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Consumer goods
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VETERINARY PHARMACEUTICAL COMMITTEE
18th Meeting
20 March 2007

Meeting Report

The Veterinary Pharmaceutical Committee held its 18th meeting on 20 March 2007 in Brussels. The meeting was chaired by Martin Terberger, Head of Unit of ENTR/F/2, Pharmaceuticals.

This meeting report intends to provide a brief summary of the outcome on the different topics on the agenda. It will be complemented by the publication of a summary record of the meeting.

- **Better regulation of pharmaceuticals: revision of the Variations Regulations**

  The Commission representative debriefed the Committee about the Consultation paper, and comments received. The Committee generally supported the initiative. Members identified some relevant issues to be taken in consideration at next phases by the Commission. A public consultation will take place in 2007.

- **Transposition of Community legislation by the Member States**

  The Commission representative provided an update on the transposition of Directive 2004/28/EC and reminded the Committee that Member States must notify the Commission of their possible decision to provide for the granting of national exemptions in accordance with Commission Directive 2006/130/EC by 31 March 2007.

- **Implementation of Article 82 of Directive 2001/82/EC**

  The Committee endorsed the "Recommendations on the Implementation of Article 82 of Directive 2001/82/EC, as amended by Directive 2004/28/EC for the Official Control Authority Batch Release". The Pharmaceuticals unit will publish the recommendation, including its annexes, on its website. The progress on the implementation of Article 82 based on these recommendations will be reviewed after one year.

- **Implementation of Article 81 of Directive 2001/82/EC**

  The Committee endorsed the revised procedures and guidelines. EDQM will publish the documents on its website.

- **Nosodes and sarcodes**

The Commission representative presented the survey conducted among Member States and the opinion of the CVMP on the classification of nosodes and sarcodes, and provided an orientation on the possible classification of these products within the pharmaceutical framework.

- **Task Force on medicines availability**

The Commission presented the Report of the Task Force set up by the Heads of Medicines Agencies and outlined particular recommendations. The Chair took note of points raised by Members of the Committee and agreed to come back to the issue once the action plan is available.

- **"Cascade for bees"**

The Chair updated the Committee on the discussion on whether recourse to the "cascade " system is open to all animal species provided that the substance has been included in Annexes I-III of Regulation (EEC) No 2377/90. The Member States authorities which contributed to a questionnaire prepared by the Commission concerning the "cascade for bees" seem to be of the opinion that the "cascade" provision applies to all food-producing species, including bees, which are a minor species. A position of the Commission services will be communicated to the Committee once it is finalised.

- **Regulation of medicated feedingstuffs**

The DG SANCO representative summarised the Commission's position on the classification of medicated feedingstuffs as feed, based on existing Community legislation. Several Members questioned this interpretation because they considered medicated feedingstuffs as a veterinary medicinal product and suggested a review of Directive 90/167/EC. DG SANCO, as responsible Commission service for feed legislation, will be following these issues.

- **Revision of Annex I to Directive 2001/82/EC**

The Committee generally supported the draft revision of Annex I. The Chair noted the comments raised in the meeting and invited the Member States to further comment on several issues identified during the meeting.

- **International aspects**

The Commission informed the Committee on different activities ongoing at international level, as follows:

  - **Mutual Recognition Agreements (MRA) – Good Manufacturing Practice (GMP) Annex:** The Commission representative proposed to the Member States a way forward towards inclusion of new Member States under the MRAs GMP Annex.
  - **International Cooperation on Harmonisation for Veterinary Medicinal Products (VICH):** The Committee was updated on the state of play of the different topics stemming from the Steering Committee meetings of 2006 and 2007. The next Steering Committee meeting will be held on 17-18 October 2007.
  - **Codex Alimentarius – Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF):** The 17th meeting of CCRVDF will take place on 3-7 September 2007 in Colorado, USA. The preparatory meeting of the Council Codex working party will be held on 19 July 2007 in Brussels.

- **Better regulation – relevant in the context of Directive 2001/82/EC**

The UK delegation gave a presentation on the better regulation/simplification exercise in the UK and suggested that Member States and Commission give further focus on this veterinary issue.