



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

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

VETPHARM 253-revised

**VETERINARY PHARMACEUTICAL COMMITTEE
FINAL MINUTES of 14th MEETING
12 June 2003**

The Chairman, Head of Unit F2 of DG Enterprise, welcomed the participants, in particular observers from the new Member States. He informed that a joint session with the Competent Authorities for the “Biocide directive”(Dir. 98/8) will take place at 2:30 PM to discuss and endorse the document VETPHARM 248 –Revised- agenda point 8 on “Borderline issues”.

The list of participants is annexed to the draft minutes.

1. AGENDA

The draft agenda of the 14th meeting (VETPHARM 236) was adopted with the following amendments;

- The French representative asked for information to be provided on the latest development on Commission side on the availability of veterinary medicinal products (VMPs). In particular he seeks information from other Member States (MS) representatives on the application in their respective country of Article 10.2 of Directive 2001/82/EC especially in case of minor food producing species for which no authorised VMP is available within the Community.

- The Chairman informed also the participants that under agenda point 9, they will be informed on three following guidelines (GL) EMEA/CVMP elaborated to respond to the strategic plan of containing anti-microbial resistance, recently coming into effect. [GL EMEA/CVMP/612/01-Final “*Guideline on the SPC for antimicrobial products*”; GL EMEA/CVMP/627/01-Final “*Guideline for demonstration of efficacy for VMP containing antimicrobial substances*”; GL EMEA/CVMP/244/01-Final -corr “*Guideline on Pre-authorisation Studies to assess the Potential for Resistance Resulting from the Use of Antimicrobial Veterinary Medicinal Products*”]

2. MINUTES

The draft minutes of the 13th meeting (VETPHARM 237) were adopted.

3. INTERPRETATION/IMPLEMENTATION OF CURRENT LEGISLATION

3.1 Information on recent case law and pending cases

The Commission representative presented the judgement of the Court of First Instance of 26 February 2003 in Joined Cases T-344/00 CEVA Santé Animale SA v. Commission of the European Communities and T-345/00 Pharmacia Enterprises SA v. Commission of the European Communities. (VETPHARM 238), and informed the Committee of the Commission's appeal against that judgement.

Concerning the case of establishment of MRL for Progesterone and particularly the classification in one of the Annexes Regulation 2377/90, the French representative asked the Commission to inform the participants of the last development and conclusions expected. The Chairman informed the participants that after discussion with the Marketing Authorisation Holder, it seems to be most probable that restriction to intravaginal administration could preclude diversion for other purposes than authorised therapeutic and zootechnical use. In that case progesterone will still be classified in Annex II of Regulation 2377/90. The Chairman added that until any judgement from the European Court of Justice has been issued, the Commission maintain its conclusions and interpretation on the current legal basis concerning this case.

3.2 Regulation (EEC) 2377/90:

Article 6 of Directive 2001/82/EC requires the inclusion of a pharmacologically active substance in Annex I, II or III of Regulation 2377/90 as a precondition for obtaining a marketing authorisation for veterinary medicinal products for food producing animals in the Community. Malachite green and its derivative leuco-malachite green have never been evaluated according to Council Regulation 2377/90 as no applicant applied for. The use of this substance in food producing animals is therefore illegal.

The Commission representative summarised actions engaged by the Commission with respect to indications that malachite green is illegally used in aquaculture. The issue has been raised with residue experts and in the Standing Committee for the Food Chain and Animal Health (established with Regulation 2002/178/EC 'Food Law') with Member States, Accession countries and European Economic Area Members as well as bilaterally with those countries particularly concerned including the United Kingdom, France and Chile. Subsequently Member States stepped up their control activities concerning the substances (malachite green and its metabolite leuco-malachite) and the number of samples aimed at the detection of malachite green taken increased in 2002. Samples are taken according to the targeted national residue monitoring plans established according to Directive 96/23/EC and according to general control requirements. Moreover, the Community Reference Laboratory responsible for analytical support for the respective group of substances (AFSSA-LERMVD Fougères, France) has taken action to improve the analytical methods in place (Limit of detection at 2 ppb). As a result the number of non-compliant results increased last year.

