



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single market: management & legislation for consumer goods
Pharmaceuticals: regulatory framework and market authorisations

VETPHARM 213

**VETERINARY PHARMACEUTICAL
COMMITTEE
FINAL SUMMARY RECORD OF THE
11th MEETING
1 June 2001**

1. AGENDA

The draft agenda of the 11th meeting (VETPHARM 201) was adopted without amendment. Following requests from Finland, the United Kingdom and Denmark, three additional items were added under point 10 (“Any other Business”).

2. 10th MEETING SUMMARY RECORD

The draft summary record of the 10th meeting on 25 October 2000 (VETPHARM 200) was adopted with a correction concerning line 4 of the first chapter of item 3.3 on page 3 (“Title I part 3 chapter 5 point 5.2”).

The draft summary record of the joint meeting on the Review on 27 November 2000 was adopted without amendment.

3. INTERPRETATION/IMPLEMENTATION OF LEGISLATION

3.1 Information on pending cases

The Commission representative updated the Committee on the progress in the following procedures:

- Cases T-344/00 and T-345/00, Ceva Santé animale and Pharmacia Upjohn against Commission: the two cases concerned actions against the Commission for failure to act

on the basis of Article 232 of the EC Treaty. The two cases concerned the request for inclusion in Annex II of regulation 2377/90 of progesterone substance.

- Case C-248/99, appeal against case T-112/97, Monsanto against Commission: the conclusions of the Advocate General were briefly presented.

- Case T-382/00, Monsanto against Council: Monsanto has launched an action for annulment against the Council decision, which refused the adoption of the regulation including BST in regulation 2377/90.

3.2 Bibliographic applications

Following discussions held in the previous veterinary pharmaceutical meeting, the Commission informed the Committee that exemption from ecotoxicity requirements under article 5(10) a) ii of Directive 81/851/EEC was also applicable under Article 5(10)b).

The Commission recalled its invitation to the MS to indicate whether they would see a need/ justification to amend these current provisions in the framework of a forthcoming revision exercise of the annex to Directive 81/852/EEC.

3.3 Package inserts – mentioning of local representatives

Pursuant to a request from the interested party FEDESA, the Committee discussed the issue of the appearance of names and addresses of local representatives of all Member States and the EFTA countries Iceland and Norway in package inserts for centrally authorised veterinary medicinal products. The Member States representatives which expressed views (BE, DK, FI, IT and UK) were in favour of a less strict approach for veterinary medicinal products, but maintained the view that it is necessary for the users of these products to have recourse to an information service in the national language. DK requested this issue to be addressed also for medicinal products for human use. The Commission services agreed to draft a form of words to replace the current wording in the Guideline on the packaging information for centrally authorised (human and veterinary) medicinal products to be further discussed and agreed.

3.4 Rationalisation of “Blue Box Requirements”

In the light of experience and following comments from industry, the EMEA has proposed certain changes to the Annex of the Guideline on packaging information for veterinary medicinal products authorised by the Community. The MS were encouraged to reduce the requirements as much as possible and to review the changes proposed. The deadline for receipt of the comments from MS was set for 30 September 2001.

3.5 Disclosure of confidential information (GMO)

The Commission representative informed the Committee about problems which had occurred with regard to the disclosure by the national bodies set up in accordance with Directive 90/220/EEC of information relating to an application for a veterinary medicinal product containing or consisting of genetically modified organisms. Based on Article 28 of Regulation 2309/93, the EMEA had submitted a number of documents to the UK Food Standards Agency relating to an application for a marketing authorisation of a vaccine. The UK authority intended to publish the applicant's name, the name of the product and its intended use. The applicant, supported by the EMEA, objected to such disclosure of information while the evaluation at the EMEA was still in process. On request of DG Enterprise, the Commission's Legal Service gave an opinion on 23 March 2001 confirming the confidentiality of the documents. Furthermore, the Commission representative informed that Directive 90/220/EEC will be repealed with effect of 17 October 2002 by Directive 2001/18/EC (OJ L 106 of 17.4.2001, p.1) and that a new regulation regarding public access to EP, Council and Commission documents has been adopted recently (Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001, OJ L 145 of 31.5.2001, p. 43).

In the discussion the EMEA informed the Committee that other Member States had contacted the Agency on the same issue. Denmark asked to reflect upon the impact of the recently adopted legal acts on the question at stake.

