28 May 2014
EMA/717773/2013

# Veterinary IT and Data Strategy, Roadmap and Management Overview

Endorsed by EU Telematics Management Board on 28 May 2014

# Executive Summary

The Veterinary Network, including EMA and NCAs, currently makes use of a disparate set of IT systems and data in support of their Medicinal Product regulatory procedures. Such disparity leads to duplication of effort and investment in IT systems and smaller Member States in particular may not have the resources to invest in complex systems. Furthermore, veterinary agencies only have access to the limited data generated within their territory. However, information from across the EU is equally important in order to promote public and animal health in each Member State.

This roadmap proposes a strategic direction to address these issues focusing on the Network's short-term needs in 2014 as well as long-term objectives. The first short-term objective for 2014 is the establishment of a central common European database of veterinary medicinal products as an essential pre-condition for pharmacovigilance of veterinary medicines. The second objective in 2014 is the further development of detailed proposals for projects, particularly the identification of user requirements, to achieve the long-term regulatory business objectives (up to 2017). The sequence in which the objectives are delivered, and the precise user requirements for each component, will be aligned with the outcome of the review of the veterinary legislation as it takes shape over the period 2014-2017. To plan and monitor delivery of these objectives within the context of the overall roadmap, a governance structure will be set up and operated as part of the overall EU Telematics programme.

The vision is for the veterinary network to act as a "Virtual Organisation" through collaboration focusing on further integration and centralisation of IT systems and data. This will enable the network to reduce costs, provide a service to the veterinary pharmaceutical industry and at the same time improve quality, consistency and overall service. Where possible, standards, architecture and solutions should reuse and adapt what is already in place within the Network. By following the strategic direction set out in this roadmap the veterinary network will be well placed to take on the future challenges posed by advances in technology, changing veterinary medicinal products legislation, a changing industry and the resource constraints that are expected to continue throughout the lifespan of the roadmap. The plan will enable the continued protection and promotion of public and animal health in support of the new veterinary legislation.

## *About this document*

This document describes the roadmap "first-draft" prior to agreement by the wider NCA Network. It should be noted that the current draft has been prepared anticipating the forthcoming revised Veterinary legislation, currently under preparation by the EU Commission. The understanding is that publication of the draft proposal for the revised Veterinary legislation will take place during 2014. Certain elements of the roadmap have been prioritised for work to start in 2014-15, such as the creation of a common European database of veterinary medicinal products and the ability to carry out pharmacovigilance at an EU level using this database. The user requirements for these elements are not dependent on the outcome of the review of legislation and work can therefore start immediately. Other elements, such as those relating to certain aspects of the authorisation procedures for centrally and nationally authorised products, are heavily dependent on the review. The delivery of these elements is therefore scheduled for later in the development programme, once the outcome of the review becomes clear.

Throughout the document the terms:

- "Short term" is used to describe activities that are currently clear, well known and should be delivered during 2014 in order to satisfy immediate stakeholder needs;
- "Medium term" or "Long term" is used to describe activities that are less certain, in part due to the anticipated revisions to the Veterinary legislation[1], also in part due to the need for further elaboration in consultation with the entire EU Network
  - The time-frame under consideration is from 2015-2017+, with analysis work undertaken during 2014 to fully define whole Network's requirements.

The document itself aims to provide a strategy and roadmap that:

- Satisfies immediate and known needs
  - Including the need for a common European database of Veterinary Medicinal Products
  - Manage changes related to eSubmission to align and facilitate submissions from the pharmaceutical industry, irrespective of the route to authorisation (Central, de-central or national procedure)
- Provides a view of the overall Business and therefore IT strategy in the 2-3+ year timeframe[2]
- Recommends a strategic direction for the IT and Data Architectural elements to be put in place
- Sets out the key deliverables in achieving the above and a timeframe for specific packages of work towards their achievement
- Gives high-level view of overall project governance under the agreed EU Telematics Governance framework

[1] It is anticipated that details of this will become known during 2014
[2] Noting that the Veterinary Legislation is under revision and is not anticipated to become known until during 2014

# 1. Veterinary Business Context and Strategy

## *1.1. Background and Context*

The finalisation of the EMA data strategy and completion of the first phase of the Review and Reconnect Project provide the necessary framework to initiate the planned strategic review of the needs of the Agency and the wider EU regulatory Network in relation to IT solutions and data to support the authorisation and surveillance of veterinary medicines in the EU.

Since 2011, the regulatory network, via the HMA, has been working on a business case[3] via the HMA, related to establishing a central common European database of Veterinary Medicinal Products.

Concerns were also raised by HMA in a letter to the Executive Director on 25 June 2013 regarding lack of investment in veterinary IT by the EMA. The letter in particular highlighted the need for a European Product Database: "the European veterinary product database is so critical; it is the limiting factor in ensuring veterinary Pharmacovigilance across the Network is effective".

The EMA has initiated a Telematics project to create, in cooperation with the network of NCAs, a strategy and roadmap for the delivery of IT systems in relation to veterinary medicines.

This will enable:

1. National Competent Authorities to further develop and integrate their national systems in the knowledge that they can integrate with, and contribute to, the wider European network of Veterinary IT.
2. The EMA to clarify how it intends to promote integration and harmonisation of veterinary pharmacovigilance and related data
3. The strategy to take full account of, and build on, the agreement reached at HMA to work towards the creation of a Common European Database of Veterinary Medicinal Products (CEDVMP) that allows, among other benefits, signal detection at European level for CAPs and NAPs, MRPs and DCPs, thereby securing the investment already made by several Member States.

   The revision of veterinary legislation is expected to have a large impact on the future processes and their related ICT systems. Until it becomes clear what this new legislation will change and/or add to the veterinary domain, the proposals in this roadmap will classify what is currently certain as "Short term" and what is less certain as "Medium/Long-term".
4. The project is being delivered collaboratively by the EMA and three NCA representatives (France, UK, Belgium), and will define a strategic roadmap for future veterinary business, data and IT architecture.

The Strategy takes into account the close relationship between veterinary and human medicines and their regulation. The Strategy describes the particular nature of the veterinary domain and how its small size places particular importance on producing simple, cost efficient solutions. Wherever feasible and desirable, solutions will share components and technologies with human systems in order to maximise interoperability and reduce costs. As well as being beneficial from technical and financial perspectives, such an approach also promotes the 'One Health' strategy whereby expertise in human and veterinary domains is brought together to achieve shared goals in public and animal health. Such cooperation in the areas of antimicrobial resistance, pharmacovigilance, pandemic preparedness, zoonotic diseases and the control of residues of veterinary medicines in the food chain is greatly facilitated by IT systems that are interoperable.

[3] 69_HMA_V_6a_PCDOCS-#391162-v2-HMA_June_2012_-_Cover_paper_and_business_case_-_product_database: EMA/697219/2013 https://docs.eudra.org/webtop/drl/objectId/090142b2824f61f8

**Key Stakeholders**

This roadmap supports the overall framework in place in the EU that regulates veterinary medicinal products. The main partners are the competent authorities and the pharmaceutical industry and the veterinarians are the main stakeholders. A number of specific stakeholder groups have been identified by the roadmap analysis and an extensive list of these as well as a brief description of each is provided in Annex 1.

### 1.1.1. Key facts and figures

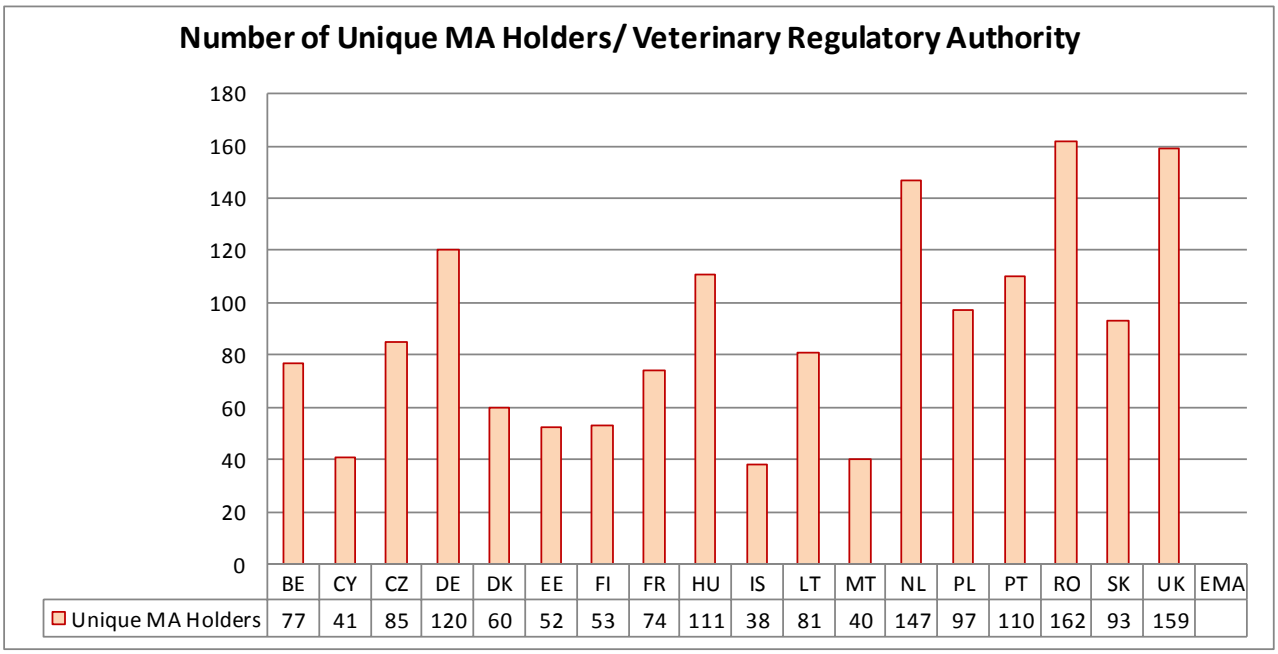
A number of key facts and figures are provided in this section to give overall context to the roadmap.

### The size of the EU veterinary medicinal product industry and its regulation

The Veterinary Medicinal Product industry is estimated to have total annual sales of €4.3bn[4], which represents approximately 2.8% of the European human pharmaceutical industry[5]. Of this, the cost of regulation (the regulatory burden) is estimated to total 13% of gross sales or €537.9million per year. The median profit margin for companies operating in the Veterinary medicines pharmaceutical industry sector is estimated to be 10.3%.[6]

It is estimated that circa 15000[7] people are directly employed in the production, marketing, sales, administration and R&D of Veterinary Medicinal Products.

