

The safety of veterinary medicines authorised in the EU is of great importance to the Commission. In August 2014, in the absence of any action on the part of the Member States, the Commission requested a scientific advice from the European Medicines Agency (EMA) on the risk that the use of veterinary medicinal products containing diclofenac may represent to vultures and other necrophagous birds in the EU and if a risk is identified, any actions or mitigation measures that could be implemented to manage effectively this risk.

The EMA delivered its opinion¹ in December 2014 with the following conclusions:

- 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 the EU have been authorised through national procedures, the Commission requested Member States to carry out analysis of the risk mitigation measures as recommended by the EMA, taking on board the particular situation of their country and notify to the Commission their national action plan and in particular which measures they have implemented or will implement to safeguard the European populations of vultures and other necrophagous birds.

In addition, the Commission discussed this issue with the Member States in 2 meetings organised in Brussels: on 9 February 2015 and on 15 June 2015.

Conclusion

There has been no evidence of vulture poisoning attributed to diclofenac products in the EU since 1993. No EU Member State expressed support for the initiation of a Union referral procedure where the withdrawal of the marketing authorisations for veterinary medicinal products containing diclofenac would be considered.

The most appropriate way to address the issue at the moment in the EU is to introduce suitable and effective risk management measures by Member States at national level, taking into account the specificities of the individual Member States' situation.

Risk mitigation measures implemented by the Member States should allow to contain effectively the risk where diclofenac is used and vultures or other relevant necrophagous birds are present on their territory.

The Commission will continue to follow closely this issue and take appropriate and swift action should new information requiring it become available.

¹ http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/12/WC500178925.pdf