It was agreed that as a first step, the Commission would send a letter regarding the disclosure of information under the current legal situation to all Member States and the EMEA. At a later stage, the Commission will prepare a broader document on the general question of transparency in the evaluation procedures, considering the new legal acts (Directive 2001/18/EC and Regulation 1049/2001).

3.6 Information on Volume 9 (Pharmacovigilance) and other publications

The Commission representative informed the Committee about the finalisation of Volume 9 (Pharmacovigilance). The guideline covers both human and veterinary pharmacovigilance. The document is at the moment undergoing formatting and will probably be published in English on CD-ROM and on the website in June or July 2001.

Volume 6 (Notice to Applicants) probably will be published in English on CD-ROM and on the website. It is not planned to print a paper version. Volume 7 (Quality, safety and efficacy guidelines) will be probably edited in English on CD-ROM and on the website in June 2002. Volume 8 (Notice to Applicants and Note for guidance) will probably be published end of 2001 first in English on CD-ROM, on the website and in a printed version.

The chairman added that due to budget problems more and more publications will be published only on CD-ROM (with an automatic update function) and on the website. He also emphasised that, though Member States have the right to insist on translations, there will have to be a discussion about the "language problem" because the budget will not be available to finance translations in every future language.

3.7 Implementation of guidelines

The Commission presented a letter from FEDESA concerning different dates of implementation of a VICH guideline between the CVMP and certain Member States. The Commission stressed the need for a harmonised date of implementation, and informed the Committee that similar requests had already been addressed to the EMEA in order to avoid comparable problems in the future. The EMEA stated that since the initiation of VICH, all guidelines adopted within this framework to date had achieved a harmonised implementation date in the EU with one exception, that being phase I of environmental safety. This guideline was implemented in all Member States and CVMP as of 1 June 2001.

Except when already stated in the legislation, the Committee agreed on the need for developing, in co-ordination with the CVMP and the VMRFG, a more general position on the date and precise scope of application of any guideline (new substance, new product, new application...).

4. Veterinary Medicinal Products – Legislative Issues

4.1 Transmissible Spongiform Encephalopathy (TSE)

Member States were asked about the state of play. The detailed “tour de table” showed that there were more or less similar situations in all MS: contact with companies, listing of products, validation processes using the HEVRA decision tree, priority to veterinary products for ruminants and little chance of meeting the deadline. MS were asked to send their written summaries to the Commission before the end of July.

One of the main points of the discussion was the action to be taken with respect to VMPs for which the companies had not applied for an assessment of the TSE-status. The Commission representative stressed the fact that 90 % of the directive is well known by all stakeholders since the early nineties and that companies had enough time to be prepared. According to the directive the suspension of authorisation is possible. Nevertheless he advised to act with a certain flexibility, in order to avoid further availability problems.

The EMEA representative also gave a comprehensive report on the status of the 10 concerned centrally authorised VMPs: for the two products requiring a type I variation EDQM certificates were awaited. The other products have been evaluated according to the risk assessment procedure agreed to by CVMP leading to type II variations.

4.2 Codification – update

The chairman explained the state of play of the legislative procedures of the human and the veterinary codification. If there were no unexpected objections, the two texts could be passed by the Council in July 2001.

4.3 Review – update

The chairman announced that the review of the pharmaceutical legislation would be dealt in a special joint meeting of the human and veterinary pharmaceutical committee which

would be held on 5 July 2001 instead of 15 June 2001. Working documents in English and French would be communicated before the meeting.

5. Marketing Authorisation Procedures

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

The EMEA representative provided a verbal status report on the number of centralised applications (including variations and extensions) and MRL applications (including extensions) received in 2001. The EMEA noted also the outcome of the EMEA/FEDESA questionnaire, which in general indicated a high degree of satisfaction with the centralised procedure.

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

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.

5.3. Notice to Applicants

The Commission services informed the Committee of the latest accomplishments of the NTA Working Party. Revised versions of chapters 2, 4 and 7 have been published on the web site of DG Enterprise - pharmaceuticals and the publication of chapter 1 is foreseen in June. The Committee was also informed about the ongoing work aiming to revise the Regulations on variations.

6. Availability of Veterinary Medicinal Products

The Commission representative presented the Commission Communication to the Council and the European Parliament on the availability of veterinary medicinal products, and the outcome of the discussion on this issue in the European Parliament.

The work done by the CVMP on the extrapolation of Maximum Residue Limits and its position paper on this subject was outlined. The Agency representative presented further details on the issue.

