European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 10-12 February 2009

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for the vaccine **Netvax** (*Clostridium perfringens type A toxoid*), from Intervet International B.V., intended for the active immunisation of chickens to provide passive immunisation against necrotic enteritis to their progeny, during the laying period.

The Committee adopted by consensus a positive opinion on an initial application for a marketing authorisation under exceptional circumstances for **BTVPUR Alsap 8** (*Blutongue virus serotype 8 antigen*), from Mérial S.A.S. intended for the active immunisation of sheep and cattle to prevent viraemia and to reduce clinical signs caused by bluetongue virus serotype 8.

The summary opinions are available on the EMEA web site: http://www.emea.europa.eu

The Committee adopted by consensus positive opinions for type II variation applications for:

Aivlosin – various quality changes, including an additional pack size of 400 g and an extension of the shelf-life for granules for use in drinking water for chicken;

Equilis Prequenza – amendment of adverse reactions section in SPC and leaflet;

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Novem – addition of two new presentations and update of the testing specification for the finished product and manufacturing specification;

Stronghold – various quality changes.

Further to a request from the European Commission, the Committee reconsidered the opinion adopted on 5 October 2008 recommending the refusal of the variation to the terms of the marketing authorisation for **Porcilis Porcoli**. The CVMP confirmed by majority its previous opinion that the data presented were insufficient to allow a complete assessment of the variation but amended the assessment report in order to better detail the reasons for the refusal.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Equilis StrepE**. 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.

[1] The title of the document on cephalosporins has been corrected as it had been incorrectly named as "Public Statement" instead of "Reflection Paper". The reference to the publication of a *Reflection paper regarding the assessment of environmental risks of veterinary medicinal products* on the EMEA website has been deleted (the document is to be published by the European Commission).

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Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the extension of the current Annex I entry of Council Regulation (EEC) No. 2377/90 for **diclofenac** to include bovine milk.

The summary of opinion is available on the EMEA web site: http://www.emea.europa.eu

Community Referrals

The Committee concluded the referral procedure for injectable veterinary medicinal products containing **ivermectin** which are indicated for use in cattle at a dose rate of 200µg ivermectin/kg bodyweight. The procedure was referred to the CVMP by the United Kingdom under Article 35 of Council Directive 2001/82/EC, as amended, due to concerns that the differences in withdrawal periods established across the European Union for the relevant products may present a potential serious risk to human health. The Committee confirmed that in the case of injectable products (intramuscular, subcutaneous) for food producing species, residue depletion data are normally required for generics. In the case of ivermectin however, the Committee noted that the residue kinetics of ivermectin in cattle were highly variable, even in studies performed with the same formulation. Therefore, the Committee considered it appropriate to perform an analysis of the pooled data in order to establish a single harmonised withdrawal period for all relevant products containing ivermectin alone or in combination with another active substance.

The Committee adopted by consensus an opinion concluding that on the basis of all data available a single withdrawal period of 49 days should be established for all concerned injectable products for cattle containing ivermectin whether alone or in combination with another active ingredient. Therefore, the Committee recommended the variation of the existing marketing authorisations accordingly.

The Committee started a referral procedure for all strengths of water soluble powders and oral solutions containing **doxycycline hyclate** indicated for use in chicken and turkeys intended to be administered via drinking water. The matter was referred to the CVMP by the United Kingdom, under Article 35(4) of Directive 2001/82/EC, due to concerns that differences in the posology and indications may present a potential serious risk to public and animal health.

Pharmacovigilance

The Committee reviewed the PSURs for **Econor, Flexicam, Nobivac Piro** and **Rabigen SAG2** and concluded that no further action or changes to the product literatures were required.

The Committee adopted the EMEA public bulletin on veterinary pharmacovigilance for 2008 summarising the EMEA activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMEA/CVMP/PhVWP/253196/2008). Annual public bulletins on veterinary pharmacovigilance are being produced by the EMEA 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. The bulletin includes descriptive statistics on suspected adverse reactions reports and safety updates, and provides an overview of the activities and issues addressed during 2008.

