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Press Office

Press release

Diclofenac use in animals poses a risk to European vultures

EMA recommends that measures are put in place to better protect the birds

The European Medicines Agency's (EMA) Committee for Medicinal Products for Veterinary Use (CVMP) has confirmed that vultures in the European Union (EU) may be at risk due to residues of diclofenac if they feed on carcasses of animals that have been treated with this medicine.

The Committee identified scenarios in which vultures and other bird species that consume carcasses ("necrophagous birds") may be exposed to residues of diclofenac in the EU and, for each scenario, proposed a range of measures that could be put in place to minimise or eliminate the risk identified.

This advice will inform the European Commission's decision on the best way to minimise the risk to vultures and other necrophagous birds from diclofenac.

Diclofenac, an anti-inflammatory agent and painkiller, is known to be linked to the rapid decline of vulture populations in Southeast Asia. The birds were exposed to the medicine after eating carcasses of animals that had recently been treated with diclofenac and subsequently died of kidney failure. Consequently, veterinary medicines containing diclofenac have been banned in a number of Southeast Asian countries.

In the EU, diclofenac has been authorised in animals since 1993. Currently, the medicine is authorised for use in cattle, pigs and horses in five Member States. Conservation organisations, citizens and politicians have expressed their concerns over the risks that diclofenac may present to vultures and other necrophagous bird populations in the EU.

In September 2014, the European Commission asked EMA to investigate whether the use of diclofenac in animals presents a risk to vultures and other necrophagous birds in Europe and, if a risk is identified, to provide an opinion on actions or mitigation measures that could be implemented to manage this risk effectively.

For the preparation of its scientific opinion, the CVMP invited all interested parties to provide information and share their views on the topic. Thirty five different organisations, including organisations for the protection of birds, learned societies, veterinarian associations and industry, sent their comments.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

The Committee reviewed all data from published literature as well as answers provided by stakeholders from across the EU Member States.

The CVMP identified certain defined situations in which necrophagous bird species can be exposed to harmful levels of diclofenac in the EU. The Committee considered a wide range of measures that could potentially minimise or eliminate this risk such as training, adding warnings to the product information, administration of diclofenac-containing medicines by veterinarians only, tightening controls, surveillance of carcasses at vulture feeding stations and withdrawal of marketing authorisations of medicines containing diclofenac. The Committee considered the practicality and impact of these measures from the time of administering diclofenac to an animal through to consumption of carcasses by necrophagous birds.

The CVMP opinion and assessment report, which have been published today on the EMA website, have been sent to the European Commission. On the basis of the risks identified by the CVMP and the range of proposed measures to control these risks, the Commission will decide on the next steps. The Commission may request EMA to review the authorisations and conditions of use of all diclofenac-containing veterinary medicines in the EU with a view to implementing harmonised, consistent and effective control measures across all Member States.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. In accordance with Article 30(3) of Regulation (EC) No 726/2004, the European Commission can request the CVMP to draw up a scientific opinion on any scientific matter related to the evaluation of medicines for use in animals. Upon receipt of the opinion the European Commission decides if there is a need for further regulatory action at EU or national level and can initiate follow-up procedures if necessary, usually in the form of a referral to the CVMP.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu