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

Subject: **Pharmacovigilance system master file (Article 77 (6))**

Preamble

On 6 February 2019 the European Commission sent a request to the European Medicines Agency for scientific for scientific recommendations regarding the pharmacovigilance system master file

The Committee for Medicinal Products for Veterinary Use (CVMP) adopted the scientific recommendation which was sent to the European Commission on 29 May 2020.

On 12 June 2020, the European Commission (DG Sante) contacted EGGVP with a kind request for written comments as regards the EMA advice, in the context of a targeted stakeholder consultation.

EGGVP highly values this consultation and the opportunity to share its views on this topic, and thanks DG Sante for the initiative.

EGGVP general comments

Pharmacovigilance represents the highest percentage of administrative burden for veterinary pharmaceutical companies, with a significant impact on all enterprises', including small and medium sized enterprises', daily activities and resources. EGGVP was hoping that a drastic simplification of pharmacovigilance requirements was not only necessary but possible, as it has been proved that there is room for reducing this burden without compromising neither safety of medicines nor transparency of procedures.

With regards to the proposals for a pharmacovigilance system master file (PSMF hereinafter), one of EGGVP's main concerns and requests during the process of negotiation and adoption of the new veterinary legislation was to keep the company's pharmacovigilance system description out of the

authorization dossier(s), in order to allow modifications of the system without compromising the validity of the authorization dossier(s). Pharmacovigilance system should be linked to the marketing authorization holder rather than to applications.

Unfortunately, EGGVP deeply regrets that, in the new legislation, the PSMF is related to the product (Article 8: a summary of the PSMF must be given to each product). This will involve an enormous administrative and financial burden every time a PSMF will be updated and, as such, it is contrary to one of the principal objectives of the new regulation, which is the reduction of unnecessary and disproportionate administrative burden.

EGGVP is still holding high criticism and questioning the fundamentals of this provision. EGGVP would welcome an explanation of the reasons why the PSMF is linked to the veterinary product, and the purpose and advantages of this provision, since it seems to be very problematic both for industry and competent authorities.

EGGVP specific comments

SECTIONS 2, 3 and 4: CONTENTS OF THE PHARMACOVIGILANCE MASTER FILE

- The main concern is the summary of the PSMF being part of the application, which is a very negative aspect (see above under “EGGVP general comments” and below under “Section 5 – Maintenance”).
- EGGVP is also not supportive to adaptions of the PSMF established for human medicinal products. This is by far a more complex system, not targeting the veterinary business specificities.
- EGGVP would instead welcome if the contents of the PSMF could be similar to those of the present Detailed Description of the Pharmacovigilance System (DDPS). The DDPS was drafted and agreed jointly few years ago between national competent authorities and industry representatives; this was a very positive initiative and with a successful outcome. It is presently a general document with only few detailed information to avoid updates (and thereby variations) as much as possible. A template for it would also be much welcome.
- EGGVP would appreciate consideration for marketing authorization holders to have one PSMF related to all veterinary products of the same marketing authorization holder, and one QPPV, without giving version numbers or dates.
- The contents of the PSMF (core document) should be as close as possible to the description which has been done in volume 9B.

- EGGVP regrets that Annexes are obligatory in the EMA advice (in EGGVP's view, these should be possible but not obligatory). In the provisions and recommendations made by the EMA, there is an extensive list of annexes to the PSMF that will require quite substantial and permanent work for updating all the information included. Furthermore, the dates when the PSMF and the Annexes are updated must be noted, a logbook must indicate the date, the person responsible for alteration and the reason for changes. All this will significantly increase the burden for marketing authorization holders.

SECTION 5: MAINTENANCE

- In the new legislation, the PSMF is related to the product. This will involve an enormous administrative and financial burden every time a PSMF will be updated, due to variations. Also the reference numbers will ask for a variation, if the PSMF is updated.

- While it is positive that a dossier for application of a new product must only contain a summary of the PSMF, which consists only of minimal information, it is however negative that any update to the PSMF reference number (version) is mentioned, which means that different versions will be in different product files depending on the time of submission.

- EGGVP is firmly convinced that PSMF should not be product related. There is a danger of binding one version of a PSMF to one product. This can be avoided by issuing a pharmacovigilance system certificate. EGGVP suggests that, following inspection, the national competent authorities issue a certificate of compliance with the requirements of pharmacovigilance, which can be handled by the MAH to other authorities upon request.

- Updates of the PSMF should not require variations either at the level of the PSMF or even marketing authorization related. Equivalent provisions as those in the human side (changes in the PSMF are to be notified to the authorities through the Art 57 database only, without the need for any further variation; upon a change in the PMSF, the Art 57 database should be updated by the marketing authorisation holder immediately) should be established.

- Only the marketing authorisation holder (including parent group of companies) and basic PSMF number, the location of the PSMF, and the QPPV shall be subject to variations for the products. If a variation has to be done, as there is a change in the marketing authorisation holder, a change in location of the PSMF or a change in the QPPV (and only those), a single fee for the application of variation for all products should be valid, as this requests no assessment by the competent authorities.

- Clarification is requested: what will happen with products approved before the new regulation comes into force? Will marketing authorisation holders have to submit a variation for each product?

SECTIONs 6 and 8: FORMAT, LOCATION AND AVAILABILITY OF THE PHARMACOVIGILANCE SYSTEM MASTER FILE

- EGGVP welcomes the provision that the PSMF shall be hold at the location of the MAH, subject to continuous updates. EGGVP assumes that the PSMF shall not be handled in the Union pharmacovigilance database but should be kept and be present in the companies (as e.g. the Site Master file) in an electronic form. A copy can be sent at the latest within seven days to the competent authorities (by electronic submission).

- As such, the competent authority of the marketing authorisation holder will check the PSMF during inspection (Art. 126). The results of the pharmacovigilance inspection will be given in the Union pharmacovigilance database.

- The EMA advice recommends that "the Member States and the Agency have continuous access to the information proposed for the summary, name and contact details of the qualified person responsible for pharmacovigilance as the contact point for inspections (Article 78(2)) and pharmacovigilance system master file reference and location, and any update to those, as this information is essential for risk-based inspection planning". EGGVP wonders if it would be possible to include this information directly in the Union pharmacovigilance database, including any updates, so as to guarantee continuous access.

- EMA also refers to „further improvements of the functionalities of the Union pharmacovigilance database, as referred to in Article 74, to facilitate the communication of major changes in the pharmacovigilance system to the Member States and the Agency." EGGVP would like to propose the inclusion of the PSMF summary, together with the above examples. As such, any change could be communicated directly in the database and would be immediately available to all partners; variations would be unnecessary with a consequent and substantial decrease of administrative burden.