



**COMMISSION IMPLEMENTING REGULATION (EU) .../...
of XXX laying down the necessary measures and practical
arrangements for the Union database
on veterinary medicinal products (Union product database)
*FVE Input***

The Federation of Veterinarians of Europe (FVE) is an umbrella organisation of veterinary organisations from 39 European countries, representing a total of around 300 000 veterinarians. The Federation of Veterinarians of Europe (FVE) strives to promote animal health, animal welfare and public health across Europe.

FVE thanks the European Commission for requesting our input on the Commission Implementing Regulation regarding the Union Product Database.

The Union Product Database will for practitioners be the most important tool to increase availability of veterinary medicines and enhance the single market. It will allow veterinary practitioners to search for veterinary medicines in other EU states in case they have no suitable treatment option in their home country.

FVE welcomes the implementing regulation and its annex. We only had a few queries or suggestions for improvement:

- *Implementing Reg. point (7) 'Thereafter, the Agency should continue developing additional functionalities, including such that could further reduce administrative burden and contribute to the harmonisation of processes across the regulatory network.'*

→ The main aim of the UPD is to enhance the single market and increase availability in order to allow practitioners to treat animals for which no treatment is available in their country, i.o.w. to promote animal health, welfare and public health. Additional functionalities which support this main aim should be prioritised. So we suggest to change this sentence to '*Thereafter, the Agency should continue developing additional functionalities, including such that could **enhance the single market and the provision of information on products authorised**, further reduce administrative burden and contribute to the harmonisation of processes across the regulatory network.'*

- Implementing Reg. point (8) *'In order to alleviate the administrative burden of the competent authorities, the initial input of information by the competent authorities to the Agency on all veterinary medicinal products should be permitted on a phased basis.'*

→ Phased input is absolutely fine, but it should be clarified that all data should have been inserted by January 2022. To prevent the situation we have currently with the EudraPharm Veterinary Database where after more than a decade still only part of the Member States had submitted data.

- Implementing Reg. point (10) *'The Union product database should be developed with the aim of avoiding the duplicate input of data in different Union systems.'*

→ We suggest this to be stronger and say *'The Union product database **must avoid duplicate input of data** in different Union systems.'*

- Implementing Reg. Art 2 (2) *'The Agency shall update this plan every two years in light of the progress made and the needs identified by the regulatory network'*

→ We suggest to change this to *'The Agency shall update this plan every two years in light of the progress made and the needs identified by the regulatory network **and the feedback of the users of the Union product database.**'*

Once the system is up-and-running the users (including veterinarians) should be allowed to give feedback.

- Implementing Reg. Art 11 *'Data on the annual volume of sales of veterinary medicinal products shall be visible in the Union product database only to the relevant competent authorities, the Commission and the Agency, as well as to the marketing authorisation holders to whose veterinary medicinal products those data refer.'*

→ The annual volume of sales is also needed to calculate the incidence level in the pharmacovigilance database.

- Annex implementing act point 1.10. Provide data to the Union Pharmacovigilance database

→ We very much welcome that with this point the link will be made between the union product database and the pharmacovigilance database.

- Annex implementing act point 2.8. Record availability information.

→ We very much welcome that with this point the union product database will include information on the availability of products in the different member states and potential shortages.

- Annex implementing act point 2.9. Record marketing authorisation status.

→ The marketing authorisation of the same product can differ between member state. Will the system accommodate for this?

- Annex implementing act point 3.1. Public access. *The general public shall be able to search and view publicly available data.*

→ A user-friendly system with an easy and practical search function will make or break the system. The following search criteria are especially relevant and necessary for veterinary practitioners: product name, qualitative and quantitative composition of the pharmacologically active substance(s), pharmaceutical form, countries authorised in, indications for use, target species, dosage for each species, method and route of administration, contra-indications and adverse events, drug-drug interactions, information essential for safety or health protection, withdrawal time, distribution category, Marketing Authorisation Holder (MAH), therapeutic group. In addition, a search should be possible via filtering or via “key words or wild cards”. The “Product Database” should also make it easy for the veterinarian to access the summary product characteristics (SPC), the product package Information leaflet (PIL).

Additional remarks

- Lack of availability of veterinary medicinal products (VMPs) is a serious problem within veterinary medicines, especially for Minor Use/Minor Species (MUMS) and for limited markets.
- A veterinarian prefers to use an authorised VMP for a specific species/age category/indication/dosing regime, above use outside the marketing authorisation.
- Therefore, the development of the “Product Database” is extremely important, as it will be the therapeutic tool available for veterinarians to find online which veterinary medicinal products are available in other Member States when they are lacking products.
- The “Product Database” should remain up-to-date with correct and complete data. Easy and fast procedures to exchange information should be developed with reliable and validated data. The “Product Database” should be easily readable, and written in a clear way, and containing precise and useful information to take a decision on veterinary therapeutic activities. In case of suspension, revocation or long-term shortage problems, mechanisms should exist to update this quickly in the database.
- To make the “Product Database” a success, close partnership between EMA, all national agencies, MAH’s and veterinarians ensuring a functional and practical business scenario’s is critical.