



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL

Single market: management & legislation for consumer goods

**Pharmaceuticals: regulatory framework and market authorisations**

## VETERINARY PHARMACEUTICAL COMMITTEE

### FINAL MINUTES OF THE 13<sup>th</sup> MEETING

19 September 2002

#### 1. AGENDA

The draft agenda of the 13<sup>th</sup> meeting (VETPHARM 222) was adopted with one additional item under point 3.1 ("Court cases") requested by Denmark. France asked for the possibility to discuss point 3.4.

#### 2. SUMMARY RECORD

##### **Draft summary record of the 12<sup>th</sup> meeting on 11<sup>th</sup> December 2001**

The draft summary record of the 12<sup>th</sup> meeting on 11 December 2001 (VETPHARM 223) was adopted with two minor corrections on page 8 and 9.

#### 3. INTERPRETATION/IMPLEMENTATION OF LEGISLATION

##### **3.1 Information on recent case law and pending cases**

The Commission representative informed the Committee about the judgement of the ECJ of 8 January 2002 in Case C-248/99 French Republic versus Monsanto Company and Commission of the European Communities concerning BST. Contrary to the judgement pronounced by the Court of First Instance, the Court stated that the procedures for establishing MRLs and issuing marketing authorisations are inherently linked, inasmuch as a marketing authorisation will not be issued in respect of a veterinary medicinal product for administration to food-producing animals unless an MRL has been established. By the same token, an MRL will not be established for a new pharmacologically active substance unless that substance is intended to be placed on the market. Since Monsanto had formally called upon the Commission to adopt a decision concerning the request for the establishment of an MRL for sometribove, the Commission was right, in refusing that request, inasmuch as the condition laid down in the second indent of Article 6(1) of Regulation No 2377/90 had not been fulfilled. In this context the ECJ set aside the judgement of the Court of First Instance.

A further case concerned the judgement of the ECJ of 26 February 2002 in Case C-32/00 Commission of the European Communities versus Boehringer Ingelheim Vetmedica GmbH e.a. concerning clenbuterol a particular beta-agonist. Finally the Court set aside the parts of the judgement of the Court of First Instance stating that the Commission could not lawfully

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base the limitation of the validity of the MRL established for clenbuterol on the provisions of Directive 96/22/EC. The references to permitted therapeutic indications for clenbuterol did not have the object or effect of limiting the validity of the MRL established by Regulation No 1312/96; moreover no provision prohibited the Commission from inserting in Annex III to Regulation No (EEC) 2377/90, as amended by Regulation No 1312/96, a reminder of the effects of the provisions of Directive 96/22/EC in relation to the permitted therapeutic uses of clenbuterol. Additionally, Court concluded that the Commission did not exceed the power conferred upon it under Regulation N° 2377/90 by limiting the validity of the MRLs for clenbuterol to specific therapeutic indications.

Concerning the referral in Case T-19/02 - Albert Albrecht and 17 other against Commission of the European Communities and EMEA the Commission representative pointed out the issues raised by the case and the substances of the case the ECJ will have to decide on. This concerns especially the admissibility, the referral mechanism, the information duty imposed upon companies, the question whether the case should be considered as a class referral or not, the status of the Notice to Applicants and the obligation to pay fees.

Further information has been given about the judgement of the Court of First Instance of 7 March 2002 in Case T-212/99 Intervet (former Hoechst Roussel) versus Commission concerning a request to fix an MRL under Regulation 2377/90 for the hormone Altrenogest. The Court confirmed the Commission's position by stating that the letter of 16 July 1999 was confined to explaining the reasons for the delays in including Altrenogest in one of the annexes to the 1990 Regulation and does not contain any decision as to the inclusion of Altrenogest in one of the annexes to that regulation. That letter clearly shows that the Commission was waiting for the second opinion of the CVMP before taking such a decision. Consequently, the applicant's position has not changed by that letter, which merely informed it of the state of the procedure. In those circumstances, that letter didn't constitute a decision which may be the subject of an action for annulment under Article 230 EC and the claim for annulment was dismissed as inadmissible. Finally, on 19 December 2001, Council Regulation (EC) N° 2584/2001 was adopted modifying Annexes I and III of Regulation (EEC) n° 2377/90 and including Altrenogest in annexe III to that regulation.

Some explanations were given concerning the judgement of the Court of First Instance in Cases T-13/99 and T-70/99 Pfizer Animal Health SA versus Council and Alpharma Inc. versus Council concerning the feed additives Virginiamycin and Bacitracin zinc. The judgement has to be seen as a very important example for the precautionary principle clearly stating that the political decision (risk management) can overrule the scientific risk assessment. The Court concluded that, despite uncertainty as to whether there is a link between the use of those antibiotics as additives and the development of resistance to them in humans, the ban on the products is not a disproportionate measure by comparison with the objective pursued, namely the protection of human health.

Finally, the Committee was informed about a recent judgement of the Court of Justice of 10 September 2002 in Case C-172/00 ("Ferring") regarding parallel imports of medicinal products for human use. The specific question was whether the parallel import license becomes automatically void where the marketing authorisation is withdrawn, to which the licence refers, irrespective of the reasons of the withdrawal. In this case Ferring had marketed Minirin Spray in Germany on the basis of an implied authorisation. The product was imported by another company by way of parallel import from another Member State into Germany. In 1999, Ferring obtained marketing authorisation for a new version of this product and waived

the old implied authorisation. Ferring brought proceedings against the parallel importer to stop the parallel imports. The Court held that the cessation of the validity of parallel import licence constitutes a restriction on the free movement of goods contrary to Article 28 EC. It did not see any reasons relating to the protection of public health in accordance with Article 30 EC that would justify the automatic cessation. The withdrawal of the marketing authorisation as such would not call into questions the quality, safety and efficacy of the product, in particular where this continues to be authorised in the Member State of exportation. If the Member State of importation has doubts whether the coexistence of the old and the new version could lead to risks of public health, then it would be up to the competent authority to prove this risk and not to the parallel importer.

### **3.2 Validation of generic applications in the Mutual Recognition Procedure**

The Commission representative informed about a decision of the competent authority of one Member State to not validate an application for a marketing authorisation for an essentially similar veterinary medicinal product (Article 13(1)(a)(iii) of Directive 2001/82/EC). According to the applicant, which has sent a request for interpretation of the legal basis for this decision, the reason for the non-validation decision was lack of documentation in the part of the dossier on residues (Safety tests part IIIB). The authority asked for such data due to the withdrawal period for the product being different that of the reference product authorised. Article 13(1)(a)(iii) of Directive 2001/82/EC does not require that all particulars to be included in the Summary of Product Characteristics according to Article 14 of Directive 2001/82/EC have to be identical for the reference product and the essentially similar product can never be considered a valid reason for not accepting an application. Any concerns regarding the risk for human and animal health should be addressed during the procedure after assessment of the dossier. Furthermore, for applications under Article 13(1)(a)(iii) of Directive 2001/82/EC are exempt from having to provide data on the results of toxicological and pharmacological tests or clinical trials, provided that if he/she can demonstrate that the requirements of essential similarity have been met. The Commission has previously raised the issue with the Heads of Veterinary Regulatory Agencies (HEVRA). 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 34 of Directive 2001/82/EEC may also be applied to achieve such harmonisation.

All members of the Committee agreed to the Commission interpretation.

### **3.3 Qualified person responsible for Pharmacovigilance; interpretation of Article 74 of**

#### **Directive 2001/82/EC (Art. 103 of Directive 2001/83/EC)**

A pharmaceutical company has informed the Commission that the competent authorities of some Concerned Member States do not validate applications for mutual recognition procedures if the companies do not nominate the "qualified person responsible for pharmacovigilance" with residence in those Concerned Member States. These countries argue with point 2.4.4 of Part 1A of Volume 6B (application form for marketing authorisations) where the following information is demanded: "2.4.4 qualified person in the EEA for Pharmacovigilance (for MRP and national applications, the qualified person in the country where the application is made)". According to their interpretation the qualified person responsible for pharmacovigilance should have residence in the MS and not anywhere in the EU/EEA. The company requested information whether one

person within the EU/EEA is sufficient or if a person must be nominated with residence in each Concerned Member State. The Commission clearly stated that the information given in the application form is not in line with Directives 2001/82/EC (veterinary) and 2001/83/EC (human) any more. Article 74 of Directive 2001/82/EC (Article 103 of Directive 2001/83/EC) lays down that the "qualified person responsible for pharmacovigilance has to be permanently and continuously at the disposal of the MAH" but doesn't fix the residence. According to Article 74a (veterinary) and Article 103a (human) information about all suspected adverse reactions has to be accessible "at least at one point within the Community". The Notice to Applicants Working Party has discussed this issue in June 2002 and decided to amend Volume 6B and 2B in line with the Directives.

All members of the Committee agreed to the Commission interpretation.

### **3.4 Compliance with Council Regulation (EEC) 2377/90**

The Commission has sent (8 July 2002) to the Permanent Representations with a request to withdraw the marketing authorisations for veterinary medicinal products for food-producing species for those products containing pharmacologically active substances not included in Annexes I, II or III of Regulation (EEC) 2377/90. The letter concerned in particular marketing authorisations for various subcategories of horses. The Commission again stressed that - agreed by the Legal Service - horses are food producing animals by legislation (Directive 64/433/EEC) and that no exclusion of certain categories like "sport horses" is possible. This has already and extensively been discussed with Member States in previous Committee meetings. The Commission explained that the present situation could not be tolerated any more. Member States representatives repeated all previous arguments focussing on Decision 2000/68/EC that is seen as contradictory to the Commission interpretation, the danger of a "black market" and some economical problems. The chairman repeated the provisions foreseen in the Review 2001 including the solution also for the "horse problem" but the Commission would have clearly to deal with the current situation. Some Member State representatives claimed to have received the letter just before the meeting, but indicated that they would respond as soon as possible.

### **3.5 Access to documents – Application of Regulation (EC) n° 1049/2001**

This issue was raised during the assessment of an application of a veterinary medicinal product containing or consisting of a genetically modified organism (GMO). In this context, the question that had been discussed consisted of whether and to what extent national bodies may publish parts of the information received in the process of the application for a marketing authorisation. In the meantime Regulation (EC) n° 1049/2001 was adopted and entered into force also in June 2001. This regulation has been the subject of a presentation in the last Veterinary Pharmaceutical Committee; aiming to give an overview of the new provisions governing access to documents drawn up and received by the Community institutions. The Commission had pointed out that in future the question of confidentiality could arise in any case involving exchange of information between the Commission, the EMEA scientific committees and national authorities and not only in the context of GMOs. At the occasion of this presentation the Danish delegation expressed a request that the Commission should provide Member States with a document explaining the concrete implications of the "transparency" regulation in the context of community authorisation procedures and tracing the limits between this regulation and the specific directives in the field of pharmaceuticals by highlighting their respective scopes of application. A common discussion document for both the human medicines as well the veterinary medicinal products sectors has been drafted and

communicated to the Members of both the Pharmaceutical Committee as well as the Veterinary Pharmaceutical Committee. The Commission representative highlighted again the basic principles of the Regulation (EC) no 1049/2001 and the specific issues related to the application of the pharmaceutical directives. Member States representatives welcomed this document. Though knowing the problems to draft such a document the Danish representative envisaged that there still will be problems in the concrete application of the rules in the various Member States due the fact that the national provisions on what constitute confidential information were very divergent. The Commission representative envisaged a manual "of decisions" based on probable decisions of the Court of Justice which will look very closely to the cases. This could provide further guidance on the correct interpretation of the new legislation.