It is difficult to be precise on the number companies that hold Marketing Authorisations at the EU level, however for order of magnitude an estimate of the number of unique Marketing Authorisation holders by market can be used as follows:

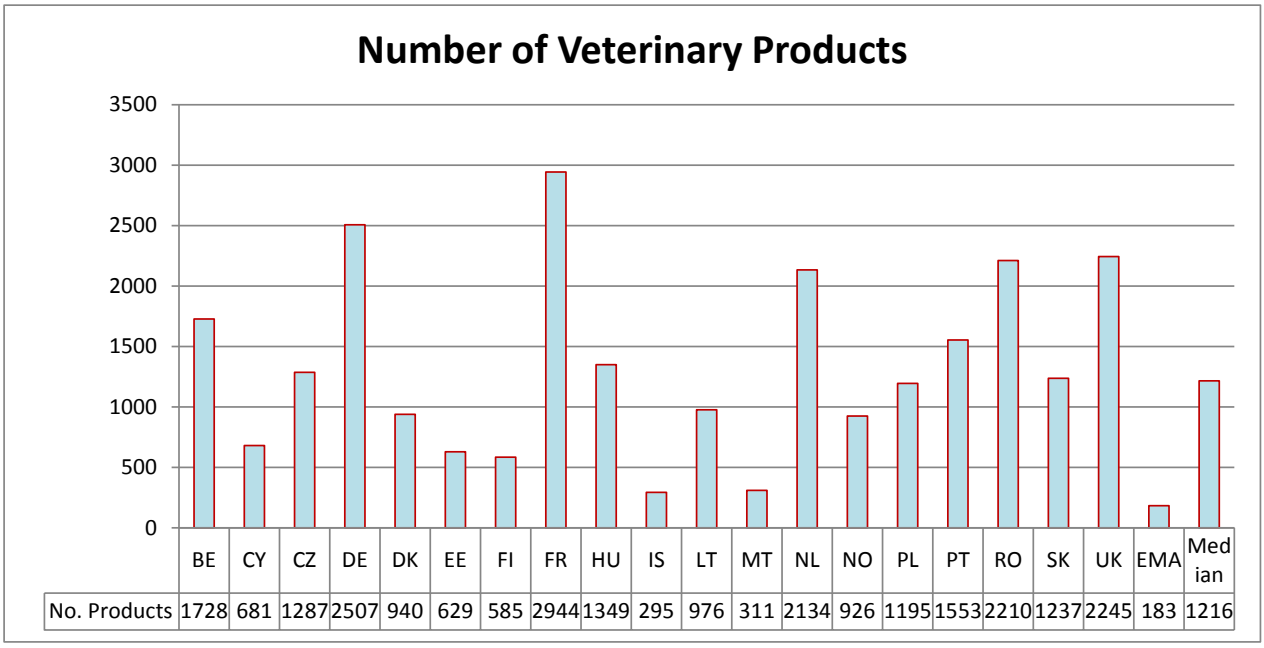



There are 33 Agencies (including HMA members and EMA) operating the Veterinary Medicines Regulatory Procedures[8] throughout the EEA and which form the "Virtual Organisation" described above in the strategic vision. It has been estimated that approximately 1000 members of staff work across these Agencies.[9]

[4] Source: Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation 11 July 2011
[5] Source: IFAH Europe - http://www.ifaheurope.org/about/about-the-industry.html
[6] Source: http://www.ncvei.org/articles/FINAL_BAYER_VETERINARY_CARE_USAGE_STUDY.pdf
[7] Source: IFAH Europe - http://www.ifaheurope.org/about/about-the-industry.html

## Number of products / procedures in the EU

The following chart describes the number of products (where data is known) per Agency. This represents 25915 in total. We do not have data for the remaining 13 regulatory authorities so using the calculated median number of products to extrapolate, a figure of closer to circa 42000 products might be a better estimate of the number of products currently authorised for the EEA market.




| | BE | CY | CZ | DE | DK | EE | FI | FR | HU | IS | LT | MT | NL | NO | PL | PT | RO | SK | UK | EMA | Median |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| No. Products | 1728 | 681 | 1287 | 2507 | 940 | 629 | 585 | 2944 | 1349 | 295 | 976 | 311 | 2134 | 926 | 1195 | 1553 | 2210 | 1237 | 2245 | 183 | 1216 |

## Frequency of access to centralised IT systems

It has not been possible during the timescale of this document to fully survey the 33 Agencies within the Network, therefore a calculation has been made based upon information from the 4 organisations represented in the team drafting this document. It is therefore assumed that, for the first iteration of the common European database of medicinal products users from across the network will each access the database and perform Create, Read, Update, Delete (CRUD) tasks 3-4 times per week. It is estimated that this would represent between 300 and 500 user sessions per week.

## Number of Veterinarians in the EU (estimated)

Veterinarians are a key stakeholder within this strategy and roadmap. In particular Veterinarians will be making use of the reference data and IT systems made available and will need access to the catalogue of Medicinal Products available within the EU for purposes of the cascade as well as for reporting of Adverse Events. It is difficult to provide an accurate estimate but it is understood that the Federation of Veterinarians of Europe represents around 200,000 individual members via their federated organisations.

## Number of users (estimated possible future scenario)

Using the above figures as a guide it is possible to estimate the maximum number of users as follows:

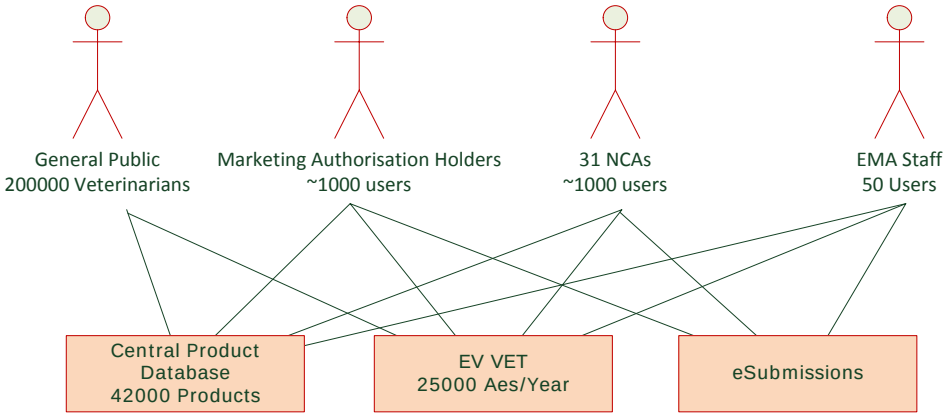
Systems that will be used internally by the Network to operate regulatory procedures: up to circa 1000 users

[8] Source: HMA Best Practice Guide
[9] Assumption based upon estimate that 10% of total staff working at EU agencies relates to veterinary medicines. As such this should be considered as an "order of magnitude" estimate.

Systems that will be used internally by the Network and also Industry: up to circa 2000 users (considered a "best case" scenario – it is likely the actual number will be significantly lower than this figure).

Systems that will be used by Veterinarians either for reporting or to transmit data, for example on Adverse Events: up to circa 200,000 users (considered a "best case" scenario – the actual number might be lower).

Number of users potentially accessing IT systems short term (2014):




## Why is a strategy and a roadmap needed?

The need for a strategy for veterinary medicines should be assessed in terms of the potential benefits it can bring to the EU in the wider political context. The impact assessment carried out by the European Commission as part of the preparation for its ongoing review of EU legislation governing veterinary medicines highlighted three main challenges that the new legislation needs to address; the need to reduce the administrative burden for both applicants and regulatory authorities; the current lack of a genuine single market in veterinary medicinal products; and, to increase the availability of veterinary medicines. There is a need for a strategy that supports the delivery of all three of these objectives as part of revised legislation.

The Veterinary Network, including the EMA and NCAs, currently operates a disparate set of IT systems and data requirements in order to operate their Medicinal Product regulatory procedures. These systems, whilst they might be fit-for-purpose on an individual or national basis, collectively do not cater for the current or projected future needs of EMA and the Network[10] as a whole. Such a disparity leads to duplication of effort and investment in IT systems and particularly smaller Member States may not have the resources to invest in such systems. Furthermore, veterinary agencies only have access to the limited data generated within their territory. However, information from across the EU is equally important in order to promote public and animal health in each Member State.

The following specific, on-going problems exist:

- Not satisfying the requirement in Article 57 of Regulation (EC) No 726/2004 which requires the regulatory network to operate a central product database of veterinary medicinal products. This means that:
  - it is not possible to undertake pharmacovigilence surveillance on an EU-level leading to gaps in our protection of public and animal health.

[10] The term "Network" is used throughout this document to refer to the EMA plus Veterinary NCAs operating throughout the EU

- Inefficiencies in the management of referrals, leading to high resource costs through the fact that the Agency is required to contact each member state individually to prepare lists of products, leading to a risk that products are missed out with corresponding negative impact on public and animal health.
- Collection of data on sales of veterinary antimicrobials is currently carried independently of any central database of products leading to duplication of effort for some member states with respect to this important activity related to minimising the risks from antimicrobial resistance.

- inability to meet the expectations of the network and the European Commission to provide a Common European Database of Veterinary Products. This means that:
  - Veterinarians would continue not to be able to identify alternative products for the use under the prescribing "Cascade" (Articles 10 and 11 of Directive 2001/82/EC, as amended), thereby preventing access to medicines available in other member states.
  - The majority of veterinary authorities lack the investment capacity to participate effectively and provide the necessary data to the network via existing EU Telematics programmes.

This strategic roadmap seeks to find solutions to these issues and more specifically answer the questions posed in Annex 5 of this document that have been put forward by the working group.

One of the immediate needs identified is a Common European Database of Veterinary Medicinal Products.[11] EudraPharm is currently offered as a database of medicinal products (human and veterinary) authorised in the European Union however, only six[12] out of 32 Veterinary NCAs are exchanging data with the database.

The central shared European database is essential to ensure effective and efficient post-marketing surveillance of all veterinary products in the EU and is also needed for veterinarians to establish which products are available for use as part of the cascade. The creation of this database would also put in place the elements to complete the vision described under Article 57 of a database of all veterinary products authorised within the EU which could become available to the general public (the "medicines web portal").

Similarly, in relation to streamlining electronic submissions (e-submissions) there is a need to decide on standards and systems to reduce costs and to improve efficiency for regulators as well as industry. In this area, technical solutions will inevitably be led by the needs of the human medicines area due to the greater needs, and capacity, of the human medical sector. The veterinary strategy will be to ensure, where possible, that the technical solutions implemented can process both human and veterinary applications (e.g. Common European Submission Portal, EMA Gateway). Where this is not possible (e.g. CTD is not envisaged for veterinary applications), human systems will be adapted to accommodate veterinary needs (e.g. ability to process vNeeS submissions as well human NeeS).

## *1.2. The Strategic vision*

The vision is for the veterinary network to act as a "Virtual Organisation" through collaboration aiming at further integration and centralisation of several data systems. The strategy is to work towards further integration by identifying and developing common service components. The tactics are to deliver this strategy through a cohesive set of short, timebound, programmes and projects with defined budgets.

Under this model each partner is able to provide services to other partners as well as to external stakeholders, for example industry or veterinarians, and to work together to deliver individual and collective regulatory obligations.

[11] www.eudrapharm.eu
[12] France, Netherlands, UK

Within this model the EMA would have a role in operating underlying services as well as operating the IT, Data and Business infrastructure to ensure the Network can collaborate and operate effectively and efficiently. This will move the Network away from developing specific tools, technologies and solutions to A service-oriented approach, as outlined below. This model where agencies have started to work together in the EU has shown to function effectively and to be most cost efficient.

This vision will enable NCAs from smaller Member States to have access to a wider set of capabilities including data sets, systems and services, to enable increased protection of public and animal health for their populations. In such a collaboration model, resources from smaller agencies are also very welcome, particularly for developing IT systems.

