Ref. Ares(2019)688882 - 06/02/2019

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels,
SANTE/E5/CD/MCD 379717

Sent by e-mail only

Dear Prof Rasi,

Subject: Implementing measures under Article 60(1) of Regulation (EU) 2019/6 on veterinary medicinal products[1] regarding the list of variations not requiring assessment

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 60(1), the Commission shall adopt an implementing act to establish a list of variations not requiring assessment. This implementing act should be adopted at latest 12 months before 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 list of variations not requiring assessment, by taking into account the following:

- the criteria listed in Article 60(2) of the VMP Regulation:
  (a) the need for a scientific assessment of changes in order to determine the risk to public or animal health or to the environment;

[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
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(b) whether changes have an impact on the quality, safety or efficacy of the veterinary medicinal product;
(c) whether changes imply no more than a minor alteration to the summary of product characteristics;
(d) whether changes are of an administrative nature;

- the experience gained with the application of the current system as established in Commission Regulation (EC) No 1234/2008 and the accompanying "Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures (2013/C 223/01)".

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

We would kindly ask for your advice by the end of August 2019. We would also ask that the Agency update our services on the main progress of its work on a monthly basis.

We would like to thank you for your collaboration.

Yours sincerely,

Anne Bucher

Encl. : Annex I

Annex I

Relevant excerpts from the VMP Regulation.

Recital 27

Taking into account the need for simple rules on changes to the marketing authorisations of veterinary medicinal products, only changes that can affect public or animal health or the environment should require a scientific assessment.

Article 60
Variations

1. The Commission shall, by means of implementing acts, establish a list of variations not requiring assessment. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

2. The Commission shall take account of the following criteria when adopting the implementing acts referred to in paragraph 1:

(a) the need for a scientific assessment of changes in order to determine the risk to public or animal health or to the environment;

(b) whether changes have an impact on the quality, safety or efficacy of the veterinary medicinal product;

(c) whether changes imply no more than a minor alteration to the summary of product characteristics;

(d) whether changes are of an administrative nature.

Article 61
Variations that do not require assessment

1. Where a variation is included in the list established in accordance with Article 60(1), the marketing authorisation holder shall record the change including, as applicable, the summary of product characteristics, labelling or package leaflet in languages referred to in Article 7, in the product database within 30 days following the implementation of that variation.

2. If necessary, competent authorities or, where the veterinary medicinal product is authorised under the centralised marketing authorisation procedure, the Commission shall, by means of implementing acts, shall amend the marketing authorisation in accordance with the change recorded as referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3. The competent authority of the reference Member State or, in the case of variation to the terms of a national marketing authorisation, the competent authority of the relevant Member State, or the Commission, as applicable, shall inform the marketing authorisation holder and the competent authorities in the relevant Member States as to whether the variation is approved or rejected by recording that information in the product database.