The Commission also presented the main objective to be addressed in the Review of the pharmaceutical legislation: namely enhancing pharmaceuticals firms' interest in certain markets, and allowing the use, under conditions, of veterinary medicinal products not available in the Member State concerned, but authorised elsewhere in the Community.

A Member State representative recalled its opposition to the latter proposal and the support given previously by 3 other Member States. In these circumstances, the Commission services expressed concern on the discrepancy between the repeated calls from Member States to the Commission for solutions, and the subsequent rejections of such solutions.

At the request of a Member State representative, the Commission services reported that one possible solution to address the horse problem by establishing certain "administrative

MRLs" was no longer under consideration, having received as unfavourable opinion both from a legal and scientific point of view. All possible short term solutions had been explored without success as far as the pharmaceutical legislation was concerned.

7. Antimicrobial Resistance

An oral report regarding strategies for minimising antimicrobial resistance was given (the report is annexed in written form).

8. Telematics

The Commission representative introduced this subject briefly. As agreed during the Telematic Steering Committee in Ispra in December 2000, a strategy plan and an implementation plan has been prepared. The implementation plan specifies the implementation priorities, by reference to projects currently in place or to be developed (EudraNet, Euro PHARM Database, Eudra Vigilance and E-Submissions), and for each of them it includes the objectives, the foreseen timetable, the projects currently involved, the institution responsible for the completion and the budget or financial implications. The implementation plan as well as the strategy paper will be discussed and probably adopted in Uppsala on 12 June 2001, during the next meeting of the Telematic Steering Committee.

9. International Issues

9.1 VICH – Update (VETPHARM 197)

The EMEA representative reported on the progress of several VICH guidelines. The Steering Committee at its meeting end of June 2001 is expected to adopt guidelines on efficacy of anthelmintics, safety guidelines on reproduction and genotoxicity, and a pharmacovigilance guideline on the management of adverse event reports. It is foreseen that another safety guideline (carcinogenicity testing) and another pharmacovigilance guideline (processing of PSURs – Periodic Safety Update Reports), as well as a guideline on pre-authorisation testing in respect to antimicrobial resistance will be released for consultation. The guideline on environmental impact assessment phase II, which was also planned to be ready for release for consultation, has been delayed.

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

The Commission representative provided an update on the progress with respect to the various MRAs. The MRA with Japan does not concern the veterinary sector.

USA: The 3-year transition/confidence building period ending in November 2001 will probably be extended for 2 years. Progress is not as fast as foreseen. Significant delays have been encountered.

Canada: The transition/confidence building period, which was expected to be 18 months, has been extended indefinitely since July 2000.

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

Australia: The 2-year confidence building period for veterinary medicinal products is expected to end in June/July 2001.

New Zealand: There is a 3-year confidence building period ending on 1 January 2002.

There has been one PECA signed in February 2001 with the Czech Republic. The 6-month preparatory work period is expected to begin in September 2001.

9.3 Enlargement – PERF – Update

The EMEA representative informed the Committee that the contract for PERF II has now been signed. Due to the delay in the finalisation of the contract the time schedule for the programme has to be revised. The PERF II activities on veterinary medicines will not begin before September 2001. The record of the first meeting of the PERF II Task Force has been tabled during the meeting.

The representative of the Czech Republic informed the Committee that a Collaboration Agreement between Veterinary Drug Regulatory Institutions in the European Union Associated Countries (CAVDRI) has been signed on 8th June 2001. Copies of this agreement were tabled during the meeting.

10. Any Other Business

Finland raised the topic of environmental assessments of veterinary medicinal products. According to the Finnish Environment Institute (FEI) it should be possible to set country/region specific restrictions to the use of VMPs within the mutual recognition and the centralised procedure. The Commission stated that it is inherent in the system that a common SPC has to be adopted. Other strategies could enclose restrictions in the context of “Good Veterinary Practice” with e.g. information for certain regions or stricter national provisions. The Finnish representative intends to get more information and will probably raise this topic again.

The **United Kingdom** informed about a problem with the advertising of a centrally authorised VMP which was not in line with the SPC (according to a CVMP opinion). UK was asking for consistent actions in all Member States. The chairman promised to analyse the issue and provide a written comment.

Denmark was asking about the previously discussed amendment of the directive on biocides. The Commission representative answered that no comment on this directive had been sent by Member States. For the moment all work on this directive has been stopped.