The following schema is a draft model that can be the basis for discussions of the final roadmap and which can be amended as necessary in line with the new legislation as it develops:

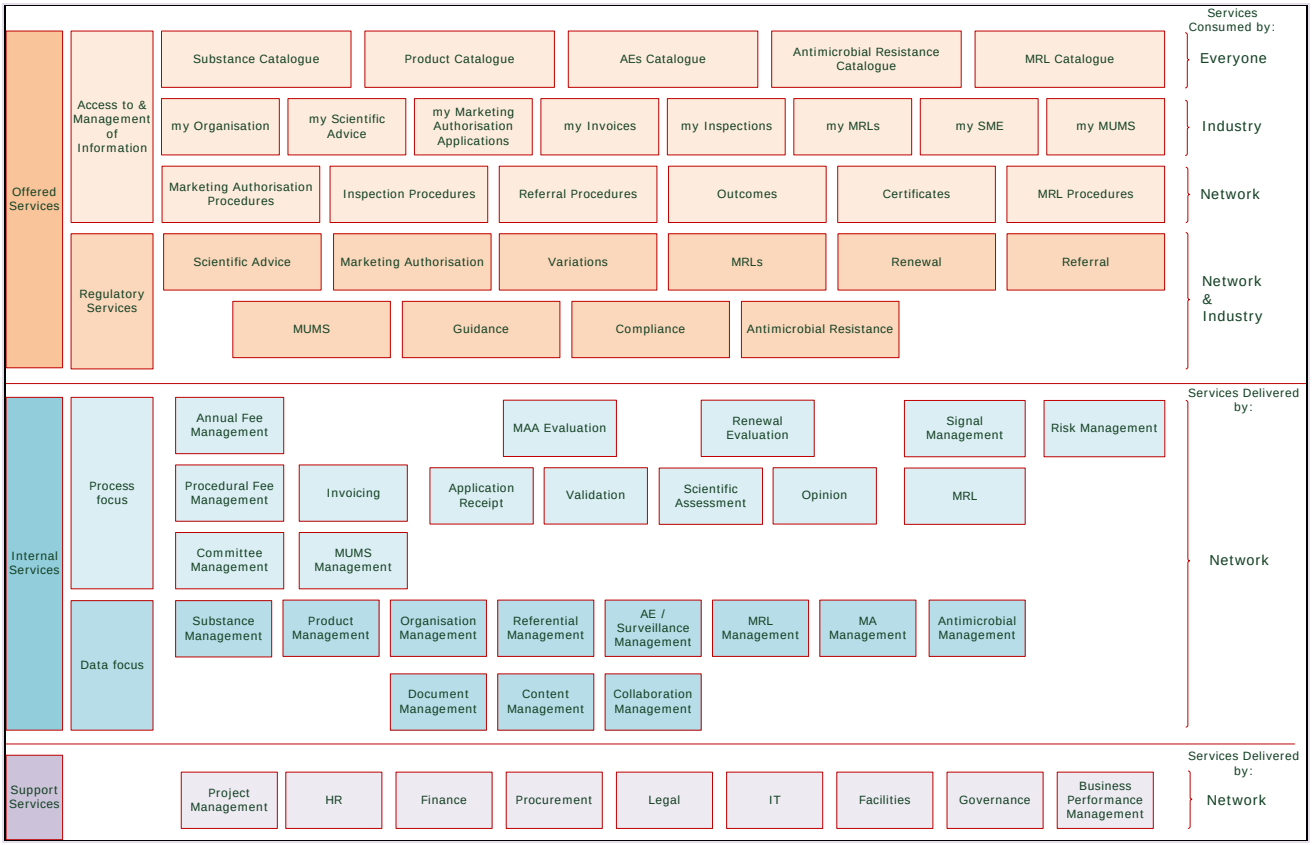



**Figure 1 - Components of a Virtual Organisation Service Model**

## *1.3. Goals, Objectives and Requirements (the "To-Be" world)*

The following goals, objectives and requirements support the achievement of the strategic vision.

### 1.3.1. Using a Component "building block" Approach

With the overall vision and strategy in mind a "building-block" approach will be used.

Each of the goals/objectives described below could, in principle, be separated out and taken forward as discreet activities or projects. Under this roadmap each component forms an element that builds towards the overall vision defined in section 1.4 above. This philosophy also applies to the key systems/data features

identified, which should also be considered as component building blocks with a focus on re-using technologies, systems, data, processes and services to support multiple business needs.

### 1.3.2. Short-term Business Goals and Objectives (during 2014)

The following lists the already known high level requirements that have been articulated and elaborated by the Network and that will be the subject of a specific business case for funding approval by the EMA.

- Enable EU-wide veterinary Pharmacovigilance
- Allow NCAs to begin product data sharing, starting with a maintenance process for the veterinary substance list and with a flow of national authorisations to the central database.
- An agreed governance structure for steering veterinary projects (or veterinary aspects of joint Human/Veterinary projects)
  - Including a change control process for eSubmission and Eudranet
- Fully elaborate the Medium-Long term business goals and objectives in collaboration with the entire Veterinary NCA Network and in light of the (to be) published new veterinary legislation.

### 1.3.3. Medium-long term Business Goals

The following medium-long term goals are provided as an overall direction at this stage, subject to further elaboration in consultation with the entire Network and to amendment as required following publication of the new veterinary legislation during 2014. They should, therefore, be considered as recommendations at this stage.

#### *1.3.3.1. Goal 1 – EU-Wide Integrated Pharmacovigilance*

- Provide access to high quality, pan-EU data on Adverse Events
- EU-wide signals management and information linking substances to products

#### *1.3.3.2. Goal 2 – Supporting Marketing Authorisation throughout the EU*

- Reduce the administrative barrier for submission and maintenance of Marketing Authorisations, whilst not affecting the scientific requirements
- Share resources and data to support national and multi-national marketing authorisations (for example ASMF, substance information)
- Standardisation, benchmarking and best practice sharing

#### *1.3.3.3. Goal 3 – Establish the Network as a Reference Authority*

- The Network as a definitive, quotable source of reliable data
- Become the “go-to” source of information about veterinary medicine and related issues for all stakeholders including the scientific establishment, veterinarians, the general public and the media
  - e.g. for healthcare professionals in the field to access definitive information about available veterinary medicinal products in the EU (cascade use)
- Develop appropriate EU-Wide standards and support for achieving those standards

#### *1.3.3.4. Goal 4 – Reduce Costs, Work Collaboratively, Support Smaller Agencies*

- Work together as a Network to leverage economies of scale
- Access for all to the best available expertise in the EU ensuring the highest scientific credibility
- Facilitate the coordination of the management and execution of inspections (primarily GMP)
- Follow the eSubmissions roadmap

#### *1.3.3.5. Goal 5 – Develop the Network On-line Device and information provision*

- As far as possible allow stakeholders to self-serve (e.g. eSubmission)
- Provide the EU best available regulatory guidance (consistency)
- Translation into local languages, where possible

#### *1.3.3.6. Goal 6 – Promote Innovation and Sustainable Development*

- Support the development of new active substances
- Support development of products satisfying unmet needs (minor species/MUMS)
- Produce a technology roadmap to ensure that future technology developments are anticipated and supporting infrastructure put in place
- Facilitate the work of the Network with respect to
  - monitoring sales of antimicrobials as part of the measures to limit antimicrobial resistance
  - promoting access to medicines
  - food safety
  - zoonosis and emerging diseases (e.g. Avian Influenza)
  - Control of diseases that affect trade (e.g. FMD, Blue Tongue)
- Delivering a positive impact on public health by sharing information between regulatory domains

### 1.3.4. Business Systems / Data High-level Objectives

The following high-level business requirements for systems and data have been identified. It is anticipated that these will be further elaborated in consultation with the entire network as the roadmap progresses.

#### *1.3.4.1. Short-term business, systems and data objectives to be delivered in 2014*

The following are required in 2014 to support the short-term goals listed in 1.3.2 above:

- The first iteration of the EU veterinary medicines data base and corresponding first iteration of the data model for vet substances
- Set up of a procedure to ensure (initial) data cleaning and data quality assurance.
- Detailed analysis of medium-term/long-term requirements listed below.

#### *1.3.4.2. Medium/Long-term High Level Objectives*

The following set of features have been identified as needed in order to achieve the goals/objectives highlighted in 1.3.3

**Objectives supporting Goal 1: EU-Wide Integrated Pharmacovigilance**

- An Adverse Event repository aligned to VICH requirements[13]
- A Data warehouse
- Tools for signal detection linked to the common database
- A Surveillance tracking database
  - Including QPPV access

**Objectives supporting Goal 2: Supporting Marketing Authorisation throughout the EU**

- Harmonised submission procedures including:
  - A common EU submissions gateway
  - A common EU repository for veterinary regulatory information/data (including Marketing Authorisation, ASMF)
  - A single communication mechanism for regulatory information
  - eApplication Form adapted to Veterinary Needs e.g. VNeeS, ability to distinguish between a new application and response to a question
  - Electronic submission and management of VNeeS
  - Automation of Technical and Content Validation
- Inspections Database – to be confirmed if required in consultation with Inspections colleagues within the Network
- A configurable workflow engine for tracking CAPs, DCP, MRP, NAPs
- Integrate MRLs with Workflow, Product and Substance

**Objectives supporting Goal 3: Establish the Network as a Reference Authority**

- Network adaption/adoption of SPOR model and Reference Architecture as defined in sections 2.2 and 2.3
- LinkCommon European Database of Veterinary Medicinal Products to ESVAC, align with agreed standards and with any new requirements in the revised veterinary legislation
- Ability to link specific manufacturing sites to products to support Inspections/Pharmacovigilance; also links between OMCLs[14] and OCABR[15] certificates & OBPR releases (subsequent iteration)
- Establish a Substance Management Service (SMS) as a single point of reference for high-quality substance data (It should be established to what extent and the timeline for possible integration with human medicines).
- A single source of information regarding legal entities, sites and organisations involved in Marketing Authorisation/Pharmacovigilance activities
  - Including a way to confirm the legal status and proof of establishment
- An agreed standard for referential data, translated into all National languages (which could differ from the “Official” EU languages)

[13] May or may not use EV-Vet
[14] Official Medicines Control Laboratories
[15] Official Control Authority Batch Release

**Objectives supporting Goal 4: Reduce costs, Work Collaboratively, Support Smaller Agencies**

- Tools to enable collaboration and resource sharing
  - in particular document collaboration
- Standardisation/best-practice sharing of working practices where relevant e.g. dossier validation
- A fees and billing engine
- An Agreed Network Target Operating Model
- Business intelligence and reporting against agreed metrics
- Ability to operate a SAAS (Software As A Service) to support smaller NCAs

**Objectives supporting Goal 5: Develop the Network On-line Service and Information Provision**

- Self-serve for industry, and regulators e.g. registering a new substance
- Define the overall strategy and roadmap for on-line services and information in line with the new legislation.

**Objectives supporting Goal 6: Promote Innovation and Sustainable Development**

- An antimicrobials usage database linked to the central product database

#### *1.3.4.3. High Level Non-Functional Business Requirements*

- Simplicity and lowest possible cost
- As far as possible avoidance of dependencies (e.g. between H and V domains, between individual building block business services)
- Adopt standards and architectures that are light-weight and appropriately sized for Veterinary Medicines and the needs of smaller Agencies
- Flexibility and rapid deployment in order to support efficient operations
- High degree of security
- Re-use what is already available in preference to developing something new
- Support collaborative working
- High uptime during working hours of each NCA partner

## *1.4. Expected Benefits of Delivering the Roadmap*

Implementing the roadmap described in this document will yield the following benefits:

***Short-term benefits***

The following tangible benefits relate specifically to addressing the immediate need for the first iteration of the envisaged Common European Database of Veterinary Medicinal Products:

| Title | Description | How measured | Target | When achieved | Reason benefit is not available now |
|---|---|---|---|---|---|
| Improved Surveillance | Able to conduct surveillance activities across the EU VMPs in particular for national products | Number of Member States using the Data Warehouse for national products | Minimum 10 NCAs | Q2 2015 | No common European Database of Medicinal Products exists to support this benefit |
| Use of the Cascade and accessibility of information on medicines | Veterinarians able to access the list of products in order to identify appropriate medicines in line with the Cascade[16] | Number of Veterinarians accessing the data | TBC | Q2 2015 | No such list currently exists |
| Compliance with Article 57(l) | Requires creation and maintenance of a database of medicinal products | Binary | Database in production. | Q2 2015 | No common European Database of Medicinal Products exists to support this benefit |
| Availability of product data | NCAs are able to submit data to and query the database | Number of NCAs submitting data | Minimum 15 NCAs | Q2 2015 | Described in paragraph 1.2.1 above |

***Medium and Long-term benefits***

The following benefits relate to the delivery of the strategy and roadmap in its entirety:

| Title | Description | Reason benefit is not available now |
|---|---|---|
| Managed change for Veterinary eSubmissions | Reintroduce specific governance and support of veterinary eSubmission guidance and validation methods and harmonisation | There currently is no governance framework in place for veterinary-specific eSubmissions |
| Improved Referral Process | Referrals require identification of all of the VMPs subject to the referral in question. | Lack of common European database of veterinary medicinal products to support cross-reference between national, decentralised and centralised products |

