EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – quality, safety and efficacy

VETPHARM 332

VETERINARY PHARMACEUTICAL COMMITTEE
6 February 2012
19th meeting

SUMMARY RECORD

The 19th meeting of The Veterinary Pharmaceutical Committee took place on 6 February 2012 in Brussels. The meeting was chaired by Patricia Brunko, Head of Unit SANCO D5 – Medicinal products – authorisations, EMA and co-chaired by Stefano Soro, Head of Unit SANCO D6 – Medicinal products – quality, safety and efficacy.

AGENDA AND MINUTES

- The draft agenda of the 19th meeting **(VETPHARM 312)** was adopted with no additional items under A.O.B.
- The draft minutes of the 18th meeting were adopted.
- The Commission provided information on the new organisational structure of DG SANCO in which the pharmaceutical unit is split in units D5 and D6.

1. LEGISLATIVE ISSUES

a) Maximum residue limits for veterinary medicinal products administered by injection and draft Commission Implementing Regulation amending the Annex to Regulation (EC) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance tildipirosin (VET PHARM 314)

The Commission gave a brief presentation of the state of play emphasising that Member States requested the Commission to set a MRL for muscle as reference point for residue controls and currently a disharmonised situation exists in the Union for controls. Discussions focussed mainly on the impact of the recommendations of the CVMP of having two MRLs for the same target tissue (muscle). The members of the Committee taking the floor generally expressed that two MRLs for the same tissue are not feasible from control point of view. At

more detailed level, some members supported having one MRL for the target tissue muscle without stimulating any provisions regarding injection sites, and others pointed to the risk of extended withdrawal periods with the establishment of one MRL for muscle and/or stated to be in favour of further discussing the topic at international level and not to set a MRL for muscle in this stage. The Chair took note of the comments, and stated that the Commission has to act after the reception of the recommendations of the Agency. The Chair encouraged the members of the committee to discuss this topic with their control authorities.

b) Implementing regulation on extrapolation under Article 13(2) b of Regulation (EC) No 470/2009 (VET PHARM 315)

The Commission informed that it has to adopt measures regarding extrapolation and requested the CVMP to give a scientific recommendation on it.

c) Maximum residue limits in honey for substance oxytetracycline (VETPHARM 316)

The Commission gave a brief oral update on this topic and emphasised that the Commission cannot establish MRLs that result in residue levels above the ADI. Therefore it is the intention of the Commission to ask CVMP to revise the MRLs for the substance oxytetracycline for all target tissues in order that the ADI would be respected. Members of the committee supported the revision of the MRLs. However, several members questioned whether a MRL for honey would result in applications for bee medicines with the substance oxytetracycline and/or the need to treat bees with this specific veterinary medicine.

d) Maximum residue limits for cascade (VETPHARM 317)

The Commission informed the Committee that the Commission has to adopt detailed rules on MRLs in the context of the 'cascade' which should resolve the disharmonised approach taken by control authorities. CVMP has provided a draft recommendation on MRLs on this topic. The Commission will provide as soon as possible a feedback to CVMP on this recommendation.

Frank

e) Variation regulation (VETPHARM 318)

The Commission gave a brief oral update on this topic.

Rocio

f) Amendment of Commission Regulation (EC) No 1950/2006 concerning essential substances for horses (VETPHARM 319)

The Committee was informed that Regulation (EC) No 596/2009 of 18 June 2009, one of the "omnibuses" to align the *acquis* with the regulatory procedure with scrutiny (PRAC), did not take over the new legal text for Article 10(3) of Directive 2001/82/EC as introduced with Article 30 of Regulation (EC) No 470/2009 of 6 May 2009. Therefore, the legal basis to extend the list of substances for the treatment of horses (Regulation (EC) No 1950/2006) with "substances bringing added clinical benefit" was lost. The Council Secretariat was contacted and the Council Legal Service agreed to a correction of Regulation (EC) No 596/2009. Any discussion concerning the draft regulation as well as the

draft list as provided by the Committee for Medicinal Products for Veterinary Use (CVMP) may take place during the Standing Committee procedure to be launched once the correction comes into force.

g) Volume 6 - Notice to Applicants (NtA) for Medicinal Products for Veterinary use (VETPHARM 320)

The Commission gave a brief update on the state of play of Volume 6 of the publications "The rules governing medicinal products in the European Union" containing a range of regulatory guidelines. A further meeting of the NtA Working Group is scheduled (but not confirmed) for 30.03.2012.

h) Volume 9B – Pharmacovigilance for Medicinal Products for Veterinary Use (VETPHARM 321)

The Committee was informed about the publication of Volume 9B "Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use" on 30.11.2011. Volume 9B provides general guidance on the requirements, procedures, roles and activities in this field for Marketing Authorisation Holders, National Competent Authorities, the Agency and the European Commission. Although, it was not possible to introduce an official 6 months transitional period, it was recommended to implement this comprehensive guidance with common sense to enable industry to adapt their Standard Operation Procedures, IT systems and to train their staff accordingly.

2. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

a) Recent judgments of the European Court of Justice (VETPHARM 322)

The Commission called the Committee's attention to recent rulings, to the Court's conclusions and one pending case:

- Case C-350/08, judgment of 28 October 2010 "Commission v. Lithuania"
- Case C-385/08, judgment of 22 December 2010, "Commission v. Poland"
- Case C-108/09, judgment of 2 December 2010, "Ker-Optika".
- Case C-145/11 (pending case).

