EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

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

Dear Prof. Rasi,

Subject: Implementing measures under Article 95(8) of Regulation (EU) 2019/6 on veterinary medicinal products[1] as regards the measures on good distribution practice for active substances used as starting materials in 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 95(8), the Commission is to adopt, by means of implementing acts, measures on Good Distribution Practice (GDP) for active substances used as starting materials in 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 active substances used as starting materials in veterinary medicinal products, by taking into account the following:

- the view of the policy reasoning and purpose of GDP to ensure a quality warranty system on the movement of active substances used as starting materials from the premises where they have been manufactured to the manufacturer of veterinary medicinal products by means of various transport or storage methods;

[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.

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- the experience gained with the application of the current EU system on the human medicines side as established in the *Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use*;
- existing international standards and guidelines on GDP of active substances for medicinal products, *e.g.* WHO *Good trade and distribution practices for pharmaceutical starting materials*, the 2018 PIC/S *Guidelines on the principles of Good Distribution Practice of active substances for medicinal products for human use*;
- the similarities and potential differences between the requirements towards GDP for active substances used as starting materials in human and in 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 active substances used for 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 ACTIVE SUBSTANCES

(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.

Article 93

Obligations of the holder of a manufacturing authorisation

1. The holder of a manufacturing authorisation shall:

(j) comply with good manufacturing practice for veterinary medicinal products and use as starting materials only active substances which have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practice for active substances;

Article 95

Importers, manufacturers and distributors of active substances established in the Union

1. Importers, manufacturers and distributors of active substances used as starting materials in veterinary medicinal products, that are established in the Union, shall register their activity with the competent authority of the Member State in which they are established and shall comply with good manufacturing practice or good distribution practice, as applicable.

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

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.