

DICLOFENAC LICENSING IN EU

We are expressing our concern regarding the recent authorisation of the NSAID, Diclofenac, in certain Member States of the EU. For background, a number of BVZS members have over a decade of ongoing involvement in the field of vulture conservation worldwide. The role of the legal use of Diclofenac in the precipitous decline of the vultures in the Indian sub-continent is well-recognised and led to the statutory authorities in the range countries legislating to ban the medication for veterinary use.

Following the imposition of the ban, Diclofenac has been replaced by a number of alternative licensed NSAIDs in the Indian sub-continent, without any apparent adverse impact on the welfare of the target domestic livestock species. The alternative anti-inflammatory medications currently appear to be demonstrably safe should they be ingested by vultures. This chain of events is regarded as one of the conservation successes of the last decade, driven by evidence-based science. Although the recovery of vulture populations in the range countries is expected to take some considerable time following a 99% decline, the absence of Diclofenac in the environment has ensured it is at least achievable.

The critically-important vulture population in Europe has never been numerically similar to populations seen historically in the Indian Sub-continent and therefore would be expected to be particularly susceptible to any additional cause of mortality. There are four rare vulture species in Europe protected by EU law, namely the Griffon, Bearded, Egyptian and Cinereous Vultures and significant EU investment has already been provided towards the conservation of these species. The British Veterinary Zoological Society (BVZS) is therefore extremely concerned to learn Diclofenac has been authorised for use in Spain and Italy, for use in domestic livestock as any additional threat to the indigenous vulture population would be unwelcome.

BVZS consider there is not only an obligation to preserve our European vulture populations under the EU Birds Directive, but also a responsibility to demonstrate to those countries who have already banned Diclofenac for veterinary use that Europe takes a similar serious view to vulture conservation .

The BVZS therefore fully supports the Vulture Conservation Foundation's campaign seeking the expeditious withdrawal of the product authorisation for Diclofenac in the EU.

EAZA has had discussion around history of vulture declines in Indian sub-continent and concerns for birds in southern EU. Defra agreed would raise at next 'risk' meeting as a 'horizon-scanning' risk which government should be aware of and potentially lobby against. Diclofenac use in ruminants in the EU presents two major threats – a) scavenging birds in southern Europe will be exposed (even if the chances of this are much lower than in India it is still possible due to probable derogations on dumping of carcasses), b) developing nations such as those in the Indian sub-continent that have banned the drug for veterinary use will see this as gross double-standards. It does appear that a multi-pronged 'attack' is in train from many concerned stakeholders, but any discussion amongst BVZS Council and broader membership that could contribute to this would be very helpful.

You can find all details about the diclofenac issue in the webpage – please visit www.4vultures.org

Please note that vet diclofenac does not have any central marketing authorisation from the EU/EMA, but has managed to get national permits in at least two counties – Italy and Spain.

[4vultures](http://www.4vultures.org) has been targeting DG Sanco, and have already asked for them to start a Referral process to ban diclofenac (you can download the document we sent them in our webpage). They are discussing internally the issue, through their Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv). Enlisting the help of veterinarians is a must in this campaign.