16 March 2018
EMA/CVMP/157690/2018
Committee for Medicinal Products for Veterinary Use

Public consultation concerning a request for CVMP opinion under Article 30(3) of Regulation (EC) No 726/2004 on the risk for the consumer resulting from the use of diethanolamine as an excipient in veterinary medicinal products for food-producing species (EMEA/V/A/127)

Consultation procedure: 16 March 2018 – 14 May 2018

1. Background

The European Medicines Agency ('the Agency') has received a request from the Belgian Federal Agency for Medicines and Health Products for a scientific opinion regarding the risk for the consumer resulting from the use of diethanolamine as an excipient in veterinary medicinal products for food-producing species, in accordance with Article 30(3) of Regulation (EC) No 726/2004. Under Article 30(3), the Committee for Medicinal Products for Veterinary Use (CVMP) is required to draw up an opinion on any scientific matter related to the evaluation of medicines for use in animals upon request from the Executive Director of the Agency, the European Commission or a Member State. In order to make recommendations, the CVMP considers all available data in relation to the subject under consideration. As with any other evaluation, the Committee appoints a rapporteur and one or more co-rapporteurs, who will perform the scientific evaluation and prepare a draft report. The Committee will then review this draft report and conclude the procedure by adopting an opinion and a report that will be sent to the European Commission and published on the Agency website. Where possible, this opinion is adopted by consensus but where this is not possible, a majority opinion will be adopted and divergent views will be recorded in an annex to the CVMP opinion. Upon receipt of the opinion, the European Commission will decide if there is a need for further regulatory action at national or EU level and, if necessary, will initiate follow-up procedures, usually in the form of a referral to the CVMP.

In the interest of transparency, and in order to provide stakeholders with the opportunity to input any information or data that they consider may be helpful to the CVMP in reaching its opinion, the Agency has agreed to conduct a public consultation exercise as part of the preparation of the opinion.

2. Consultation procedure

The CVMP invites all interested parties such as the pharmaceutical industry, learned societies, governmental institutions, as well as EU and EEA-EFTA Member States, to submit scientific data for use

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in the review of the consumer safety assessment of diethanolamine. The Committee is seeking to obtain relevant data on the genotoxic/carcinogenic potential of diethanolamine and the risk resulting from this for the consumer, and in particular:

- data aimed at establishing the mechanism of carcinogenic activity of diethanolamine and whether the carcinogenic activity results from DNA reactivity of the substance,
- if it is considered that the substance is not DNA-reactive, data to establish a threshold for the carcinogenic activity of diethanolamine,
- any relevant data on the metabolism and residues in target animal species allowing an estimate of the consumer exposure to diethanolamine.

It is currently not foreseen for stakeholders to present directly to the Committee. However, should the CVMP consider it necessary, relevant stakeholders may be invited to present information on a particular topic during a plenary meeting.

Comments on this public consultation and scientific contributions should be submitted no later than 14 May 2018 by email to Diethanolamine-127@ema.europa.eu.

In all cases the name and contact details of the interested party providing the scientific contributions is required along with a list of all scientific contributions provided and copies of accompanying references.

Unpublished data may be included. However, the consent of the data owner is a necessary requirement. The owner of the data will be given the opportunity to review the assessment report and to propose deletion of any confidential data. The CVMP will consider such submissions on a case-by-case basis. Submitting parties are bound to obey existing copyrights. The CVMP opinion and assessment report will be made public in accordance with measures taken by the Agency to ensure an appropriate level of transparency.

As regards **copyright**, it is important to clarify that the use by the CVMP of the bibliographic material is entirely for a non-commercial purpose. As its non-commercial use by the Committee is guaranteed, any interested party will not incur any liability as to the use intended by the CVMP by forwarding the bibliographic literature to the Committee. The CVMP is in all cases willing to confirm in writing the non-commercial use of documents sent in by interested parties.

Documents should be submitted in **English** where possible since this is the working language of the CVMP, but documents in other official languages of the European Union will be accepted. However, in order to facilitate the assessment, the CVMP would appreciate the submission of an abstract in English when original references are provided.

Conditions for data submissions

Scientific contributions should be relevant to the purpose of the assessment.

The acceptance of scientific contributions will be based on compliance with the following general criteria:

1. Scientific contributions should be classified by the interested party as (i) peer-reviewed data; or (ii) non peer-reviewed data. The Agency encourages submission of peer-reviewed data/publications (not just the reference) as the most relevant and reliable documents. Non peer-reviewed data/publications can be taken into consideration provided that they are of an adequate quality.

2. A document providing a specification of the literature search strategy, the date of the search, search terms (inclusion/exclusion terms) as well as a listing of databases used for the search should be enclosed.