VETERINARY MEDICAL PRODUCT AND PHARMACOVIGILANCE DATABASE

FVE Input

Background:

- Regulation 2019/6 on veterinary medicinal products lays down in article 55 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. The European Commission shall develop an implementing act to define the technical and functional requirements. In article 56, access to the database is defined.
- Article 74 defines the setting up of a “Pharmacovigilance Database”, linked with the “Product Database”. Several implementing acts need to be defined in relation to the pharmacovigilance database and system.

Main inputs FVE:

UNION DATABASE:
(a) 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.
(b) A veterinarian prefers to use an authorised VMP for a specific species/age category/indication/dosing regime, above use outside the marketing authorisation.
(c) Therefore, the development of the “Product Database” is 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.
(d) A user-friendly system with an easy and practical search function will make or break the system.
(e) 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.
(f) 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”.

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

(h) As an example, a very user-friendly “Product Database” is available from the UK: https://www.vmd.defra.gov.uk/ProductInformationDatabase/Search.aspx

(i) 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.

Example of search scenarios veterinary surgeons will use:

- A vaccine against a specific disease is temporarily unavailable in a country. With the database, the veterinarian can see which other MAH’s have a similar vaccine marketed in other Member States.
- A veterinarian only has a broad-spectrum penicillin in his country for a certain species/indication. For reasons of prudent use, the veterinarian wants to use a narrow spectrum penicillin. With the “Product Database”, he/she can look which products are available for the required species, indication and administration route in other Member States.
- A veterinarian has a horse with chronic laminitis. No product is marketed for this in the country. With the “Product Database”, searching for ‘horse’, ‘locomotory’ or by putting in key words ‘chronic laminitis’, he should easily find what is available in other Member States.
- A veterinary surgeon needs a product with a pharmacologically active substance in a certain pharmaceutical form e.g. injectable versus tablets. He/she can search the “Product Database” to see if this product exists in another pharmaceutical form in another Member State.

PHARMACOVIGILANCE DATABASE

a) Currently, the main weakness of the pharmacovigilance system is underreporting and the lack of reports on pharmacovigilance, especially for food producing animals and on lack of efficacy in the target animal patient.

b) To strengthen the system, it is vital for Member States to ensure that easy means for reporting adverse reactions and lack of efficacy are available to veterinarians, e.g. an easy online form which only asks the minimum data essential to allow assessment of the individual case report, while access to pharmacovigilance results needs to be ensured.

c) FVE welcomes the aim to make publicly available the reported adverse reactions, similarly to the way it is published in the human field (Pharmacovigilance article 57 database). Nevertheless, it is highly important that those results and outcomes are published in a validated, reliable,
understandable and practical form. The published data should be consultable for veterinarians per VMP and not only per group/class of VMPs in order to be useful and advisory for the veterinarians! To give an example: traditionally anaphylactic reactions occur regularly with immunological veterinary medicinal products. To say, that we have seen this year more anaphylactic reactions than the year before, is not useful information for veterinarians. It is necessary to define for which vaccines an increase has been seen e.g. Vaccines against disease X and to specify even which vaccines e.g. Brand name X 50%, Brand name Y 30%, Brand name Z 20%

d) It should be easy to flag to veterinarian and to see for veterinarians which SPC’s have been changed to adapt the pharmacovigilance data or to add extra warnings.

Considerations:

- Seen the drastic change proposed by the new Regulation moving from periodic safety update reports (PSUR’s) to Signal Detection, it is important to make sure that the development of the “Union Product and Pharmacovigilance Database” is prioritized, that enough resources are foreseen and that all is ready on time.
- To make sure both databases are useful for their most important end users, namely veterinarians, it must be ensured that they are develop according to their needs. Sufficient and proper stakeholder involvement should be ensured.
- Awaiting SPC harmonization, now similar products can have other specification such as regarding dosing, indications for use, withdrawal time, etc. A method has to be found how to deal with this.