet Change Programme Board

- A body to prioritise between the different projects to deliver NVR IT systems.
- One Member state representative from each of the NVR IT-type projects.
- One member representing the EU Commission and with considerable experience in managing IT programmes.

VC-UPD Project Steering Group

- Suggested members:
  EMA (Accountable Executive, Vet Change Programme manager, Change manager, Senior Provider)
  European Commission
  Member States representation (veterinary business experts; from approx. 4-5 Member States)
  IT DEC representative (link to EU TMB)
  Representative of MS Business Champions (1-2 members from key user group, see below, if not covered through MS representation above)
- To agree/propose scoping and product vision for (subsequent) phases; prioritise activities within given budget/resource allocation and timeline; for review/approval by EU TMB and Agency Portfolio Board (as required)
- To meet at least once per month, more often if required

It is strongly recommended that the monthly meetings of the Steering Group are held as physical meetings at EMA premises.

Key User Group (5-6 members)

- Suggested members:
  System owner: EMA (business/IT)
  European Commission representation, if required
  MS Business Champions (several member states, ideally combined business/IT role profiles)
- To agree & sign off requirements, user stories and acceptance on behalf of Steering Group; escalating as necessary
- The members of this group would be closely involved in the implementation project on a daily/weekly basis (significant resource allocation required); some smaller MS could rotate membership with a maximum of 2 members at a time in rotation

Annex IV: Technical Glossary

Term	Description
Active Substance	Article 4(3) NVR: any substance or mixture of substances intended to be used in the manufacture of a veterinary medicinal product that, when used in its production, becomes an active ingredient of that product.
Antimicrobial	Article 4(12) NVR: any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals.
Application Functions	**ArchiMate® 3.0.1 Specification** An Application Function describes the behaviour to realize one or more Application Services. An Application Function describes an application behaviour that could be exposed externally through one or more services. An Application Function abstracts from the implementation, only the necessary behaviour is specified.
API - Application Programming Interface	An application program interface is a set of routines, protocols, and tools for building software applications. An API specifies how software components should interact.
Application Service	**ArchiMate® 3.0.1 Specification**[8] An Application Service is an externally visible unit of behaviour, provided by one or more Application Functions, exposed through interfaces meaningful to the environment and having business relevance. The Application Service element provides a way to explicitly describe the functionality to be shared and made available to the environment. This functionality serves to one or more Business Roles.
ATCvet	The ATCvet system for classification of veterinary medicines is based on the same overall principles as the ATC system for substances used in human medicine, where active substances are classified in a hierarchy with five different levels. The ATCvet system is a tool for exchanging and comparing data on drug use in veterinary medicine at international, national or local levels.
Authorised Medicinal Product	EMA Enterprise CDM glossary: Proprietary Medicinal Product for veterinary use intended to be placed on the market or industrially manufactured Medicinal Products, the marketing of which has been authorized by a Competent Authority or the European Commission.
Business Actor	**ArchiMate® 3.0.1 Specification**: A Business Actor is a business entity that is capable of performing behaviour. A Business Actor may be assigned to one or more Business Roles. It can then perform the behaviour to which these Business Roles are assigned.
Business Case	A document that describes the cost/benefit/risk of an intended project. **APM**[9] (Association for Project Management) - The business case provides justification for undertaking a project or program. It evaluates the benefit, cost and risk of alternative options and provides a rationale for the preferred solution.

[8] https://pubs.opengroup.org/architecture/archimate3-doc/chap08.html#_Toc489946039
[9] https://www.apm.org.uk/body-of-knowledge/delivery/integrative-management/business-case/

