



**VETERINARY PHARMACEUTICAL
COMMITTEE
SUMMARY RECORD OF THE
12th MEETING
11 December 2001**

1. AGENDA

The draft agenda of the 12th meeting (VETPHARM 212) was adopted without amendment. Following requests from France and Denmark, two additional items were added under point 9 (“Any other Business”).

2. SUMMARY RECORD

2.1 Draft summary record of the 11th meeting on 1st June 2001

The draft summary record of the 11th meeting on 1 June 2001 (VETPHARM 213) was adopted with the following addition to the first chapter of item 3.7 on page 4 proposed by the EMEA: “The EMEA stated that since the initiation of VICH, all guidelines adopted within the 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.”

**2.2 Draft summary record of the 2nd special joint meeting on the Review of the
Pharmaceutical Committee and the Veterinary Pharmaceutical Committee
on 5th July 2001**

The draft summary record of the joint meeting on the Review on 5 July 2001 (VETPHARM 214) was adopted without amendment.

3. INTERPRETATION/IMPLEMENTATION OF LEGISLATION

3.1 Information on pending cases

The first information concerned the MRLs for 5 hormonal substances the Standing Committee gave no favourable opinion to Commission proposals. Therefore the procedure has to continue in the Council. According to the outcome of a meeting on 10 December 2001 the regulation proposing MRLs for Altronegest, Flugestone acetate and Chlormad-

inone got a qualified majority. No solution was achieved for the substances Progesterone and Norgestomet. They will be subject to further meetings at the Council.

A presentation was given by the Commission representative on a case, which is before the ECJ following a request for a preliminary ruling (Astra-Zeneca case, C-223/01). This case refers to the conditions necessary for applying for an generic application in the context of human medicines, however it could also apply by analogy in the field of veterinary medicines since the conditions for the application of article 4(8)(a)(iii) of former directive 65/65/EC (now Article 10(1)(a)(iii) of Directive 2001/83/EC) and of article 5(10)(a)(iii) of former Directive 81/851/EC (now Article 13(1)(a)(iii) of Directive 2001/82/EC) are alike. An overview of the Commission's position was given, according to the line traced in the "Notice to applicants" Volume 2A:

- In case where a company applies for a marketing authorisation on the basis of a generic application, and states that the product for which marketing authorisation is sought to be essentially similar to a reference product which has been approved in the Community for the necessary period of time pursuant to the directive, it is necessary that the reference product "is marketed" at the time of the application for the generic medicinal product.
- Furthermore, it was highlighted that in this case the Commission took the approach also adopted in the context of the "review 2001", namely that the notion "is marketed" in Article 4(8)(a)(iii) of Directive 65/65/EC means that it is sufficient and necessary that the reference medicinal product is authorised and not necessarily effectively commercialised.

3.2 Imposition of a variation (Article 5.10(a) iii of Council Directive 81/851/EEC)

Based on letters from the Irish Medicines Board and from the European Commission (VETPHARM 215) the Commission representative stated that the concept of maintaining essential similarity in the domestic market and the harmonisation achieved through the mutual recognition procedure may in certain cases not be totally compatible. In this sense, harmonisation on the European level is one of the main goals of the Community pharmaceutical legislation. Article 19 of Directive 81/851/EEC may also be applied to achieve such harmonisation.

3.3 Application submitted under Article 5.10(a) ii of Council Directive 81/851/EEC

The correspondence between the Irish Medicines Board and the European Commission (VETPHARM 216) was tabled for information and transparency. In the case referred to an application for a marketing authorisation is to be viewed as a full application, the necessary documentation to support the application should cover all parts of the dossier and bio-equivalence studies are of no meaning in this regard.

3.4 Rationalisation of "Blue box requirements"

The Draft–Revision 1 of Notice to Applicants Volume 6 C "Guideline on the Packaging Information of Veterinary Medicinal Products by the Community" with an amended wording on the local representative has been sent by e-mail on 23 October 2001 asking for final comments until 1 December 2001. Member States comments will be discussed

during the next Notice to Applicants meeting and a final version will be published on the web.

