EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

Brussels,
SANTE/E5/CS/mcd ares (2019) 4599820
Sent by e-mail only

Dear Prof Rasi,

Subject: Implementing measures under Article 99(6) of Regulation (EU) 2019/6 on veterinary medicinal products[1] as regardc the measures on good distribution practice for veterinary medicinal products

On 7 January 2019, the new Regulation on veterinary medicinal products ('VMP Regulation') was published.

In accordance with its Article 160, it will start applying 3 years from its entry into force, i.e. on 28 January 2022.

According to Article 99(6), the Commission is to adopt, by means of implementing acts, measures on Good Distribution Practice (GDP) for veterinary medicinal products.

Article 153(1) requires the Commission to adopt the necessary implementing acts before 28 January 2022. In light of the strict timeline set for the adoption of the required implementing acts, I would like to request the Agency to provide scientific advice to inform the adoption of measures on GDP for veterinary medicinal products, by taking into account the following:

- the view of the policy reasoning and purpose of GDP to ensure the quality and identity of veterinary medicinal products during all aspects of their distribution process, *e.g.* procurement, storage, distribution, transportation, documentation and record-keeping;
- the experience gained with the application of the current EU system on the human medicines side as established in the *Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use;*

[1] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L 4, 7.1.2019, p. 43.

Prof Guido Rasi
Executive Director
European Medicines Agency
PO Box 71010
1008 BA Amsterdam
The Netherlands

- existing international standards and guidelines on GDP for medicinal products, *e.g. WHO Good distribution practices for pharmaceutical products, Guide to good storage practices for pharmaceuticals, Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical product*s, the 2014 PIC/S *Guide to Good Distribution Practice for medicinal products*;
- as appropriate and available, the experience gained by certain Member States (such as France, Hungary, Poland, Portugal, Romania, the United Kingdom), which have adopted national GDPs and conduct GDP inspections for veterinary medicinal products;
- the similarities and potential differences between the requirements towards GDP for human and for veterinary medicinal products;
- the fact that more often than not GDP inspections are to be performed by the same experts for both types of medicines or that the same wholesaler distributes both veterinary and human medicinal products and therefore, in order to avoid unnecessary administrative burden, it is not practicable to deviate significantly from the human side, unless practical needs dictate otherwise.

Relevant excerpts (non-exhaustive list) from the VMP Regulation are included in Annex I for your convenience.

We expect the Agency to provide the requested scientific advice as soon as practically possible and by the end of June 2020 at the latest. We require the Agency to update our services on the progress of its work on a monthly basis.

I would like to thank you for your collaboration.

Yours sincerely,

Anne Bucher

Annex I

EXCERPTS FROM THE VMP REGULATION CONTAINING REFERENCES TO GOOD DISTRIBUTION PRACTICE FOR VETERINARY MEDICINAL PRODUCTS

(69) In order to ensure the uniform application of principles of good manufacturing practice and good distribution practice, the compilation of Union procedures for inspections and exchange of information should serve as a basis for competent authorities when performing controls on manufacturers and wholesale distributors.

(71) Companies should hold an authorisation to be able to distribute wholesale veterinary medicinal products and should comply with the principles of good distribution practice, so as to guarantee that such medicinal products are appropriately stored, transported and handled. It should be the responsibility of the Member States to ensure that those conditions are met. Those authorisations should be valid throughout the Union and should also be required in the case of parallel trade in veterinary medicinal products.

Article 99

Wholesale distribution authorisations

6. The Commission shall, by means of implementing acts, adopt measures on good distribution practice for veterinary medicinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 101

Obligations of wholesale distributors

5. A wholesale distributor shall comply with the good distribution practice for veterinary medicinal products as referred to in Article 99(6).

Article 153

Transitional provisions regarding delegated and implementing acts

1. The delegated acts referred to in Article 118(2) and the implementing acts referred to in Articles 37(5), 57(4), 77(6), 95(8), 99(6) and 104(7) shall be adopted before 28 January 2022. Such delegated and implementing acts shall apply from 28 January 2022.