European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 10 – 12 July 2007

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion under exceptional circumstances on an initial marketing authorisation application for **Nobilis Influenza H5N6** (inactivated whole influenza virus H5N6), from Intervet International BV, a vaccine intended for active immunisation of chickens against avian influenza type A, subtype H5. Taking into account the epidemiological situation within the EU, the assessment of the vaccine was carried out under an accelerated procedure and the opinion was adopted in 120 days.

The recommendation of the Committee with regard to this vaccine was made according to Article 39(7) of Regulation No (EC) 726/2004 for an authorisation under exceptional circumstances and subject to specific obligations and follow-up measures by the marketing authorisation holder, including enhanced pharmacovigilance measures to ensure the safe use of the product. The use of this product will be restricted to administration as part of disease control campaigns implemented by national competent authorities. A separate press release on this topic is available on the EMEA web site.

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

The Committee adopted by consensus a positive opinion on the annual re-assessment for **Nobilis Influenza H5N2** (inactivated whole influenza virus H5N2), from Intervet International BV, a vaccine intended for active immunisation of chickens against avian influenza type A, subtype H5. The CVMP having reviewed the evidence of compliance with the specific obligations submitted by the marketing authorisation holder and having re-assessed the benefit/risk profile of the medicinal product, recommended that the Community marketing authorisation be continued and updated.

The Committee adopted by consensus a positive opinion on the annual re-assessment for **Poulvac FluFend H5N3 RG** (recombinant inactivated avian influenza virus), from Fort Dodge Animal Health, a vaccine intended for active immunisation of chickens and Pekin Ducks against avian influenza type A, subtype H5. The CVMP having reviewed the evidence of compliance with the specific obligations submitted by the marketing authorisation holder and having re-assessed the benefit/risk profile of the medicinal product, recommended that the Community marketing authorisation be continued and updated.

The Committee adopted by consensus a positive opinion for a Type II variation for **Advocate** to add indications for the treatment of biting lice in dogs and for the treatment of *Angiostrongylus vasorum* (French heartworm) in dogs.

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

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The Committee adopted by consensus a positive opinion for a Type II variation for **Aivlosin** regarding an update to the quality part of the dossier including changes to the finished product specifications and associated analytical methods.

The Committee adopted by consensus a positive opinion for a Type II variation for **Econor** regarding an update to the quality part of the dossier including changes to the manufacturing process, specifications and associated analytical methods.

The Committee adopted by consensus a positive opinion for a Type II variation for **Nobilis IB4-91** regarding the addition of an alternative site for final product quality control testing and the implementation of Ph. Eur 2.6.25 for extraneous agents testing.

The Committee adopted by consensus a positive opinion for a Type II variation for **Prac-Tic** regarding additional wording in relation to the treatment of fleas.

The Committee adopted by consensus a positive opinion for a Type II variation for **Oxyglobin** regarding a change in the composition of the primary packaging.

Maximum Residue Limits

The Committee adopted by majority an opinion recommending the establishment of provisional maximum residue limits (MRLs) for **gamithromycin** (*semi-synthetic macrolide antibiotic*) in cattle (excluding dairy cattle).

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

Community Referrals

The Committee started a referral procedure for **Ecomectin (*ivermectin*)**, oral paste for horses, from Eco Animal Health Ltd. The product is indicated for the treatment of nematode or arthropod infections in horses. The matter was referred to the CVMP by Ireland, the Reference Member State for the mutual recognition procedure, under Article 33(4) of Directive 2001/82/EC, as amended, due to concerns raised by a Concerned Member State during the mutual recognition procedure on a potential serious risk to the environment. The Committee is requested to consider if a Phase II environmental impact assessment is required to complete the environmental risk assessment of the product and if specific risk mitigation measures should be recommended.

The Committee started a referral procedure for **Tribrissen (*trimethoprim and sulfadiazine*),** oral paste for horses, from Schering Plough (including associated names) and its generics authorised in the EU Member States. These products were referred to the CVMP by France, under Article 35 of Directive 2001/82/EC, as amended, due to concerns over under-dosing in relation to lack of efficacy and potential antimicrobial resistance development. The Committee is requested to consider whether the recommended dose of each of the products is justified.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Nobivac Bb**. The Committee concluded that the benefit-risk assessment of the product continued to be favourable and, therefore, recommended the renewal of the marketing authorisation. Furthermore, it was agreed that one further renewal would be required.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Aivlosin, Profender, Purevax RC, Purevax RCCh, Purevax RCP, Purevax RCP FeLV, Purevax RCPCh** and **Purevax RCPCh FeLV** and concluded that no further action or changes to the product literature were required.

Concept Papers, Guidelines and SOPs

Efficacy

The Committee adopted a "*Guideline on the summary of product characteristics for anthelmintics*" (EMEA/CVMP/EWP/170208/2005) for implementation by February 2008 following the close of the public consultation. The purpose of the guideline is to provide standard warnings, which should be followed when using anthelmintics in order to reduce the risk of development of anthelmintic resistance. During the drafting of this guideline, a focus group meeting with interested parties was held at the EMEA on 23 February 2006.

The overview of the comments received during the public consultation of this guideline including the minutes of the focus group on the matter will be published on the EMEA website (EMEA/CVMP/EWP/413825/2006).

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

Immunology

The Committee adopted a "*Guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species/limited markets*" (EMEA/CVMP/IWP/123243/2007) for implementation by February 2008 following the close of the public consultation. The purpose of this guideline is to define acceptable data requirements for the demonstration of quality, safety and efficacy for Immunological veterinary medicinal products (IVMPs) intended for these minor uses or minor species/limited markets.

The overview of the comments received during the public consultation of this guideline will be published on the EMEA website (EMEA/CVMP/IWP/279839/2007).

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

Quality

The Committee adopted a "*Guideline on the Declaration of Herbal Substances in the SPC*" (EMEA/HMPC/CHMP/CVMP/287539/2005), for implementation from 1 February 2008 following the close of the public consultation. The purpose of this guideline is to ensure consistency in expression of the qualitative and quantitative composition of herbal substances/preparations in SPCs for herbal medicinal products/traditional herbal medicinal products.

The overview of the comments received during the public consultation of this guideline will be published on the EMEA website (EMEA/HMPC/230249/2006).

The Committee also adopted a "*Guideline on the Quality of Combination Herbal Medicinal Products / Traditional Herbal Medicinal Products*" (EMEA/CHMP/CVMP/QWP/221930/2007-CONSULTATION) for release for a 3-month period of public consultation.

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

The Committee noted that draft ICH Q10 guideline on pharmaceutical quality systems will be published requesting specific input on its potential application to veterinary medicinal products and manufacturers.

Regulatory Issues

The Committee adopted two reflection papers following the close of the public consultation period:

- "*Reflection paper on Withdrawals of Marketing Authorisation Applications for Veterinary Medicinal Products*" (EMEA/CVMP/425558/2006)

- "*Reflection paper on the publication of the CVMP's Negative Opinion and Refusal to Recommend the granting of a Marketing Authorisation for Veterinary Medicinal Products*" (EMEA/CVMP/459912/2006).

The overviews of comments received during the public consultation of both reflection papers will be published on the EMEA website (EME/CVMP/247808/2007; EMEA/CVMP/247827/2007-Rev.1; EMEA/CVMP/248860/2007).

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

The Committee updated the composition of its Scientific Advisory Group on Antimicrobials (SAGAM). The membership of the group will be shortly published at the EMEA web page.

The next meeting of the CVMP will be held on 11-13 September 2007

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