[16] See: Article 10 of Regulation 2001/82/ec

| Title | Description | Reason benefit is not available now |
|---|---|---|
| A single version of the "Truth" | By adopting the SPOR model[17] and rationalising the number of databases containing the same information across the EU will support good/consistent regulatory decision making. It will also allow processes to operate more efficiently and remove opportunities for error both from a regulatory and also from a transactional perspective. | Multiple databases currently exist within the EMA and NCAs including for national, decentralised and centralised products. |
| Single communication mechanism for all EU Veterinary Regulatory procedures (National and Centralised) | The Roadmap has as one of its essential deliverables a common agreed communications mechanism (possibly building upon CESP[18]) and entry point for all regulatory submissions. Any company submitting to any regulatory agency would be mandated to use this system as would the Agencies themselves when communicating official documents within and externally to the Network. This would greatly simplify the process for Industry and for Regulators. | Currently submissions can be made nationally, centrally via CESP (for DCP/MRP) or centrally to the EMA. |
| Common repository and collaboration platform for regulatory information and data. | When implemented, an EU common repository for Veterinary regulatory submissions and related working documents would have a high-potential beneficial impact by alleviating the need to send multiple copies to different regulatory authorities and difficulties in version control. This would need to take into account the needs of the Veterinary Network and Stakeholders in supporting the VNeeS dossier structure. | There is no common repository for all EU regulatory information and data. A common repository is planned for centralised procedures but this benefit goes further incorporating all medicinal products within the EU. |
| Improved management of substance/product related issues across the EU Network | Having a system in place to link manufacturing sites with products and substances will allow more rapid and comprehensive response to issues found at either the site, substance or product level. For example, needing to inform all affected MAHs if an issue is found at a particular manufacturing site in their supply chain, ability to cross reference product issues and trace back to a particular common cause at a manufacturing site. | There is currently no such system in place covering all EU products and substances used for veterinary medicine. |
| Work-sharing of Pharmacovigilance procedures | Having a common submission mechanism for EU Veterinary regulatory authorities will facilitate cross-Agency work-sharing for example of surveillance and PSUR evaluation. | At the moment there is no common submission mechanism for PSURs. |

[17] The SPOR model relates to a set of managed business services supported by systems and data that will be built around the 4 main types of structured data identified in terms of "Substances", "Products", "Organizations" and "Referentials".
[18] Common European Submission Platform

| Title | Description | Reason benefit is not available now |
|---|---|---|
| Decoupling of technology from capability | The reference architecture approach being adopted under the EMA's data roadmap will eventually decouple the dependency that currently exists between the technology and the business capabilities that it supports. In practice this would mean that technology changes/upgrades can be performed without impacting or being noticeable to users unless specifically designed/required to be the case by users. | At the moment there is a tight coupling between technology and business capabilities. This means that for business processes to change a corresponding IT change is needed and vice versa. |
| Better links to the network | The governance structure that will be set up by this project will allow for a greater level of interaction with the network on topics related to the scope of this business case. | There is currently no specific pan EU forum to discuss Veterinary IT and Data including future standards development. |
| Strategic investment decisions | With the roadmap in place and thinking developed, future IT development decisions will be made with the overall strategy in mind. This is likely to increase the lifespan of investments and also to allow the re-use of functionality as far as reasonably practicable, thereby reducing costs. | Lack of a strategy and roadmap. |
| Compliance with future legislation | New legislation is anticipated and will be accounted for during the lifespan of the roadmap. This will facilitate adoption and adaption of supporting business and IT architecture. | The legislation has not yet been published. The roadmap will be revised to take account of changes in legislation as they are agreed and come into force. |
| Strategic Alignment | Having a roadmap in place also offers the opportunity for the strategy to be taken into consideration when making operational decisions as well as when drafting secondary legislation. This will include monitoring the success | Lack of a strategy and roadmap. |

# 2. The Veterinary IT Strategy

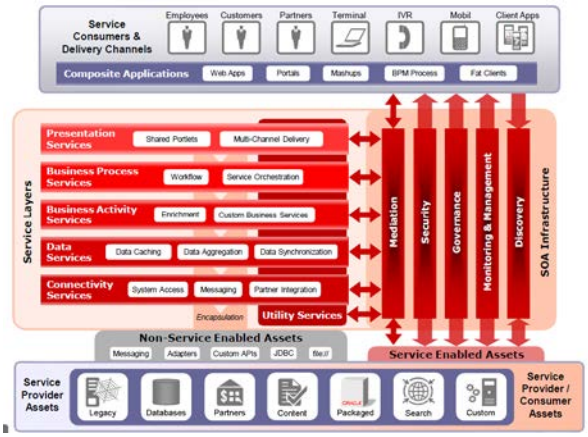
## 2.1. Strategic IT Principles

The Veterinary IT Roadmap will adopt the same overall strategic principles as under development by the EMA for its reference architecture. These are listed in Annex 3.

## 2.2. IT Technical Strategy

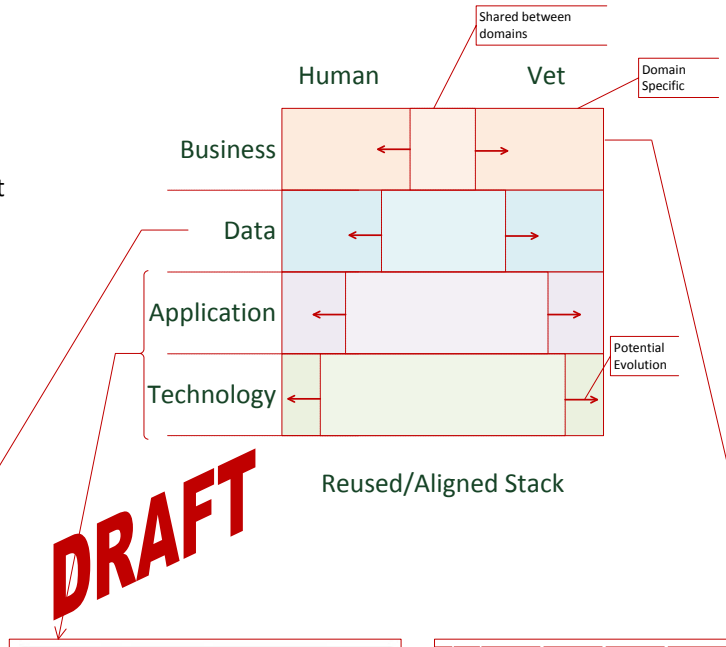
**The overarching strategy is to align with the Enterprise Reference Architecture Model, adopting a light-weight approach (Recommended option - to be confirmed)**

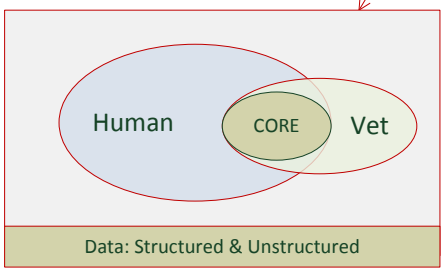
It is recommended that Veterinary Medicine adopts the Enterprise Reference Architecture Model, which describes a set of building-block technologies and services that can be re-used for a variety of needs. For example multiple processes (Human and Veterinary) require the calculation of a deadline or time interval (e.g. Access to Documents, Initial Marketing Authorisation). Under the model, a single service would offer this functionality, rather than each IT system/process that requires it needing to re-build/re-code it from scratch every time.



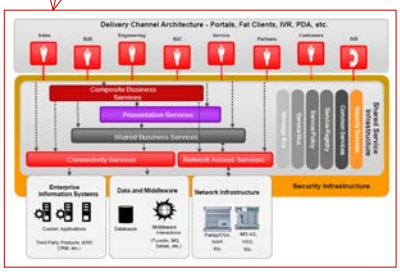

- Allows the greatest level of standardisation across EMA/NCA activities enabling greater use of a Service Oriented Architecture model.
- A “Light-weight” approach to veterinary applications is possible under the reference architecture
- Offers the potential for business services to be offered to the Network.
- Ability to re-configure as requirements change e.g. responding to the introduction of new legislation.
- The model is flexible to account for the specific needs of human and veterinary domains. The following diagram illustrates the possible way the architecture could be implemented in order to satisfy the needs of both human and veterinary medicine. It is foreseen that the level of separation between domains can differ from layer-to-layer within the stack, for example there could be a very high degree of alignment in technology but a high degree of separation in the operation of the business services.

Separating the business, data, application and technology layers will allow a more tailored approach with differing levels of integrations/reuse at each layer.

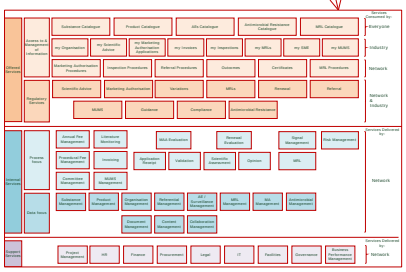



Core data can be shared between both domains. Other data can be domain specific.




During the evolution of an Enterprise Reference Architecture, various layers maybe bypassed until required maturity is achieved. This for example could simplify implementation and allow flexibility between Human and Veterinary domains.



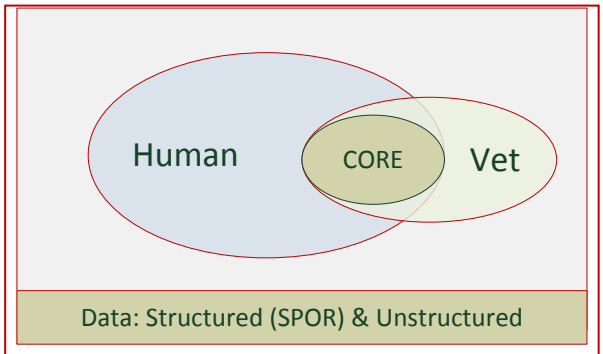
Business Service model could involved shared services between Human and Veterinary domains or separate services, which if appropriate could be operated using common reference architecture elements.

## *2.3. IT Data Strategy*

The overarching data strategy is to (over time) have a high-quality single source of "the truth". Meaning that there is only a single version of any piece of data, which is up to date and accurate according to an agreed standard. Under this strategy the data should be owned, managed and supplied by the users of that data.

### 2.3.1. Structured Data

The EMA data strategy has developed a concept for offering managed business services supported by a corresponding systems and data architecture for Substances, Products, Organisations and Referential data (commonly referred to as **SPOR**). The aim is to move from having such data held and managed in multiple places and databases, to offering a single reference point of high quality and well maintained data under clear ownership to support regulatory processes. This requires a unified approach to data management and the deployment of dedicated, expert resources to support external and internal providers and users.




Core data can be shared between both domains. Other data can be domain specific.

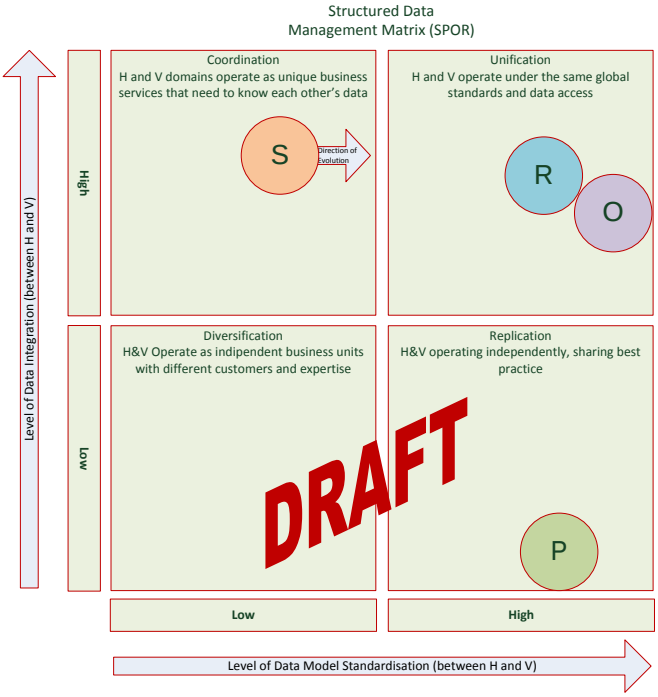
The strategic approach for Veterinary Medicine is to apply the SPOR model to the veterinary domain and as operated by the Network with specific additions and/or simplifications for the needs of the veterinary domain. The features of this option are:

- This provides the greatest integration and re-use of information between human and vet domains.
- The model is also flexible in the sense that in iterative development, the first iterations are aligned with this SPOR model, and that the latter iterations are fully aligned with this model. Each iteration must have this model as a 'file rouge'. As said before, the first iterations allow a more flexible compliance to this model.