3.5 Disclosure of confidential information (GMO)

The Commission representative reminded the context in which the issue of disclosure of confidential information was raised, namely during the assessment of an application of a veterinary medicinal product containing or consisting of a genetically modified organism (GMO). In this context, the issue that had been discussed consisted in whether and in how far national bodies may publish parts of the information received in the frame of the application for a marketing authorisation. The Commission representative insisted on the fact that the question of confidentiality could arise in any case including that kind of information and not only in the context of GMOs. She then made a short presentation of the main points of Regulation n° 1049/2001/EC regarding public access to documents:

- Access to documents should be granted by the European institutions not only to documents drawn up by them, but also to documents they have received.
- All agencies established by the institutions should apply the principles laid down in the Regulation – including the EMEA.
- Certain public and private interests should be protected by way of exceptions. The institutions should be entitled to protect their internal consultations and deliberations where necessary to safeguard their ability to carry out their tasks. In assessing the exceptions, the institutions should take account of the principles in Community legislation concerning the protection of personal data.
- All rules concerning access to documents held by the institutions should be in conformity with this Regulation – that means that rules included in the pharmaceutical directives on disclosure of confidential information should be in line with this regulation. At this stage, the Commission representative traced the limits between the scope of these directives, especially the transparency rules included in the “review 2001” on publicity of assessment reports, SmPCs etc, and the general transparency requirement provided for in this regulation.
- A two-stage administrative procedure is provided for in the regulation, with the additional possibility of court proceedings or complaints to the Ombudsman.
- Regarding more particularly documents in the Member States, where a Member State receives a request for a document in its possession, originating from an institution, the Member State shall consult with the institution concerned in order to take a decision that does not jeopardise the attainment of the objectives of the Regulation.
- A special procedure for the treatment of sensitive documents is foreseen – nevertheless no common criteria are being established for qualifying a document as “sensitive”.

After this presentation the Danish delegation repeated a request that had been expressed also in the pharmaceutical committee for human medicines: the Commission should produce a document tracing the limits between the transparency regulation and the specific directives in the field of pharmaceuticals and highlighting their respective scopes of application. The chairman promised that the pharmaceutical unit will draft a document as soon as possible and send it to the members of both committees.

3.6 Transmissible Spongiform Encephalopathy (TSE)

The EMEA representative gave a short report on the status of the concerned centrally authorised VMPs: where no EDQM certificates were provided, the HEVRA decision tree has been used for the evaluation. The procedures are expected to be finished in the next 2-3 months.

In the last meeting Member States has been asked to send their written summaries on the further implementation of the Directive 99/104/EC to the Commission before the end of July 2001. The Commission only received a few reports; the recently sent report from Ireland was tabled for information. Member States were again asked to send written reports. A short and comprehensive form would be accepted. The representative of the European Directorate for the Quality of Medicines (EDQM) stressed out that in cases where certificates are awaited they could be treated as priority provided the EDQM receives more information to speed up.

4. VETERINARY MEDICINAL PRODUCTS – LEGISLATIVE ISSUES

4.1 Codification and Review

The chairman informed the Committee about the publication of the two codifying Directives 2001/82/EC and 2001/83/EC on the Community Codes relating to medicinal products for veterinary and human use in Official Journal no. L 311 of 28 November 2001. They will come into force on 18 December 2002. From this date on references have to be made to these new directives. The codified texts has neither to be transposed into national law nor does they change Member States obligation to meet the time limits for transpositions set in Annex 2/B.

Based on the codification the final proposals concerning the review (COM(2001) 404 final) will be published in the Official Journal maybe in December or January. A first reading in the European Parliament (EP) is foreseen before July 2002 followed by a “common position” during the Spanish or Danish Presidency. All the procedure has to follow the new provisions of codecision. Rapporteur (EP) for the directives will be Mrs Françoise Grossetete (France) and for the regulation Mrs Müller (Germany). There could be also 2-3 “shadow rapporteurs”.

Answering questions from some Member State representatives the chairman informed that most of the meetings foreseen under the Belgian Presidency have been cancelled. Only a general meeting will be held on 17 December 2001. The next meetings will be organised by the Spanish Presidency.

4.2 Modification of the Council Regulation (EEC) No 2377/90

The Commission representative gave a short update on the modification of Council Regulation (EEC) No 2377/90. Changes may include more detailed definitions, extrapolation of MRLs and timeframes for MRLs. For the moment the discussion is still ongoing between the services.

4.3 Variations regulations

The Commission representative gave a short update on the variations procedures. A lot of discussion regarded Annex 2 of regulations subject to new application (possible type 2a and type 2b procedures). The Commission shared Member States (especially NL) representatives opinion that the whole procedure is going to become more complicated then to become easier, but is up to member States scientists to make the appropriate amendments. Therefore the members should forward the idea of “real simplification” to their responsible authorities.

5. MARKETING AUTHORISATION PROCEDURE

5.1 Centralised procedure and referrals

The EMEA reported that of the 10 applications forecasted for the centralised procedure in 2001, 9 had been received and a similar number are anticipated for next year. Extensions have exceeded that forecasted by approximately 50%, whereas the applications for establishment of MRLs had slightly exceeded the five forecasted with seven applications received. This was seen to be indicative of a rather sluggish development of new chemical entities in the food animal sector. The EMEA representative also commented on the very positive improvements recorded in the benchmarking exercise undertaken as a joint EMEA/FEDESA questionnaire.

5.2 Mutual recognition procedure

The Chairman of the VMRFG gave a comprehensive report on the mutual recognition procedure, including information about the HEVRA-website, Eudra-Track activities, participation of CAVDRI countries and the informal meeting in August 2001. Due to some mistakes the results of a joint FEDESA/VMRFG survey will be adopted delayed.

5.3 Notice to applicants (NTA)

The Commission representative gave a short update on the ongoing work. Most of the chapters on general procedures, MRPs, centralised procedures and referrals have been updated and sequentially published in the web. Probably the references have to be changed, but for the time being the main topic for NTA are the variations.

6. BATCH RELEASE

Strongly supported by the EDQM the Commission representative pointed out that a system consisting of documentation review only, without effective re-testing of samples of all batches of a given immunological veterinary medicine, cannot be seen as falling under the current provisions of Art. 3.3 of Directive 90/677/EEC (future Art. 82 of Directive 2001/82/EC). The following extensive discussion between the Commission, the EDQM and Member States representatives showed again that there is an urgent need for establishing a harmonised procedure for official control authority batch release (OCABR) of

immunological veterinary medicinal products (IVMPs) amongst the concerned Member States. Summarising this difficult situation, the draft proposal “Administrative procedure for official control authority batch release of immunological veterinary medicinal products” was tabled for information and Member States were asked to send comments and their provisions currently in force to the Commission and the EDQM until 31 January 2002. Further information should be given on the IVMPs which are subject to OCABR and the official laboratories approved.

7. TELEMATICS

The Commission representative introduced this subject briefly. Since the last meeting of the Telematic Steering Committee meeting in Uppsala (12 June 2001) the Belgian Presidency had meetings with the Member States concerned and the Agency on the future of EudraTrack. From 2004/2005 on, once the review proposals will entry into force, the system can be run by the EMEA. For the interim period, the system needs to be maintained by a different operator. Applications have been presented by the JRC, by Spain and by France, which have to be assessed. On the basis of a template document comparing the three applications the decision for this temporary solution will probably be taken in January 2002 under the Spanish Presidency. Furthermore the Commission representative informed the Committee that the problems, which had occurred within the EudraNet are solved on a temporary basis. A long-term solution is being prepared at present, but requires further discussions.

8. INTERNATIONAL ISSUES

8.1 Mutual Recognition Agreements (MRAs)

The Commission representative provided an update on the progress with respect to the various MRAs including the veterinary sector (VETPHARM 217).

Switzerland: The final ratification is expected to take place in December 2000 or January 2001. In the meantime the legal references are amended according to the codified Directive 2001/82/EC.

Canada: There are still severe problems for the MRA with Canada, provoked by the situation in Italy. An investigation in Italy by inspectors from other Member States is foreseen in the first quarter of 2002. The Commission is urgently seeking for volunteers. For the moment only France will provide an expert. Italy has set up an action plan, however its implementation taking longer than expected. Further time and monitoring is needed to solve the outstanding problems. The European Commission has therefore proposed a further 12 months extension of the transition period.

USA: The problems with Italy obviously also affects the MRA with USA. Though the transition period has been finished, USA seems to have problems with confidence. After an inspection of the UK system, USA will come up with a new action plan early next year. To discuss the way forward there will be a videoconference between the joint sectoral committee and the FDA on Wednesday 12 December 2001.

Australia: The 2-year confidence building period for veterinary medicinal products has been completed. The operational phase is in force since 1 July 2001.

