EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General

Brussels,
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Dear Professor Rasi,

Subject: Request for an 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

I would like to request an opinion from the Committee for Medicinal Products for Veterinary Use (CVMP), in accordance with Article 30(3) of Regulation (EC) No 726/2004. This opinion concerns the possible risks of toxicity to vultures and other necrophagous birds following exposure to veterinary medicinal products authorised in the Union containing diclofenac.

Veterinary medicinal products containing diclofenac authorised in third countries:

Diclofenac is known to be linked to the death of vultures in the Indian subcontinent. The authorisation of this substance for veterinary use in this region has led to a dramatic decline of vulture colonies since the 1990s; this has eventually led to strong measures and a ban on the sale of veterinary medicinal products containing diclofenac in India, Nepal, Pakistan and Bangladesh.

Veterinary medicinal products containing diclofenac authorised in the Union:

In the Union, diclofenac has been authorised for veterinary use since the 1990s, according to the national authorisation procedure in a limited number of Member States. Today these Member States include Spain and Italy. Following the national authorisation in 2013 of two veterinary medicinal products containing diclofenac by the Spanish competent authority AEMPS, conservation organisations, members of the public and politicians wrote to the European Commission expressing their concerns on the risks that these products may represent to vultures and other necrophagous bird populations. Following these representations the Commission services contacted AEMPS to have their views on this subject. Following these contacts, AEMPS informed us that the summaries of product characteristics for the products containing diclofenac authorised in Spain have been modified to include specific warnings.

The Commission is not aware of any incidents involving necrophagous birds linked to the veterinary use of diclofenac in EU Member States.

Mr Guido Rasi
Executive Director
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

This issue was recently on the agenda of the Coordination Group for Mutual Recognition and Decentralised Procedures-veterinary (CMDv). The Commission is not aware of any follow-up to these discussions.

EU rules on animal by-products:

The disposal of fallen stock in the Union is regulated by Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption. Article 18 of this Regulation provides that for special feeding purposes and by way of derogation, under conditions which ensure the control of risks to public and animal health, the collection and use of category 1, 2 and 3 materials is allowed for the feeding of endangered or protected species such as vultures.

The associated implementing measure – Commission Regulation (EU) No 142/2011 of 25 February 2011 – lays down animal and public health rules for animal by-products and products derived thereof. Its Annex VI, Chapter II, Section 2 point (a) lists the Member States and the animal species where and for which such a derogation has been granted as regards the feeding of certain species in feeding stations (Bulgaria, Greece, Spain, France, Italy, Cyprus, Portugal, Slovakia and Croatia[i]).

Those Member States have been requested by the Commission to transmit by 1 August 2014 information on the implementation of the above mentioned derogation and the measures put in place to prevent vultures and other necrophagous birds from ingesting materials containing residues of veterinary medicinal products containing diclofenac.

Request for a scientific opinion:

The safety of veterinary medicinal products authorised in the Union, including safety to the environment, is of paramount importance to the European Commission. Therefore, I would like to ask the CVMP for an opinion regarding:

- **The risk that the use veterinary medicinal products authorised in the Union containing the substance diclofenac may present to vultures and to other necrophagous birds in the Union, taking into account the EU rules on animal by-products;**

- **If a risk is identified, any actions or mitigation measures that could be implemented to manage effectively this risk.**

I would be grateful if the opinion could be finalised by 30 November 2014.

We remain at your disposal for further information.

Yours sincerely,

Paola Testori-Coggi

[i] Extension of the list of species of necrophagous birds in the Member States with inclusion of Croatia had been done at the 3 and 4 July 2014 Standing Committee on Animal Health and Welfare.