Term	Description
BP - Business process	A business process is as a set of activities and tasks that, once completed, will accomplish an organizational goal.
BR – Business Requirement	Business requirements are the critical activities of an enterprise that must be performed to meet the organizational objective(s) while remaining solution independent.
Business Role	**ArchiMate® 3.0.1 Specification**: A Business Role is the responsibility for performing specific behaviour, to which an actor can be assigned. A Business Actor that is assigned to a Business Role is responsible that the corresponding behaviour is carried out. A Business Role may be served by one or more Application Services.
Competent Authority	**EMA website glossary** - A body that carries out regulatory activities relating to medicines, including the processing of marketing authorisations, the monitoring of side effects, inspections, quality testing and monitoring the use of medicines. If used in relation to roles in this document: A controlled user, employed by the Agency, the European Commission or a National Competent Authority. The National Competent Authorities include authorities from the EEA countries.
Consolidation of data	Refers to an internal storage process that will create a new record version in the UPD. This process of updating data while making sure that the updates are done resolving potential data conflicts caused by parallel changes in the data.
Controlled User	A controlled user is any user that must successfully authorise to perform actions in the UPD based on access rights assigned to the user profile.
DCP - Decentralised Procedure	The procedure for authorising medicines in more than one European Union Member State in parallel. It can be used for medicines that do not need to be authorised via the centralised procedure and have not already been authorised in any Member State.
European Phase	In case of an MRP/DCP procedure, the phase of the common European assessment during which the scientific assessment of the application is done. Subsequently, a 'national phase' follows, during which national specific aspects of the medicine, such as the local name of the product, national translations of product information documents are assessed and the product authorisation granted or refused.
European Union Telematics Management Board (EU TMB)	The European Union Telematics Management Board is the strategic governance body that operates on behalf of the European Medicines Regulatory Network. It provides strategic oversight of the EU Telematics Programme. It reports to the Management Board of the Agency and the Heads of Medicines Agencies (HMA), and acts as the formal point of contact with the European Commission on matters relating to the EU telematics Programme.
Excipient	Article 4 (4) NVR: any constituent of a veterinary medicinal product other than an active substance or packaging material.

Term	Description
External System	Any telematics system or systems belonging to the Agency, the European Commission, a Competent Authority or industry, which will interact with the UPD.
General Public	**EMA SPOR Glossary**[10] (Guest User) - Any user (controlled or not) who accesses/views the publicly available information web portal without logging in.
EU DPR - EU Data Protection Regulation	The EU Data Protection Regulation (EU) 2018/1725 is a regulation in EU law on data protection and privacy for all individual citizens of the European Union and the European Economic Area.
HMA – Heads of Medicines Agencies	A network of the heads of the National Competent Authorities (NCA) whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area.
Homeopathic Registration	Registration to market within the Union of a homeopathic medicinal product according procedure described in Chapter V of the Regulation (EU) 2019/6.
Industry User	**EMA SPOR Glossary**: A logged in user, employed by an organisation within the pharmaceutical industry that is not a National Competent Authority and authorised by the super-user of that organisation. They will be able to view and download data and to submit change requests. (They will also be able to authorise 'Unaffiliated Users' to become 'Industry Users').
JSON - JavaScript Object Notation	An open-standard data-interchange format that uses human-readable text to transmit data objects consisting of attribute–value pairs and array data types (or any other serializable value).
Manufacturing Site	The place where a veterinary medicinal products is manufactured.
MA - Marketing authorisation	**EMA Website Glossary**[11]: - The approval to market of a medicine in one, several or all European Union Member States.
MAH - Marketing Authorisation Holder	**EMA Website Glossary** - The company or other legal entity that has the authorisation to market a medicine in one, several or all European Union Member States.
Marketing Status	The marketing status describes whether or not a medicinal product is available on distribution chain and on the market (placing in the market) in a specific member state.
MoSCoW	The acronym MoSCoW stands for 4 different categories of initiatives/requirements: must-haves, should-haves, could-haves, and will not have at this time.
MRP – Mutual Recognition Procedure	A procedure through which an authorisation of a medicine in one European Union Member State is recognised by another Member State.

[10] https://www.ema.europa.eu/documents/other/substance-product-organisation-referentials-spor-glossary_en.xlsx
[11] https://www.ema.europa.eu/en/about-us/about-website/glossary

Term	Description
NVR - New Veterinary Regulation	Regulation (EU) 2019/6 of the European Parliament and the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.
Organisation	EMA Enterprise CDM glossary: A representation of a legal entity (e.g. a business, government department, regulatory body).
Packaged Medicinal Product	EMA Enterprise CDM glossary: Medicinal Product in a container being part of a package, representing the entirety that has been packaged for sale or supply.
PD - Parallel Distribution	**EMA website glossary** - The distribution of a medicine package from one Member State to another by a pharmaceutical company independently of the marketing authorisation holder. This applies only for centrally authorised medicinal products.
Parallel Trade	The distribution of a veterinary medicinal product obtained in one Member State ('source Member State') to another Member State ('destination Member State'), whereas this veterinary medicinal product shares a common origin with a veterinary medicinal product already authorised in the destination Member State. The veterinary medicinal products are considered as sharing a common origin if they fulfil all the conditions set out in NVR Article 102. Article 102 shall not apply to centrally authorised veterinary medicinal products.
Parallel Trade Approval	Approval of veterinary medicinal product to be parallel traded. *Synonym to parallel import.*
PDF – Portable Document Format	A standardised file format for capturing and presenting electronic documents in exactly the intended format in a manner independent of application software, hardware and operating systems.
Pet Product Exemption	Marketing Authorisation exemption for veterinary medicinal products intended for animals which are exclusively kept as pets (Article 5(6) NVR).
PhV – Pharmacovigilance	The practice of monitoring the effects of medicinal products after they have been authorised for use, especially in order to identify and evaluate previously unreported adverse reactions.
PhVSMF – Pharmacovigilance System Master File	A Pharmacovigilance System Master File is a document describing the pharmacovigilance system used by the marketing authorisation holder (MAH) with respect to one or more authorized medicinal products.
QPPV - Qualified Person Responsible for Pharmacovigilance	The Qualified Person Responsible For Pharmacovigilance is an individual, usually an employee of a MAH, who is responsible for carrying out tasks aimed at ensuring the safety of veterinary medicinal products (for which marketing authorisation is held by MAH) in the EU.

Term	Description
Requirements	**EMA documentation standards**: List of atomic Solution and User Requirements split in Functional, Non Functional, Business Rules and Technical Constraints in the form of a requirements catalogue High-level business requirements represent the main justification for the project hence is expected to be presented on the business case. They could be for instance specific objectives or regulatory requirements. As a good practice (indicator) there should be no more than 10 business high-level requirements. Functional requirements are clear statements of concrete results to achieve. For instance in the case of a move: “There need to be windows in each office” or in IT “The system allows the user to display the list of adopted report”. A requirement should not be expressed in a way that forces in a particular technical choice. Non-functional requirements are for technical projects, which need to answer specific questions to anticipate the scalability and robustness of the technical solution proposed. These requirements are not necessarily explicit for the business.
RMS - Referential Management Services	The RMS provides referential lists and terms (such as routes of administration, dosage forms) in multiple languages. RMS supports the continuous exchange of data between information systems across the European medicines regulatory network and the pharmaceutical industry.
Sales Information	Volume of sales per country and year of a specific veterinary medicinal product.
SPC – Summary of Product Characteristics	The Summary of Product Characteristics (SPC) is a document approved as part of the marketing authorisation of each veterinary medicinal product.
Substance	EMA Enterprise CDM glossary: Any matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical.
Target Species	EMA Enterprise CDM glossary: Species for which the veterinary medicinal product is intended for as described in the Product literature.
UPD – Union Product Database	The UPD is a concept of interacting systems fulfilling the legislative requirements set in the NVR.
UC - Use Case	EMA documentation standards: Use cases (UC) describe how a user (actor) uses a system to accomplish a particular goal in the form of user – system interaction steps. The use case model includes the list of all the discrete functional units that represent human – system interaction (Use Cases) and their relations. It also shows actors and system boundaries.

Term	Description
VMP - Veterinary Medicinal Product	Article 4 (1) NVR: Any substance or combination of substances which fulfils at least one of the following conditions: (a) it is presented as having properties for treating or preventing disease in animals; (b) its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; (c) its purpose is to be used in animals with a view to making a medical diagnosis; (d) its purpose is to be used for euthanasia of animals.
Withdrawal Period	Article 4 (34) NVR: the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which under normal conditions of use is necessary to ensure that such foodstuffs do not contain residues in quantities harmful to public health.
XML - eXtensible Markup Language	Extensible Markup Language is a markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable.