FEDERATION OF VETERINARIANS OF EUROPE

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EMA ADVICE REGARDING THE UNION DATABASE ON VETERINARY MEDICINAL PRODUCTS
FVE Input

Background:

- Regulation 2019/6 on veterinary medicinal products lays down in article 55(1) that a Union database on veterinary medicinal products ("Product Database") shall be developed and maintained by the European Medicines Agency (EMA) in collaboration with the Member States.
- On 27 February 2019, the European Commission mandated the European Medicines Agency to provide advice on the measures and arrangements required to deliver the technical and functional analysis allowing for the actual development of the Union Product Database to be launched.
- The European Medicines Agency on 29 Auguest published its advice.

Main inputs FVE:

FVE welcomes the EMA advice on the Union Database. Veterinarians, being the future primary users of the Database, look forward of having this tool available to find online which veterinary medicinal products are available in other Member States when they are lacking products. Therefore the Union Product Database will be an essential tool in overcoming availability problems.

FVE supports the two main recommendations, namely to built utilising existing functionalities and functionalities and to focus on the minimum viable product fulfilling only legislative requirements and those additional requirements that ensure legally required business processes can be operated effectively.

Vital for its usability is that the system will be **user-friendly with an easy and practical search function**. 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.

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 on “key words”.

As an example, if you are a veterinary practitioner with a case of pneumonia in fattening pigs and you have no product available in your country, you want to search the database on a combination of active substance, animal species and/or indication.

The “Product Database” should also make it easy for the veterinarian to **access the summary product characteristics (SPC), the product package Information leaflet (PIL).**

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.

We suggest also to take into consideration the language issue in respect to the Union Product Database. All data should at least be available in English.

Main recommendations:

- Further work out the ‘search’ function in the document.
- EMA to work with stakeholders including representative practicing veterinarians to develop business case scenario’s.

Specific recommendations:

- Page 5: is not clear what is the difference between ‘should’ and ‘could’
- Page 7: ‘Provide data to PhV database’ – should this not be a must requirement
- For veterinarians it would also be extremely useful when logging on to the product database to see alerts of relevant SPC changes of products authorised in their country. E.g. if due to pharmacovigilance outcomes a safety warning has been added. We suggest this as an additional ‘could’ requirement.

EXTRACT REGULATION

Article 55: Union database on veterinary medicinal products

1. The Agency shall establish and, in collaboration with the Member States, maintain, a Union database on veterinary medicinal products ('product database').

2. The product database shall **contain at least the following information**:
(a) for **veterinary medicinal products** authorised within the Union by the Commission and by the competent authorities:
(i) name of the veterinary medicinal product;
(ii) active substance or substances, and the strength of the veterinary medicinal product;
(iii) summary of product characteristics;
(iv) package leaflet;
(v) the assessment report;
(vi) list of sites where the veterinary medicinal product is manufactured; and
(vii) the dates of the placing of the veterinary medicinal product on the market in a Member State;

(b) for **homeopathic veterinary medicinal products** registered in accordance with Chapter V within the Union by the competent authorities:
(i) name of the registered homeopathic veterinary medicinal product;
(ii) package leaflet; and
(iii) lists of sites where the registered homeopathic veterinary medicinal product is manufactured;
(c) veterinary medicinal products allowed to be used in a Member State in accordance with Article 5(6);
(d) the annual volume of sales and information on the availability for each veterinary medicinal product

3. The Commission shall, by means of **implementing acts**, adopt the necessary measures and practical arrangements laying down:
(a) the ***technical specifications*** of the product database including the electronic data exchange mechanism for exchanging with the existing national systems and the format for electronic submission;
(b) the ***practical arrangements*** for the functioning of the product database, in particular to ensure protection of commercially confidential information and security of exchange of information;
(c) ***detailed specifications of the information*** to be included, updated and shared in the product database and by whom;
(d) ***contingency arrangements*** to be applied in case of unavailability of any of the functionalities of the product database;
(e) where appropriate, data to be included in the product database in addition to the information referred to in paragraph 2 of this Article.

Article 56: Access to the product database

1. The competent authorities, the Agency and the Commission shall have full access to the information in the product database.
2. Marketing authorisation holders shall have full access to the information in the product database as regards their marketing authorisations.
3. The **general public** shall have access to information in the product database, without the possibility to change the information therein, as regards the list of the **veterinary**

medicinal products, the summary of product characteristics, package leaflets and, after the deletion of any commercially confidential information by the competent authority, assessment reports.