EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Programme ZX-00017: VMP-Reg
Project ZX-00017-004: Union Product Database

Webinar on UPD for Industry
15 September 21

Objective of the webinar

Brief on the current status of the Union Product Database for marketing authorisation holders for veterinary medicines in the EU.

Provide an overview of the system and demonstrate the current functionalities designed for marketing authorisation holders

Agenda:

#	Topic	Presenter	Timing	
1	Connection to virtual room and technical checks		1100	1105
2	The Union Product Database: introduction	Olivier Simoen	1105	1125
3	Overview of the system functionalities for marketing authorisation holders	Ana Vicente	1125	1145
4	Demo of the available functionalities: search, view,	Ana Vicente	1145	1205
5	Q&A session	Irene Zanetti	1205	1230
	End of webinar		1230	1230

Logistics:

- The session is being recorded and made available on EMA's website.
- By participating, you agree to the session being recorded and published.
- We are numerous so please mute microphones.
- Some potential questions might be answered in later slides so we suggest keeping your questions until after the presentations.
- Please type your questions in the chat box.
- We will start addressing questions at the end of the session and send out answers to all questions jointly with the slides in the next few days.

2. UPD Project Overview:

- Reminder of programme and project context
- Project schedule
- Project status

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Regulation (EU) 2019/6 on veterinary medicinal products

Replaces Directive 2001/82/EC within the overall aim of achieving 'Better Regulation' in the EU

- *provides for a modern, innovative and fit for purpose legal framework*
- *gives incentives to stimulate innovation*
- *gives incentives to increase the availability of veterinary medicines*
- *strengthens the EU action to fight antimicrobial resistance*

UPD Overview: VMP-Reg Programme

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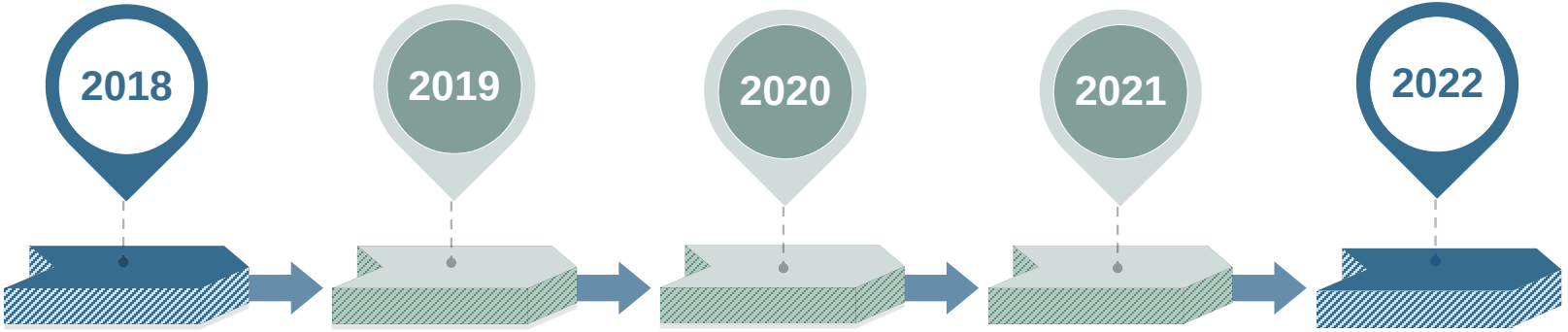
Timeline

Approved on 11 December 2018

Published on 7 January 2019; effective since 27 January 2019

Becomes **applicable in January 2022**



3-year implementation period

20 Implementing or Delegated Acts foreseen to be developed during the implementation period

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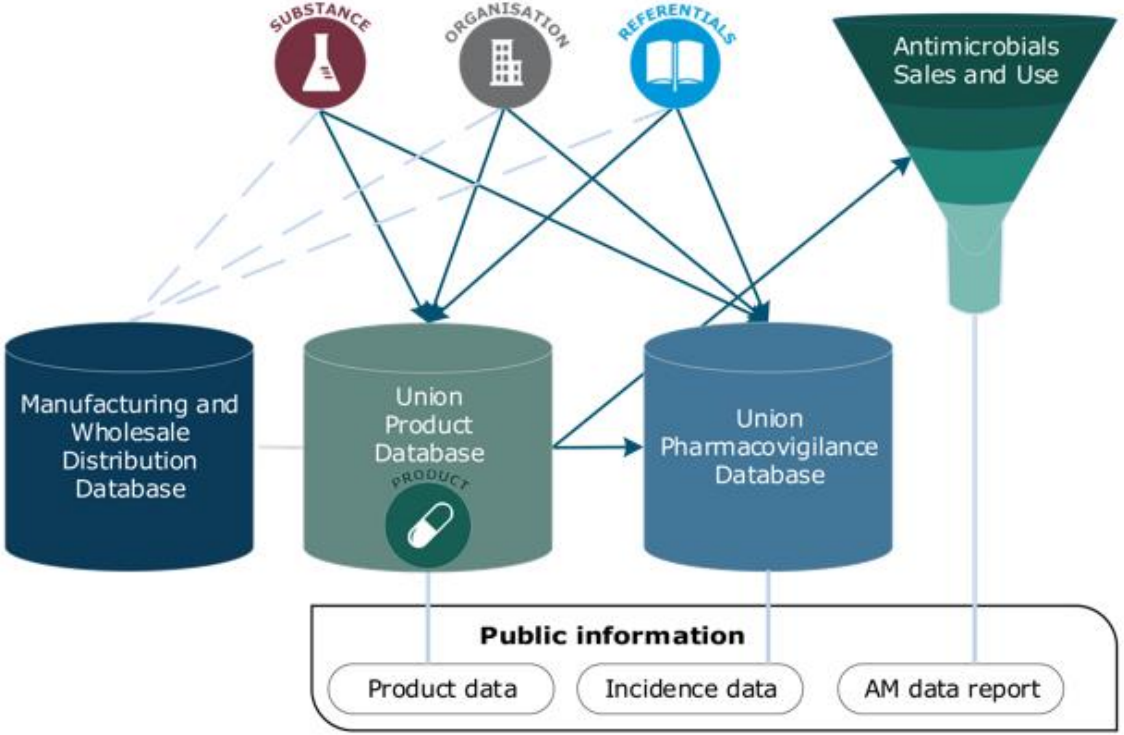
VMP-Reg programme – IT systems overview



VMP-Reg programme – out of scope

Achievement of the overall objectives of the VMP-Reg, other than those specifically included in the programme scope, in particular but not limited to:

- *The implementation of revised business processes* to fit the VMP-Reg and related IT solutions *in Member State authorities or Industry stakeholder entities*
- *Any required changes to Member State and/or Industry stakeholders' IT systems* to complete the envisaged integration or avoid duplication of data in systems outside the programme scope
- *Quality assurance of any data prior to submission* to the systems in scope of the programme is the responsibility of the Member State authorities and Industry stakeholder entities

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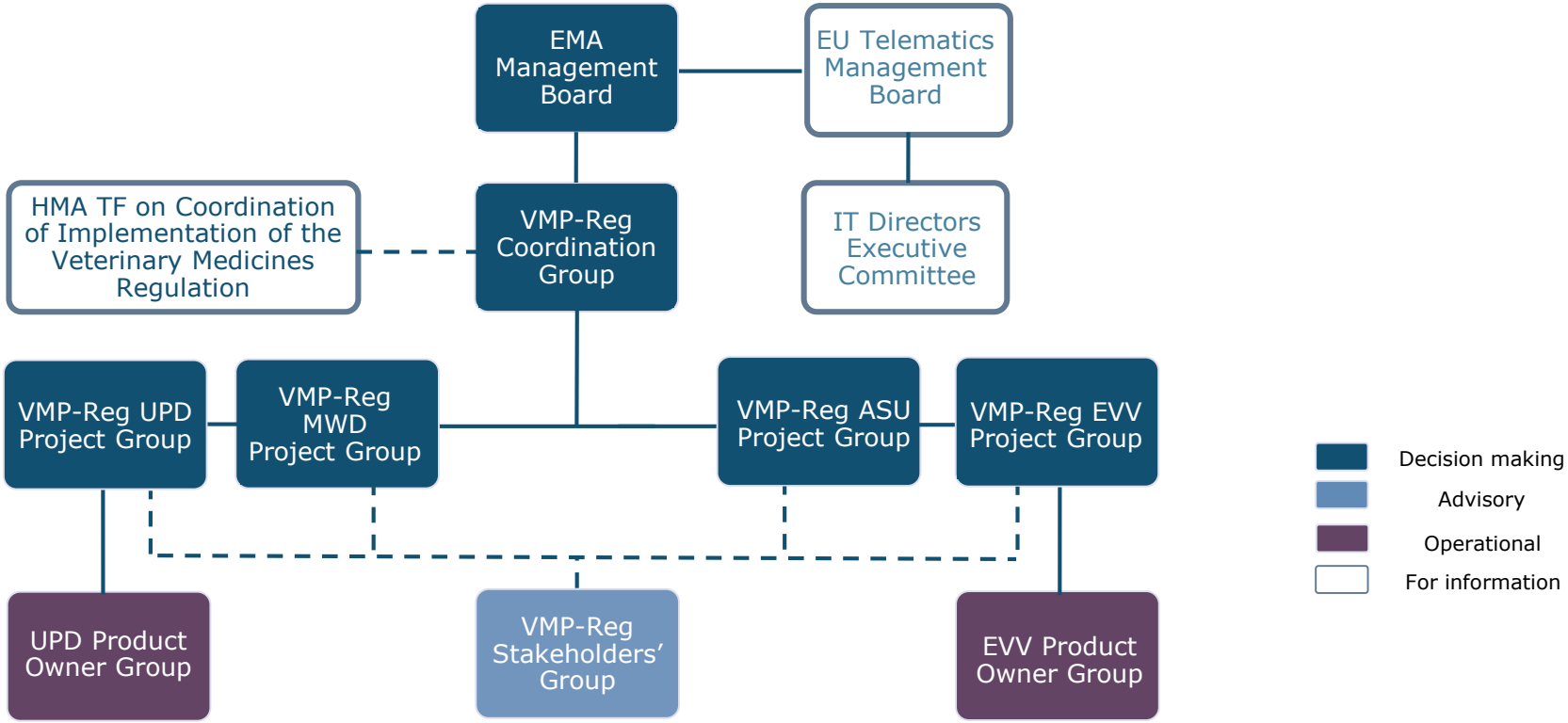
Overview of governance structure



Governance highlights (1/2)

VMP-Reg Coordination Group

- Programme Steering Group; monitors implementation activities in relation to Regulation (EU) 2019/6
- Coordinates the activities of the various working groups contributing to the preparation of implementation of the VMP-Reg
- Identifies critical issues and finds solutions, and coordinates communications in relation the VMP-Reg implementation
- Chaired by European Commission, composed of representatives from EMA Management Board, EU Telematics Management Board and the HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation

VMP-Reg Stakeholders Group

- Advisory group
- Composed of industry and healthcare professionals

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Governance highlights (2/2)

Project groups

- Project steering groups, provide expert input into the development of the relevant systems required for implementation of the VMP-Reg
- Composed of EMA, European Commission, 3-6 MS representatives and 1 representative from EU Telematics Management Board
- Currently EVV and UPD, to be established for upcoming projects

Product owner groups

- Agree and sign off detailed requirements and user stories for the releases under development
- Active participation in UAT
- Feedback on functionalities following participation in demonstrations, tests and verifications as relevant

UPD Overview: Context and Objectives

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- The Union Product Database (UPD) is a legal requirement as per Reg 2019/6, Art 55: "*The Agency shall establish and, in collaboration with the Member States, maintain, a Union database on veterinary medicinal products ('product database').*"
- 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 be the common database to collect, store and provide information on availability of veterinary medicinal products (VMP)
  - 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 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

UPD Overview: Main Functionalities

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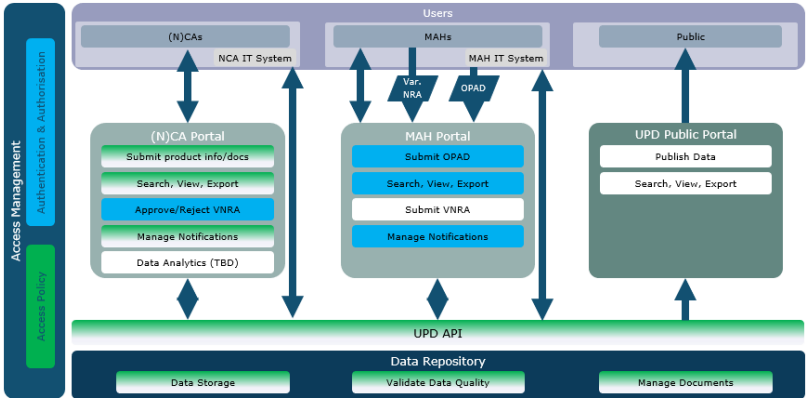
- Provision of product information by NCAs
  - Via a Web UI or an API
  - Manual or via provision of a file with the product information
    - FHIR
  - Stored in PMS
  - Including provision of all legacy data held by NCAs (Art 155)
- Provision of sales and availability information by MAHs
  - Via a Web UI or an API
- Support the processing of variations without assessment by MAHs and NCAs
- Provide access to product information:
  - Public website for general public
  - Restricted area for NCAs and MAHs
- Access management via EAM
- Usage of SPOR



UPD Overview: Functional Overview

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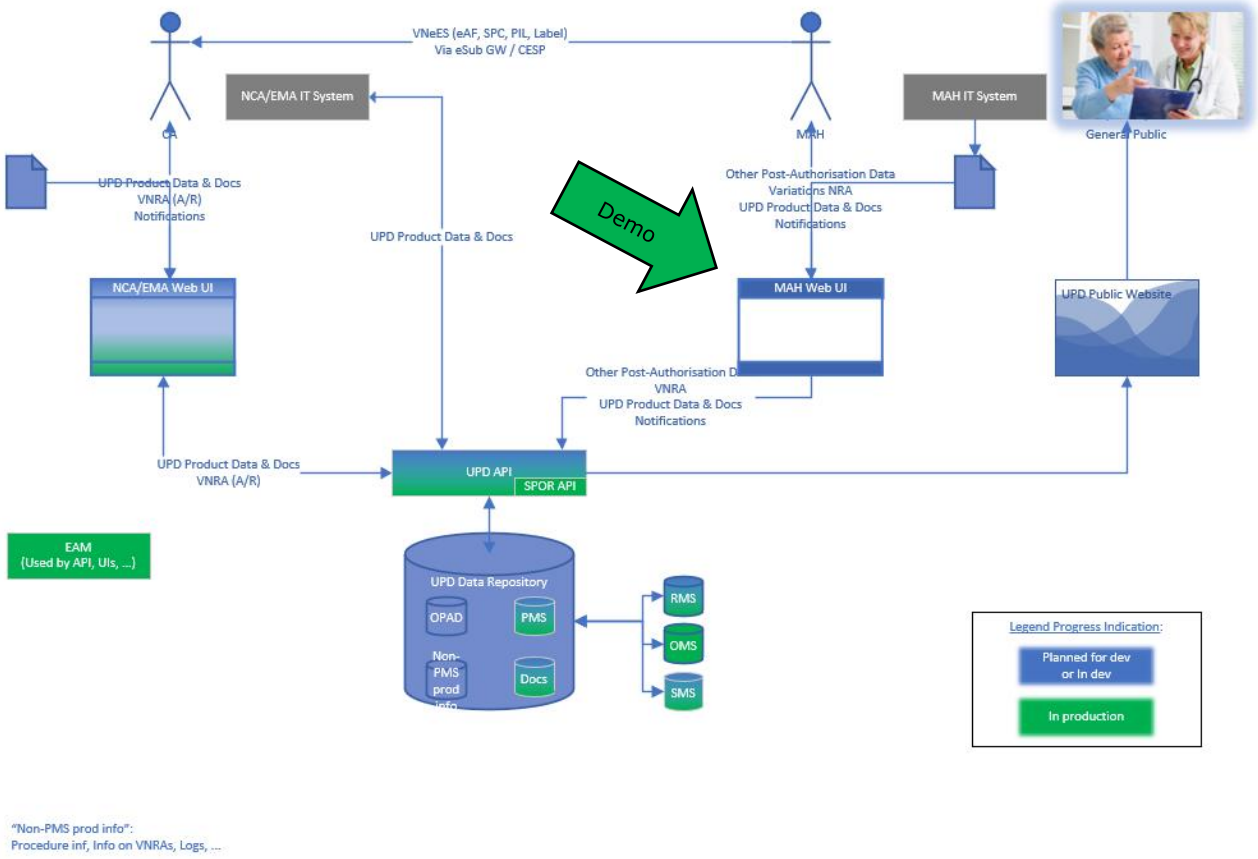
System overview:



UPD Overview: Information in the UPD

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- Categories of products in scope:
  - Veterinary medicinal products authorised within the Union by the Commission and by the competent authorities
  - Homeopathic veterinary medicinal products registered in accordance with Chapter V within the Union by the competent authorities
  - Veterinary medicinal products allowed to be used in a Member State in accordance with Article 5(6): "… for animals which are exclusively kept as pets…" (Note, this is not part of the Jan 22 release).

- Information in the UPD:
  - Product information
  - Documents: SPC, PL, Labelling, AR
  - Information on the annual volume of sales and information on the availability of each veterinary medicinal product
  - Information related to the processing of variations without assessment: Approval/rejection by NCAs, …

UPD Overview: Milestone Schedule

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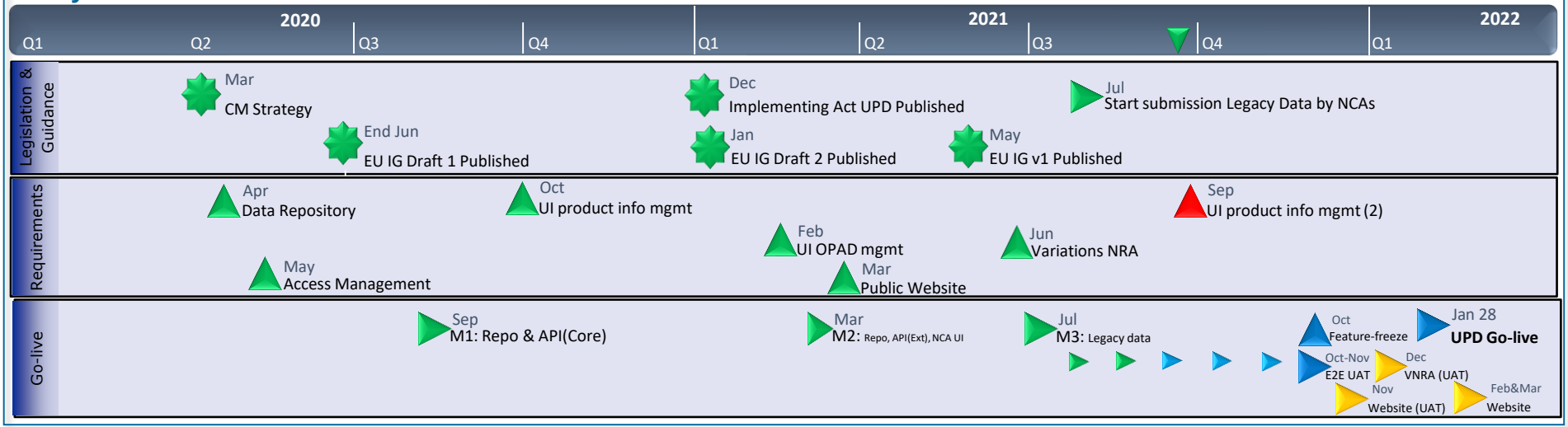
Key Milestones



Notes:

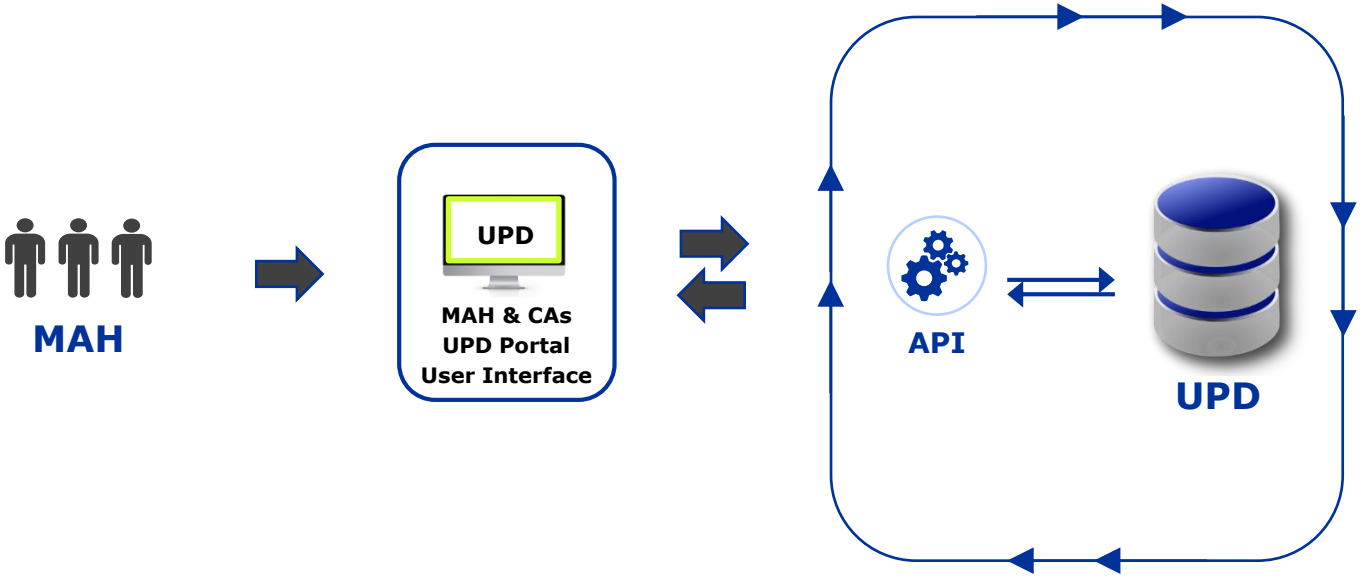
- The current version of UPD in UAT and in production is aimed at NCAs, who need to upload legacy product data
- As soon as we have implemented authorisation functionality, we can open the test system for MAHs. This is currently expected for November.
- The specifications for provisioning of data to UPD by MAHs, are available at:
    - https://www.ema.europa.eu/en/veterinary-regulatory/overview/veterinary-medicines-regulation/union-product-database#implementation-guide-section
- Three monthly post-MVP releases are being planned for after Jan 22

3. Overview of the system functionalities for marketing authorisation holders (MAH)

- Data Submission overview
- Functionalities overview
- Submission of information by MAH
- Notifications in UPD

Marketing Authorisation Holder - Data Submission overview

Marketing Authorisation Holders (MAHs) will be able to **submit, retrieve and view data** related to veterinary medicinal products for which they have a role **via the UPD Portal**



Marketing Authorisation Holder - Functionalities overview

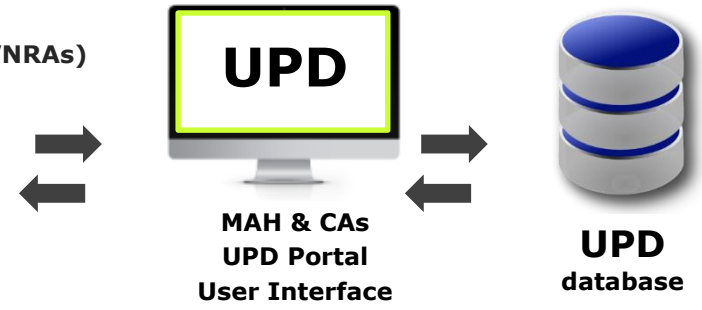
The scope of the UPD Portal is being defined in collaboration with the Product Owner group, representatives from competent authorities (CAs) and marketing authorisation holders (MAHs).

CA

- **Create products**
- **Update products**
- **Approve/reject variations not requiring assessment (VNRAs)**
- **Search & View products & notifications**

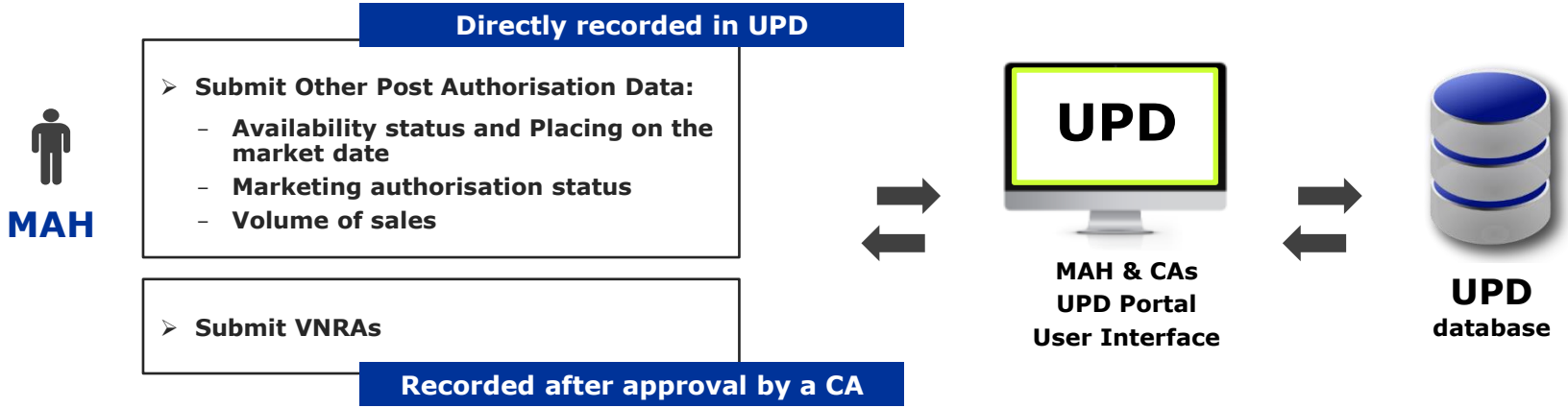
MAH

- **Submit Other Post Authorisation Data:**
  - **Availability status and Placing on the market date**
  - **Marketing authorisation status**
  - **Volume of sales**
- **Submit VNRAs**
- **Search & View products & notifications**