#### *2.3.1.1. SPOR Alignment between Human and Veterinary Medicine*

A key decision point is the level of alignment of each of the SPOR elements between human and Veterinary medicine. In order to assess this, the following matrix has been developed that plots the level of data model similarity between domains against the level of data integration that exists[19].

This analysis has concluded that:




- Substance – A key issue to consider for substance is that ISO as currently understood is considered elaborate for veterinary needs and also lacks key attributes e.g. Target species, MRL. The concerns that quality standards may be higher than required for veterinary needs must also be addressed. Therefore, to begin with, it is anticipated that this will operate as a separate managed service for the Network with limited mandatory fields.[20] This data will be available to Human Medicine and vice versa. Subject to confirmation of how standards will be implemented, this could be integrated over time and managed as a single managed service between human and veterinary medicine.
- Product – this will be a specific managed service set up for Veterinary Medicine, operated by the Network. This may use the same data model and applications architecture as for human medicine. If that is the case a separate instance will be used for veterinary medicine which could represent a forked development from that point onwards.
- Organisation – this will be a single managed service for both human and veterinary medicine.
- Referential – this will be a single managed service for both human and veterinary medicine. Veterinary medicine may have specific lists (e.g. target species) maintained by the Referential Managed Service.

### 2.3.2. Unstructured Data

A significant quantity of the data used by the Network is unstructured. Examples include Marketing Authorisation Dossiers which are in the VNeeS format, guidance documents, assessment reports. Some of

[19] Data integration refers to data that is shared between domains.
[20] Active Substance name, which will be mapped to an EU unique reference Substance with corresponding reference number.

this information is used only internally by the network to deliver its activities and is confidential in nature; some is made available for public consumption.

The overarching strategic principles apply to unstructured data. This means that there should be a single source of each data entity, for example a marketing authorisation dossier or guidance document for the entire Network. Standards will need to be developed to support this as well as common repositories and communication mechanisms. Document management tools will be needed to manage this unstructured data.

### 2.3.3. Solution Design and Delivery Approach

IT solutions are governed by the key principle: **Keep it simple and appropriate**. The approach should therefore be iterative:

- distinguish between essential requirements and non-essential requirements
- implement essential requirements and deliver a solution within a few months to keep investment low
- test the solution with the nominated representatives of (multiple) Network members
- adoption by network and go-live
- after a period of operation, collect new requirements to evolve the system and implement lessons learned from the real use

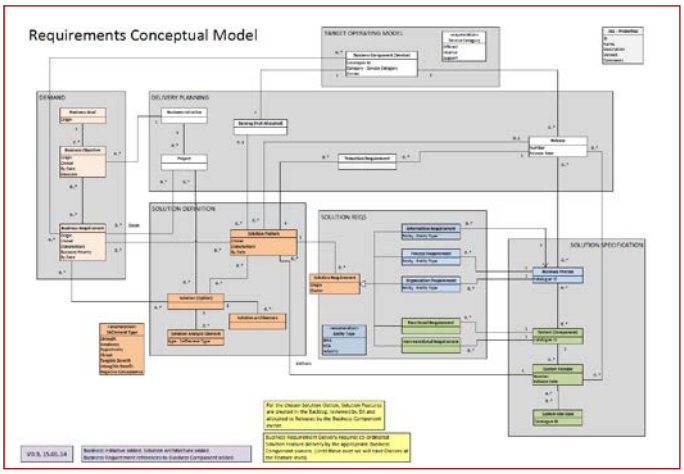



**Figure 2- A Requirements Conceptual Model will be used to define solutions - see Annex 4 for larger version**

Any solution provided for the Veterinary network will include agreeing on a business case including understanding the demand in terms of goals, objectives and requirements. For example:

- benefits for sharing the data
- the data structure and fields
- how this data should relate to other kinds of data (dependencies)
- message format requirements for sharing across the network

Once this has been understood the solution can be defined taking more practical aspects into consideration such as:

- do we need a new system or can an existing system in the network be altered to satisfy the needs?
- the network's non-functional requirements standard
- which Competent authority (e.g. EMA, NCA) will take the lead in providing the solution and who will participate in the project e.g. in the acceptance testing phase

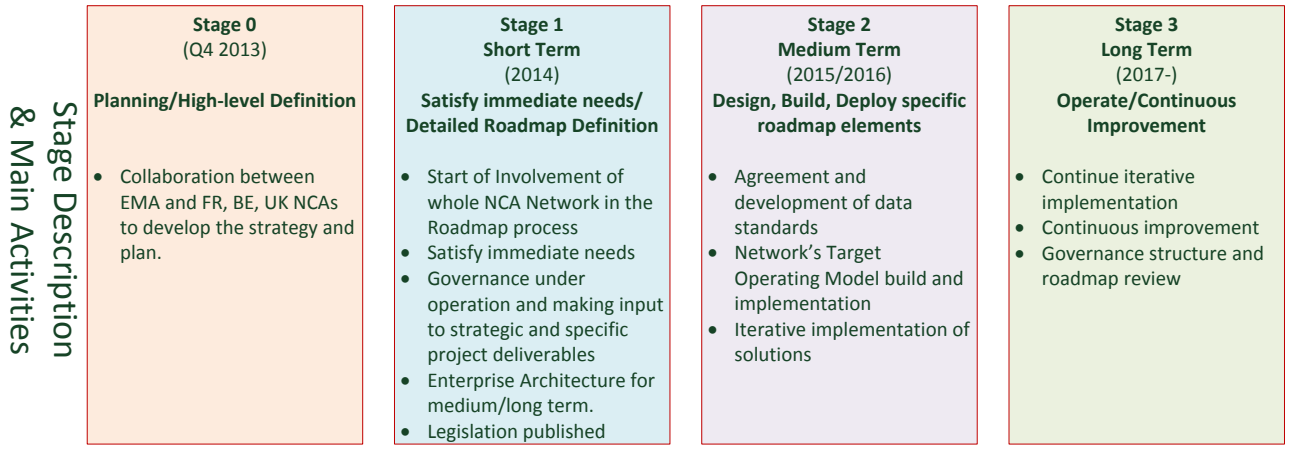
## *2.4. IT Operations Approach*

For applications hosted by the EMA, IT Operations approach should remain common to both Human and Veterinary medicine. For applications hosted nationally, these should align as a minimum to an agreed set of non-functional requirements to be agreed by the Network.

# 3. Veterinary IT Tactical Plan

## *3.1. The Roadmap and the Plan*

The diagram below describes the high-level roadmap stages including, where currently known, the key deliverables within each stage. Detailed descriptions of the thus-far envisaged activities and deliverables are listed below.




The roadmap on the following page lists a number of objectives to be delivered.

Those objectives listed for delivery in 2014 are required to satisfy immediate needs. Objectives identified from 2015 onwards are subject to consultation with the Network and the detailed requirements gathering, analysis / architecture work that is proposed for delivery during 2014.

The results of this analysis will be reviewed in consultation with the Network and specific proposals submitted for approval according with the governance approach described in chapter 4.

The roadmap, where known, also identifies where other programmes/projects already proposed can be reused to deliver the Veterinary requirements.

| When needed (Year) | Objective Name | Objective Description | Aligns with business goal(s) | Supports Which Business Goals | Delivered by which programme (proposed)? | MoSCoW |
|---|---|---|---|---|---|---|
| 2014 - 2017 | Network Governance and Steering | Establish the Network Roadmap delivery project Governance under the overall EU Telematics Programme structure. Manage the network adaption/adoption of SPOR model and supporting Reference Architecture as defined in section 2.3.1 of the roadmap | 3 | Establish the Network as a Reference Authority | Veterinary IT and Data (non-IT/Change Management) | M |
| 2014 | Veterinary Product Databaser - Iteration 1 | The first iteration of the EU veterinary medicines data base and corresponding first iteration of the data model for vet substances. Set up of a small business unit to undertake (initial) data cleaning and data quality assurance. | 1 | EU-Wide integrated Pharmacovigilance | Veterinary IT and Data Roadmap Implementation | M |
| 2014 | Roadmap Detailed Analysis | Detailed analysis of medium-term/long-term requirements for projects listed for 2015. | All | All | Veterinary IT and Data Roadmap Implementation | M |
| 2015 | Adverse Event Repository | Adverse Event repository aligned to VICH requirements | 1 | EU-Wide integrated Pharmacovigilance | Veterinary IT and Data Roadmap Implementation | M |
| 2015 | Veterinary Network Data Warehouse - Iteration 1 | Data warehouse - containing Veterinary PhV data | 1 | EU-Wide integrated Pharmacovigilance | Veterinary IT and Data Roadmap Implementation | M |
| 2016 | Veterinary Network Data Warehouse - Iteration 2 | Data warehouse - containing Veterinary PhV and MA data | 2 | Supporting Marketing Authorisation throughout the EU | Veterinary IT and Data Roadmap Implementation | S |
| 2016/2017 | Signals Management Tool | A Surveillance tracking database and tools with QPPV access | 1 | EU-Wide integrated Pharmacovigilance | Veterinary IT and Data Roadmap Implementation | M |
| 2016 | eSubmissions | A common EU submissions gateway for all procedures including CAPS, NAPS, DCP/MRP including Electronic submission and management of VNeeS | 2,5 | Supporting Marketing Authorisation throughout the EU; Develop the Network On-line service and information provision | e-submissions gateway v3 | M |
| 2016 | eSubmissions | A common EU repository for Veterinary Regulatory information/data (including Marketing Authorisation - VNeeS, ASMF) | 2,5 | Supporting Marketing Authorisation throughout the EU; Develop the Network On-line service and information provision | e-submissions | M |
| 2017 | Veterinary Regulatory Communications Platform | A single communication mechanism for regulatory information (other than submissions covered within the scope of the eSubmissions Programme) e.g. ad-hoc communications with applicants/Assessors. Possibility to extend scope of eSubmissions to cover this or merge with the Collaboration Tools project. | 2,5 | Supporting Marketing Authorisation throughout the EU; Develop the Network On-line service and information provision | Veterinary IT and Data Roadmap Implementation, (check online) | M |
| 2017 | eSubmissions | eApplication Form adapted to Veterinary Needs e.g. new legislation, VNeeS, ability to distinguish between a new application and response to a question | 2,5 | Supporting Marketing Authorisation throughout the EU; Develop the Network On-line service and information provision | e-submissions | M |
| 2017+ | Validation Tools | Automation of Technical and Content Validation | 2 | Supporting Marketing Authorisation throughout the EU | Veterinary IT and Data Roadmap Implementation | M (Technical), C (Content) |
| 2016 | Inspections Database | Inspections Database – to be confirmed if required in consultation with Inspections Colleagues within the Network | 2 | Supporting Marketing Authorisation throughout the EU | Enterprise Reference Architecture Implementation - Document Management Project | ?? |
| 2016 | Workflow - Iteration 1 | A configurable workflow engine for tracking CAPs, DCP, MRP, NAPs (e.g. CTS ) MA and PhV processes - Pilot for a selected CAP(or DCP) and NAP process | 2,4 | Supporting Marketing Authorisation throughout the EU; Reduce costs, Work Collaboratively, Support Smaller Agencies | Enterprise Reference Architecture Implementation - Document Management Project | M |
| 2017 | Workflow - Iteration 2 | A configurable workflow engine for tracking CAPs, DCP, MRP, NAPs (e.g. CTS ) MA and PhV processes - Operation, including self-serve and SAAS model. | 2,4 | Supporting Marketing Authorisation throughout the EU; Reduce costs, Work Collaboratively, Support Smaller Agencies | Enterprise Reference Architecture Implementation - Document Management Project | M |
| 2017+ | Workflow - Iteration 3 | Integrate MRLs into Workflow, Product and Substance databases/services | 2,3 | Supporting Marketing Authorisation throughout the EU; Establish the Network as a Reference Authority | Veterinary IT and Data to provide requirements | M |