The delegate from Norway confirmed that the use of malachite green in aquaculture is prohibited in her country and that its illegal use is censured.

vious application forms in Volume 2C and 6C of the Notice to Applicants for medicinal products for human use and veterinary medicinal products. The previous explanatory note on how to fill in the form is therefore redundant and will be deleted.

[Regulations (EC) No 1084/2003 and No 1085/2003) have been published in the [Official Journal L 159 of 27.6.2003](#)

4.2 Review of the veterinary pharmaceutical legislation (VETPHARM 239)

The Chairman informed the participants on the latest events concerning the Review 2001 process. On 2nd June 2003, a political agreement has been concluded during the Health Council on the Directive 2001/83/EC “Human code” and on Regulation 2309/93.

The same political agreement still has to be finalised for the Directive 2001/82/EC “Veterinary code” during the next meetings of the Council-working group under the Greek or Italian presidency.

As soon as the political agreement will be obtained for all 3 legal texts, it is planned to adopt the Common positions by September 2003, to allow starting the 2nd Reading by the European Parliament at the latest in its October session.

The Commission services are very confident with this planning as both Greek and Italian presidencies are working very actively towards this objective. Indeed, the Chairman stressed that the Review 2001 should optimally be completed before two important date's -Election in the EP in the next spring of 2004, and accession of new Member States. (May 2004).

5. MARKETING AUTHORISATION PROCEDURE

5.1 Centralised procedure and referrals

The EMEA representative informed the participants on the status of the application received in the Agency for;

- MRL applications; it was planned for 2003 to receive 2 new MRL applications dossiers but just one has been received yet.

- Applications for marketing authorisations under Centralised procedure; it was planned to receive 10 new applications but just 3 have been received yet, plus 5 hopefully starting in the autumn.

The French representative questioned about the criteria applying for extrapolation of existing MRL. The Commission representative underlined that there is a difference between extrapolation and extension of MRL. Concerning MRL extension application, the Agency (EMEA) is in charge of receiving them and to assess the documentation. Concerning the MRL extrapolation to others species, the CVMP is still working to elaborated further on this issue.

5.2 Mutual recognition procedure

The Greek chairman of the VMRFG, gave an exhaustive summary of the work accomplished in Mutual Recognition Procedures (MRP) developed during the Greek presidency.

5.3 Suspension of marketing authorisation.

The Commission representative informed the participants about the *favourable opinion* delivered by the Standing Committee for Veterinary Medicinal Products, acting by qualified majority (Yes 79/87 – No: ES 8/87 – Absent: FR 10/87)) Commission Decision of 22/04/03 C(2003) 1401 concerning the suspension of marketing authorisations for VMPs containing the substance “Benzathine Benzylpenicillin” intended for intramuscular and/or subcutaneous administration to food-producing species (VETPHARM 240). She reminded them about their obligation to inform the responsible Commission service about the implementation in their respective country of the above Commission decision. Only Finland had as yet complied with this obligation.

5.4 Notice to applicants

The Commission representative informed the participants that the revision of Volume 6A for Veterinary medicinal products (Chapters 4 and 7)(VETPHARM 241) had been published last April, on the following web page <http://pharmacos.eudra.org/F2/eudralex/vol-6/home.htm>

6. OFFICIAL CONTROL AUTHORITY BATCH RELEASE (OCABR) OF IMMUNOLOGICALS VETERINARY MEDICINAL PRODUCTS (IVMPs)

The European Directorate Quality of Medicine (EDQM) representative presented the Summary of progress on OCABR of IVMPs by Veterinary Official Medicines Control Laboratories (OMCL) prepared by EDQM and tabled during the meeting (VETPHARM 242). He added that the drafting group among veterinary OMCLs network who has drafted the 12 first specific guidelines [Currently out for internal consultation within the Network of OMCL vet by end of August 2003], planned to finish its work by early 2004.

