EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods

Pharmaceuticals

VETPHARM 315

VETERINARY PHARMACEUTICAL COMMITTEE

DRAFT SUMMARY RECORD OF THE 18th MEETING

20th March 2007

OPENING

Mr. Martin Terberger, Head of Unit, along with Ms Irene Sacristán Sánchez, of the Pharmaceuticals Unit of DG Enterprise and Industry, opened and co-chaired the meeting.

1. AGENDA AND MINUTES

The Draft agenda of the 18th meeting (VETPHARM 302) was adopted.

The minutes of the 17th meeting were adopted by taking into account an amendment to point 4.1 a) concerning draft Commission Regulation establishing a list of substances essential for the treatment of horses (Article 10(3) of Directive 2001/82/EC).

2. IMPLEMENTATION OF PROVISIONS ON BATCH RELEASE

a) Implementation of Article 82 of Directive 2001/82/EC, as amended (Official Control Authority Batch Release - OCABR)

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.

b) Implementation of Article 81 of Directive 2001/82/EC, as amended (Official Batch Protocol Review OBPR)

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

3. LEGISLATIVE ISSUES

a) Better Regulation of Pharmaceuticals: Revision of the Variations Regulations

The Commission representative debriefed the Committee about the Consultation paper on the revision of Commission Regulations (EC) No 1084/2003 and 1085/2003 ("the Variations Regulations"), and comments received. This initiative is a major contribution of the Commission to the "Better Regulation" policy in the specific field of pharmaceuticals.

The Committee generally supported the initiative. At more particular level, it was pointed out that the veterinary and human medicinal industries basically share same concerns with regard to the Revision. The following specific issues to be taken in consideration at next phases by the Commission were tabled by Members of the Committee:

Firstly, caution was expressed on the consequences that the Revision may have on the work of Member States' competent authorities, in terms of workload between various departments and allocation of resources.

Secondly, it was pointed out that clear rules are needed for the application of the Key item 2 (ICH Q8-Q9-Q10). Although ICH Q8-Q9-Q10 apply to medicinal products for human use only, the related concepts are expected to be useful in the context of veterinary medicinal products.

Thirdly, as to the Key item 3 concerning "Do and tell" procedure, a need for guidance on practical control of the procedure was expressed. The Chair invited the Member States to assist the Commission services in this exercise.

The Chair closed this point by mentioning that a public consultation on the revision will take place in 2007.

b) Revision of Annex I to Directive 2001/82/EC

The Commission representative gave an update on the revision of Annex I of Directive 2001/82/EC. The Committee generally supported the draft revision of Annex I and discussed several outstanding major points.

The Chair noted the comments raised in the meeting and invited the Member States to further comment on the issues identified during the meeting. It was agreed that the dead-line for such comments is 20 April 2007.

c) Regulation of medicated feedingstuffs

A DG ENTR representative summarised the historical background of this issue in the Veterinary Pharmaceutical Committee (2005 and 2006) and introduced the latest request for discussion from the French and German authorities. A DG SANCO representative summarised the Commission's position on the classification of medicated feedingstuffs as feed, based on existing Community legislation (Regulation (EC) No 178/2002; Regulation (EC) No 183/2005; Directive 90/167/EEC). According to this interpretation, a medicated feedingstuff as such (final product ready prepared for marketing and intended to be fed to animals) falls within the definition of "feed" laid down by Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Community legislation concerning animal feed, and in particular Regulation (EC) No 178/2002, thus applies to medicated

feedingstuffs, without prejudice to the provisions of Directive 90/167/EEC, including Regulation (EC) No 183/2005 laying down requirements for feed hygiene.

Several Members questioned this interpretation because they considered medicated feedingstuffs as a veterinary medicinal product and suggested a review of Directive 90/167/EEC. DG SANCO, as responsible Commission service for feed and food legislation, will be following these issues.

d) 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. The Chair stressed the importance of the full implementation of EC legislation by the Member States.

4. AVAILABILITY OF VETERINARY MEDICINES

a) Task Force on Medicines Availability

The Commission presented the Report of the Task Force set up by the Heads of Medicines Agencies. Generally, the report provides a comprehensive overview of the situation of veterinary medicinal products in the EU identifying that there is no need for new legislative tools. Particular short-, medium- and long-term recommendations were outlined. 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.

b) "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 that 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. Having addressed the issue to the Commission's Legal Service, the position of the Commission services will be communicated to the Committee once it is finalised.

5. 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. On the basis of the information received, the Chair concluded that it was not possible to take a position on the classification which would apply to all nosodes and sarcodes. When such products fulfil the definition of a medicinal product under Directive 2001/82/EC, they will be subject to the pharmaceuticals legislation. Moreover, if the definition of homeopathic medicinal product and the requirements of Directive 2001/82/EC (in particular as regards dilution) are met, the simplified registration procedure of that Directive will be applicable. It did not, however, seem possible to completely rule out that some of these products may not fulfil the definition of medicinal product. In such cases, the Community pharmaceuticals legislation will not apply although other Community legislation may be applicable.

6. INTERNATIONAL ASPECTS

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

a) Mutual Recognition Agreements (MRA) – Good Manufacturing Practice (GMP) Annex

A discussion took place on questions raised in the context of the MRAs with different partners concerning the inclusion of the new Member States under the Sectoral Annexes on GMP.

The Commission representative explained that certain MRA partners had raised questions concerning the equivalency of new Member States with their systems and asked the Commission to release the pre-MRA audit reports and/ or consider equivalency audits in the new Member States. However, DG Enterprise and Industry has taken a restrictive position on this question as the EU Pre-MRA audit was initially designed to be a consultancy programme to Member States and audit reports should from its intention remain confidential unless Member States wish to exchange them by themselves. As Member States have changed structures, systems and/ or legislation on the basis of the reports, in addition the past reports do not necessarily reflect the current situation.

At a proposal of the Commission representative, there was general consent from the Member States concerned for the reports issued by Health Canada following their MRA audits to be exchanged with other MRA partners. The exchange of reports will be initiated following agreement with the Member State concerned on a case-by-case basis. The Commission services will not initiate the exchange of other reports than the Canadian ones, unless otherwise agreed with the Member States concerned.

b) International Cooperation on Harmonisation for Veterinary Medicinal Products (VICH):

The Committee was updated on the state of play of the different topics under discussion in VICH Expert Working Group and stemming from the VICH Steering Committee meetings of May 2006 (EU) and of January 2007 (USA). The next Steering Committee meeting will be held on 17-18 October 2007 in Japan.

c) Codex Alimentarius – Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF)

The Commission representative informed the Committee of the current work on preparation of European Community comments on different Codex Circular Letters (CL-2006-35-RVDF; CL-2006-38-TF AMR) to be discussed at the 17th meeting of CCRVDF that 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 (the date is to be confirmed).

7. BETTER REGULATION/SIMPLIFICATION

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 to this veterinary issue.

8. ANY OTHER BUSINESS

The Chair informed the Committee about the recent Commission legislative proposals concerning the “New Approach”.