### **3.6 Codification of pharmaceutical legislation: Directives 2001/82/EC and 2001/83/EC**

As previously explained, Directive 2001/82/EC on the Community code relating to veterinary medicinal products and Directive 2001/83/EC on the Community code relating to medicinal products for human use have each gathered in a single text the provisions of a number of Directives and their successive amendments. Those directives have been repealed and replaced by the provisions of the codes. Some adaptations in terms of terminology and linguistic clarification were also inserted in the texts. In terms of legal obligation, a codification exercise does not imply new implementing obligations for the Member States, since it does not create new substantial Community provisions that would require an implementation. Consequently, there is no formal obligation imposed upon Member States to notify any measures – new ones or provisions already in place – to the Commission. Although there is no legal obligation to adopt implementing measures, Member States might reflect on adapting the existing legislation, in order to replace, for example, references to the old directives with references to the new texts, or, for the sake of clarity and legal certainty, proceed to a codification of the respective national legislation.

At this stage, the Commission is aware of the situation only in a limited number of Member States. One Member State (ES) considers that no implementation or further legislative adaptation is needed, taken into consideration that the two directives simply codify in a single text the provisions which previously existed in the human and veterinary sectors and do not create new obligations for Member States. Some other Member States (UK, IRL) have adopted regulations adapting the references to the articles of the old EC directives included in the national legislation to the articles of the codes. Some terminology adaptations have also been included in those texts. The Danish representative mentioned that there would be the possibility, as regards the Medicinal Products Act, to publish or promulgate a consolidated text in the Danish official journal. Concerning the secondary legislation i.e. provisions laid down with the legal basis in the Medicinal Products Act, the correct reference to the two codified directives would have to await other amendments of the various texts.

At the same time the Commission is asking about observations from Member States on linguistic or translation errors in their respective linguistic versions of the codifying Directives.

### **3.7 Transmissible Spongiform Encephalopathy (TSE)**

The EMEA representative gave a short report on the status of the concerned centrally authorised VMPs. All EDQM certificates have been provided and the procedures are completed. The actual update is on the EMEA website. The Commission representative reminded the members to send their written updates in a short and comprehensive form.

### **3.8 Council Regulation (EEC) No 2377/90**

The Commission representative gave a short update. The internal discussion is still ongoing and it has been decided to produce a reflection paper on the basic problems encountered in the application of the MRL Regulation, from the point of view of the involved Commission services. It is foreseen to present this paper to the Committee when a draft has been agreed. These items include extrapolation of MRLs, clarification of issues related to data protection, control possibilities and alignment with international agreements and obligations.

## **4. VETERINARY MEDICINAL PRODUCTS – LEGISLATIVE ISSUES**

### **4.1 Variation regulations**

The Commission representative gave a short update on the ongoing discussions to amend the regulations on variations. The subgroup of this Working Party has finalised reviewing all comments received in the consultation phase and the next meeting in the Notice to Applicants Working Party will be devoted almost entirely to this issue. The main remaining discussion point is the Annex on type I variations. It is foreseen to submit the recast regulations in the first quarter of 2003 to the Standing Committee.

### **4.2 Review**

The chairman informed the Committee that the European Parliament proposed about 900 amendments that are currently discussed between the political groups. A lot of topics are discussed very controversially and the Commission has to wait for the amendments being finally adopted at the plenary end of October 2002. The Commission probably will face problems to update the review proposals following the Parliament's discussions in time for the Health Council on 2-3 December 2002. The Danish representative informed that the Danish Presidency - focussing on the review of the Regulation - will try and delete as many of the 80 footnotes as possible that are currently contained in the Council working document and to achieve a political agreement on the regulation. Answering questions from the Irish representatives on the possible finalisation and timeframes the chairman informed that the treaty sets only time limits once a Common position has been drawn up. To reach the common position in the first reading, there is no time limit at all.

