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: **List of variations not requiring assessment (Art 60(1))**

Preamble

On 6 February 2019 the European Commission sent a request to the European Medicines Agency for scientific recommendations regarding the list of variations not requiring assessment.

The Committee for Medicinal Products for Veterinary Use (CVMP) adopted the scientific recommendation, which was sent to the European Commission on 30 August 2019.

On 18 September 2019, 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; we thank DG Sante for the initiative.

EGGVP general comments

1. General approach

EGGVP welcomes the EMA approach for establishing the list of variations not requiring assessment, where the sole criterion for inclusion in the list has been if scientific assessment is required or not. After benchmark of EMA and EGGVP recommendations, it can be confirmed that both documents are much aligned (general principles as well as the list itself), which is very positively valued.

2. Future guidelines and collaboration with marketing authorization holders

EGGVP is of the opinion that the list of variations not requiring assessment should be consolidated into an open and flexible (future-proof) list. The list of variations not requiring assessment should be designed

- in a way that allows flexibility, so that updates can be easily performed.
- in a searchable format.

In this regard we value that EMA recommends that specific veterinary variation guidance is developed before the new veterinary regulation comes into force.

EGGVP supports the development of such guidance and will be happy to contribute in the discussion about any possible updates in the list of variations not requiring assessment along the way.

EGGVP also supports that conditions and documentation requirements are based on the future system, and will be also happy to contribute in this field.

EGGVP requests for an active and constructive exchange of views between regulators and stakeholders for an effective, smooth and correct implementation in the future.

3. Managing variations not requiring assessment in the Union Product Database

EGGVP is concerned that, although the general EMA advice is to classify variations based on criteria in the legislation and not on possible database limitations, the document also states that practical management will depend on the functioning of the Union Product Database (UPD).

- EGGVP hopes that the goal is still to have a single submission in the UPD (e.g. for address/name changes, CEP/EP changes etc… This is now not clearly mentioned in the EMA advice, which is regrettable. The list should be usable entirely as from the date of application of the regulation, and the UPD specifications should allow a company to record all changes not requiring assessment.
- All the variations included in the list require provision of documentation during the procedure. For these variations a mechanism to allow provision of documentation should be considered in the UPD. In order to be able to submit variations without assessment but with documentation in UPD, good description of conditions and documents is essential and therefore there will be the need for a new guidance document

EGGVP specific comments

4. EGGVP considers very positive that unforeseen variations have been taken into account with the proposal that a number of overarching variations is included to enable flexibility with respect to these unforeseen variations.

5. While EGGVP understands the reasons why pharmacovigilance variations appear on the list with a reference to the Detailed Description of the Pharmacovigilance System (DDPS), this should be fixed as soon as possible so as to delete this reference and replace by reference to the summary of the pharmacovigilance masterfile.

6. EGGVP would like to know what is the rationale for the following variations not being included in the list of variations not requiring assessment:

- B.II.a.3.a.1. addition, deletion or replacement of excipient of the flavouring and colouring system

- C.II.8. change in the frequency and/or date of submission of PSUR's

7. EGGVP disagrees that current variation codes should be retained. The numbering should be relevant for the future system e.g. referring to the relevant parts of the dossier.