EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single market, regulatory environment, industries under vertical legislation
Pharmaceuticals and cosmetics

VETPHARM 200

VETERINARY PHARMACEUTICAL COMMITTEE
DRAFT SUMMARY RECORD OF THE 10th MEETING
25 October 2000

1. AGENDA

The draft agenda of the 10th meeting (VETPHARM 188-rev.1) was adopted without amendment.

Austria requested information on ways to deal with substances that have no published MRLs but only a positive CVMP opinion (to be dealt with under item 9).

The chairman introduced the new veterinary team: Annika WENNBERG from Sweden, Jean WEISSENBERGER from France and Karin KRAUSS from Germany are now working on the veterinary sector for DG ENTERPRISE unit F4. Niels BEHRNDT, a new lawyer from Germany, replaces Fabian LUTZ.

He also informed the meeting that the EMEA Management Board met on 23 October 2000. The Board appointed Thomas LÖNNGREN from Sweden as the new Executive Director. This follows the nomination of Fernand Sauer as Director for public health policy in DG SANCO, with effect from 1 December 2000.

The chairman announced that a joint meeting of the Pharmaceutical and the Veterinary Pharmaceutical Committees on the subject of the "Review 2001" will take place on 27 November 2000. The invitation and documents will soon be transmitted.

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2. 9th MEETING SUMMARY RECORD

The summary record of the 9th meeting on 24 May 2000 (VETPHARM 187) was adopted with a correction requested by Ireland. This concerned a quotation on the topic of "horse problem" (point 7 of the draft summary). Ireland had stressed that Decision 2000/68 provided an adequate basis for the availability of veterinary medicinal products for horses. Germany also underlined this fact and again referred to the preamble of Decision 2000/68.

3. INTERPRETATION/IMPLEMENTATION OF LEGISLATION

3.1 Extension of provisional MRLs

The EMEA/CVMP had asked the Commission whether a provisional MRL, set for a "new" active substance according to article 4 paragraph 2 of Council Regulation 2377/90 could be extended. The Commission position was presented (vetpharm 189 add) and discussed. The Committee agreed on the general principle that to extend provisional MRLs for a new substance is not generally compatible with the exceptional character of such MRLS, notwithstanding the discretionary power to judge each single case on its own merits.

3.2 Batch release

Concerns have been raised that official control authority batch release (OCRAB) procedures used to implement Article 3 § 3 of Council directive 90/677 vary widely between the MS from a purely "administrative" procedure to a full re-testing of all technical specifications applicable to the immunological product concerned. This situation may jeopardise the mutual recognition principle.

The EDQM secretariat (European Directorate for the Quality of Medicines) presented its work, in collaboration with the veterinary OMCLs (Official Medicine Control laboratories) on a harmonised procedure between MS who have national OCRAB. The EDQM secretariat stressed that similar difficulties have been encountered in the past for human immunologicals, but that MS had come to an agreement to all apply similar procedures. The general proposal would be to base OCRAB on a documentation review process (QA/QC) plus re-testing on batches according to common specifications developed in the framework of the EDQM/OMCL network.

The Commission representative pointed out that OCRAB could not be based solely on documentation review (QA/QC) as article 3 § 3 clearly refers to "samples from the bulk and/or finished products for examination by a … laboratory". Having recalled the "historical background of this official batch release provision", the Commission reminded the Committee that OCRAB is a "may provision" for MS, but subject to mutual recognition. The need to develop and agree on common procedures was stressed if MS were to justify further this additional control to all those already in place for ensuring the quality of products put on the market. In addition, the Commission representative expressed concerns on the fact that MS could agree to common procedures for immunologicals for human use while this seemed impossible in the veterinary sector up to now.

Some MS reported having no OCRAB system in place, while several delegations and the EDQM considered that the OCRAB process has brought a real added value to improve the quality of immunologicals.

The EMEA representative also pointed out the need to put in place, as appropriate, an official batch release system for immunologicals approved according to the centralised procedure.

While no MS could comment on the EDQM paper at this stage, several delegations already gave their support to the principles presented. It was decided that all MS and the Commission would send their comments on the draft paper to the EDQM Secretariat by the end of November.

3.3 Bibliographic applications

Following a preliminary discussion during the 9th meeting (see item 10.4 of the summary record of the 9th veterinary pharmaceutical committee meeting), the Commission services informed the Committee that, as provided for in the Annex of Directive 81/852/EEC (Title I part 3 chapter 5 point 5.2 and Title II, part 7, chapter E, §2) there is no requirement for ecotoxicity documentation for applications submitted under article 5(10) a) ii) of Directive 81/851/EEC.

The Commission representative informed the Committee that comparable clarifications had been requested due to ongoing discussion in VMRFG. He recalled that ecotoxicity data were not required for any of the provisions of article 5(10) a), namely i), ii) or iii). The Commission will further evaluate the links with article 5(10) b).
For applications with the consent of the "owner company" (i) or generics (iii), the competent authority should already be in possession of those data. For purely bibliographic application however, such data would not necessarily be available to the competent authorities. The Commission therefore invited the MS, through the VMRFG in particular, to indicate whether they would see a need/justification for it.

Clarification was given, as a result of a request from a company, on the necessity for the legal basis for an application for a marketing authorisation for a veterinary medicinal product to be the same in all MS where the application is submitted. With regard to the continued possibility to submit bibliographical applications through a national procedure, the Commission Communication C 229/98 gives in principle such provisions. However, this approach should be accepted very cautiously by MS.

3.4 Data Protection

FEDESA raised concerns about the implementation of data protection provisions (articles 5.8 and 5.10 of Directive 81/851/EEC) and the possible need for review. The Commission reminded the MS to apply the rules in force on data protection for documentation to support applications for marketing authorisations. FEDESA has submitted to the Commission a number of comments and requests concerning a change to the data protection rules. In the process of the review of the pharmaceutical legislation the Commission may introduce changes related to data protection.

3.5 Electronic mail addresses in the package leaflet

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has sent a letter to the Commission requesting the optional possibility of including in the package leaflet the email address, in addition to the mailing address, of the marketing authorisation holder, of the manufacturer and of the local distributor. This question was discussed during the 50th Pharmaceutical Committee (20-21 September 2000) and a favourable opinion to allow inclusion of electronic mail addresses which clearly excluded all promotional links was given to the EFPIA request. In coherence with the approach for human medicinal products a similar approach should be taken for veterinary medicinal products. The Committee agreed.

Portugal recalled its opposition to the decision regarding the logo of the distributors of human medicinal products, and noted that it was waiting for the ruling of the court of justice on this matter.

3.6 Borderline medicinal products/biocides

Since the previous discussion on this subject (see item 3.2 of the summary report of the 9th meeting), no further comments had been received regarding veterinary medicinal products. A proposal to amend Annex V of the "Biocide Directive" is under consideration. The issue has also been submitted to the "Biocide Committee" on 11 October 2000. After a short discussion MS were asked again to give comments to the Commission by 15 November 2000.

3.7 Veterinary medicinal products for horses in the absence of MRLs

This item was discussed in length in association with item 6 "Availability of veterinary medicinal products".

Following previous discussion in the Committee and a request for clarification from the CVMP, the Commission representative presented to the Committee the opinions of the Legal service on the status of horses and related questions for the use and marketing authorisations of veterinary medicinal products.
In summary:

- the provisions of both Directive 81/851/EEC and Regulation 2377/90 apply to "food-producing species" (and not to individual animals).

- Decision 2000/68 does not currently permit a vet to treat a horse with a substance, which is not included in Annexes I, II or III of Regulation 2377/90

- Competent authorities should refuse to grant marketing authorisations for a veterinary medicinal product intended for administration to a food-producing animal as indicated above and whose file does not contain the data required for evaluating the safety of residues in foodstuffs.

Responding to several MS (IRL, supported by UK and F) who argued on the basis of the political discussion in the Council in 1999, the Commission representative recalled that any proposal for a solution concerning the current general legislative framework would need also to associate the European Parliament, and that no such legal change could be foreseeable before several years. New provisions cannot be expected to be in force before 2004 or 2005 at the earliest.
Short terms solution can only be found in the present framework and MS were invited to provide any possible contributions in this context. The possibility of some "administrative MRLs" was mentioned and will be further evaluated if appropriate and possible.

In conclusion, the Commission emphasised the fact that marketing authorisations for veterinary medicines for "non food producing" animals of a species are not possible.

4. Veterinary Medicinal Products – Legislative Issues

4.1 Review – update

The Chairman informed MS that the independent audit of the current pharmaceutical legislation was about to be finalised soon, and that it will be made public immediately thereafter (published on the web site).

As already stated in the previous meeting, the chairman recalled that a special joint human and veterinary pharmaceutical committee would be held on 27 November to discuss the need for a review 2001. A general working paper from the Commission would be communicated before the meeting.

4.2 Transmissible Spongiform Encephalopathy (TSE)

The Commission representative updated the Committee on the revision of the Note for Guidance CPMP/BWP/1230/98 rev.1 (annex to Directive 75/318/EEC) adopted in October concerning wool and milk derivatives. The latter are excluded from the scope of the NFG provided they are from healthy ruminants. This prerequisite does not entail the delivery of a certificate of suitability of the European Pharmacopoeia. The EMEA representative informed the Committee that the chairman of the BWP will be invited to the next CVMP meeting in November to explain the position taken by the CPMP.

4.3 Variations Regulations (541/95 and 542/95): Possible amendments – for preliminary discussion

The Commission representative introduced the working document prepared by Comission services on the following subjects: creation of a type 0 variation (“tell and do”); possible deletion of the type I variation procedure for conventional medicinal products; the specific situation of biological and biotechnological medicinal products; classification of some annex II examples as type II variations; suppression of type I variations treated as type II variations (biologics); implementation in case of urgency; a simple application when a variation impacts on several medicinal products belonging to the same Marketing Authorisation Holder; relationship between type II variations and 5-year-renewal.

Participants agreed upon the orientations defined by Commission services. They, however, drew attention to the relationship between changes to the MA in case of type 0 variations and the particular situation as a result of pharmacovigilance events. It was noted that discussion of this matter will continue at the next meeting of The Notice to Applicants Working Party (human use and veterinarian products).

4.4 Codification - Update

The Chairman informed MS that the revised Commission proposal for the Codification of the veterinary legislative package had just been adopted by the Commission and had been sent to the Council and Parliament.
It was stated again that the codification exercise was not intended to introduce any changes of substance to the legislation. A rapid finalisation of the codification process would provide a significant benefit to the review process.

5. Marketing Authorisation Procedures

5.1 Centralised procedure – Progress on applications for marketing authorisations and MRL establishment (EMEA Status report)

The EMEA representative informed MS that the centralised procedure follows its usual rhythm. He reported on the first case of suspension of a centrally authorised veterinary medicinal product (Econor), in relation with serious adverse reactions reported under the pharmacovigilance system.

Some MS requested further clarification on the legal process. The Commission informed the Committee that the formal community procedure concerning the suspension of the marketing authorisation was ongoing without delays. However, in view of the situation, MS were reminded on their possibility, provided for in article 40 of Council Regulation n° 2309/93, to adopt immediate conservative measures by suspending the use of the product on their territory.

5.2 Mutual recognition procedure – Report from the chairman of the VMRFG (FR)

The Chairman of the VMRFG gave a comprehensive report on the mutual recognition procedure, including results of a joint FEDESA/VMRFG survey of the system (VETPHARM 198).

6. Availability of Veterinary Medicinal Products
Update – for information/discussion

See item 3.7

The Chairman informed MS that the Commission would shortly adopt a Communication on this matter in which it would address the possible lines to pursue.

The French representative informed the Committee that the Presidency was envisaging the possibility of having a CVO meeting addressing the availability of veterinary medicinal products before the end of 2000.

The EMEA representative reported on the suspension of the work of the task force on this subject waiting for further progress. He also reported on the CVMP position paper that proposes some possibilities for extrapolating MRLs.

7. Information Society in the Pharmaceutical Sector

The Commission representative reported on the Telematic Steering Committee meetings in Lisbon (12 June 2000) and St Denis (11 October 2000). He updated members on the four groups that had been formed.

8. International Issues

8.1 VICH – Update (VETPHARM 197)

The EMEA representative, in his capacity as EU co-ordinator for VICH, presented on the basis of the tabled documents the proceeding of several VICH guidelines (e.g. Quality, Pharmacovigilance, Safety & Task Force on Microbial Safety). He also invited the participants to make full use of the information available at the VICH webside (http://vich.eudra.org).

8.2 (Mutual) Recognition Agreements (MRA) and Protocols to the Europe Agreements on Conformity Assessment and Acceptances (PECAs) Update

USA: The 3-year transitional period is well underway, and the EU assessment of the system is expected to be completed on time. There are some differences in understanding between the EU and US, particularly with the obligation to assess all Member States within this timeframe.

Canada: There are some problems with GMP recognition of the Italian system which are under review. The Commission has asked that a team of inspectors be assembled to address these. The EU team has confirmed the findings of the Canadians. Therefore it is imperative that the Commission takes action with the Italian Ministry of Health as soon as possible to avoid any escalation of these problems.

Switzerland: Ratification can be expected to take place in December 2000 or January 2001

Australia: The 2-year confidence building period is due to end on 1 January 2001. Based on the information and documentation the EMEA had recently received from NRA (National Registration Authority) and TGA (Therapeutic Goods Administration) it was possible, that the phase for veterinary medicinal products can not be completed in January. There is a need for further information regarding veterinary immunological products be-

cause due to the time limit it was not possible to assess equivalence of veterinary immunological inspections.

New Zealand: There is a 3-year confidence building period ending on 1 January 2002. Therefore it has currently a lower priority.

8.3 Enlargement – PERF – Update (VETPHARM 195)

MS were informed that additional funding for PERF II had been agreed in principle, thus allowing a programme to be developed. This could be expected to start in November 2000. The proposed programme for PERF II was based on the conclusions reached at the end of PERF I.

PECAs (Protocol of Europe Confirming Assessments Agreements) with Hungary and the Czech republic had been initialled. The 6-month preparatory work period is expected to begin in early 2001.

9. Any Other Business

Austria informed the Committee that they are in the process of reviewing all marketing authorisations to ensure, in line with community legislation, that only substances listed in annexes I, II or III of Council regulation N° 2377/90 are authorised for use in food producing animals. However some substances that have been subject to CVMP evaluation were not yet included in the annexes of Council Regulation 2377/90. They therefore requested clarification.

The Commission representative informed the Committee that a significant number of "pending" MRLs had just been adopted or could reasonably be expected to be agreed soon. As regarding a class of substances, he also stated that recent political positions did not give a favourable signal in support of further possible Commission proposals for the concerned substances.