| When needed (Year) | Objective Name | Objective Description | Aligns with business goal(s) | Supports Which Business Goals | Delivered by which programme (proposed)? | MoSCoW |
|---|---|---|---|---|---|---|
| 2015,2016,2017 | Veterinary Product Management Service - Iteration 2, Iteration 3, Iteration 4 | **P -** Future iterations of the Common European Database of Veterinary Medicinal Products including: alignment to Reference Architecture (if appropriate), links to ESVAC, alignment with agreed standards and the new Veterinary Legislation, Ability to link specific manufacturing sites to products to support Inspections/Pharmacovigilence; also links between OMCLs and OCABR certificates & OBPR releases (timing and scope of specific iterations to be confirmed) | 1,2,3 | EU-Wide integrated Pharmacovigilance; Establish the Network as a Reference Authority; Supporting Marketing Authorisation throughout the EU | Veterinary IT and Data Roadmap Implementation | M |
| 2015 | Veterinary Substance Management Service | **S** - Establish a Substance Management Service (SMS) as a single point of reference for high-quality substance data - iteration 1 (Separate Vet service). Includes agreement of standards to be used for Veterinary Data. | 3 | Establish the Network as a Reference Authority | Data Integration Roadmap (Stage 1) | M |
| 2016 or 2017 | Substance Management Service Integration (Optional) | **S** - Establish a Substance Management Service (SMS) as a single point of reference for high-quality substance data - iteration 2 (Integration of H and V services - if applicable) | 3 | Establish the Network as a Reference Authority | Data Integration Roadmap | S |
| 2016 | Data Integrateion Stage 3 | **O** - A single source of information regarding legal entities, sites and organisations involved in Marketing Authorisation/Pharmacovigilance activities | 3 | Establish the Network as a Reference Authority | Data Integration Roadmap | M |
| 2015 | Data Integration Stage 1 | **R** - An agreed approach for managing referential data, translated into all National languages (which could differ from the "Official" EU languages) | 3 | Establish the Network as a Reference Authority | Data Integration Roadmap | M |
| 2014 (pilot) 2015 (operation) | Collaboration Tools and Document Management | Tools to enable unstructured collaboration and resource sharing, in particular document magement, and SAAS model for NCA's to manage own documents securely and confidentially | 4 | Reduce costs, Work Collaboratively, Support Smaller Agencies | Enterprise Reference Architecture Implementation - Document Management Project | S |
| 2015,2016,2017+ | Best-Practice Sharing | Standardisation/best-practice sharing of working practices where relevant e.g. dossier validation | 4 | Reduce costs, Work Collaboratively, Support Smaller Agencies | Veterinary IT and Data Roadmap Implementation (non-IT) | S |
| 2015 | Fees and Payments | A fees and billing engine, including SAAS model | 4 | Reduce costs, Work Collaboratively, Support Smaller Agencies | ?? | M |
| 2015 | Target Operating Model | Establish the Target Operating Model for the Network to operate as a virtual organisation | 4 | Reduce costs, Work Collaboratively, Support Smaller Agencies | Veterinary IT and Data Roadmap Implementation (non-IT) | M |
| 2015,2016,2017+ | Self-serve reporting Iterations 1,2 and 3 | Veterinary Network Business intelligence, reporting and benchmarking, including self-serve reporting. Needs to include ability for all stakeholders to access and produce reports with varying access/permission levels according to roles e.g. NCA/EMA, Industry, Veterinarians/Public. | 4,5 | Reduce costs, Work Collaboratively, Support Smaller Agencies; Develop the Network On-line service and information provision | Veterinary IT and Data Roadmap Implementation to provide requirements to ?? | M |
| Q4 2014/2015 (Depends on when new legislation will be published) | Online Strategy Development | Define the overall strategy and roadmap for on-line services and information in line with the new legislation. | 5 | Develop the Network On-line service and information provision | ?? (Online programme scope includes Network and Veterinary?) | M |
| 2016 | Antimicrobial Usage | An Antimicrobials usage database detailing all sales | 6 | Promote Innovation and Sustainable Development | Veterinary IT and Data Roadmap Implementation | M |
| | | | | | | |
| | | = projects already planned that Veterinary Network will need to provide requirements to / ensure scope adequately covered | | | | |
| | | = a new veterinary-specific project | | | | |
| | | = a project proposed, subject to approval that could deliver Veterinary requirements subject to confirmation | | | | |
| | | = status unknown at this stage | | | | |

## *3.2. Proposed 2014 Work Programme Scope and deliverables*

Subject to formal approval it is proposed that a programme management approach will be set up to take forward the roadmap objectives. There are three projects under this programme:

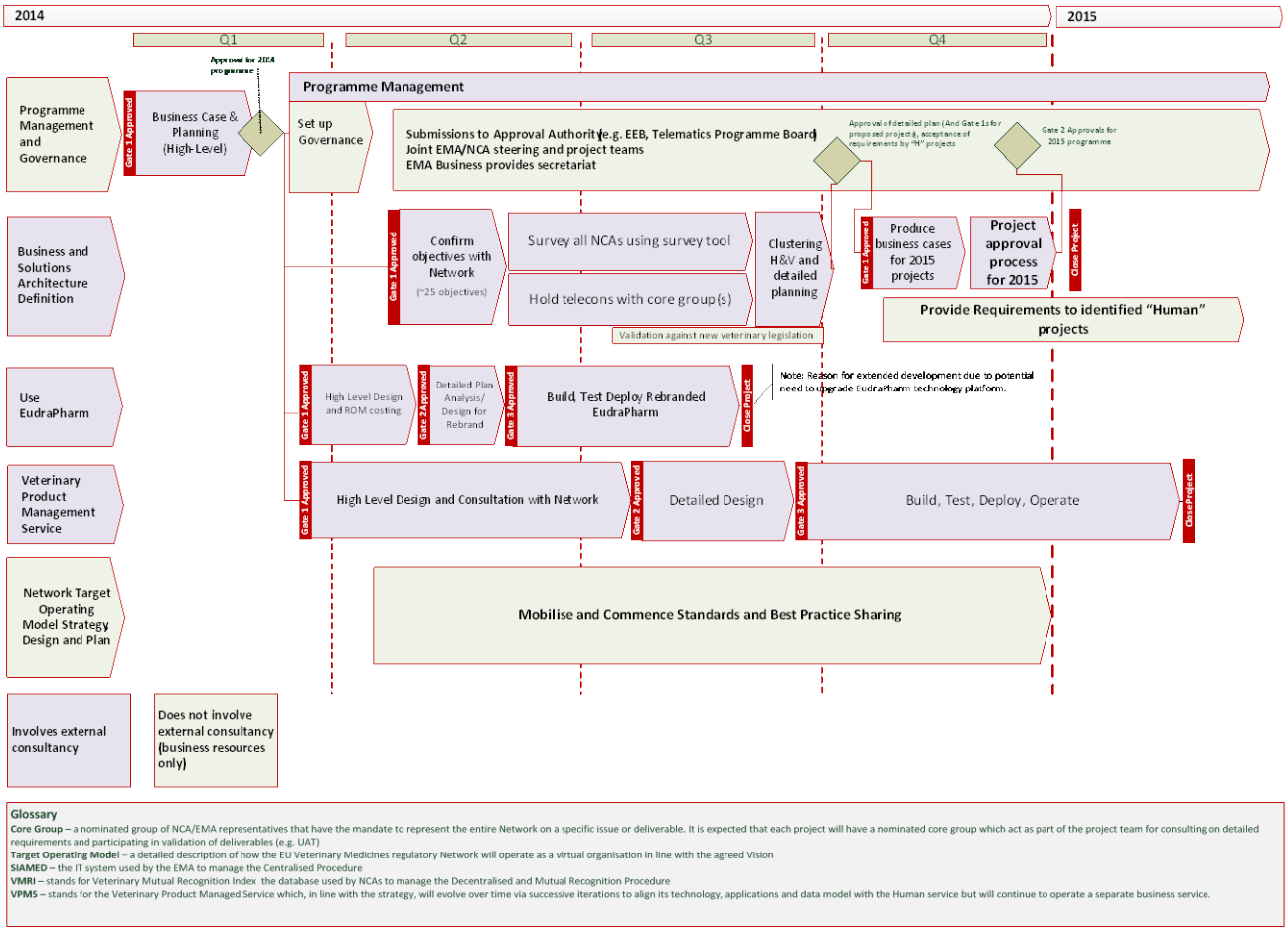
1. A project to **use EudraPharm**[21]**,** confirming it as the Common EU Database of Veterinary Medicinal Products.
    - This project will deliver:
        - This will implement a specific user interface for Veterinary Medicines (currently it is used for Human and Veterinary medicines).
    - The benefit of doing this project is:
        - **NCAs and EMA** will have certainty over the future of EudraPharm as the platform for the common EU Database of Veterinary Medicinal Products
        - Answers the **HMA** request for a Veterinary product database
2. **Veterinary Product Management Service**: A project to deliver **version 1 of the service** along with improvements to the common European database of veterinary medicinal products. This is considered by the network as the priority objective and one that will not be impacted by the forthcoming revision of the Veterinary legislation.
    - This project will deliver:
        - Business work stream deliverables include: operating model, business processes, defined inputs/outputs, SLA, funding model, plan for EMA data cleansing
        - IT work stream will focus on delivery of functionality including (to be confirmed by analysis): integration with available SPOR components, Synchronisation with external databases[22], interface to enable individual and bulk create/upload of products, reporting, transmission of data to EV Data Warehouse
    - The benefit of doing this project is:
        - **EMA and NCAs** will be able to increase the scope and effectiveness of their Pharmacovigilance activities across the EU and a database of veterinary medicines available in the EU will be accessible by veterinary surgeons and the general public
3. **Business and Solution Architecture Definition for Veterinary:** A project to define the enterprise architecture for each of the other roadmap objectives (defined in 3.1). This architecture will be progressively refined as the shape of the revised Veterinary Legislation becomes clear and in collaboration with the entire Network. To support the overall programme, roadmap adoption and implementation, this project will also set up a steering group to govern the projects under the overall EU Telematics programme.
    - This project will deliver:
        - Elaborated requirements for each of the objectives under the roadmap
        - Define the enterprise architecture (people, process, technology, data) to deliver the strategic vision
        - Business cases for funding projects in 2015

[21] Proposing EudraPharm as the solution platform follows an Architectural options assessment.
[22] For example the VMRI database

- A steering group to steer projects and motivate network buy-in

- The benefits of doing this project is:
  - **NCAs and EMA** will have a shared understanding of the related impacts of the new legislation
  - **NCAs and EMA** will have a detailed business and IT solutions plan to fulfil the roadmap objectives

## The proposed phasing of the 2014 work is as follows:[23]




[23] Subject to formal budgetary approval

# 4. Project Approach

## 4.1. Communications Plan

The network governance and steering project will draft a communications plan as one of its deliverables.

