12 September 2014
EMA/545597/2014
Veterinary Medicines Division

Public consultation regarding the request to the European Medicines Agency from the European Commission for a scientific opinion regarding the risks to vultures and other necrophagous bird populations in the Union in connection with the use of veterinary medicinal products containing the substance diclofenac

Consultation procedure

1. Background

The European Medicines Agency ('the Agency') has received a request from the European Commission for a scientific opinion regarding the risks to vultures and other necrophagous bird populations in the Union in connection with the use of veterinary medicinal products containing the substance diclofenac, in accordance with Article 30(3) of Regulation (EC) No 726/2004. Under Article 30(3), the Committee 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 or the European Commission. 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 will initiate follow-up procedures if necessary, 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 is proposing to conduct a public consultation exercise as part of the preparation of the opinion.

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2. Consultation procedure

The European Medicines Agency would like to consult stakeholders on the questions posed to the Agency in the request for a scientific opinion regarding the risks to vultures and other necrophagous bird populations in the Union in connection with the use of veterinary medicinal products containing the substance diclofenac. The questions can be found here. The European Commission has requested the Agency to provide the scientific opinion by 30 November 2014.

In order to focus the input received on those areas where additional information would be of most value, the CVMP has identified the following topics where they would particularly value input from stakeholders:

- Procedure of feeding vultures and other necrophagous birds species with animal by-products in and outside feeding stations and measures put in place to mitigate risks related to the potential for the by-products to contain residues of veterinary medicines.

Input on this topic is sought in particular from those stakeholders most knowledgeable in the practical aspects of the feeding of vultures and other necrophagous birds including, but not limited to, bird conservation organisations and veterinary regulatory bodies.

- Depletion of diclofenac residues in food-producing species.

Input on this topic is sought in particular from those stakeholders possessing residue depletion data including, but not limited to, marketing authorisation holders and academia/research organisations. Unpublished data provided in response to this public consultation may be included in the scientific opinion prepared by the Agency. However, the party submitting such data will be given the opportunity to review the data in the form that it would be published and to request the removal of any confidential information.

- Use of veterinary medicinal products containing diclofenac in the field – which species are treated and how often? What measures are taken to ensure that necrophagous birds are not exposed to residues of diclofenac in treated animals either through feeding stations or inadvertent exposure (e.g. death of treated animals in regions where necrophagous birds are present)?

Input on this topic is sought in particular from stakeholders possessing information or data on the patterns of use of diclofenac in animals which may potentially be consumed either deliberately or inadvertently by necrophagous birds. Information on such use may be held by, among others, veterinary practitioners and marketing authorisation holders.

Comments on this public consultation should be submitted using the template provided to vet-guidelines@ema.europa.eu by 10 October 2014.

The comments received will be published on the Agency website and will be taken into account by the CVMP when preparing the scientific opinion. In order to obtain input in a way that allows efficient and practical management of responses, priority will be given to comments received from associations rather than from individuals. Due to the extremely short deadline it will not be possible to publish responses to individual comments.

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.