## **5. MARKETING AUTHORISATION PROCEDURE**

### **5.1 Centralised procedure and referrals**

The EMEA reported that it is quite disappointing that no centralised applications have been received to date though the original forecast of 10 was realistic since it was based on information from the companies in 2001. The revised estimate of 6 to year-end would be fairly certain since letters of intent have been received for the applications concerned advising submission dates in quarters 3 and 4 of 2002. The forecast of 10 Type II variations should also be achieved since companies with mineral oil vaccines have been asked to submit Type II variations to amend their product literature to include the standard warning agreed by the CVMP. There have been more requests for scientific advice.

### **5.2 Mutual recognition procedure**

The representative of the VMRFG (DK) gave a comprehensive report on the mutual recognition procedure, including information about IT issues, topics under current discussion, number of procedures and the informal VMRFG/CVMP meeting in June 2002.

### **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. The main topic for NTA is the revision of the variation regulations and guideline, and the final guidance on the common technical document for human medicinal products.

## **6. OFFICIAL CONTROL AUTHORITY BATCH RELEASE (OCABR)**

The Commission representative pointed out, as in previous meetings, that a system consisting of documentation review only, without effective re-testing of samples of all batches of a given immunological veterinary medicinal product, cannot be seen as falling under the current provisions of Article 82 of Directive 2001/82/EC. A procedure for official control authority batch release (OCABR) (to harmonise the procedure in those Member States performing actual re-testing as drawn up in the EDQM draft proposal “Administrative procedure for official control authority batch release of immunological veterinary medicinal products” would seem to be a way forward. Some Member States had already commented on this draft proposal. On the occasion of the annual meeting of OMCLs on 15 October 2002 the EDQM foresees a session with those OMCLs who are performing batch release to further discuss and elaborate a final administrative procedure for the OCABR of IVMPs. The UK representative completely disagreed with the Commission interpretation stressing that they are re-testing when they consider it necessary. The Commission representative stated that this could be the case, but it could still not be considered as official batch release if re-testing was not performed on all batches. Finally, in the proposal to amend Directive 2001/82/EC, the Commission has put forward a proposal to harmonise official batch release.

## 7. TELEMATICS

The Commission representative gave a brief update on this subject. During the last meeting of the Telematic Steering Committee (28.05.2002) necessary adjustments to the implementation plan and the strategy paper as well as a precise calendar have been discussed. These two new versions of the documents as well as other related issues will be discussed in depth during the next Telematic Management Committee and confirmed by the next Telematic Steering Committee.

## 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.

**EC - Canada MRA:** At the last Joint Committee meeting on 27 September 2001, it was agreed to postpone the start of the operational phase for 12 months. However it was recommended that contacts between the respective competent authorities be maintained. The delay is related to alleged difficulties with the implementation of GMP in Italy. The Commission has visited the Italian authorities and been provided with a detailed overview of the measures taken. Additionally there have been evaluation visits in June (human) and July (veterinary) showing encouraging progress in both sectors. Final EU evaluation visits will follow beginning of November 2002 (human sector) and January 2003 (veterinary sector) enabling a final assessment of equivalency with EU GMP requirements. The Canadians will already visit the human GMP sector in November/December 2002.

**EC - United States MRA:** There has been little activity on this MRA since the last Veterinary Pharmaceutical Committee pending agreement on the extension of the transition period, which officially ended on 30 November 2001. FDA has been asked to provide a programme indicating that all Member States will have been assessed within the period of time during which it will be extended. Two-way alert systems are already in operation and discussions on a pilot programme for exchange of inspection reports have begun. FDA has performed a visit to the UK inspection authorities and has requested to visit the Irish inspectorate. This latter request is on hold pending the outcome of discussions on extension of the transition period.

**EC - Australia MRA:** The Sectoral Annexes on Medicinal products GMP Inspection and Batch Certification to the MRA in relation to conformity assessment, certificates and markings between the European Community and Australia are in operation since 1 January 1999 for human and 1 June 2001 for veterinary medicinal products. The agreement is based on exchange of certificates of GMP compliance for manufacturers and batch certificates. The contents of these certificates have been agreed with Australia. A Two Way Alert System based on the European system is in operation.