## 4.2. Funding

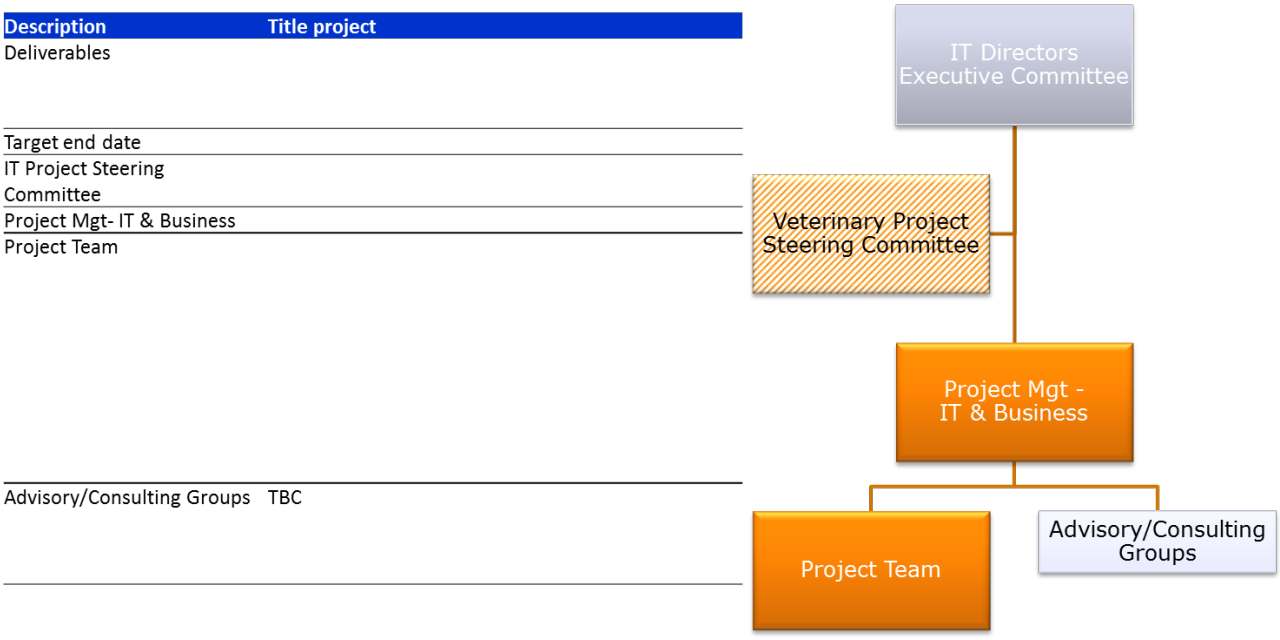
There is no specific budget foreseen for projects under the EU Telematics Programme and each project requires funding from one or more of the Telematics Partner organisations (EU NCAs and EMA). There is a general assumption that the EMA will provide principle funding for any pan-European IT systems development, however NCAs may also wish to provide funding or contribute human resources.

It is understood that, regardless of the funding mechanism for a given project, to enable successful delivery business and IT resources will need to be committed by both EMA and NCAs in particular to support analysis, testing and implementation/change management activities.

With respect to the common European database of veterinary projects, this will be by nature a joint enterprise whereby the EMA will provide the database together tools for its management and the network will provide the data in terms of information on the veterinary medicinal products on their markets.

## 4.3. Project Governance

Under the EU Telematics Programme, each project will operate the following generic governance structure. This can be tailored to suit the specific needs of each project:




## 4.4. Project Management

Project proposals under the roadmap will each follow a defined project methodology and require a valid business case and regular stage-gate reviews. Each project will have an agreed managing partner, which will normally be the organisation that provides the largest share of project funding.

It is assumed that the project will use the project methodology in place within the managing partner, which should be aligned to a recognised project management best practice e.g. PRINCE2, PMI(PMBOK). If required RUP@EMA can be used, this adopts PRINCE 2 as the overall framework with RUP used for the solution development.

## *4.5. Risks and Issues*

| Risk Name | Description | Likelihood | Severity | Planned Mitigation |
|---|---|---|---|---|
| Network Buy-in | For this project to succeed it is critical that NCAs buy-in at every stage. The need for the VPMS database has been agreed at the HMA level (hence all NCAs have signed up).<br><br>There remains a risk of insufficient buy-in at the detailed level which would undermine the project's business case especially related to NCAs sending their Data to the VPMS. It is noted that, as agreed by HMA, the detailed work was done by EMA + 3 NCAs on behalf of the entire Network. | M | H | • Establish a robust project governance structure, integrating NCA and EMA business teams under the approved overall EU Telematics programme governance.<br><br>• Appoint business resources to act as secretariat to this structure in order to ensure proactivity and actions are carried out.<br><br>• Put in place stage gates to stop the projects if insufficient buy-in is deemed at key stages.<br><br>• Establish data quality standards that are acceptable to the entire Network in transmitting their data.<br><br>• Proposal to be tabled to ETMB to confirm EudraPharm's future as the mechanism for sending data to common EU systems for Vet*. Proposal will also be to stop using EudraPharm for human use and make it a vet-only system. |

| Risk Name | Description | Likelihood | Severity | Planned Mitigation |
|---|---|---|---|---|
| Repeating data entry / transmission due to use of free text fields | The Veterinary Business has requested a data standard that includes provision to receive data "as Authorised" using free text fields. This is to help mitigate the Network Buy-in risk and facilitate the sharing of data at the earliest point.<br><br>The Veterinary Network has a strategy to move it over time as maturity grows into alignment with the PMS, SMS, OMS, RMS data, applications and technology. There is a future risk that, there will be costs incurred either by the EMA or by NCAs in resubmitting data in a more structured form. | M | M | • Request business acknowledgement and acceptance of this risk<br><br>• During the project's inception and elaboration phases work with the project team to raise this risk with the NCA network with a view to adopting a more structured approach from the outset.<br><br>• Also during Inception/Elaboration Clarify the future steps following the 2014 project with regard to Data and how well the data being transmitted will fulfil the related business needs.<br><br>• Change the EudraPharm XEVPRM message format to align with the simplified model defined by the Business Requirements. |
| Availability of EMA/NCA business resources | This project requires a significant workload from EMA and NCA business resources. This will be throughout its lifecycle and in particular (for NCAs) during the requirements analysis, User Acceptance Testing and Roll-Out phases. | M | H | • Establish the governance structure, including commitment of business resources from EMA and NCAs.<br><br>• 1 FTE EMA Business Project management (EMA + NCAs) requested as well as 64 days from other colleagues acting as Subject Matter Experts.<br><br>• "Worst-case" estimate of 3 FTE needed for a 6 month period to map all 42,000 products to referentials should be budgeted for. Further mitigation for this would be to ask NCAs to submit data already mapped and/or to use the bulk update use case to reduce the time involved. |

| Risk Name | Description | Likelihood | Severity | Planned Mitigation |
|---|---|---|---|---|
| Regulatory changes/Scope creep | For a variety of reasons this project could be subject to scope change/creep that will need to be closely managed. These reasons include:<br>• The multi-stakeholder nature of the project.<br>• The envisaged new Veterinary Medicines Regulation – details of which should become known during the lifecycle of this project.<br>• Changing business requirements/governance as a result of any business re-engineering activities. | M | H | • Implement a structured change request process involving the EMA/NCA governance structure.<br>• Establishment of clear project tolerances up-front.<br>• Keep a watching brief on regulatory developments and where required, seek to ensure that regulatory development takes accounts of EMA/NCA operational needs. |
| Multi-language support | It is likely that stakeholders would require interactions with EMA systems to be possible in local languages. This could risk increased costs for EMA related to translations or management of synonyms especially for substance information. | M | H | • Work has already been undertaken to map Veterinary substance terms<br>• This risk would be further mitigated by making use of the Substance Management Service (SMS) that is being set up during Q4 2014 |
| Unusable data due to free text transmission | Some of the data to be collected as free-text actually refers to controlled terms (where reference is EDQM, WHO or EUTCT) This data will only be interpretable by a human user (i.e. not a system). The risk is therefore that this data does not get used at all. | M | M | • Eliminate such data from the data collection process.<br>• Use the mechanism in place for EV where free-text submissions are recoded and associated to a controlled term. This would require human resource effort to deal with new free-text entries as they are submitted.<br>• It is noted that one approach to dealing with this risk is for the EMA/NCA business users to accept the risk as an acceptable trade-off for receiving data from across the Network. |

| Risk Name | Description | Likelihood | Severity | Planned Mitigation |
|---|---|---|---|---|
| Withdrawl of funding for key components | Funding could be withdrawn from veterinary projects due to re-prioritisation in light of pressure on budgets | L | H | • EMA has in place a revised ICT Strategy whereby projects are delivered incrementally based on budgets agreed and committed in advance. Any changes in future commitments to veterinary projects would be known at least one year in advance. |

# Annex 1 – The Veterinary Ecosystem

The following have been identified as the key actors within the roadmap's ecosystem:

- **NCAs** – The EU National Competent Authorities, along with the EMA, form the core "Partners" under the virtual organisation collaborative model. Some are joint human and veterinary agencies with common organisations and tools. Some are veterinary-only agencies, many of which are very small with limited IT resources and budgets.
- **EMA** – Along with the NCAs, the European Medicines Agency is a core "Partner" under the virtual organisation collaborative model. The EMA provides pan-EU IT tools and platforms.
- **HMA** – The Heads of Medicines Agencies is an informal network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of Medicinal Products for human and Veterinary use in the European Economic Area. The EMA is not a member of the HMA but attends key meetings as an observer. HMA members provide pan-EU IT tools and platforms.
- **VICH** - an EU-Japan-USA programme aimed at harmonising technical requirements for veterinary Product registration. Its full title is the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.
- **Associations (Industry)** – Veterinary Industry trade associations (e.g. IFAH-Europe) that represent the collective interests of member companies both at an individual member-state and at the EU level.
- **MAHs (Industry)** – All companies that hold Veterinary Medicine Marketing Authorisations within the Regulatory Network's jurisdiction. These are the organisations whose activities are regulated by the Network.
- **MAHs SMEs (Industry)** – A subset of Marketing Authorisation Holders that have approved SME status. They may qualify for incentives under EU Veterinary Medicinal Product legislation and as such may be entitled to or require an additional level of service. Small industry players with very little IT resources.
- **FDA** – The US Food and Drugs Administration.
- **EURLs** – EU Reference Laboratories aim to ensure high-quality, uniform testing in the EU and support Commission activities on risk management and risk assessment in the area of laboratory analysis.
- **Third party consultants** – Companies, most notably SMEs, are able to make use of third-party consultants to undertake tasks related to the regulation of Veterinary Medicinal Products. This, for example, might include the preparation of dossiers for submission and testing for safety and efficacy of medicines.
- **Distributors** – companies that act in the sourcing and distribution chain for medicinal products. This could include parallel distribution and/or the re-packaging of medicinal products.
- **Veterinarian associations** – Professional bodies representing veterinarians
- **Veterinarian software providers.**
- **ASMF holders** – Active Substance Master File holders produce medicinal product active substances on behalf of Marketing Authorisation Holders. It is possible for one ASMF to be applicable to multiple pharmaceutical products for both human and veterinary medicine.
- **EFSA** – The European Food Standards Agency
- **Veterinarians** – The Network would like Veterinarians to use the common European database of Veterinary Medicinal Products to identify medicinal products to be used in the cascade

- **ISO** – The International Standards Organisation. Human medicines have adopted a strategy of using ISO standards for describing Active Substances in medicinal products.
- **JECFA** - Joint FAO/WHO Expert Committee on Food Additives
- **Animal owners/ General public**
- **EU Telematics IT Directors Group and Executive Committee**

# Annex 2 – List of current IT systems used

At present it is only possible to list systems operated by the EMA including those used solely by the EMA and those made available via the Telematics programme to the entire Network. They are as follows:

- **EudraLink** – Used by EMA, NCAs and Industry for communications related to the Centralised Procedure.
- **EURS** – Used by the EMA as the repository for Marketing Authorisation dossiers (not used for lifecycle management by Veterinary medicine)
- **SIAMED** – This is the EMA's procedure management tool, also includes product, substance and organisation information.
- **Oracle Business Intelligence** – Used as a business reporting tool.
- **EUTCT** – The European Union Telematics Controlled Terms used as the Community repository and provider of controlled terms in multiple languages for the ongoing exchange of data between information systems and applications throughout the European Medicines Regulatory Network EV Vet
- **EPITT Vet** – Used by the EMA for Pharmacovigilance – logging of Adverse Events and surveillance.
- **Corporate GXP** – Used by the EMA to track inspections.
- **EudraGDMP** - the Union database referred to in article 111(6) of Directive 2001/83/EC and article 80(6) of Directive 2001/82/EC. It contains the following information: Manufacturing and import authorisations; Good Manufacturing Practice (GMP) certificates; Statements of non-compliance with GMP; GMP inspection planning in third countries.
- **EudraPharm** - intended to be a source of information on all medicinal products for human or Veterinary use authorised in the European Union (EU) and the European Economic Area (EEA).
- **ECD** – The Eudra Common Directory is used by the EMA to store information about organisations (legal entities, sites, people).
- **DREAM** – Based on Documentum, it is used by the EMA as its central document management and repository.
- **MMD** – This is the EMA's Managing Meeting Documents system and is used by the EMA and NCA Delegates.
- **SME Database** – Provided by the EMA to record details of organisations qualifying for SME incentives linked to the Centralised Procedure.
- **SAP** – Used by the EMA to bill fees and make payments.
- **ESVAC** – Used for tracking European Union sales of Antimicrobial products used in Veterinary Medicine.
- **Ask EMA** – Based on JIRA, the Ask EMA system is used by the EMA to track general enquiries (requests for information) and requests for Access to Documents under regulation 1049.

