13 October 2014

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

Template for comments

Comments to be provided by 10 October 2014

Comments from:

Name of organisation or individual

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These comments are a joint response from BVA and BVZS. This response has also been prepared with particular involvement from the BVA’s Overseas Group, as well as our Veterinary Medicines Subgroup.

BVA is the national representative body for the veterinary profession in the United Kingdom and has over 14,000 members.

BVZS is a specialist division of the BVA which is involved in almost every aspect of the care and welfare of exotic pets, zoo animals and wildlife.

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received. Supporting documentation which has been provided together with the comments will not be published. When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

1 For further information see the original request
Comments on Topic 1

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.

In replying to this request from the EC, the CVMP welcomes comments and information from concerned stakeholders.

Comment

We wish to advise that we broadly support the comments submitted by BirdLife International, which we have had sight of. However, we would like to stress the importance of NSAIDs in general, and their therapeutic indication, which impact on the welfare of animals.

In principle, a wide choice of active products is desirable for veterinary surgeons to choose the most appropriate treatment for the specific case, but all veterinary products, including NSAIDs must be safe for target species and for wildlife. Their conditions of use should also take special risks for endangered species into account. This has long been applied in the environmental assessments on molecules such as ivermectin, where environmental risk mitigation measures are applied across Europe, and also specific measures are applied in some special areas, such as National Trust land in the UK, where rare species such as the Chough or the Horseshoe bat are found.

We are seriously concerned about the impact that the use of diclofenac could have on the European vulture population, concentrated in Italy and Spain, and have previously called for the EMA to undertake an in-depth Environmental Risk Assessment.

The role of the legal use of veterinary diclofenac in the decline of vultures in India is well recognised, where numbers fell by 99% in the early 2000’s, leading to the Indian government to ban veterinary diclofenac as an anti-inflammatory treatment for livestock in 2006.

Although we understand that veterinary regulations are relatively strict in Europe when applied to safety of licensed medicines to the target species, the user/consumer and the environment, the evidence is clear that even a very small proportion of contaminated carcasses exposed through the environment would have a very serious impact on vulture populations because of the high toxicity of diclofenac in these birds.

We recognise that EU regulations prohibit the illegal disposal of carcasses. However, disposing of carcasses at feeding stations is a permitted and recognised means of disposal in Spain and therefore provides a serious risk of exposure to diclofenac residues for these birds in animals treated with the product. There is also a risk that some European zoos may take fallen stock to feed their captive raptors, vultures or cats etc., which could contain diclofenac.

Even in the UK, there remains some confusion as to the adequacy of the environmental risk assessment in this particular context. In a recent response to a question from Professor the Lord Trees in the House of Lords on this issue, the DEFRA minister Lord de Mauley stated that the environmental risk assessment (ERA) looks first at the exposure to assess the hazard and whether it becomes a risk, but then went on to say that there is no exposure in the case of diclofenac. Clearly there is which is why birds have died in such worrying numbers outside the UK. Recent work with Steppe eagles suggests there is a risk,
Comment

not just to European endangered vulture populations, but also to other scavenging raptors.

The environmental risk assessment for NSAIDs for livestock must address the risk to vultures and similar cases, and recommend suitable risk mitigation measures, including warnings and restrictions on use where appropriate. There is a precedent on the SPC for barbiturate euthanasia products, which specifically warns against feeding euthanased carcasses to other animals. The final risk-benefit analysis must balance the risk to endangered wild fauna against animal welfare for livestock, in a scientific and reasonable way, based on evidence.

It should be noted that alternative veterinary medicines, for example meloxicam, as generic and affordable preparations, are available for use in livestock which are safe for vultures and have replaced diclofenac in India. (Although we recognise that meloxicam is a poor analgesic in horses).

Though the finding of flunixin in a Griffon vulture carcass (as highlighted in the BirdLife International response) cannot provide evidence of exposure to diclofenac, it does demonstrate that veterinary NSAIDs can be found in wildlife. The assumption must be that diclofenac could follow a similar route, despite instruction and user guidance.

It may also be prudent to monitor raptor carcasses to determine the impact of flunixin.
Comments on Topic 2

Depletion of diclofenac residues in food-producing species.

In replying to this request from the EC, the CVMP welcomes comments and information from concerned stakeholders.

Comment

According to the European Agency for the Evaluation of Medicinal Products Committee for Veterinary Medicinal Products’ MRL public summary report on Diclofenac ([http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_Report/2009/11/WC500013751.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_Report/2009/11/WC500013751.pdf)), high levels of residues occur in pigs and cattle. The report notes (paragraph 17, page 7) that the data from radiometric studies in cattle and pigs indicate that a non-extractable residue was formed through interaction of diclofenac and liver and kidney tissue. It was found that 30 to 40% of the residues were practically irreversibly bound. This evidence therefore suggests that a significant portion of the residues of diclofenac, and or its metabolites, are extremely persistent in treated animals. We therefore believe that regardless of any withdrawal period required in the SPC, however long and even if correctly complied with, these residues in discarded carcasses of treated animals present a very dangerous and toxic threat to scavenging vultures.
Comments on Topic 3

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)?

In replying to this request from the EC, the CVMP welcomes comments and information from concerned stakeholders.

Comment

We are not aware for which species diclofenac is authorised for in Spain and Italy but from the MRL public summary report we note that MRLs have been established for pigs and cattle so one can assume these are the target species for which this active is formulated for use.