European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 13-15 October 2009

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for an extension application for **Aivlosin** (*tylvalosin*), from ECO Animal Health Ltd., concerning the addition of new target species (pheasants).

The Committee adopted by consensus a positive opinion for an extension application for **Aivlosin** (*tylvalosin*), from ECO Animal Health Ltd., concerning the addition of new pharmaceutical form (42.5 mg/g oral powder).

The Committee adopted by consensus a positive opinion on an extension application for **Equioxx** (*firocoxib*), from Merial concerning the addition of a new pharmaceutical form (20 mg/ml solution for injection).

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

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

Dexdomitor – addition of a new indication for cat preanaesthesia, removal of the warning regarding the use of this product in young animals and improvement of the legibility of the SPC;

Improvac – removal of the potency test in pigs from control test performed on the finished product in the interest of animal welfare;

Convenia – relating to manufacturing changes;

Metacam – relating to manufacturing changes for Metacam chewable tablets for dogs;

Metacam – quality changes for Metacam 0.5 mg/ml oral suspension for cats.

Community Referrals

The Committee concluded the referral procedure for **Poulvac Bursa Plus** (*live Infectious Bursal DiseaseVirus, strain V877)* from Fort Dodge Animal Health Ltd. The matter was referred to the CVMP by the United Kingdom, as the reference Member State in a decentralised procedure, under Article 33 of Directive 2001/82/EC, due to disagreement among the Concerned Member States regarding the safety and efficacy of the product. The Committee adopted by majority an opinion concluding that the safety and efficacy data provided are sufficient to consider that the overall benefit/risk balance of the product is positive and therefore the objections raised by Belgium should not prevent the granting of a marketing authorisation. The opinion will be forwarded to the European Commission.

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The Committee started a referral procedure for **Porcilis PRRS** (*live attenuated PRRS virus strain DV*) from Intervet International B.V. The matter was referred to the Committee by the UK as the reference Member State in the mutual recognition procedure for a type II variation, under Article 39 of Directive 2001/82/EC by reference to Article 6(12) of Regulation (EC) No 1084/2003 due to concerns raised by Spain relating to the quality and efficacy of the simultaneous administration of Porcilis PRRS with Porcilis M Hyo.

The Committee started a referral procedure for **Porcilis M Hyo** (*Inactivated whole cell concentrate of Mycoplasma hyopneumoniae strain 11*) from Intervet International B.V.. The matter was referred to the Committee by the United Kingdom on behalf of France as the reference Member State in the mutual recognition procedure, under Article 39 of Directive 2001/82/EC by reference to Article 6(12) of Regulation (EC) No 1084/2003 due to concerns raised by Spain relating to the quality, safety and efficacy of the simultaneous administration of Porcilis M Hyo with Porcilis PRRS.

Pharmacovigilance

The Committee reviewed the PSURs for **Easotic**, **Equilis Prequenza**, **Equilis Prequenza Te**, **Fevaxyn Pentofel**, **Masivet**, **Meloxivet**, **NAXCEL**, **PRILACTONE**, **Promeris, Promeris Duo** and **Yarvitan** and concluded that no further action or changes to the product literatures were required.

Immunologicals

The Committee discussed authorisation requirements for vaccines against canine influenza in view of the epidemiological situation in the USA and the potential for this agent to enter the EU. No legal mechanism was identified within the current veterinary legislation that would allow the Committee to authorise a vaccine against this disease but prevent its marketing until such time as the epidemiological situation would make its use appropriate and the necessary studies had been completed to demonstrate the relevance of the strains included in a candidate vaccine. Further discussion will take place between the EMEA and the European Commission to explore any possibilities for an alternative approach to meet this potential need.

Concept Papers, Guidelines and SOPs

General

The Committee adopted a "*Concept paper for the revision of the assessor guideline*" (EMEA/CVMP/626480/2009-CONSULTATION) for a 2-month period of public consultation. This concept paper has been developed in view of changes to the underlying legislation (revised Annex I to Directive 2001/82/EC (Directive 2009/9/EC)) and the finalisation of guidance on benefit:risk assessment.

The document will be available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/genguidance/genreg.htm

Efficacy

The Committee adopted a revised "*Guideline on demonstration of target animal safety and efficacy of veterinary medicinal products for use in farmed fish*" (EMEA/CVMP/EWP/459868/2008-CONSULTATION) for a 6-month period of public consultation. This guideline has been revised to take into account the development in fish production in recent years, and feed-back from users of the previous guideline.

The Committee adopted a revised "*Guideline on veterinary medicinal products controlling Varroa destructor parasitosis in bees*" (EMEA/CVMP/EWP/459883/2008-CONSULTATION) for a 6-month period of public consultation. This guideline has been revised to provide clearer and more specific guidance on the dossier requirements, focusing on Varroa parasitosis only.

The documents will be available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/vetguidelines/efficacy.htm

Antimicrobial Resistance

The Committee adopted a joint report on antimicrobial resistance focused on zoonotic infections. The report has been jointly prepared by ECDC, EFSA, EMEA and SCEHNIHR and their responsible scientific committees at the request of the European Commission. The report provides a summary of the state of play to gain a proper understanding of the public health problems linked to Antimicrobial Resistance. Following adoption by the relevant scientific committees, the report will be published on the EMEA web page in synchrony with publication by the other institutions.

MUMS/Limited markets

The Committee reviewed five requests for classification under the new MUMS/limited markets policy which commenced on 1 September 2009. Two of these requests were considered as eligible for financial incentives as intended for MUMS/limited markets- one product for a viral disease in koi carp and one immunological product for dogs. The other three requests concerned an immunological for rabbits, an immunological for horses and a product for anemia in dogs which were all considered as indicated for MUMS. However, due the existence of currently authorised alternative treatments these latter products were not considered as eligible for financial incentives for authorisations.

Availability of medicines

The Committee endorsed the organisation of the EMEA workshop on "*Medicines for bees and what the EMEA can do to increase availability*", planned to be held at the EMEA on 14-15 December 2009. The workshop will bring together experts from the bee keeping and honey production areas, experts in bee diseases and treatment of bees, and representatives from the regulatory authorities of Member States, the European Commission, the animal health industry and other interested parties. The aim is also to provide the opportunity to discuss possible ways forward to identify the most needed treatment options for bees and suggestions on how to improve the availability of medicinal products for this species. Further details regarding the workshop maybe found on the EMEA web site and an agenda will be published shortly.

http://www.emea.europa.eu/meetings/conference.htm

Organisational Issues

The Committee reviewed and adopted mandates for the CVMP Efficacy Working Party (EMEA/CVMP/EWP/208686/2004-Rev.1) and for the CVMP Immunologicals Working Party (EMEA/CVMP/IWP/208689/2004-Rev.1) for another period of 3 years. No changes were introduced to the documents.

The documents will be available on the EMEA web site:
http://www.emea.europa.eu/htms/general/contacts/CVMP/CVMP_WPs.html

Product related e-mail correspondence for the centralised procedure (CP) – New requirements for Applicants, Marketing Authorisation Holders and the regulatory network

As of 15th of October 2009, correspondence concerning a centralised procedure or a product authorised via the centralised procedure should be copied by the sender to a specific e-mail address created for the product. This procedure applies routinely to all concerned products and all issues with the exception of pharmacovigilance (PSURs, questions) and post opinion translation checks that will continue to have dedicated mailboxes.

Further details and additional guidance will be provided to relevant parties. More information is available from concerned Project Managers.

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