



VETPHARM 343

**VETERINARY PHARMACEUTICAL COMMITTEE**  
**15 June 2015**  
**21<sup>st</sup> meeting**

---

**SUMMARY RECORD**

---

The 21<sup>st</sup> meeting of the Veterinary Pharmaceutical Committee took place on 15 June 2015 in Brussels. The meeting was chaired by Stefano Soro, Head of Unit SANTE D6, Medicinal products – quality, safety and efficacy.

**1. AGENDA**

- The draft agenda of the 21<sup>st</sup> meeting (VETPHARM 340) was adopted with addition of Letter of 8 June 2015 – follow-up of gentamicin case under A.O.B.

**2. DISCUSSION ON DICLOFENAC (VETPHARM 341)**

**A. Member States' analysis of the possible risk mitigation measures listed by EMA and action plan**

→ A Commission representative gave a presentation on the risk to vultures and other necrophagous bird populations in the European Union in connection with the use of veterinary medicinal products containing the substance diclofenac.

→ The presentation focused in particular on the risk mitigation measures listed in the CVMP opinion and their implementation into action plans by the Member States as appropriate.

→ Information on Member States' status as regards their vulture populations and national authorisation of veterinary medicinal products containing diclofenac was given and discussed.

**B. Exchange of views on the analysis and concrete measures set at national level and on possible further steps**

→ The suitability and effectiveness of the risk mitigation measures proposed were discussed in the light of these elements and risk assessments conducted at national level.

→ The situation in the Member States' varies greatly as regards vulture population (number of animals varies between Member States from around 100 birds up to around 30 000, there are also many Member States that do not have any wild vultures at all) and the use of veterinary diclofenac (from non-existent or marginal to more significant).

→ All Member States have put in place measures on the disposal of fallen stock as required by Regulation 1069/2009 on animal by-products. This Regulation was adopted in the wake of past crises to address the serious risks to public and animal health and to the environment (and to biodiversity in particular) that animal by-products not intended for human consumption may pose.

→ Although the risk mitigation measures listed by the EMA in its opinion have been found valuable in Member States' action plans, it appeared however from the discussions not appropriate to have a set of common RMMs applying to all Member States. In effect, it should be noted that even when Member States appear to share the same situation e.g. "diclofenac and vultures" or "no diclofenac but vultures", individual risk assessments differ when taking into account as mentioned animal by-product treatment or farming practices. Therefore, the development of suitable and effective risk management measures taking into account the specificities of the Member States' situation seems more appropriate.

#### Specific comments:

→ The use under the cascade is considered very limited given that alternatives to diclofenac are available. In that regard, one Member State took measures to prevent the import of veterinary medicines containing diclofenac.

→ Several Member State representatives underlined that there are some other veterinary medicinal products which could be harmful to species other than those for which they have been authorised and for wild fauna in particular (e.g. products used for euthanasia or anti-parasitic medicines). They argued for having adequate risk mitigation measures following risk assessment instead of introducing the general ban of a veterinary medicine, not least given that one of the most serious issues relating to animal health and well-being is the lack of available and suitable medicines.

→ The Chairman underlined that the raising of issues like that concerning the use of veterinary diclofenac by stakeholders such as NGOs and civil society organisations is welcome and provides is a good opportunity to re-think the use of a product and when needed re-assess its benefit-risk ratio or the risk mitigation measures in place. This is why the Commission proactively decided to ask for EMA's scientific advice on this issue. The Chairman also pointed out that, as already communicated to the Member States in writing, the Commission intends to share the Member State replies with the organisations which expressed an interest in this issue.

→ While agreeing with this approach, and describing the measures already in place or about to be implemented on their territory, Member States pointed out that certain risk mitigation measures listed in the EMA opinion are considered as being disproportionate, costly or not effective, in particular:

- Sampling of fallen stock (dead animals in pasture)
- The daily visit of a veterinarian during the 3 to 5 days of treatment.

### **C. Conclusions**

→ No Member of the Committee expressed any support for the initiation of a referral where the withdrawal of the marketing authorisations would be considered.

→ Mitigation measures implemented by the Member States should guarantee that where diclofenac is used and vultures (or other relevant necrophagous birds) are present on their territory that they are able to contain effectively the risk.

→ The Commission will proceed with sharing the details of the Member States planned measures with the stakeholders who expressed an interest in them.

### **3. THE RISKS ASSOCIATED WITH THE USE OF ZINC OXIDE IN ANIMALS (VETPHARM 342)**

→ The point has been included on request from the Netherlands.

→ The Netherlands gave a presentation which was followed by discussion, in particular to consider possible risk mitigation measures, including triggering an Article 35 referral, regarding veterinary medicinal products containing zinc oxide as active substance. The main issues raised by NL regarding the use of ZnO were

- The development of antimicrobial resistance
- Irreversible environmental risks

→ EMA representative explained the scope of different types of referrals under the current EU rules.

→ This point raised moderate comments from the Member States.

→ Some Member States expressed their general interest in this issue being considered in the course of the referral procedure, but no Member State clearly expressed their wish to start a referral.

### **4. AOB**

#### **A. Letter of 8 June 2015 – follow-up of gentamicin case**

→ A Commission representative reminded about the deadline to reply to the letter sent by the EC on 8 June 2015 regarding Article 6(3) of Directive 2001/82 which is 1 July 2015.

→ A Commission representative explained that the Commission asks the MS to provide the Commission with:

- relevant extracts from their national legislation implementing Article 6(3) of Directive 2001/82/EC;
- a list of all registered veterinary medicinal products used in their country for animals of the *equidae* family, highlighting the ones which received authorisations under the derogation provided for in Article 6(3) of Directive 2001/82/EC. Clarification was provided regarding the pending applications for marketing authorisations under this provision, such products should be included in the list.