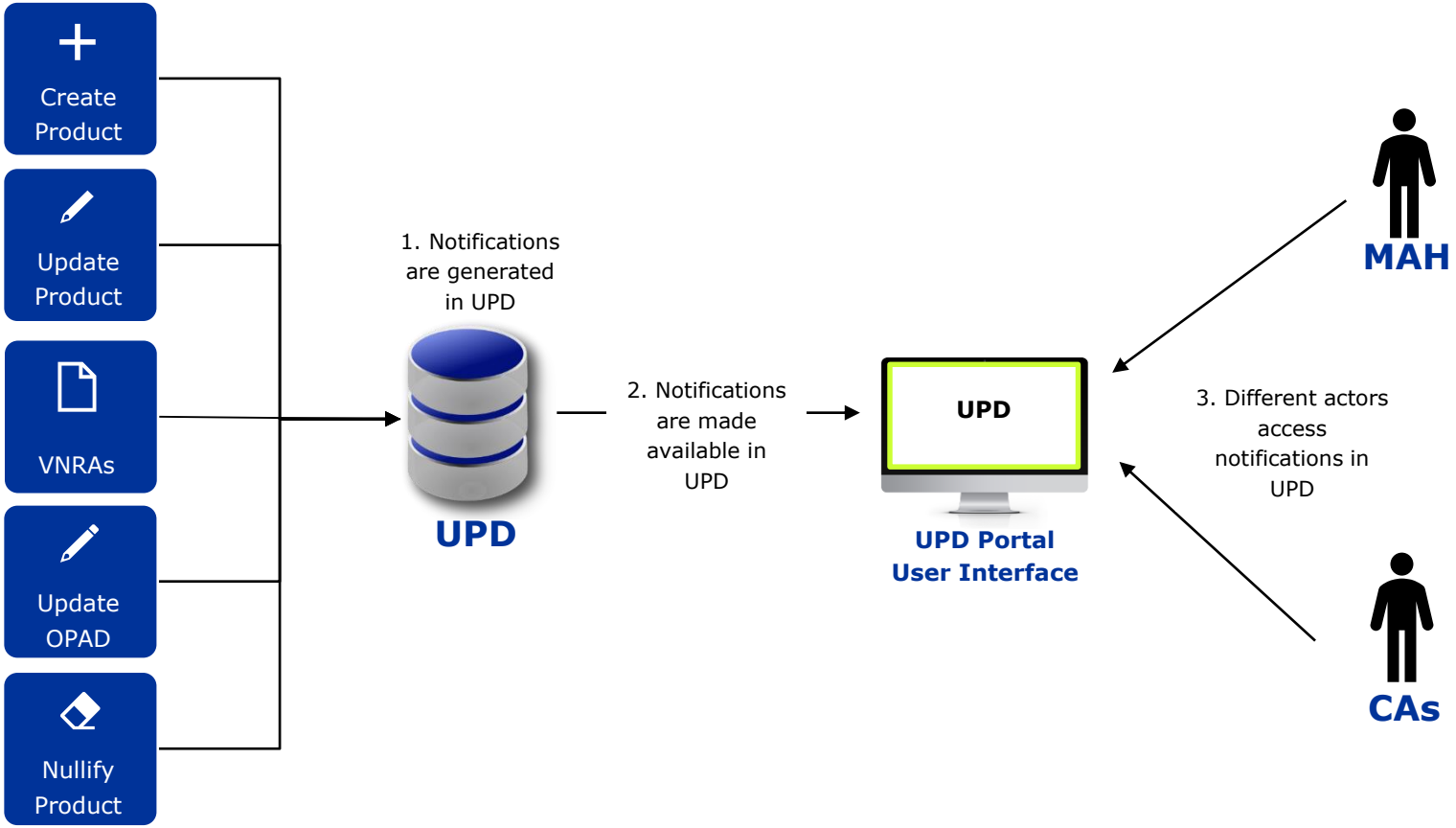


Marketing Authorisation Holder - Submission of information

Information submitted by the MAH related to Other Post Authorisation Data will be directly recorded in UPD, while data submitted via Variations not requiring assessment will be recorded only after approval by a Competent authority.



Marketing Authorisation Holder - Notifications in UPD



4. Demo of the available functionalities in the UPD Portal:

- **Search and View product**
- **Search and View notifications**
- **Submission of volume of sales**

Objectives of the Demo

- Demonstrate in the UPD Portal

  → the current system capabilities for searching and viewing products in UPD

  → the functionalities that will allow a MAH to search and view notifications

  → The End-To-End process flow for the Submission of volume of sales

- Provide an overview of the look & feel of the UPD Portal

- Collect valuable feedback that will be taken into account for future releases

Preliminary Considerations

- The UPD Portal is under development and some functionalities might not be completed or optimised for this DEMO
- The authorisation mechanism has not been implemented yet and therefore functionalities that are exclusive to Competent Authorities will be visible
- The DEMO will be performed in a test environment hence the data used for this presentation is not real
- The current UI is based on the Vet EU IG July 2021
- Audit capabilities have been implemented although they will be not accessible from the Portal

Demo High Level User Journey

The following flow describes at a high level the main actions that will be performed during the Demo regarding the **Search and View of Products and Notifications** and **Submission and View of Volume of sales.**

The user can search and view products for which he/she has a role

The user can search and view notifications generated by the system for product for which he/she has a role

The user accesses the UPD area for Volume of sales and selects **Download list of packages**

The user prepares the file with the data on Volume of Sales to be submitted

The user accesses the UPD area for Volume of sales and selects **Submit volume of sales**

After submission, the system will validate the data provided by the user

The user will be able to check the status of the submission (failed or valid) in the **View submission of volume of sales screen**

The user is able to download the error reports of failed submissions

The user can download the volume of sales that have been successfully submitted per product from the **View volume of sales screen**

Any questions?

Further information

General questions on the VMP-Reg programme and UPD project:
vetchange.programme@ema.europa.eu

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Annex 1:
Questions and Answers from Webinar

Questions and Answers

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1. *Are parallel distribution products of veterinary medicines in scope of UPD?*

Parallel *distribution* products will exist in the UPD already as products authorised in all EU Member States under the centralised procedure. The parallel distribution *activities* will not be reflected in the database.

Parallel *traded* products are within the UPD scope and will be provided into the UPD by the NCAs of the destination country as stand-alone products with reference to the source product and country and a destination reference product.

2. *What is a "post-MVP-release"?*

Post-MVP releases are the approximately quarterly releases of the UPD after the go-live of the MVP (minimum viable product) in January 2022, with the aim to provide additional or improved functionalities.

3. *How the existing MAHs will receive the PSMF location code (MFL code)? Is that a code allocated from UPD/EMA automatically before 28 Jan 2022 or are MAHs expected to request the code for their PV systems?*

MAHs will set the code themselves as free text (it is not set automatically, nor does it need to be requested). Additional guidance/recommendations on how to structure the number are being discussed.

4. Will UPD API be available for use of customised software products, independently from UI?

Yes. As long as the software product is used by a NCA or MAH, this can use the UPD API functionality available for the corresponding NCA or MAH after passing basic quality tests in the UAT environment.

5. What will happen with the volume of sales? Would it be public data?

According to the UPD Access policy, data on the volume of sales will only be accessible by CAs and the MAHs who own the relevant products. The data will not be publicly available.

6. Will EMA perform at some point a demo for the sending of VNRAs?

Yes, once the functionality is available. Please refer to the VMP-Reg newsletter and the EMA website for the relevant upcoming webinar announcements.

7. *When a variation not requiring assessment is approved by the CA, will it be possible to print a pdf document of this approval (in order to provide it to international authorities relying on approvals from EU)?*

In the MVP release of the UPD, this will be possible by printing via the browser (e. g. print to pdf within the browser). A built-in functionality to generate a pdf document is part of the post-MVP requirements to be prioritised by the future governance for the continuous improvement of the UPD.

8. *If you have multiple MAHs in one procedure. Will all MAHs be able to enter/change data? Or will only the IP owner have access to these products? It is not preferred by the IP owner that every MAH can make changes.*

The relevant MAHs will have to agree on that on a case by case basis. The IP owner super user can assign roles to anyone inside or outside their organisation to perform actions on their behalf. Please note that a user can only make changes to products where s/he has the relevant role for the organisation owning that product. However, if access is given by the super user to a user outside the organisation, they would be able to perform the permitted actions within the role on the *whole* product portfolio of that organisation (e. g. product-based access allocation is part of post-MVP requirements to be prioritised by the future governance).

9. Will it be possible to search products by dosage form?

The dosage form corresponds to the 'Authorised dose form' or the Manufactured Dose Form, and it is part of a product in UPD as stated in the Vet EU Implementation Guide. However, products in the UPD restricted area will not be searchable based on this filter in the MVP.

10. Are the information/search results going to be downloadable?

Yes.

11. Is the MAH responsible for updating its portfolio on UPD or will NCAs do it based on their information about the products for each MAH?

The NCAs are responsible for updating product information resulting from an initial marketing authorisation and/or from a variation. The MAHs are responsible for updating information on availability status, placing on the market date, marketing authorisation status (in case of revocation/suspension/withdrawal) and volume of sales.

12. If we want to correct the data and contact the CA, can this be done without a submission?

According to the Article 18(9) of the Commission Implementing Regulation (EU) 2021/16, if MAHs identify data or document quality issues in their UPD products, they shall immediately notify to the relevant competent authority which shall correct the data. Therefore, in these cases a submission is not required by the MAH. Of course, in case the change the MAH requests constitutes a variation not requiring assessment or amendment of the marketing authorisation, that would require a submission (e.g., a change of the QPPV).

13. *Regarding the volume of sales to be submitted. Is it required for all kind of products or only for antimicrobials?*

According to Article 58(12) of Regulation (EU) 2019/6, a MAH has the obligation to record in the UPD the annual volume of sales for each of their veterinary medicinal products. The data will be used, for example, to calculate incidence which will be published from 2024 onwards as a result of the requirements arising from Article 75(3)(b).

14. *What will happen with parallel traded products in this UPD context? Are subject of UPD? Also, they have received longer period of validity from local authorities, but some of them say that all existing parallel authorisation will be cancelled. Opinions are contrary, and I am looking for some clarification. Could you please redirect me where I could find more information related to the parallel's law modification?*

Parallel traded products are within the UPD scope and will be provided into the UPD by the NCAs of the destination country as stand-alone products with reference to the source product and country and a destination reference product.

The provisions set in Regulation (EU) 2019/6 can be found in Article 102.

For guidance on national implementation of parallel trade provisions, we recommend that you contact the relevant competent authority.

15. *If you have multiple MAHs in one procedure, will all MAHs be able to view sales data from all territories relating to the procedure? Or will only the IP owner be able to view the sales data relating to the whole procedure? It is preferred by IP owner that only IP owner can view sales data relating to the whole procedure.*

A MAH will be able to see volume of sales data for products for which s/he has a role. However, this is not the case with the view of 'submission of volume of sales', where only a user who has **all** the roles of the products included in the submission will be able to see the status of the submissions and the report on errors, as applicable.

16. *Will it be possible to access UPD as reader only for people not MAH and not CA (e.g.: foreign authorities outside EU)?*

Authorities outside the EU will be able to access the *UPD public portal*, which does not require registration and makes information available based on the data access policy, for example excluding information on volume of sales.

17. Will it be possible to see the date for the latest update of a product and not only the marketing authorisations date?

After performing a search, the UPD Web UI will display the latest version of a product. A user will be able to view the different product versions identified by a version number, but not the date of the update. Addition of the timestamp could be discussed and prioritised for post-MVP releases.

18. How many accounts to work in UPD UI will be dedicated per MAH?

No limit to the number of UI accounts per MAH is foreseen. For the API, only account will be available per MAH (as this is would constitute a machine to machine interaction). The same applies for NCAs.

19. What about annual updates for parallel importers?

Parallel importers have no submission obligations in relation with the UPD and thus no access to restricted areas of the UPD. They will be able to access the UPD Public Portal for any information provided there.

20. Regarding CSV file (packages): How do we get those packages?

MAH users can retrieve the list of packages from the Web UI. The list will contain only information on products of the organisation linked to their assigned access rights.

21. What is a "dose factor"?

The 'dose factor' is part of the information that an MAH will have to provide as part of the volume of sales submission. The dose factor refers to the number of animals that can be treated with the relevant pack on average. In combination with the number of packs sold, it will be used to calculate the estimated number of treated animals (ENTA), information needed to support pharmacovigilance activities, including publication of incidence from 2024 onwards.

22. Is it mandatory to be registered as MAH in SPOR to use the UPD?

MAHs will need to be registered and request SPOR OMS roles to keep their organisation and location data up-to-date. For legacy products, NCAs are mapping organisation data to ensure MAHs are correctly recorded in OMS SPOR. MAHs will have to register and request UPD roles to use the UPD for data submission. It is not necessary that the same MAH representative registers both in SPOR OMS and in the UPD, unless they have to perform both types of activities.

23. To submit "a package" we have to fill a .csv file?

For the MVP, all information (on volume of sales) will have to be submitted in .csv file format.

24. In case of multispecies products, is this correct that we need to have as many lines as species for each product and country? I didn't see really well the excel file, it seems the example was with 100% in only one species, hence the question.

Yes, for multispecies products one line per target species, product and country is needed. Users shall indicate from the total volume of sales of a package which percentage is estimated to be used in each of the target species.

25. Is the package identifier unique per product/country or by SKU? Meaning, how will the multilingual/multicountry packs be handled?

A package of a product that has been approved under the same decentralised, mutual recognition or subsequent recognition procedure will share the same package identifier among the countries involved in the procedure. When submitting volume of sales and availability status, a MAH will have to complete a line for each package, country and (if applicable) target species.

26. Will written instructions on how to use UPD be available ?

User guidance will be made available.

27. How is volume of sales managed for products in parallel importation, in order to avoid adding volume of sales from the export country to the volume of sales of the import country (mainly related to calculation of incidence of ADRs)

Wholesalers do not have reporting obligations within the UPD. Therefore, any cross-border movements through parallel distribution, import or parallel trade will not be taken into account in the calculation of incidence. Considerations on the subject have let to the conclusion by pharmacovigilance experts that such cross-border movements would be expected to have no significant impact on incidence calculations. Should that situation change, or a significant impact be detected on an exceptional case, it could be considered to make adjustments manually.

28. When and how often will sales volume need to be provided? Do I have to submit yearly sales per target species or monthly sales? Will I be able to submit monthly sales data annually, rather than monthly?

MAHs must provide the annual volume of sales according to Article 58(12) of Regulation (EU) 2019/6. In the MVP implementation of the UPD, MAHs will have flexibility to decide the frequency (quarterly, monthly, yearly) for the data submission, with granularity fixed at monthly level.

29. Can we choose the time point for volume of sale submission and do it at different time points for several products?

The MAH will have flexibility to submit any number of products per submission, and any number of submissions per year, with granularity fixed at monthly level. The frequency of this submission will be decided by the MAH (monthly, quarterly, etc.). It is expected that the submission timelines will be aligned to the calendar year. For new products, the first year reporting would cover the period from the date of placing into the market until 31 December. Additional guidance will be reflected in the relevant Pharmacovigilance guidelines under development.

Further guidance is being prepared as to the deadline for submission, ie. by when after a certain date the overall annual submission has to be complete.

30. Would it be possible to establish some restrictions to some data: for example, avoid that distributors can have access to volumes of sales for the full portfolio?

Volume of sales will only be accessible to NCAs and to MAHs for the products of the organisation for which they have been assigned the relevant role. Please note that wholesale distributors have no reporting obligations in the UPD under Regulation 2019/6 and therefore will not have access to the restricted areas of the UPD. Volume of sales is not published on the UPD public portal. As a consequence, wholesale distributors cannot access volume of sales information.

31. If the MAH is able to export/download the following data from UPD (list of VMP, INN (international non-proprietary name) of the active substances, Member States, type of procedure for authorisation, authorisation numbers in each MS), from when (which date) will we be able to export those data from UPD ?

The MVP version of the UPD that will be launched on the 28 January 2022 will allow the user to export in a .csv format the following fields of a product: Procedure number, Product name, Active substance and strength, Target species, MAH/Product owner, Marketing authorisation number, Pharmaceutical form and Authorisation country. MAHs can export their data as soon as the NCA has created or uploaded their products in UPD.

32. Can MAHs grant access to consultants to submit VNRAs on their behalf?

Yes, the MAH super user will be able to grant the relevant role to any external user by approving that user's request for the relevant role for the MAH super users organisation. Please note that the access will be as per role and organisation, product-based restrictions or access are not foreseen in the initial version of the UPD. It is assumed to be understood that the administration of access to any users internal or external to the organisation lies within the responsibility of the MAH super user and that relevant contractual or confidentiality agreements would be in place, as required by the organisation in question.

33. How we can transform the downloaded file in excel?

The downloaded file will be in .cvs format. MS Excel recognises this format. Within MS Excel you can transform the data as per your needs.

34. If we have two products with several forms of packaging, is it necessary to upload sales for each product or can we upload a single file?

UPD does not set a limit to the number of products that can be included in a submission, as long as the user who makes de submission has the relevant roles of the organisation(s) to which these products belong.

35. Would it be possible to add some generic species to the RMS species list, such as "poultry"?

In case industry users consider that the current RMS species list does not have any existing terms that may be appropriate, they may raise a change request to the RMS team. The request should contain a justification for the term required and supporting documentation (e.g. product information) referring to the term required. Please refer to the guidance provided on the SPOR portal (https://spor.ema.europa.eu/rmswi/#/viewDocuments).

36. Regarding the reporting of sales data: if a product has several target species, will there be more columns added at the end of the excel sheet or must the sales be reported for each species separately?

The volume of sales are reported at package level. If a package refers to different target species, the MAH will need to submit one row for each of species, no new columns will need to be added.

37.Is there a possibility to change the csv-delimiter from "," to "."? It's a possible error on non-English keyboards.

Currently this cannot be changed and a "," delimiter must be used. The functionality may be changed in post-MVP releases, if prioritised by the future governance.

38. Do notifications contain the exact change in the product data?

That is not implemented in the MVP, but will be discussed for prioritisation in future post-MVP releases.

39. Will Google Sheet files be accepted instead of Excel?

The format used to exchange volume of sales information by UPD is .csv, not Excel.

40. What are the links between the UPD and the Union pharmacovigilance database? Only product names?

The Union Pharmacovigilance Database (EVVet) will be one of the systems that will consume data from UPD. The identification of veterinary medicinal product information reported in EVVet will be based on the name and, when possible, on the UPD Permanent ID. In the EVWeb application this can be done by selecting the product from a list of product names provided or by specifying a new name (free text). The selection list is composed of names that correspond to one or more products. When a name that correspond to a single product in UPD is selected then the Permanent ID is populated in the correspondent field in the Adverse Event report (B.2.1.1 - Product Code). Should the reporter not be able to select one of the available values from the list in EVWeb, the name of the product/composition will be accepted as a free text and the system will attempt to automatically 'recode' such information based on the tradename of the medicinal product and/or its scientific composition (i.e. Active ingredients, pharmaceutical form and strength) as available in UPD.

41. How does the MAH submit the first date when a VMP is marketed?

The UPD will consider as "date of placing on the market" the date when the product is first reported as marketed in any EEA country. Therefore, the system shall record this date in the database for a product whenever the MAH sets the availability status value 'marketed' for the first time for any of the packages of that product in any EEA country. For legacy data where the first marketed date (or estimate) is not known, this date can be set as 28 January 2022 (the date Regulation (EU) 2019/6 becomes applicable).

42. Will EMA be presenting similar webinar for Union Pharmacovigilance Database?

Yes, webinars will be provided also for the Union Pharmacovigilance Database. Please keep reading the VMP-Reg newsletter and the event announcements on the EMA website.

43. Can a product be used in different countries to different percentages?

The question is not entirely clear; however we assume the species spread is meant here, e. g. product x package 2 is sold in Latvia (200 packs) and Slovenia (500 packs). If the product is for cats and dogs, it is entirely possible that the species spread could be 40% cats, 60% dogs in one country, and 30/70 in the other. This is why the volume of sales is submitted in one line per package, country and species.

44. Regarding the reporting of sales data: if a product has several target species, how will it be possible to know how veterinarians use the product, for what species?

The species spread should be estimated by MAHs based on experience or market data (it does not have to be an exact use indication). Please note that the information will be used to calculate an estimated number of treated animals for each species (as was submitted in PSURs previously), and subsequently incidence.

45. If a product was registered, for instance, 3 years ago, being subject for renewal after 5 years, as per current regulation will the renewal be carried out, or will the marketing authorisation have unlimited validity?

This question is not related to the UPD implementation and the requester is advised to consult the EMA website for post-authorisation guidance, or contact the relevant national competent authority with their question.

46. What to do in case an insecticide can be used for cattle only in one country, for cattle and sheep 50% and 50% in a second country, and for cattle sheep and pigs 33% sheep 33% cattle 33% in a third country?

It is assumed in the answer that the question refers to volume of sales and also that the numbers refer to the percentage that each species has in the total sales. Considering that they are going to be submitted per country, a MAH will need to report:

- For the first country, the total volume of sales of the insecticide will be allocated to 'cattle' → 1 row in the submission file (.csv)
- For the second country, the sales will be allocated to 'cattle and sheep' → 2 rows in the submission file
- For the third country, the sales will be allocated to 'pigs, sheep and cattle' → 3 rows in the submission file

47. Are sales to non-EU countries to be reported?

As a result of pharmacovigilance requirements, a MAH will need to submit also the annual volume of sales in non-EEA countries for each of their veterinary medicinal products. In this case, considering that the volume of sales are submitted at package level, one single value will be submitted for all non-EEA countries against an equivalent package in UPD (either same pack size or adjusted to equivalent pack size).

48. When will the portal be open for the MAHs to complete the relevant information, after the testing? Will they access the UPD portal via SPOR account?

The UI for MAHs will open for production purposes on 28 January 2022. If you have an existing account (for other EMA-hosted systems such as IRIS, SPOR, …) you will use the same credentials, but you will have to request access to UPD for that account on the EMA Account Management Portal first. The detailed instructions on how to register will be shared in due course.

49. Regarding the volume of sales, how will parallel distribution be handled?

Parallel traded products will be provided into UPD by the NCAs as stand-alone products with reference to the source product and a destination country. Sales of the products that have been parallel traded or moved across borders in parallel distribution (ie. how many packs were moved from one country to the other) will not be reported separately – the sales will be reported by the MAH as sales in the source country only. For pharmacovigilance purposes these cross-border movements are expected to have no significant impact on incidence and it was therefore recommended that this could be disregarded for the UPD implementation of sales volumes reporting, also considering that there is no legal base to ask wholesale distributors to report sales volumes into the UPD.

50. Should sales outside the EU (I mean quantities) have to be implemented/declared? Sometimes the same products marketed in EU have been sold outside EU countries; do I have to declare such quantities?

Yes, as part of the pharmacovigilance requirements, a MAH will need to submit annual volume of sales in non-EEA countries for each of their veterinary medicinal products in EEA. In this case, considering that the volume of sales are submitted at package level, one single value will be submitted for all non-EEA countries against an equivalent package in UPD.

51. Why does the volume of sales need to be submitted? What is going to be done with these data?

The volume of sales data together with the species spread and dose factors submitted will be used to calculate an estimated number of treated animals, which will subsequently be used, in combination with the number of adverse event reports received for the product, to calculate incidence (to be published from 2024). The sales volumes for antimicrobials might also be used by NCAs as a starting point for the antimicrobials sales data to be submitted by NCAs into the future antimicrobials sales (and use) data collection system.

52. A MA holder needs to report some data to UPD. What is the timing for MA holders to report these data?

MAHs will need to report information on availability status and volume of sales for their own products:

- For volume of sales a MAH will need to ensure that in early 2023 all the sales data for 2022 have been submitted. Guidance on due dates will be provided separately.
- For availability status, for existing veterinary medicinal products that were placed on the market before 28 January 2022 the dates for placing on the market and availability are recommended to be submitted as soon as possible after 28 January 2022, as the public portal will display this information to the general public (incl. veterinarians and animal owners). For products approved after 28 January 2022 or under the new Regulation, it is also in the interest of the MAH to submit this information as soon as is available, bearing in mind that until it is updated, the value that will appear published in the *UPD public portal* will be 'not marketed' (at package level).

53. How can consultants make submissions on behalf of MAHs -- often on behalf of many differing MAHs?

Consultants must request rights (a role on behalf of an organisation, *e.g.* submit variations on behalf of organization XY) in the EMA Account Management Portal. The super user of the respective MAH will approve and subsequently administrate the access rights in the EMA Account Management Portal.

54. It was mentioned that MAHs should review the product data uploaded by NCAs, for their products. Should MAHs review all the data or only specific data fields?

It is recommended MAHs review all data related to their VMPs and contact the respective NCA should they disagree with any data entered.

Annex 2:
List of acronyms

Acronyms

AM – Antimicrobials

API – Application Programming Interface

AR – Assessment Report

ASU – Antimicrobials Sales and Use

CA – Competent Authorities

CESP – Common European Submission Portal

eAF – Electronic Application Form

EAM – EMA Account Management

ENTA – Estimated number of treated animals

EU IG – EU Implementation Guide

EVV – Union Pharmacovigilance Database

FHIR - Fast Healthcare Interoperability Resources

GW – Gateway

HMA TF – Heads of Medicines Agencies Task Force

MAH – Marketing Authorisation Holder

MVP – Minimum Viable Product

MWD – Manufacturing and Wholesale Distribution Database

NCA – National Competent Authority

NVR – New Veterinary Regulation (EU) 2019/6

OMS – Organisation Management Services

OPAD – Other Post-Authorisation Data

PL – Package leaflet

PMS – Fast Healthcare Interoperability Resources

RMS – Referentials Management Services

SMS – Substance Management Services

SPC – Summary of Product Characteristics

SPOR – Substances, products, organisations and referentials

UAT – User Acceptance Test

UI – User Interface

UPD – Union Product Database

VMP-Reg – Veterinary Medicinal Products Regulation (EU) 2019/6

VNRA – Variations Not Requiring Assessment