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Media Release

Experts Warn of Dangers of Veterinary Pharmaceuticals to Wildlife on the Eve of Key EU Agency Decision

European Medicines Agency Will Soon Make Recommendation to European Commission on Use of Diclofenac in Livestock

Diclofenac Use is Shown to Endanger Fragile Vulture Populations

The Current Approach to Risk Assessment of Veterinary Pharmaceuticals is Flawed

BRUSSELS (December 5, 2014) – The use of the veterinary pharmaceutical diclofenac in Spain is placing Europe's vulture populations at risk and should be banned, according to a paper published by a team of veterinarians and biologists in the journal *Science* this week.

Diclofenac, a non-steroidal anti-inflammatory drug, has already been banned for veterinary use in several South Asian countries, but has been recently been approved for use in Spain and Italy. Traces of diclofenac in livestock carcasses are lethal to vultures who eat them, and contamination of fewer than 1% of dead animals led to the near extinction of three Asian species. Most vultures in Europe are already endangered and thus particularly vulnerable to this threat.

The paper, "One Health approach to use of veterinary pharmaceuticals," argues that as the world's consumption of meat continues to rise, we must take a holistic approach to assessing the impacts of veterinary pharmaceuticals (VPs) that accounts for all environmental effects, including contamination of the natural food chain.

This month, the European Medicines Agency is expected to release a recommendation to the European Commission on the future veterinary use of diclofenac in Europe. While diclofenac is not currently licensed for veterinary use in most European Union countries, Spain authorized marketing of diclofenac as a veterinary pharmaceutical for use in cattle, pigs and horses in 2013. The paper makes a strong argument for the implementation of an EU-wide ban.

Thijs Kuiken, Professor of Comparative Pathology at the Erasmus Medical Center and lead author of the study, said, "I was shocked when I first heard that diclofenac had been authorized for use in—of all places—Spain, which is a stronghold for vultures in Europe. This example shows that we need to radically change the way we deal with pharmaceuticals, both those used in human and veterinary medicine."

The paper cites diclofenac as the cause of rapid declines in vulture populations to nearextinction in Pakistan, India and Nepal in the 1990s. Residues of diclofenac remained in livestock carcasses which were then eaten by vultures. Even very low concentrations of diclofenac then caused renal failure and death in some of the vultures. In 2006, the government of India enacted a ban on production, importation and sale of veterinary diclofenac products, followed soon after by Pakistan, Nepal, and Bangladesh. Since then, vulture population declines in South Asia have slowed or reversed.

Martin Gilbert, Wildlife Conservation Society veterinarian and co-author of the study, said, "The near total loss of South Asia's vultures was a tragedy, and one that could be repeated here in Europe if action is not taken to prevent the introduction of diclofenac to the food chain. We now have the advantage of foresight, and can only hope that the EU follows the commendable response of their South Asian counterparts, who acted quickly to remove the drug from vultures' food."

Vultures play a vital role in European ecosystems, especially in Spain where more than 95 percent of the continent's vultures reside. Spanish vultures remove more than 8000 tons of livestock carcasses per year, which helps control disease and pests and also serves to recycle nutrients. These ecosystem services provide an estimated economic saving of 1.5 million Euros.

Antoni Margalida, researcher at University of Lleida and co-author of the article, said, "The recent approval of the use of diclofenac in Spain (holding more than 95 percent of European vulture populations) shows the gap between conservation science and the environmental impact assessment for veterinary drugs, making it necessary to improve the dialogue between scientists from different disciplines with policymakers and practitioners."

The impact of diclofenac on vultures is just one example of a problem that has much wider implications. In 2004, an estimated 6051 tons of biologically active substances were included in the production of veterinary pharmaceuticals in the EU. While these drugs may benefit the health of domestic animals and the efficiency of livestock production, they can contaminate the environment indirectly. This is a threat to non-target species, including humans. The paper recommends strengthening of current procedures in assessing risk of VPs to the environment and the addition of a more pro-active, holistic, One Health approach applicable to all VPs.

Environmental risk assessment for new VPs is currently necessary for national licensing in EU countries. But there are approximately 2000 pharmaceuticals already in use in the EU, most of which have never been fully tested. Some VPs are exempt from assessment if they are used in a non-food species or a minor food species, or belong to certain classes of drugs including anesthetics, sedatives, injectable antibiotics and others. The assessments also do not account for key issues including low-dose effects, chronic effects, interactive effects of multiple VPs, and effects on non-target species. These rules allow many VPs to fall through the cracks; this includes diclofenac, which is exempt because injectable non-steroidal anti-inflammatory drugs do not currently require an environmental impact assessment.

The study recommends fostering a precautionary principle, in which major efforts are made to prevent VPs contaminating the environment and coming into contact with nontarget species in the first place. The authors advocate "cradle-to-cradle" stewardship that promotes environmental sustainability and mirrors similar programs proposed for human pharmaceuticals. Linking the effects on target species, humans, and the environment encapsulates the One Health approach, which should guide the way toward a more sustainable future.

Wildlife Conservation Society (WCS)

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