**EC - New Zealand MRA:** The Sectoral Annexes on Medicinal products GMP Inspection and Batch Certification to the MRA in relation to conformity assessment, certificates and markings between the European Community and New Zealand are in operation since 1 January 1999 for human medicinal products. The agreement is based on exchange of certificates for manufacturers and batches. The contents of these certificates have been agreed



with New Zealand. A Two Way Alert System based on the European system is now in operation. For veterinary medicinal product the conditions for entry into force were fulfilled and the operational phase started on 1 June 2002.

**EC - Switzerland MRA:** The agreement on mutual recognition in relation to conformity assessment came into operation on 1 June 2002. The entire text is published in the Official Journal L 114 on 30 April 2002. Chapter 15 details the medicinal and veterinary medicinal product GMP inspection and certification. The revised explanatory note to Chapter 15 and other documents for the operational phase are currently in preparation. The certificate of GMP compliance for manufacturers and batch certificate have been agreed and posted on the EMEA website.

**EC-Japan MRA:** Not covering veterinary medicinal products.

## **8.2 Enlargement**

### **8.2 a) PERF II**

The EMEA representative gave a comprehensive presentation on PERF II and a perspective for PERF III stressing that there is still a lot of work to do for Candidate Countries under the premise that there are no minimum requirements below the standards set in hard laws. The Commission representative gave a short update on the work of the PERF Acquis Working Group and on possible further meetings under PERF III.

### **8.2 b) Protocol to the Europe Agreements on Conformity Assessment and Acceptances (PECAs)**

The Commission representative briefly updated on PECA activities. There are PECAs with Hungary, the Czech Republic, Latvia and Slovakia, but only the PECA with the Czech Republic covers the veterinary part. Unfortunately the veterinary GMP system has been assessed as non-equivalent end of 2001. In the case of imports of medicinal products for veterinary use from the Czech Republic to the EU, it has therefore been agreed, that for a period of 18 to 24 months, or until there has been a satisfactory evaluation of the outstanding matters, it should be ensured that manufacturers concerned have undergone a joint inspection with the participation of an EU inspector. Details as to how this will work are laid down in the draft "Implementation Measures for the Veterinary Medicinal Products covered by the Good Manufacturing Practice for Medicinal Products (GMP) Annex to the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (PECA)". Until now the Czech Republic has not accepted this draft.

## **8.3 VICH**

The EMEA representative gave an update on the VICH activities. Compared to the good progress made in ICH on the human sector there are many problems on the veterinary sector especially concerning the Pharmacovigilance guidelines. Further perspectives, progress on guidelines and their implementation were given in a short presentation. The next VICH conference will take place in Tokyo from 9-11 October 2002.

## **9. Codex Alimentarius Commission – CCRVDF (Codex Committee on Residues of Veterinary Drugs in Foods)**

The Commission representative gave a brief report on the ongoing activities with respect to the Draft Code of Practice to minimise and contain antimicrobial resistance. The drafting group met in Washington in July 2002. Dr Kaartinen (FI) had served as technical adviser to the Commission. The draft guideline will be submitted to the Codex Secretariat and distributed for comments by Member States through the normal consultation procedure. The next meeting in CCRVDF will take place in Washington 4-7 March 2003.

## **10. ANY OTHER BUSINESS**

### **10.1 Update on borderline issues – Guidance documents adopted by the Competent**

#### **Authorities for biocidal products (Directive 98/8/EC)**

The members of the Veterinary Pharmaceutical Committee were again updated by Commission representatives from DG Environment and DG Enterprise on the last developments regarding borderline issues guidelines that have been discussed now since two years. Though Members of the Veterinary Pharmaceutical Committee had in some meetings expressed their opinion that this document would not be very helpful but had never sent any written comments on the proposals they received. Again two documents had been sent to Member States representatives for this meeting.