The Chairman asked for comments from the participants. The British representative informed the Chairman and the EDQM representative that she was not able to comment immediately on a document tabled during the meeting but that written comments will be provided to the Commission services with copy to EDQM as appropriate.

The Chairman questioned the participants as well as the EDQM representative on the following issues;

- Real involvement of Member States, which already carry out OCABR of veterinary vaccines, in the Vet OMCL Network?
- Is there any planned study in EDQM on the respective and compared cost effectiveness of Human OMCL and Vet OMCL?

- Which new Member State is currently participating actively in the Vet OMCL network and would be interested in applying OCABR as described in Article 82 of Directive 2001/82/EC?

The EDQM representative informed that these issues are to be looked at, especially in the context of the Review 2001. He informed the participants of an annual meeting of the Veterinary OMCL network to be held in EDQM, Strasbourg, late in October 2003 and of another one in May 2004, during which the necessary tools to fully implement OCABR, as described in Article 82 of Dir.2001/82/EC, by those member states involved, would be finalised (Procedures and guidelines).

7. INTERNATIONAL ISSUES

7.1 Mutual Recognition Agreements (MRA): *Update* (VETPHARM 243)

The Commission and EMEA representatives informed that regularly updated version of the "Current status of Mutual Recognition Agreements - GMP sector" and a table "Mutual Recognition Agreements - Key Elements and Product Coverage" are now available on <http://pharmacos.eudra.org/F2/mra/index.htm>. The Committee was updated on the actual status of MRAs.

The MRAs will extend to the new Member States from the first day of their accession, without the need to amend the texts of the MRA framework agreements, since they do not list the countries to which the respective MRA applies. The only place where the Member States are referred to be the list of Designating/Regulatory Authorities contained in the Sectoral Annexes.

However, the GMP sectors present certain difficulties, since they rely on mutual recognition of systems generally on the basis of reciprocal evaluations carried out to build up confidence in each other's inspection systems. In this respect, the situation will differ in those MRAs that have directly been implemented (Australia, New Zealand, Switzerland) and those that foresee a period of confidence building (Canada, Japan, USA). As regards the former, the Commission did not receive any comments from Australia and New Zealand until now, and intends to engage in discussions with Switzerland during the next Joint Committee meeting in June 2003. If there are no objections the amendment of the respective sectoral Annexes will suffice. On the contrary, Canada will not accept new Member States automatically but insist on inspections. Further modalities have to be discussed with Canada. The Commission would prefer if new Member States could apply for inspection by Canada. To avoid difficulties, the Commission is offering "pre-inspections" and recommending the new Member States not to apply for inspection by Canada until they are well prepared for it. In the meantime and in order to be able to export to Canada, the new Member States will be able to ask for validation by Member States' agencies already listed in the system.

Answering a question from France the Commission representative informed that the EU re-evaluation of the Italian veterinary GMP sector beginning of June 2003 has been successful. At present there would be the re-evaluation by Canadian inspectors and the Commission would be confident that also this sector is going to prove equivalency with Canadian GMP requirements.

7.2 Enlargement

7.2.1 PERF III: Update on Acquis.

The Commission representative gave a short update on the last meeting of the PERF III Acquis Working Group in Tallin from 2-4 June 2003. Most of the topics concern both the human and the veterinary sectors especially focussing on a smooth phasing in of the centrally and the mutual recognition authorisation procedures. Reflection papers have been drafted or already been published. A special veterinary outbreak session concentrated upon teat dips, packaging and labelling issues and on the preparation of the Veterinary PERF III Conference, which will take place in Warsaw from 24-26 September 2003. Additionally the Commission plans to publish a "Communication on the application of Community legislation on medicinal products in the context of the European Union's enlargement" by the end of 2003.

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

The Commission representative informed that a table concerning key elements of the GMP sector of PECAs and the Guidance Document on the "Implications of the Operational phase of the GMP annexes to the Protocol to the European agreement on Conformity assessment and Acceptance of industrial products (PECA) with European Union associated countries", are available on <http://pharmacus.eudra.org>, in a new section "PECAs". Additionally participants were updated on the actual status of the PECAs.

