EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – quality, safety and efficacy

VETPHARM 339

VETERINARY PHARMACEUTICAL COMMITTEE
3 October 2014
20th meeting

SUMMARY RECORD

The 20th meeting of the Veterinary Pharmaceutical Committee took place on 3 October 2014 in Brussels. The meeting was chaired by Stefano Soro, Head of Unit SANCO D6, Medicinal products – quality, safety and efficacy.

AGENDA

- The draft agenda of the 20th meeting (VETPHARM 333) was adopted with no additional items under A.O.B.
- Stefano Soro clarified that for the agenda points related to the legislative proposals, the Commission will only answer to clarification questions as the proposals will be discussed on the 9 (veterinary medicinal products) and 10 October (medicated feed) at Council level within the working party of veterinary experts (Animal Health).

1. LEGISLATIVE ISSUES

1. REVISION OF THE LEGISLATION ON VETERINARY MEDICINAL PRODUCTS (VETPHARM 334)

   a) Presentation on the Impact Assessment report supporting the revision of the framework on veterinary medicinal products;

   b) Presentation on the proposals for a Regulation of the European Parliament and the Council on veterinary medicinal products and Proposal for a Regulation of the European Parliament and the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

c) Presentation of the proposal for a Regulation of the European Parliament and the Council on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC.

Clarification's requests were made by the Member States in relation to:

→ Recital 31, Commission clarified that it was a standard recital regarding the precautionary principle for risk assessment and risk management.

→ The costs associated with enforcement activities stemming from the proposal

→ AMR: MS highlighted the fact that the preventive use of antimicrobials will not be possible anymore according to the proposal on medicated feed while such a ban is not foreseen in the proposal revising the veterinary medicinal products.

→ Definition of medicated feed: MS communicated that the new definition raises some concerns in their opinion. To be discussed in the Council.

→ "Premixes" and the fact that the terminology in not used anymore in both proposals. Commission clarified that "premixes" are covered by the definition of veterinary medicinal product.

2. ANTIMICROBIAL RESISTANCE (AMR) (VETPHARM 336)

Update on state of play of Action Plan on antimicrobial resistance and discussion of draft Commission staff working document on guidelines for prudent use of antimicrobials in veterinary medicine.

→ A MS asked whether and how the expected benefits related to the new provisions related to antimicrobial resistance (AMR) were measured. The Commission explained that all available data had been used to assess the impacts of the new provisions but that nevertheless the issue remains complex as there is a lack of data.

3. MAXIMUM RESIDUE LIMITS (VETPHARM 335)

d) Presentation by the Commission of the forthcoming report from the Commission to the Parliament and Council on the application of Regulation (EC) 470/2009 of the European Parliament and of the Council;

e) Notice on forthcoming work leading to the preparation of the Implementing and Delegated acts from Regulation (EC) 470/2009.

4. INTERNATIONAL COOPERATION ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH) (VETPHARM 337)

→ Commission's presentation on the adoption process of VICH documents and indication of the steps where MS may be consulted

5. POLLUTION OF WATER BY PHARMACEUTICAL SUBSTANCES (VETPHARM 338)

Feedback from the EU workshop on the development of a strategic approach to pollution of water by pharmaceutical substances that took place in Brussels on 11 September 2014 and next steps to be expected in the course of 2014 and 2015.

Next committee meeting: A Standing Committee is scheduled for 20 October at the request of Germany concerning Maximum Residue Limits of pharmacological active substances and in particular the draft Commission Regulation amending Regulation (EU) No 37/2010 regarding lasalocid.