EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Animal nutrition, veterinary medicines

VETPHARM 349

VETERINARY PHARMACEUTICAL COMMITTEE
4 July 2016
22nd meeting

SUMMARY RECORD

The 22nd meeting of the Veterinary Pharmaceutical Committee took place on 4 July 2016 in Brussels. The meeting was chaired by Stefano Soro, Head of Unit SANTE E5, Animal nutrition, veterinary medicines.

1. AGENDA

- The draft agenda of the 22nd meeting (VETPHARM 344) was adopted. No items were added under A.O.B.

2. MAXIMUM RESIDUE LIMITS – DISCUSSION ON DRAFT IMPLEMENTING MEASURES TO THE REGULATION (EC) NO 470/2009 (VETPHARM 345)

A. Draft Commission Implementing Regulation on the form and content of the applications and requests referred to in Articles 3 and 9 of the Regulation (EC) No 470/2009;

→ The Commission services presented the Draft Commission Implementing Regulation to the Member States for discussion. The Commission services explained that this legal draft deals with the form and content of the applications (dossier) and lists the kind of information required when submitting an MRL application.

→ The Commission services explained that the legal draft was prepared based on the European Medicines Agency (EMA) advice.

→ The Commission services asked the Member States to provide written comments, if any, by the end of August 2016.

B. draft Commission Regulation implementing Regulation (EC) No 470/2009 with regard to the rules on the use of a maximum residue limit established for a pharmacologically active substance in a

particular foodstuff for another foodstuff derived from the same species, or a maximum residue limit established for a pharmacologically active substance in one or more species for other species;

→ The Commission services presented the Draft Commission Regulation to the Member States for discussion. The Commission services explained that this legal draft deals with the principles for extrapolation that should be followed by the EMA when preparing opinions regarding maximum residue limits.

→ The Commission services explained that the legal draft was prepared based on the EMA advice which was presented to the Member States in the meeting of the Standing Committee on Veterinary Medicinal Products on 9 February 2015.

→ The Commission services asked the Member States to provide written comments, if any, by the end of August 2016.

C. update on the planned Commission implementing measure regarding the methodological principles for the risk assessment and risk management recommendations referred to in Articles 6 and 7 of Regulation (EC) No 470/2009, including technical requirements in accordance with internationally agreed standards.

→ The Commission services explained that it is preparing another Commission Implementing Regulation that would provide for the methodological principles for the risk assessment and risk management recommendations for the establishment of MRLs.

→ The Commission services explained that EMA has already been requested for a scientific advice in this regard and that the EMA is currently working on its advice. The advice should be given to the Commission by the end of 2016.

3. MAXIMUM RESIDUE LIMITS – STATE OF PLAY AND EXCHANGE OF VIEWS ON DRAFT IMPLEMENTING MEASURES TO THE REGULATION (EC) NO 470/2009 (VETPHARM 345)

A. draft Commission Regulation on the maximum residue limits to be considered for control purposes for foodstuffs derived from animals which have been treated under Article 11 of Directive 2001/82/EC of the European Parliament and of the Council;

B. draft Commission Regulation on reference points for action for non-allowed pharmacologically active substances present in food of animal origin.

→ The Commission services informed the Member States on the developments with the two legal drafts. The Commission services explained that the presented drafts were prepared on the basis of comments received and thanked the Member States for their contributions.

→ The Commission services informed the Member States that the above drafts will be discussed again in the meeting of the experts for residue monitoring in autumn 2016.

→ The Commission services asked the Member States to provide written comments, if any, by the end of July 2016.

4. **MAXIMUM RESIDUE LIMITS –UPDATE ON LATEST DEVELOPMENTS** (VETPHARM 345)

→ The Commission services gave a general update to the Member States on how many MRL opinions were given by the EMA. In the last year, six MRL applications were evaluated by the EMA and were concluded with a positive opinion and adopted by the Commission.

→ The Commission services also informed the Member States on the state of play with regard to the work on biocides and the establishment of MRLs for those used in animal husbandry. Discussions are ongoing within the Commission and with the two Agencies: EMA and ECHA. Once an agreement is reached on how such substances are to be evaluated, the information will be shared with the Member States.