The Czech representative gave an oral report on the improvements made by the Czech Veterinary Institute. A re-evaluation together with an observed inspection of a company exporting to Italy would be envisaged but not yet confirmed for May 2003. (After meeting note: the re-evaluation has been successfully carried out in July 2003)

7.3 VICH

The Commission representative reported the conclusions of the 12th VICH Steering Committee meeting held on 7-8 May 2003 in London;

- Importance of international harmonisation on the collection and evaluation pharmacovigilance data;
- Signed-off of VICH GL 36 and VICH GL 37 on Safety issues and released for consultation until November 2003;
- Review of VICH Work Plan 2000-2005; what continuation of harmonisation activities after 2005?

A press release from the 12th VICH SC meeting is available on VICH Web site http://vich.eudra.org/pdf/06_2003/pr03021.pdf.

Next VICH SC is scheduled for 7-8 October 2003, in Washington D.C, USA.

7.4 Codex Alimentarius

The Commission representative reported the status of major issues discussed at the 14th session meeting of the CCRVDF held in Washington, 4-7 March 2003 (VETPHARM 246). In particular, she underlined that;

- Concerning the “*Code of practice to minimise and contain antimicrobial resistance*”, CCRVDF members were request to send their comments to the Codex Secretariat not later than 30 June 2003. A drafting Group, chaired by US, will meet in 14-15 July 2003 in Washington D.C for revision and finalisation of the proposed draft code. A Commission representative assisted by an EU expert (CVMP member, actual chairwoman of the efficacy WP in CVMP) will participate in this meeting. The revised version of the draft code of practice will be forwarded to Codex secretariat for circulation by end of 2003 and further consideration at its 15th Session.

- Concerning the “discussion paper on Risk management methodologies, *including Risk assessment Policies*”, European Commission services will convey a drafting working group, chaired by France, to develop the document that should be presented to the CCRVDF after the drafting group meeting to be held in January 2004.

- Concerning the proposed “*revised draft guidelines for the establishment of a regulatory program for the control of veterinary residues in foods*” CCRVDF members were request to send their comments to the Codex Secretariat not later than 30 June 2003. A drafting Group, chaired by New Zealand will revise and finalise the proposed revised guidelines that will be forwarded to Codex secretariat for circulation by end of 2003 and further consideration at its 15th Session.

8. BORDERLINE ISSUES

The chairman welcomed the Commission representative (DG Environment) [chairman of the meeting of Competent Authorities for the Biocide directive (Dir. 98/8)] and all Competent Authorities for the joint session. He introduced the issue and proposed to all participants to discuss the revised document - **VETPHARM 248-revised** - [Doc-Biocides-2002/02 –rev3 –11.06.03] – that was tabled, and if agreed to endorse it.

He explained that the latest revisions were introduced to specify that full compliance with all requirements of Directive 2001/82/EC of any application for teat dip product have to be met, before any marketing authorisation as Veterinary Medicinal Product could be granted by the responsible authorities. He recalled that the following requirements are deemed compulsory: GMP certification for the process and the manufacturer production site of the active substance; pre-clinical and clinical trials.

As long as all requirements of Directive 2001/82/EC are not met, the product (containing the biocide substance) could not be granted a marketing authorisation as Veterinary Medicinal Product by any responsible authority.

The UK representative informed the participants about the UK opinion on the classification of teat dip products. All the 189 teat dip products currently authorised in UK are authorised as Veterinary Medicinal Products; none is authorised as biocidal product. Indeed UK considers these teat dip products are to be considered VMPs either by presentation or by function. The Chairman thanked the UK representative for the information provided but reminded her that this would necessitate that for each UK marketing authorisation for a teat dip product, full compliance with directive 2001/82/EC is

achieved and that in particular efficacy trials criteria are adequately performed and assessed. The UK could not confirm that this was really the case.

The Irish representative indicated that teat dips have up to now been classified in Ireland as Veterinary Medicinal Products, adding that his authorities will now review the situation in light of the draft guidance document. In conclusion and after some further debate, it was generally accepted that the amended guidance document in **VETPHARM 248-revised** to classify teat dip products as generally falling under Dir.98/8/EC in the future was endorsed.