New Zealand: There is a 3-year confidence building period ending on 1 January 2002. A report from the UK on an inspection undertaken in October 2001 has to be discussed during the inspectors meeting in London. Because the inspection process as observed in

NZ seems to differ significantly from that implemented in the EU, it is not sure whether there will be a moving to the operational phase or an extension of the transitional phase.

8.2 Enlargement

PERF II

The EMEA representative reiterated that the joint Acquis working group had not dealt with specific veterinary items to date and at the last meeting in Bratislava, the veterinary representatives of the candidate countries in conjunction with the EMEA had highlighted veterinary issues that need to be addressed. These will be on the agenda of the next two meetings of the joint Acquis working group. Flyers for the Tallinn conference on PERF II were distributed at the meeting. In addition, the EMEA representative reported on the meeting of the veterinary Task Force, which also expressed concerns at the apparent lack of implementation of Community law into the law of candidate countries and that this too needs to be monitored carefully within the Acquis. Otherwise good progress has been made with the workshops since the initiation of PERF II with a workshop having been held on efficacy testing requirements, requirements for licensing of immunologicals and a continuation of the safety workshops addressing further issues with MRLs, Antimicrobial Resistance and finally a Procedures workshop where major issues on the centralised and decentralised procedures were highlighted and reviewed. In addition, under the Pharmacovigilance umbrella, secondments of experts from the candidate countries to the Member States have been implemented early in the New Year.

Protocol to the Europe Agreements on Conformity Assessment and Acceptances (PECAs)

The Commission representative briefly updated on PECA activities (VETPHARM 218). There are PECAs with Hungary, the Czech Republic, Latvia and Slovakia, but only the PECA with the Czech Republic covers the veterinary part. Concerning the veterinary part of the PECA with the Czech Republic an inspection has been undertaken in the pre-operational phase during October 2001. Unfortunately the veterinary GMP system has been assessed as non-equivalent. In order to find a solution the problem will be discussed in the inspectors meeting in London on 13 December 2001.

8.3 VICH

The last major event had been the Steering Committee, which met in June 2001 at the EMEA in London. Guidelines adopted at Step 3 and released for consultation at Step 4 are “The requirements on pre-authorisation testing for minimising resistance of antimicrobials”, “Safety guidelines of carcinogenicity”, “Pharmacovigilance – management of PSURs” and “Pharmacovigilance – controlled list of terms”. Final guidelines released by VICH included the remaining anthelmintic guidelines on equine, porcine, canine, feline species as well as poultry. In addition, safety studies guidelines on genotoxicity and reproductive safety were also finally adopted.

8.4 Report from the meeting of the Codex Committee on Residues of Veterinary Drugs in Food (4-7 December 2001 in USA)

The Commission representative gave a comprehensive report on the Codex meeting in Charleston. Delegations from 32 countries participated including 11 EU Member States. Belgium as holder of Presidency intervened on behalf of the European Community. The Commission and EMEA representatives were present as observers providing regulatory and technical expertise. Chinese representatives participated for the first time and in a very active way. Main topics concerned the evaluation of MRLs, the discussion paper and the related guidelines for prudent use of antimicrobial veterinary medicinal products (EU put forward agreed Community comments) and the assessment of the Codex system in general.

The work on the draft guideline on the residues at the injection site was discontinued due to major practical concerns with this guideline raised by several delegations including the EU. This issue is more related to the marketing authorisation of a veterinary medicinal than the establishments of MRLs.

9. ANY OTHER BUSINESS

9.1 Update on borderline issues – Guidance document adopted by the Competent Authorities for biocidal products (Directive 98/8/EC)

The members of the Veterinary Pharmaceutical Committee were updated on the last developments regarding borderline issues (biocides/ human and veterinary medicinal products), in particular the classification of products containing antiseptics, substances with repellent effects and external parasiticides. The guidance document developed by the Commission and agreed with the Competent Authorities for biocidal products was tabled for endorsement (VETPHARM 219).

In the extensive discussion Member States expressed their opinion that this document is not very helpful neither to understand the terminology nor to assess national products. In fact there still would be no clear Commission legislation between veterinary medicinal products, biocides and other substances. The chairman agreed that the problem is how to define the different products but maybe there will be a solution in form of the proposed definitions in the Review documents. Finally Member States were asked to send comments to DG Enterprise to be forwarded to the responsible DG ENVIRONMENT.