5. **FOLLOW UP TO THE DISCUSSION ON DICLOFENAC: MEMBER STATE'S UPDATE ON THE MEASURES TAKEN AT NATIONAL LEVEL, INCLUDING IN PARTICULAR INFORMATION ON REPORTED VULTURE DEATHS IN THE MEMBER STATES THAT HAVE DICLOFENAC AUTHORISED AND DISCUSSION ON THE STATE OF PLAY AND POSSIBLE FURTHER STEPS** (VETPHARM 346)

→ The Commission services gave background information and a reminder of the discussions and conclusions reached in previous meetings. Given the Commission's commitment to follow up on the effectiveness of the risk mitigations measures introduced in the Member States and on any new information with regard to vulture deaths, Member States were invited to provide an update of the situation in their territories.

→ Most Member States indicated that they still did not have diclofenac authorised. Those that have authorised products indicated that appropriate safety warnings were included in the product literature and that appropriate measures are in place for the safe disposal of fallen stock and the feeding of carrion to birds of prey.

→ None of the Member States reported deaths of vultures in their territories.

6. **FOLLOW UP TO THE DISCUSSION ON GENTAMICIN: OUTCOME OF THE CONSULTATION WITH THE MEMBER STATES ON THE IMPLEMENTATION INTO THE NATIONAL LEGISLATION OF ARTICLE 6(3) OF DIRECTIVE 2001/82/EC AND OVERVIEW OF THE SITUATION IN THE MEMBER STATES WITH REGARD TO THE VETERINARY MEDICINAL PRODUCTS FOR ANIMALS OF THE *EQUIDAE* FAMILY** (VETPHARM 347)

→ The Commission services provided the Member States with a short summary on the background of the "gentamicin case".

→ The Commission services presented the outcome of the consultation with the Member States on the implementation into the national legislation of Article 6(3) of Directive 2001/82/EC as well as the result of the analysis carried out on the basis of the list of all registered veterinary medicinal products sent by the Member States. The majority of the Member States have implemented the provision fully and correctly into their legislation as well as have applied the derogation in compliance with all the conditions laid down in Art 6(3) of Directive 2001/82/EC. Those Member States that have not implemented the provision concerned correctly or might misuse it in practice will be contacted by the Commission in order to clarify and address this issue.

→ The Commission services explained how the provision needs to be interpreted presenting all the consequences following from the application of this derogation which have to be taken into account by each Member State.

→ The Commission services highlighted that this provision excludes the horses forever from the food chain even if the active substance (AS) could be deemed to be safe as an MRL is already established for other species (in cases where the AS is listed in Table 1 of Regulation (EC) No 470/2009 but not especially with an MRL for horses).

→ The Commission services proposed that in the aforementioned case the use of extrapolation could be considered as a possible solution so that animals of the *equidae* family will be able to enter the food chain at some point.

7. NOTICE TO APPLICANTS VOLUME 6A: LATEST DEVELOPMENTS (VETPHARM 348)

→ The Commission services gave a general update of the outcome of the last Notice to Applicants (NtA) meeting that took place in Brussels on 7th June 2016.

The Commission services indicated that agreement was reached on Chapters 1 and 3 but because some elements in human Chapter 1 were going to be updated, it was agreed to see the proposed change before finalising the veterinary Chapter 1.

With regard to Chapter 2, the Commission services reported that it would be deleted as a more up-to-date guidance is currently available on the CMDv website. However, it was agreed that the CMDv website will be checked to ensure the completeness of the information before deleting Chapter 2. FR indicated its wish to retain Chapter 2 until the new Regulation on veterinary medicines is in place.

With regard to Volume 6C – Guideline on the packaging information of VMPs authorised by the Community – the NtA group agreed to delete the guideline once it has been confirmed that all the information from the guideline is incorporated in the QRD.

Regarding Volume 6C – Proposals for a guideline on the change in classification for the supply of VMPs – the NtA group did not agree to have such a guideline as classification is not harmonised across the Member States. It was agreed that EMA will prepare a Q&A document covering only centralised products.