**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: **Good distribution practices (GDP) for veterinary medicinal products (Article 99 (6))**

## Preamble

On 1st July 2019 the European Commission sent a request to the European Medicines Agency for scientific recommendations on good good distribution practices (GDP) for veterinary medicinal products.

The Committee for Medicinal Products for Veterinary Use (CVMP) adopted the scientific recommendation which was sent to the European Commission on 30 June 2020.

On 8 July 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 comments

- EGGVP fully supports implementation of a legal framework which ensures a safe, documented and qualitative supply and distribution of veterinary medicinal products (VMPs) so that the needs for animal and public health in the Union are covered.

- In many Member States, national inspectors auditing VMPs wholesalers and distributors already adopt the requirements of the European Commission Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (or national GDPs) as the legal basis for the inspection. In this regard, EGGVP welcomes that the EMA has taken

such human medicines guidelines as the basis for its recommendations. Today many businesses on the veterinary field implement these standards and therefore most sections of the EMA recommendations could in principle be implemented without disproportionate effort by these companies.

- Nevertheless it should be noted that this position is built upon the views of EGGVP members, marketing authorisation holders of veterinary medicines. Marketing authorisation holders with manufacturing activity have systems in place to comply with good manufacturing practices (GMP) also, and therefore they will more easily adapt to the new GDP requirements. However, EGGVP cannot evaluate the impact and potential difficulties for companies working exclusively as wholesalers / distributors. These may have other considerations regarding the implementation of the new provisions.

- EGGVP supports that the quality management system should incorporate quality risk management principles, and that the requirements should be proportionate to the size, structure and complexity of the distributor activities.

  In accordance, focus in the future Implementing Act should be on clearly defining what should be achieved (e.g. risk-based monitoring of contract acceptor performance, risk-based change control system, effective implementation of any withdrawal or recall), while allowing flexibility for the wholesaler in choosing how that goal is actually achieved, commensurate with the inherent risks.

- The EMA suggests that the quality system should ensure that the operations do not pose a risk to the environment or risk of development of antimicrobial resistance. EGGVP recommends that additional guidance is developed, in particular with regards to the provisions to prevent the risk of development of antimicrobial resistance, as a support for wholesalers and distributors to help them implementing this rule.

- EGGVP particularly welcomes that proportionality with the veterinary pharmaceutical market is stressed and has been considered along the EMA recommendations. A big proportion of the veterinary marketing authorisation holders and distributors are small or medium sized companies, and care should be taken so that requirements are adequate with small business capabilities. As a stakeholder association representing mainly such small and medium sized enterprises, EGGVP appreciates the efforts for considering the differences between the human and the veterinary domains, and the needed adaptations for veterinary distributors, in particular the removal of the provision for human medicines that:

- a degree in pharmacy is required for the responsible person.

  EGGVP is pleased that this has not been taken on board, and appreciates the more proportionate proposal from the EMA that the responsible person should meet the qualifications and all conditions provided for by the legislation of the Member State concerned, and should have appropriate competence and experience as well as knowledge of and training in good distribution practices compliance.

- defined limits for the the storage conditions during transportation are required.

  EGGVP welcomes the more practicable approach regarding the definitions and requirements for transportation of VMPs, as this will not affect product quality, safety and efficacy of the finished product. As stated before, the guiding principle should be a risk-based approach, allowing a maximum of flexibility while ensuring storage and transportation of VMPs in accordance with their conditions for storage – in as far as such information is actually available to the wholesaler.

  Furthermore, secondary legislation should ensure that wholesalers are not put at a disadvantage to e.g. pharmacies offering retail at a distance which are not subject to GDP and ship pharmaceuticals under uncontrolled conditions by regular mail or courier services.