EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2010
EMA/CVMP/286802/2010
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 18-20 May 2010

CVMP opinions on veterinary medicinal products

The Committee adopted by majority a positive opinion for a type II variation application for **Ingelvac CircoFLEX** regarding amendments to sections of the Summary of Product Characteristics (SPCs) concerning mixing with Ingelvac MycoFLEX.

The Committee adopted by consensus a positive opinion for a type II variation application for **Cortavance** regarding amendments to sections of the Summary of Product Characteristics (SPCs) concerning special precautions for use of the product.

The Committee noted a request by the marketing authorisation holder for a re-examination of the CVMP opinion on a Type II variation (extension of claims) for **Masivet** that was adopted during the April 2010 meeting. The re-examination procedure was initiated with the receipt of the grounds for the re-examination request from the applicant.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Equilis Te, Equilis Prequenza Te** and **Equilis Prequenza**. The Committee, having re-assessed the benefit-risk balance of these products, concluded that the quality, safety and efficacy continues to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations.

Community referrals and related procedures

The Committee started a procedure for **Pregsure BVD and associated names** (*inactivated Bovine Viral Diarrhoea (BVD) type 1 virus*) from Pfizer Animal Health. The matter was notified to the

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8416
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Committee by Germany under Article 78 of Directive 2001/82/EC, due to concerns relating to animal safety.

The Committee started a procedure for **retrovirus RD114** in relation to live attenuated vaccines for use in dogs and cats. The procedure responds to the request from the Executive Director of the European Medicines Agency for the Committee to give a scientific opinion under Article 30 of Regulation 726/2004 due to a recent scientific publication reporting the presence of the feline endogenous retrovirus RD114 in some vaccines produced on feline cell lines. This publication was initially considered during the April 2010 meeting of the Committee.

The Committee concluded the 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 adopted by majority an opinion concluding that the objections raised during the mutual recognition procedure should not prevent the approval of the type II variation applied for Porcilis PRRS.

The Committee concluded the 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 UK 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. The Committee adopted by majority an opinion concluding that the objections raised during the mutual recognition procedure should not prevent the approval of the type II variation applied for Porcilis M Hyo.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of derquantel in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for ovine species.

The summary opinion is available on the Agency's website:

http://www.ema.europa.eu/htms/vet/mrls/mrlop.htm

The Committee adopted a revised list of substances considered as not falling within the scope of Regulation (EC) 470/2009 (EMA/CVMP/519714/2009), in order to include:

- *Lipids as constituents of the human diet*

The document is available on the Agency's website:

http://www.ema.europa.eu/htms/vet/mrls/background.htm

Scientific advice

The Committee agreed scientific advice concerning data requirements for a fixed combination cardiovascular product for use in dogs.

MUMS / Limited markets

Following the Committee's review of two requests for classification under the MUMS/limited markets policy, which concerned products for minor species - fish (sea bass, sea bream, carp and tilapia) and bees – and where no other products are currently authorised for the same indications, the CVMP

considered that these two products were indicated for MUMS/Limited market and were eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Cerenia**, **EQUIOXX and Previcox oral paste for horses, Gonazon**, **Melovem**, **Naxcel**, **Nobilis OR inac**, **Oxyglobin**, **Porcilis PCV**, **Porcilis Porcoli**, **PRILACTONE**, **Reconcile**, **Rheumocam**, **Slentrol** and **Ypozane** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted the draft Recommendation for the basic surveillance of Eudravigilance Veterinary data (EMA/CVMP/PhVWP/471721/2006) for a 6-month period of public consultation. This recommendation has been developed to provide a simple approach for surveillance of veterinary medicinal products and to facilitate harmonised surveillance across the European Union with efficient use of resources.

The recommendation will be published on the Agency's website:
http://www.ema.europa.eu/htms/vet/phvwp/genguidance.htm

Efficacy

The Committee adopted a concept paper on proposed revision to the guideline for the conduct of efficacy studies for NSAIDs (EMA/CVMP/EWP/62867/2009) for a 3-month period of public consultation. This concept paper has been developed to provide clearer guidance on dose finding, study design, rating scales and internal data validity.

The guideline will be published on the Agency web site:
http://www.ema.europa.eu/htms/vet/vetguidelines/efficacy.htm

International harmonisation

The Committee adopted two quality guidelines for release in the EU following their sign-off by the VICH Steering Committee:

- Draft revised VICH GL18(R) on Residual solvents in new veterinary medicinal products, active substances and excipients (EMA/CVMP/VICH/502/1999-Rev.1) for a 6-month period of public consultation. The revision only concerns changes to two of the solvents (a lower permitted daily exposure (PDE) for N-methylpyrrolidone and for tetrahydrofuran a change from class 3 to class 2) and these changes are consistent with the revised ICH GL Q3C;
- VICH GL45 on Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products (EMA/CVMP/VICH/581467/2007). This is a new guideline which provides guidance on bracketing and matrixing study designs for stability studies conducted in accordance with principles outlined in the VICH GL 3. The guideline will come into effect by April 2011.

Organisational matters

The Committee adopted a revision of the Policy on scientific publication and representation for European Medicines Agency's scientific committees and their members (EMA/231477/2005/Rev. 1). The main changes to the policy during this revision refer to the section on scientific publication. This section has been revised in order to harmonise it with the existing internal EMA publication policy.

The publication of the document will follow the adoption by all other Agency's scientific committees.

Notes

1. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

Contact our press officers

Martin Harvey Allchurch or Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu