European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 11-12 January 2005

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by majority a positive opinion on an initial marketing authorisation application from Pfizer for **Naxcel,** containing ceftiofur as solution for injection for the treatment of bacterial infections in pigs. The application procedure was initiated on 28 October 2002 and the opinion was adopted on 11 January 2005, with an active review time of 210 days.

For further details please see the Summary opinion available on the EMEA web site: http://www.emea.eu.inthttp://www.emea.eu.int

Maximum Residue Limits

The Committee adopted by consensus a positive opinion by recommending the inclusion of **phenoxymethylpenicillin** in Annex I of Council Regulation (EEC) No. 2377/90 for poultry. Phenoxymethylpenicillin has already maximum residue limits established for pigs. The extension application procedure for poultry was initiated on 13 February 2004 and the opinion was adopted on 12 January 2005 with an active review time of 120 days.

The Committee adopted by consensus a positive opinion recommending the inclusion of **thiamphenicol** in Annex III of Council Regulation (EEC) No. 2377/90 for pigs. Thiamphenicol has already maximum residue limits established for cattle and chicken. The extension application procedure for pigs was initiated on 20 June 2003 and the opinion recommending the establishment of provisional MRLs was adopted on 12 January 2005 with an active review time of 119 days.

The Committee adopted by consensus a positive opinion recommending the inclusion of **phoxim** in Annex I of Council Regulation (EEC) No 2377/90 for chickens. Phoxim has already maximum residue limits established for pigs and sheep. With regard to chickens provisional maximum residue limits expiring on 1 July 2005 have previously been established. The evaluation of the data submitted further to the establishment of provisional maximum residue limits was initiated on 15 October 2004 and the opinion was adopted on 12 January 2005 with an active review time of 90 days.

The Committee adopted by consensus a positive opinion recommending the inclusion of **norgestomet** in Annex I of Council Regulation (EEC) No. 2377/90 for cattle, restricted to therapeutic and zootechnical purposes only, further to the establishment of provisional MRLs in April 2003.

For further details please see the Summary opinions, which will be available on Monday 17 January 2005 on the EMEA web site: http://www.emea.eu.int

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion by for the renewal of the marketing authorisation for **Ibraxion**. The Committee concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Scientific advice

The Committee agreed within a 30-day procedure, scientific advice regarding safety data requirements for an oncology product to be used in the treatment of adrenal carcinoma in dogs.

Further to the recommendation of the Committee, it was confirmed the Executive Director had granted free scientific advice regarding an intended MRL application for a substance to be used against nosemosis in bees and for proliferative kidney disease in trouts according to previously agreed criteria in the context of Availability of Medicines for minor species.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **ProteqFlu, ProteqFlu-Te, Nobivac Bb, Nobilis OR inac, Eurican Herpes 205** and concluded that no further action or changes to the product literature of the products were required.

The Committee endorsed the public bulletin on veterinary pharmacovigilance for 2004 summarising the EMEA activities regarding pharmacovigilance for veterinary medicinal products during the passed year. Yearly public bulletins on veterinary pharmacovigilance are being produced by the EMEA since last year with the intention to improve communication to all stakeholders, but particularly to veterinary health professionals, on the surveillance of the safety of veterinary medicines in the EU. Following a general overview and introduction of the EMEA's role regarding veterinary pharmacovigilance for 2003 the 2004 bulletin now provides an analysis of the spontaneous reports of serious adverse reactions that were received for centrally authorised products and updates on all major issues related to pharmacovigilance that occurred during 2004.

The document will be available on the EMEA web site on 17 January 2005: http://www.emea.eu.int

Antimicrobial Resistance

The Committee agreed that Dr Liisa Kaartinen, member of the Committee from Finland and chairperson of the CVMP Scientific Advisory Group on antimicrobials would represent the Committee at the OIE ad hoc group on antimicrobial resistance to be held on 26-28 January 2005 in Paris. The objective of the meeting is to revise the OIE guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine and identify criteria for selecting critically important antimicrobials for veterinary/animal husbandry. This work follows the agreement by the OIE/FAO/WHO for the WHO to prepare criteria for "critically important" antimicrobials for human use and for the OIE to do the same exercise for the veterinary use.

Guidelines, SOPs and Position Papers

Safety

The Committee adopted a guideline on user safety after consideration of comments received during the public consultation (EMEA/CVMP/543/03-FINAL). The document provides guidance on data requirements and assessment methods for use in identifying risks and measures for risk reduction from the potential hazard that may result from exposure of humans to veterinary medicinal products, for example during administration to animals. The guideline will enter into effect on 13 July 2005 and will apply to new applications for marketing authorisation for pharmaceutical veterinary medicinal products.

The Committee also endorsed a summary of the comments on the draft injection site guideline received during the public consultation after their consideration by the CVMP (EMEA/CVMP/543/03-FINAL).

Quality

The Committee endorsed the following guideline prepared by the Joint CHMP/CVMP Quality Working Party:

- Annexes to CPMP/ICH/283/95 Impurities: Guideline for Residual Solvents & CVMP/VICH/502/99 Guideline on Impurities: Residual Solvents – Annex I: Specifications for Class 1 and Class 2 Residual Solvents in Active Substances & Annex II: Residues of Solvents used in the Manufacture of Finished Products

The document, applicable to both human and veterinary products, does not introduce any new requirements, but merely clarifies the existing guidelines (to which it forms two annexes).

The documents will be available on the EMEA web site on 17 January 2005: http://www.emea.eu.int

Others

Further to the agreement of the Notice to Applicants Working Party, the CVMP invited its Working Parties to commence work on the updating of the SPC guidelines, in line with the amending Directive 2004/28/EC, due to come into force on 30 October 2005. The documents will also be sent for comment to the Quality Review of Documents Working Party (QRD) and the Veterinary Mutual Recognition Facilitation Group (VMRFG).

NOTE

The figures related to the status of the different procedures assessed by the CVMP which would normally be presented as an annex to the CVMP Press Release will now be published on the EMEA Website as a stand alone document to be updated by the end of each month.

The next meeting of the CVMP will be held on 8-10 February 2005

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This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int