9.2 Information on new standard rules of procedure for standing committee

The Commission representative informed the Committee members that following the adoption of the new Comitology decision n° 468/1999/EC (VETPHARM 220), standing committees have to adopt their rules of procedure in conformity with this decision and in conformity with the new standard rules that the General Secretariat published in February 2001. After a short overview of the changes introduced by the new comitology decision (mainly four types of procedures instead of seven, “droit de regard” and constant information of the European Parliament), the Commission representative reminded that the new comitology rules only apply to the standing committee and not the to the veterinary committee which is a consultative body and does not fall under these rules. Alignment to the new typology of procedures (the new procedures I, II and III have replaced the old

procedures I, IIa and IIb and IIIa and IIIb) has already taken place via the codification exercise (adoption of directive 2001/82/EC).

The standard rules of procedure are currently being slightly modified by the Secretariat General in order to be in line with the requirements of the new transparency regulation (see above point 3.5). After these modifications have been published the standing committee will have to adopt its rules of procedure as soon as possible.

9.3 Update on translations and publications

The Updated Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01 Rev.1 May 2001) has been translated and is now available in all official languages of the European Community on the homepage <http://pharmacos.eudra.org/F2/home.html>. This joint CPMP/CVMP Note for Guidance is a revised version of the respective CPMP and CVMP Notes for Guidance on minimising the risk of transmitting TSE via medicinal products. Compliance with this Note for guidance has to be demonstrated according to Council Directive 75/318/EEC as amended by Commission Directive 1999/82/EC and Council Directive 81/852/EEC as amended by Commission Directive 1999/104/EC (VETPHARM 221).

Furthermore the Commission services informed the Committee about the finalisation of Volume 9 (Pharmacovigilance). The guideline covers both human and veterinary Pharmacovigilance. The document is also published on the above-mentioned homepage.

The chairman informed about the problems that occurred in the past with regard to translations of documents without legislative value. Due to the non-binding nature, these documents would not be translated in-house. The freelance translators very often do not possess the necessary scientific background to translate documents relating to veterinary medicinal products in an appropriate way. It is expected that this situation will deteriorate with the forthcoming accession of numerous new Member States. Especially in the light of future enlargement the system has to be checked in order to find solutions. If the system continues as it is envisaged in the treaty the translation services will be overloaded. Other options could be that Member States do their translations themselves or translations are only done on specific request for certain documents. This would nevertheless cause enormous budgetary problems because other sectors would follow the same approach. Member States therefore were asked to come back with positions, proposals and comments to the next meeting.

9.4 “Prudent use guidelines” for veterinary sector

The French representative raised the question why there are no similar approaches from the Commission for guidelines for the veterinary part as done in the human sector concerning the prudent use of antibiotics in human medicine. There seems to be the need to co-ordinate the different sectors.

In the following discussion the Commission representative explained that the communication also covers the veterinary sector making references to existing guidelines like the OIE-, Codex- and CVMP-guidelines concerning these problems. All of them are available on the web. Finally the chairman stressed out that this topic (including the training of health care professionals and veterinarians) is a pure SANCO issue and has nothing to do

with marketing authorisations DG Enterprise is originally responsible for. Nevertheless he agreed that there should be some co-ordination and he promised to forward Member States message to DG SANCO to take account of the veterinary sector.

9.5 Sales promotion

The Danish representative informed the Committee that a recent Commission proposal for a Regulation concerning sales promotion in the Internal Market (COM(2001) 546 final) might have serious and politically sensitive implications in the field of medicinal products. Article 3 of the proposal states that "Member States ... shall not impose a general prohibition on the use or commercial communication of a sales promotion unless required by Community Law".

So far, two issues had been identified. To the extent that the traditional fixed price system at the retail pharmacy level of many Member States will be covered by Article 3, the proposed regulation will give rise to problems – at least in Member States, such as Denmark, where the fixed price system is synonymous with a prohibition against discounts to the consumer.

Furthermore, with respect to veterinary medicinal products, where Community law on medicinal products is silent concerning advertising, free samples, discounts, gifts, pecuniary advantages or benefits in kind, hospitality at sales etc., Member States might have problems. In Denmark the provisions of the former directive on the advertising of medicinal products for human use had been extended to veterinary medicinal products, even if this is not required by Community law.

The Commission representative pointed out that the Transparency Directive might provide an answer to some of the concerns of the Danish representative, but agreed to consult the Commission's Legal Service on the questions raised.