As the roadmap is further matures during 2014 this list can be expanded to include NCA-specific systems.

# Annex 3 – Overall Strategic IT Principles

**Business Principles**

- Principle 1: Primacy of Principles
- Principle 2: Maximize Benefit to the Network
- Principle 3: Information Management is Everybody's Business
- Principle 4: Business Continuity
- Principle 5: Common Use Applications
- Principle 6: Compliance with Law
- Principle 7: IT Responsibility
- Principle 8: Requirements-Based Change

**Data Principles**

- Principle 9: Data is an Asset
- Principle 10: Data is Shared
- Principle 11: Data is Accessible
- Principle 12: Data Trustee
- Principle 13: Common Vocabulary and Data Definitions
- Principle 14: Data Security

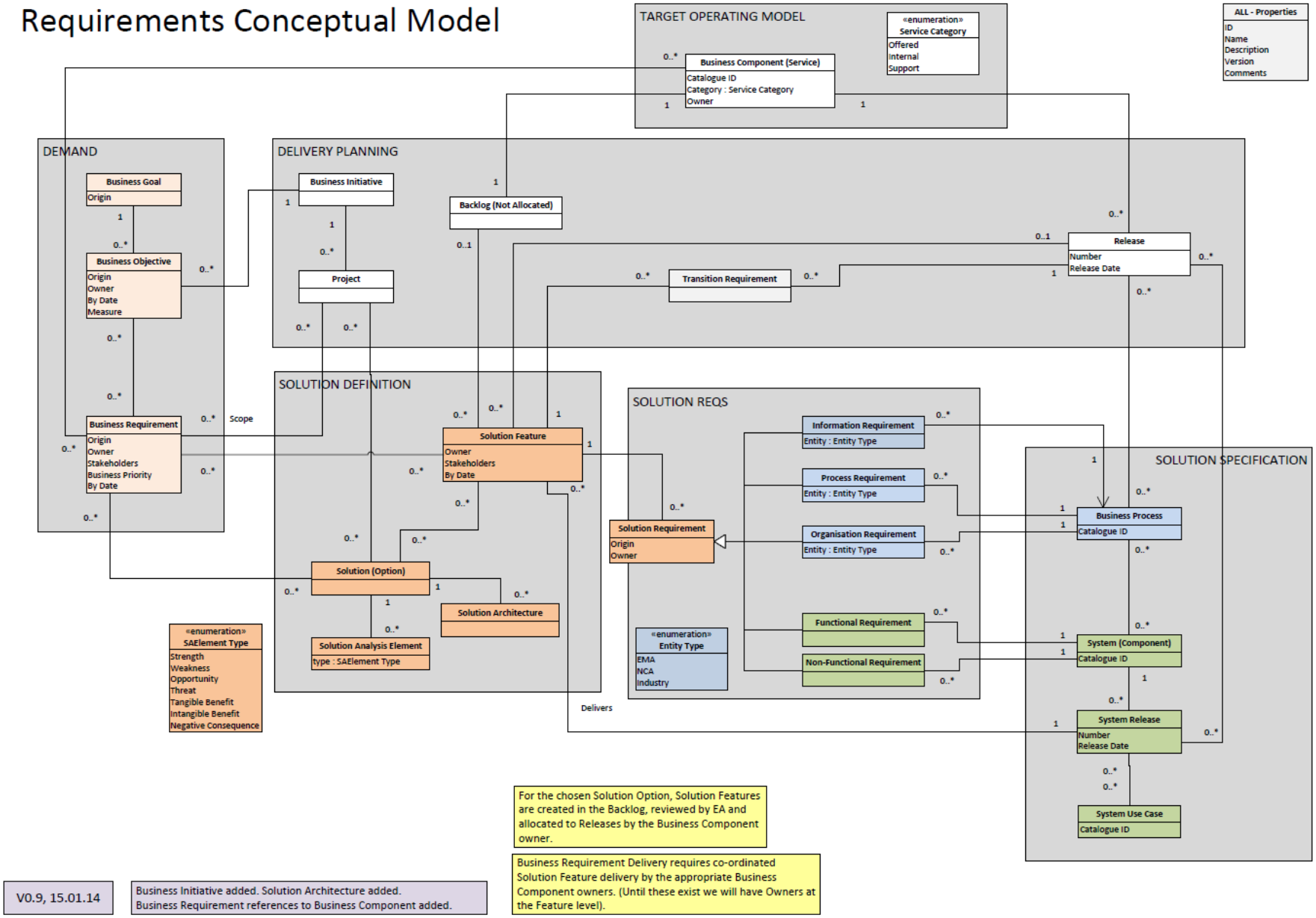
**Application Principles**

- Principle 15: Separation of Specification from Implementation
- Principle 16: Application Portability
- Principle 17: Ease-of-Use

**Technology Principles**

- Principle 18: Responsive Change Management
- Principle 19: Control Technical Diversity
- Principle 20: Interoperability

# Annex 4 – Requirements Concept Model



# Annex 5 – NCA Comments on the problem statements

The following statements and questions that should be addressed by the roadmap have been endorsed by the joint EMA/NCA project team:

## *European Pharmacovigilance*

**EudraVigilance**
*Focus point*: how can we improve the system to make it working for all procedure types? How to make it work with a complete and shared European database as a definition database? The common European database of Veterinary Medicinal products will need to serve as a dictionary for vigilance, enabling signal detection and a data warehouse - Is Eudrapharm the best tool for that?

**VPhS** (Veterinary Pharmacovigilance Surveillance database used by rapporteurs and their experts for the surveillance of centrally authorized products (CAPs) - FileMaker)
*Focus point 1:* what do we want to improve on this tool?
*Focus point 2:* from a technical point of view, could the future release of this system be available as a web application, to reduce maintenance costs?

**PSUR Common Repository**
*Focus point:* what could be the aim for the European Veterinary sector to build such a new system?

## *European Marketing Authorization*

**EudraPharm**
*Focus point 1*: HMA has validated a business case on this subject. Even if it is a base for the work of the group, don't we need to complete the reflection at our level?
*Focus point 2*: how can we make it a success this time? We first have to analyse and establish where we have been going wrong, why so many NCAs didn't bring their data into it. What could be different now? We have to gain buy-in on the benefits for NCAs of having a common European data base of medicinal products. For example: The common EU DB has to be used as a dictionary in all vigilance activity in Europe. This way, Pharmacovigilance data can be processed and exchanged within the EU. We need to identify a clear benefit and gain buy-in from all the actors (EudraVigilance, cascade, etc.?), before starting a second attempt with a new IT project.
*Focus point 3*: most of necessary data are already included in CTS (MRP/DCP) and the publication of these data is possible with the VMRI (SPC harmonised in English, PuAR…). Could we improve the database to include Centralised and National data, so that we could partly or fully feed Eudrapharm? (for the worksharing of national variations procedures, the CMDv discuss the possibility of using CTS for the follow up of the procedures and to introduce national procedures in CTS).
*Focus point 4*: regarding the clear benefits and uses, we have to decide on such strategic choices as language, controlled terms, etc.
*Focus point 5*: do we plan to use EUTCT for all procedures? Very likely an iterative approach would be successful, starting with a rather permissive data quality requirements, which yearly will be tightened, using EU TCT terms. This way, opportunity is also given to have the substances list cleaned and made available for the common European database of Veterinary Medicinal Products.

**Common European Database of Veterinary Medicinal Products**
*Focus point*: do we need this and what are the benefits and constraints for NCAs? If we have one common H/V or only V maintained list of substances in the EU, could it be an asset in further systems? (today, without such list, we have duplicated data everywhere and so much "free text" information it is so hard to operate in a EU context without extra cost)? Benefits from the GInAs initiative for the Veterinary sector? Other solutions?

**CTS**
*Focus point 1*: it's important to synchronize data between CTS and a EU Veterinary medicinal common European database of Veterinary Medicinal products (like EudraPharm or derivatives). So could we manage to interface with other systems? As mentioned above, couldn't we use data gathered in CTS to feed an EU common European database of Veterinary Medicinal products?
*Focus point 2*: is there an opportunity to use CTS for other data interpretation needs?

**ASMF Repository**
*Focus point:* what could be the aim for the veterinary sector? Active substances could be used both in Human and Veterinary medicinal products, should this repository be common between Human and Veterinary sectors (ASMFs are often common between H & V)?

**European Good Manufacturing Practice** *(Manufacturing and import authorisations, certificates, inspection)*
*Focus point 1:* do we need to improve the system?
*Focus point 2:* do we need other data in EudraGDMP?

## *eSubmission*

**eSubmission format**
*Focus point*: two objectives in general can be proposed: Simple and flexible format and harmonisation between the agencies in requirement. Today electronic submission is largely used in the Veterinary sector and the VNees format is mandatory and realy makes sense, so do we need to target a eCTD or equivalent format based on XML? Is there an added value in the vet sector related to life cycle management? So is it a priority for the next following years?

**CESP / eSubmission program**
*Focus point 1*: what items do we plan to include in the system: also PSUR, Inspections, etc.? And when?
*Focus point 2*: how can we get one single system in Europe? A single entry point reduces the costs of dual systems.

**eAF**
*Focus point 1*: why is the system not used today? How to improve the system and fix bugs (reported by industry) for the Veterinary sector? Do we aim to make it mandatory Q1 2015 in the veterinary sector?
*Focus point 2*: maybe we could simplify eAF for the Vet sector. Couldn't we propose to concentrate on a core of structured data fields and transform some fields as free text?
*Focus point 3*: how do we want to take advantage of the XML file? Gather data in our database? Dispatch as we do today with CESP XML? Do we need a legal base XML in the Vet sector in addition to the PDF file?

**Electronic signature**
*Focus point*: what is the benefit in our processing and at what cost, for whom is it mandatory? A clear policy – EU wide with focus on each country would help. As such, one receiving agency knows how to recognise the elect signature by a citizen of another country.

## *Antimicrobial Resistance and usage*

*Focus point1:* This is a project which starts in each of the NCA's. What could be the aim for the European veterinary sector? Could best practice be exchanged? Do we need to work together on this topic? Do we need an IT system to manage this?
*Focus point2:* Is there a need to link the ESVAC database to the EudraPharm database? Is there a need to develop an interactive database? (such as ESAC/ECDC-http://www.ecdc.europa.eu/en/healthtopics/antimicrobial_resistance/esac-net-database/Pages/database.aspx ). Is there a need to explore linking ESVAC data on antimicrobial consumption and EFSA data on resistance?

## *Information Delivery on the Internet*

*Focus point:* what should be the aim for the European veterinary sector?

**Veterinary IT representation in the new EU Telematics Governance Structure**
There is currently no representation of the Veterinary-only agencies in groups like eSubmission, eAF, etc. No more structure (TIGes stopped in June 2013) for 5 months, no way to manage changes on the VNees format. For harmonisation between the agencies, it is important that member states are kept in the loop for decisions. Otherwise, some agencies will start projects on their own. Trying to harmonise later costs much more than harmonising at the start. An agreed communications route for all proposed and actual changes to EU IT systems and procedures, where TIGs formerly carried out this role e.g. EudraNet TIG, needs to be established.
How to compose the Veterinary CMB and CAB?
How to participate to the eSubmission CMB and CA