The first document (Doc-Biocides-2002/01-rev1) on the "Borderline between Directive 98/8/EC concerning the placing on the market of biocidal products, Directive 2001/83/EC concerning proprietary medicinal products and Directive 2001/82/EC concerning veterinary medicinal products" has been adopted by the competent authorities for the Directive 98/8/EC. These authorities explicitly agreed to follow the guidance in the classification of biocidal products for review under that Directive. After some further discussion members of the Veterinary Pharmaceutical Committee endorsed this guidance apart from DE wanting some time for further assessment.

The second document (Doc-Biocides-2002/02) on the "Borderline between Directive 98/8/EC concerning the placing on the market of biocidal products and Directive 92/46/EEC concerning raw milk, heated milk, and milk products" clarifies the classification of disinfectants used in the dairy industry, on farms and on animals producing milk. This guidance was again discussed intensively. Especially UK opposed to the approach to classify teat dips as veterinary medicinal products (VMPs) only if there is a clear therapeutic claim and a full authorisation procedure, because UK would classify teat dips as biocidals if they are used before milking and as VMPs if they are used after milking. No agreement could be reached on this guidance. Therefore the chairman gave 4 weeks for written comments. If the Commission wouldn't receive further comments the guidance would be considered as endorsed.

All important information on biocides legislation, about the "Manual of Decisions" and the guidances can be found on DG Environments website:

<http://europa.eu.int/comm/environment/biocides/index.htm>

## **10.2 EU Action Plan on Drugs 2000 to 2004 – diversion of Ketamine**

The Council wants to reinforce the control of the abuse of Ketamine focussing especially on the sources. Therefore Members of the Committee have received a contribution from the Directorate-General Justice and Home Affairs, Directorate A, Unit A4 Drugs Co-ordination, which has been discussed during the last Pharmaceutical Committee in May 2002 and a questionnaire which has been sent out to Member States Authorities on 29 July 2002. If members of the Veterinary Pharmaceutical Committee want to comment on this questionnaire the Commission kindly asks to contact their colleagues working on the human medicinal sectors of their respective Member State in order to have one agreed answer per Member State. Maybe this reflection could lead also to an amendment/an improvement of the diversion of Ketamine in the veterinary sector. The EMEA offered additional information on this substance widely used in veterinary medicine if wanted. If representatives couldn't hold the deadline of 1 October 2002 they should inform DG JAI about a possible delay.

## **10.3 Proposal for a common identification system for veterinary medicinal and biological products in Europe (FEDESA)**

In September 2001, the CEESA Manufacturing and Logistics Working Group (Manulog), which is composed of senior production and/or logistics managers from 11 major multinational Animal Health companies established in Europe, decided to establish a proposal for a unique identification system of veterinary medicinal and biological products in Europe by the means of a bar code system. The objectives of this system are to facilitate traceability of Animal Health products, to be EU-wide (throughout Europe), to be uniform, single and simple, to be applicable to and mandatory for all veterinary medicinal and biological products and thus to avoid creating non-tariff barriers by single national regulations. By setting up a unique and transparent identification system registered in a central database available to EU and National Authorities, this proposal will improve the traceability and control of products in the Food Chain and will promote the consumers' confidence in safe and high quality food products of animal origin. This system intends furthermore to facilitate the recall procedures by veterinary medicinal products producers, and should assist retailers, wholesalers and others in the accurate identification of the products.

Member State representatives were kindly asked to send comments to FEDESA ([techsec@fedesa.be](mailto:techsec@fedesa.be)) and/or the Commission until end of October 2002.

## **10.4 Contamination of feed with Medroxyprogesterone Acetate (SANCO)**

The representative of DG SANCO gave an information on the contamination of feed with Medroxyprogesterone Acetate caused by a fraudulent disposal of pharmaceutical waste. Members considered this more as a problem of the control of waste disposal.