FEDERATION OF VETERINARIANS OF EUROPE

FVE/20/doc/040
6 July 2020

EMA scientific recommendations on delegated and implementing acts as part of the implementation of the new veterinary medicines Regulation 2019/6

Implementing act on Good Pharmacovigilance Practice
FVE Input

Background:

- 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.
- Based on the European Commission request, the European Medicines Agency (EMA) adopted the scientific recommendation in May 2020.
- On 12 June 2020, the European Commission contacted FVE with a request for written comments, in the context of a targeted stakeholder consultation.
- FVE is appreciative and grateful for this consultation and the opportunity to share our comments.

Main inputs FVE:

- 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 clinical efficacy in the target animal patient. We do not see how this new system will facilitate more reporting of results if reporting will not become easier or be more promoted.

- To strengthen the pharmacovigilance system, it is vital for EU Member States to ensure that **easy means for reporting** adverse reactions and lack of clinical 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 of suspected adverse events, **with access to pharmacovigilance results** ensured.

- The main aim to revise the pharmacovigilance system was for it to become **more effective and to reduce administrative burden**. It is difficult to foresee with the new system, if this will really be the case. Ideally, a pilot should have been done, such as happened in the human medicines field.

- The drastic change proposed by the new Regulation moving from periodic safety update reports (PSUR's) to Signal Detection will only be possible based on a **functional Union pharmacovigilance database and Union Product Database.** Both databases should be implemented with a sufficient time testing before the new legislation will come in place so as to allow an effective implementation. A **contingency plan** should be developed for the case that the databases are not fully functional at January 2022.

- Pharmacovigilance and **off-label use** or **use of a medicine under the cascade system**. We welcome the extension of reporting of adverse events to consider also medicinal products used off-label, including human products, and to use these adverse events in the same way as those relating to authorised clinical indications. However, it should be well reflected on how these adverse events will precisely need to be reported (maybe a special form of declaration is needed?) and how the results will be presented in the EU ADR database. Off-label use has a potentially important role in contributing to the overall safety profile of medicinal products and could clearly play a role in extending product marketing authorisations to more animal species or more clinical indications.

- FVE welcomes that the reported adverse reactions have become publicly available on the **EMA ADR website**. Currently, these data as presented are still difficult to interpret (e.g. which animals died, or had only a minor adverse problem) and as no sales data is yet available, true incidence is unknown. It is very much welcomed that this will be further improved, to also include incidence levels and severity to allow a proper interpretation. It could also be good to later include links to safety warnings e.g. not to use certain medicinal products in certain medical conditions or for certain sub-species. Practitioners are at your availability to support you in making the pharmacovigilance system more usable and and to work out satisfactory **disclaimers** as the causal relationship might not always be established between the event and the product.

- The fact that **alerts** will be centralised and reported though the Union pharmacovigilance database, with involvement of the Marketing Authorisation Holders, is welcomed.

- It is important that Marketing Authorisation holders and Competent Authorities have **fast and efficient procedures in place to communicate** pharmacovigilance issues to veterinarians. Therefore , the proposal for Marketing Authorisation holders to have a communication plan is good. However, we strongly support for it to be EU standardised, to avoid that each MAH develops a different action plan. Messages should be fact based, non-selective and neutral, and clear. **Coordination on joint messages** is essential between competent authorities and the marketing authorisation holders; in order to avoid conflicting messages. Improved communication and seeing the data driven results of their reports made, will facilitate trust in the system by veterinarians and enhance reporting.

- FVE in that aspect welcomes very much the **extra monthly bulletin** that EMA will publish regarding 'Pharmacovigilance regulatory recommendations for centrally authorised veterinary medicinal products during 2020,' to highlight the veterinary medicinal product Information changes agreed by CVMP during the current year. This is equally important for non-centrally authorised veterinary medicinal products.

- FVE welcomes the idea to include a **QR code on the product package** linking to the latest SPC information. In that aspect, it would also be very practical for veterinarians, if in the Union Product Database, veterinary medicinal products which have undergone recent SPC/leaflet changes or for which extra warnings (for example interactions with other medications) have been added could be flagged.

- FVE hopes that despite Brexit, **reciprocal arrangements will be put in place between the EU and the UK** to continue exchanging of information on any adverse events .

- Lastly, seeing the drastic changes that will be made, we would like to suggest building in the need for an **evaluation report** after e.g. 2 years.

_____