The Committee endorsed the public report on field safety data from the EU arising from the 2008 national vaccination campaigns against bluetongue disease (EMEA/CVMP/652019/2008) in which several vaccines were used. The report is based on a review prepared by the Pharmacovigilance Working Party and considers information provided by Member States' authorities. The report will be published shortly together with a separate press release.

The documents will be available on the EMEA web site: http://www.emea.europa.eu

Concept Papers, Guidelines and SOPs

Pharmacovigilance

The Committee adopted a combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMEA/CVMP/10418/2009) and List of changes agreed for the combined VeDDRA list (EMEA/CVMP/PhVWP/484082/2008).

These lists will be published on the EMEA website in due course and the implementation of the combined VeDDRA list in EudraVigilance Veterinary is provisionally scheduled for December 2009.

The documents will be available on the EMEA web site: http://www.emea.europa.eu

Quality

The Committee adopted a revised "*Guideline on the use of near infrared spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations*" (EMEA/CHMP/CVMP/QWP/17760/2009-Rev.1-CONSULTATION) for a 6-month period of public consultation. The guideline has been revised the light of technological developments, regulatory experience and feedback from the pharmaceutical industry on this relatively new analytical technique.

The Committee adopted three new Question and Answers (EMEA/555991/2007) which aim to clarify several issues associated with the use of Process Analytical Technology (PAT), for example, the use of the term "Process Signature" and inspections connected to PAT applications.

The documents will be available on the EMEA web site: http://www.emea.europa.eu

Environmental Risk Assessment

The Committee adopted a "*Concept paper on the fate of veterinary medicinal products in manure*" (EMEA/CVMP/ERA/10043/2009-CONSULTATION) for a 2-month period of public consultation. This concept paper has been developed to allow comments on the proposal to elaborate a guideline on how fate studies in manure should be conducted and how the result should be evaluated and used in the environmental risk assessment which is provided in support of an application for a marketing authorisation. Following the end of the consultation a Focus Group meeting with Interested parties, research scientists and regulatory authorities is planned.

The documents will be available on the EMEA web site: http://www.emea.europa.eu

Antimicrobials

The Committee adopted a revised "*Reflection Paper on the use of 3rd and 4th generation cephalosporins in food producing animals in the European Union: development of resistance and impact on human and animal health"* following the close of the public consultation (EMEA/CVMP/SAGAM/81730/2006). This reflection paper critically reviews recent information on the use of cephalosporins of the 3rd and 4th generation in food-producing animals in the EU, their effect on development of resistance to this category of antimicrobial agents in bacterial species that are of importance for human and animal health, and the potential impact on human and animal health.

The Committee will at one of its next meetings provide an additional document elaborating on the recommendations to National Competent Authorities and Marketing Authorisation Holders regarding the actions to contain antimicrobial resistance from the use of the 3rd and 4th generation cephalosporins in food producing animals.

The overview of comments received during the public consultation of this statement will be published on the EMEA website (EMEA/CVMP/SAGAM/464096/2008).

Regulatory Issues

The Committee adopted a "*CVMP Reflection Paper regarding the assessment of environmental risks of veterinary medicinal products*" following consideration of the comments received during public consultation and considering further legal advice from the European Commission. This paper addresses the implementation of Directive 2001/82/EC, as amended, in respect to the requirements for the environmental risks assessment of veterinary medicinal products, describing the CVMP considerations based on the legal interpretation of the provisions by the European Commission and the advice by its Environmental Risk Assessment Working Party, and consultations with the CMD(v) and Interested parties. The document will now be submitted to the European Commission. The guidance is intended to be published as part of the Notice to Applicants for veterinary medicinal products.

The next meeting of the CVMP will be held on 10-12 March 2009

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