The Guidance document will be published on DG Environment web page and DG Enterprise as soon as possible.

<http://europa.eu.int/comm/environment/biocides/prodmilk.pdf>

<http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2003/June/prodmilk.pdf>

9. ANY OTHER BUSINESS

* The Chairman introduced the Commission representative from DG Justice and Home Affairs, who presented the outcome of the questionnaire on Ketamine diversion (EU Action Plan on Drugs 2000 – 2004) – VETPHARM 250.

The chairman proposed that veterinary committee member's liase, at national level, with their colleagues from Pharmaceutical Committee, before the 15 September 2003, to propose a national common position on the conclusions of the questionnaire on Ketamine Diversion and propositions for the next Pharmaceutical Committee meeting.

* The Commission representative informed the participants about the publication and coming into force of 3 guidelines adopted by CVMP in accordance with the strategic plan for containing antimicrobial resistance [**Guideline EMEA/CVMP/612/01-Final** "*Guideline on the SPC for antimicrobial products*"; **Guideline EMEA/CVMP/627/01-Final** "*Guideline for demonstration of efficacy for VMP containing antimicrobial substances*" – these two guidelines apply from 11 June 2003; **Guideline EMEA/CVMP/244/01-Final -corr** "*Guideline on Pre-authorisation Studies to assess the Potential for Resistance Resulting from the Use of Antimicrobial Veterinary Medicinal Products*- this guideline apply from 11 January 2003]

The Chairman asked information from Member States representatives about enforcement of these 3 guidelines for VMPs authorised under the decentralised and national procedures. EMEA should also inform the Commission about their enforcement for centrally authorised VMPs.

EMEA representative informed the participants of their willingness to discuss this issue during Infoday meeting between CVMP/Animal Health Industry before end of 2003.

* The Belgium representative questioned the Chairman about the possible review of Reg.2377/90. The Chairman answered that the different Commission services concerned are considering carefully the issue but that no date could be fixed on this possible review.

* The French representative expressed the concern of France about the implementation of Article 10.2 of Directive 2001/82/EC especially in case of minor food producing species e.g. food producing rabbits or food producing quails. He stated that the inadequacies between the withdrawal period fixed in article 10.2 (28 days for meat from poultry and mammals) and short cycle of production of certain species (3 weeks for quails) preclude to use the provisions of Article 10.1 for these minor species and increased the problem of availability of veterinary medicine. He reflected to the discussions between Member States on implementation of Article 10 at the occasion of the review of the veterinary pharmaceutical legislation. He asked the Chairman about the measures that the Commission has in place to control, the enforcement of the European veterinary pharmaceutical legislation in Member States, and proposed to enlarge the missions of the Food and Veterinary Office to encompass the European veterinary pharmaceutical legislation (Directive 2001/82/EC; Regulation 2309/93/EC).

LIST OF PARTICIPANTS

Members

Austria	Mr. Eugen Obermayr
Belgium	Mrs. Françoise Falize Mr. Lionel Laurier
Denmark	Mr. Mogens Bjornbak-Hansen
Finland	Mrs. Henriette Helin Mrs. Kristina Lehmann
France	Mr. Jean-Pierre Orand Mrs Catherine Periz Lambert
Germany	Mrs. Carmen Jungbäck Mrs. Katharina Keuger Mr. Ilse-Dore Schütt Mr. Heinrich Bottermann
Greece	Mr. Nikos Mentzos Mr. Ioannis Malemis
Ireland	Mrs. Catherine Connly Mr. Ph. Kirwan
Italy	Mrs. Gaetana Ferri
Netherlands	Mr. D.G. Groothuis Mr. Gijs T.J.M. Theunissen
Portugal	Mrs. Isabel Abreu
Spain	Mr. Ramiro Casimiro
Sweden	Mr. Peter Ekstrom
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EFTA observers

Norway Mrs Tonje Høy

Observers

EMEA Mrs Melanie Leivers

Council of Europe Mr Jean-Marc Spieser

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