EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

Brussels,
SANTE/E5/CS/mcd 379717
Sent by e-mail only

Dear Prof Rasi,

Subject: Implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products[1] regarding the pharmacovigilance system master file (PSMF)

On 7th 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. from 28th January 2022.

According to Article 77(6), the Commission shall adopt an implementing act to establish the format and content of the PSMF and its summary. This implementing act should be adopted by the date of application of the VMP Regulation.

In this context, I would like to ask you to provide us with the Agency's scientific recommendations on the above-mentioned format and content of the PSMF and its summary, by taking into account the following:

[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 system as established in VOLUME 9B of The Rules Governing Medicinal Products in the European Union – Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use –.
- the experience gained by inspections of pharmacovigilance systems for veterinary medicinal products.
- the format and content of the current Detailed Description of the Pharmacovigilance System (DDPS).
- the experience gained with the PSMF in human medicine with the Guideline on good pharmacovigilance practices (GVP) Module II – Pharmacovigilance system master file and the content of PSMF as detailed in Article 2 of Commission Implementing Regulation (EU) No 520/2012
- the changes foreseen in 'VMP Regulation' from the current system of adverse event reporting and Periodic Safety Update Reports to adverse event reporting and Signal Management process.

Relevant excerpts from the VMP Regulation are included in Annex I for your convenience.

We would kindly ask for your contribution by the end of May 2020. This act is included in the first package for implementation in order to allow, on an exceptional basis, for an extended period for scientific advice. In these circumstances, we request a brief interim report by end of September 2019.

We would like to thank you for your collaboration.

Yours sincerely,

Anne Bucher

Encl. : Annex I

Annex I

Relevant excerpts from the VMP Regulation.

Article 4

Definitions

For the purposes of this Regulation, the following definitions apply: (…)

(30) ‘pharmacovigilance’ means the science and activities relating to the detection, assessment, understanding and prevention of suspected adverse events or any other problem related to a medicinal product;

(31) ‘pharmacovigilance system master file’ means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised veterinary medicinal products; (…)

Article 8

Data to be submitted with the application

1. An application for a marketing authorisation shall contain the following :

(…)

(c) a summary of the pharmacovigilance system master file. (…)

Article 77

Pharmacovigilance responsibilities of the marketing authorisation holder

2. The marketing authorisation holder shall have in place one or more pharmacovigilance system master files describing in detail the pharmacovigilance system with respect to its authorised veterinary medicinal products. For each veterinary medicinal product, the marketing authorisation holder shall not have more than one pharmacovigilance system master file.

(…)

6. The Commission shall, by means of implementing acts, adopt necessary measures on good pharmacovigilance practice for veterinary medicinal products and also on the format and content of the pharmacovigilance system master file and its summary. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

(…)

Article 145

Standing Committee on Veterinary Medicinal Products

1. The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products (‘the Standing Committee’). The Standing Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.