Members raised several questions in relation to internet sales of veterinary medicines. The Commission said that internet sales is not specifically regulated in the Union, however, general principles (e.g. mutual recognition) do apply. This implies that Member States can regulate internet sales. Jurisprudence provides clarification that internet sales should not lead to a lowering of regulatory requirements. However, Court rulings point out the type of restrictions that Member States may impose to limit internet sales of non-prescription medicines.

Florian

b) Borderline cases CMDv (VETPHARM 323)

The Commission informed the Committee on the establishment of a Borderline Working Group by the CMDv and recalled that it is, according to Court's rulings, up to Member States to decide on a case-by-case basis whether a product complies with the definition of a veterinary medicinal product.

3. POLICY INITIATIVES AND REVIEW OF LEGISLATION

a) Review medicated feed (VETPHARM 324)

The Commission introduced the review of the Directive on medicated feedingstuff. The objective is a modernisation of the legislative framework to assure that medication via medicated feed is feasible in a safe and harmonised way throughout the EU covering also the issue of antimicrobial resistance. The project is in a package with the review of the regulatory framework for veterinary medicinal products and the respective Commission proposals are expected for the beginning of 2013. The Committee confirmed the need for a revision of the medicated feed Directive.

b) Review veterinary medicines (VETPHARM 325)

The Commission provided a short state of play. The intention of the Commission is to submit the legal proposal at the outset of 2013. The Chair pointed out that this review should increase competitiveness of companies. However, the safety level has to be ensured. Members taking the floor had comments on the scope of pharmacovigilance, the requirements for packaging and labelling, the need and content of European databases, the burden of legislation, the responsibilities of competent authorities and the functioning of the single market. Members were invited to circulate their comments.

c) Animal Health Law (VETPHARM 326) and f) bee health (VETPHARM 329

The commission gave an oral update on the state of play on both topics. The Commission proposal is foreseen for the third quarter of 2012. A clarification and the name of the DE national contact for animal health matters was given to a DE question on what extent the AHL will deal with veterinary medicine: status quo will be maintained. As regards bee health, the Commission conveyed the high expectations from stakeholders that emerged in various fora and position papers during 2011 i.e. availability of effective bee medicines should be improved both by short-medium term actions and on the long term by the review of the EU veterinary medicinal rules. The UK remarked that for bee health the problem is the lack of development of new products for bees and the establishment of withdrawal periods. The Codex activities on bee medicines may provide new input.

d) Antimicrobial resistance (VETPHARM 327)

The Commission provided an overview on the state of play. The Danish representative informed the Committee about the Presidency Conference on AMR in Copenhagen on 14-15 March 2012. Sweden asked whether the effects of manufacturing outside the Union were covered by the EU rules. The chair explained that pharmaceutical legislation regulates the quality, safety and efficacy of the product. Therefore outside the EU only those rules can be imposed directly related to quality, safety and efficacy of the product. Members pointed out the need to collect appropriate data on the sales of veterinary antimicrobials and the

financing of it, antimicrobials should be considered a specific category of medicines, authorities should have the ability to refuse authorisations if there is a real risk of AMR, existing marketing authorisations for antibiotics should be revised, the need for restrictions of off-label and modernisation of prescription rules. The Chair said that for data collection of antimicrobials we have to determine what we need and what is feasible. A compromise has to be struck between scientific ideas and budgetary possibilities.

Rosa

e) Controls (review (EC) No 882/2004 and Directive 96/23/EC and review of regulatory framework for veterinary medicines) (VETPHARM 328)

The Commission gave a short presentation and reported on the planning. The intention is to have the discussion with the Impact Assessment Board on March 2012 and to launch the consultation of Commission services June 2012. France supported the view that the scope of R. 882/2004 would be extended to veterinary medicinal products as there is a need for a better harmonisation of controls. The current methods of e.g. bench marking have their limits of creating a better harmonised system. For the review of D. 96/23/EC it was pointed out by the Commission that for some substances a common risk assessment will take place and a minimum frequency of controls, however, for most substances Member States have to apply a risk based approach. It was emphasised that European and third countries would be treated the same as equivalence will be asked from third countries

Alexander/Francesca

4. INTERNATIONAL

a) International Cooperation on Harmonisation for Veterinary Medicinal Products (VICH) (VETPHARM 330)

The Committee was informed about seven meetings of the VICH Steering Committee which took place since March 2007. Particular information was provided concerning initiatives to open up VICH to other regions and the creation of the VICH Outreach Forum in November 2011. The first official meeting of this VICH Outreach Forum will be held together with the next Steering Committee meeting in June 2012 in Brussels.

Additionally, the Committee was informed about South Africa's application to gain the status of an observer in the VICH Steering Committee.

b) Codex Alimentarius – Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) (VETPHARM 331)

The Commission indicated that on 25 April a preparatory meeting will take place in Council. In this meeting should be discussed the situation that the proposed Codex MRLs are lower than the existing EU MRLs. Therefore no food safety

concerns exist. However, accepting the Codex MRLs may lead to a trade conflict. CVMP is preparing recommendations on the proposed Codex MRLs.

Risto / Kornelia

5. A.O.B.