

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation Animal nutrition, veterinary medicines Head of Unit

> Brussels, SANTE/NJ/ia/ddg2.e.5(2016)3580621

Dear Petitioner,

Subject: Veterinary use of diclofenac and risks to vultures and birds of prey

Thank you for your email to Commissioner Andriukaitis on the veterinary use of the drug diclofenac and its risk for vultures and other birds of prey. Commissioner Andriukaitis has asked me to reply on his behalf.

The European Commission was made aware of this issue in early 2014 following the reported decline of vultures due to the use of diclofenac in the Indian subcontinent. The European Commission then took the initiative to submit early 2014 a request for scientific advice to the European Medicines Agency's (EMA) Committee for Medicinal Products for Veterinary Use (CVMP) as to whether or not veterinary medicines containing diclofenac present a risk to vultures and other necrophagous birds in Europe.

EMA then published its Opinion¹ in December 2014 and concluded that:

- Vultures/necrophagous birds in the EU may be at risk due to residues of diclofenac if they feed on carcasses of animals that have been treated with this substance;
- Risk management measures are needed to contain this risk and efforts should focus on determining the most suitable and effective ones to ensure that contaminated carcasses do not end up in the food chain of vultures and other necrophagous birds.

Given that all veterinary medicines containing diclofenac in Europe have been authorised through national procedures in a limited number of Member States, the most appropriate way to address the issue at the moment in the EU is for Member States to introduce risk management measures taking into account the specificities of the situation in their territory.

The Member States adopted national action plans where the most appropriate risk management measures have been put in place to contain the risk effectively.

Furthermore, it is worth pointing out that diclofenac has been authorised for veterinary use in a limited number of EU Member States since 1993 without any evidence of vulture

 $^{^1\} http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/12/WC500178925.pdf$

poisoning. Animal husbandry and veterinary conditions in Europe are considerably different from those in the Indian subcontinent where the decline of vultures was observed. In particular, there are very strict provisions in the EU legislation on the handling of animal by-products and the disposal of fallen stock²³. These rules have been established to ensure the control of risks to public and animal health regarding the feeding of endangered or protected species such as vultures.

The Commission will continue to follow this issue closely and take appropriate and swift action should it be deemed necessary.

Yours sincerely,

Stefano Soro

² 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)

³ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal byproducts and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive