8 March 2013
EMA/CVMP/124461/2013
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 5 – 7 March 2013

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Oncept IL-2** from MERIAL an immunotherapy product to be used in addition to surgery and radiotherapy in cats with fibrosarcoma without metastasis or lymph node involvement. The product has been classified previously as MUMS/Limited Markets. More information about the above mentioned medicine, including the full indication, can be found on the Agency's website.

The Committee adopted by consensus a positive opinion for a grouped variation application (subject to a worksharing procedure) for **Procox** relating to manufacturing changes.

Safety of Residues

The Committee noted the request from the European Commission (DG SANCO) for a joint statement from the European Medicines Agency and the European Food Safety Authority on the presence of residues of phenylbutazone in horsemeat. The statement is anticipated to be available before the end of April 2013.

An announcement on the issue was published on the homepage of the Agency's website.

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Posatex**. The Committee, having re-assessed the benefit-risk balance of the product, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and therefore recommended the renewal of the marketing authorisation.

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

Community referrals and related procedures

The Committee started a procedure for **Deltanil 10 mg/ml Pour-on Solution for cattle and sheep and Deltanil 100 mg Spot-on Solution for cattle** (*deltamethrin*) from Virbac S.A. The matter was referred to the Committee by the United Kingdom as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC due to concerns raised by the Netherlands and Germany relating to a potential risk to the environment from use of the product.

The Committee started a procedure for **Suifertil 4 mg/ml oral solution for pigs** (*altrenogest*) from aniMedica GmbH. The matter was referred to the Committee by France as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC due to concerns raised by Germany relating to a potential risk to the environment from use of the product.

The Committee concluded the referral procedure for **Florgane 300 mg/ml suspension for injection for cattle and pigs** (*florfenicol*) from Emdoka bvba. The matter was referred to the Committee by Germany as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC due to concerns raised by Denmark relating to the proposed dosing regimen for pigs. The Committee adopted by majority an opinion concluding that the objections raised by Denmark during the decentralised procedure should not prevent the granting of the extension of the marketing authorisation for Florgane 300 mg/ml suspension for injection for cattle to the target species pigs.

The Committee concluded the referral procedure for **Soludox 500 mg/g powder for use in drinking water for pigs and chickens** (*doxycycline hyclate*) from Eurovet Animal Health bv. The matter was referred to the Committee under Article 13 of Commission Regulation (EC) No. 1234/2008 by the United Kingdom as the reference Member State in the type II variation work-sharing procedure, due to concerns raised by the Netherlands relating to the potential risk to human health resulting from the proposed withdrawal period for chickens. The Committee adopted by consensus an opinion concluding that the objections raised by the Netherlands should not prevent the granting of the variation to the terms of the marketing authorisations subject to changes in the product information recommending a withdrawal period of 9 days for chicken meat and offal at a dose rate of 20 mg/kg body weight for 4 consecutive days.

Scientific advice

The Committee adopted two scientific advice reports concerning safety and efficacy requirements for a centrally acting product in dogs and safety and efficacy requirements for a product with an orthopaedic indication for horses. The first request was a parallel scientific advice procedure with the FDA-CVM.

MUMS / Limited markets

Following the Committee's review of three requests for classification under the MUMS/Limited Markets policy concerning an immunological product for ferrets, a product with a musculo-sketal indication for use in horses and an anti-inflammatory product for use in horses, the CVMP considered that the three products were indicated for MUMS but were not eligible for financial incentives as alternative authorised products already exist for the specific indications.

Antimicrobial resistance

The Committee received a request for scientific advice from the European Commission on issues related to the impact on public and animal health of the use of antibiotics in animals. The Commission has requested that in formulating its advice, the EMA should coordinate input from the CVMP and CHMP, as well as EFSA and ECDC as appropriate. The advice should cover four aspects; the use in animals of antibiotics that have a potential to affect the continued effectiveness of antibiotics that are used in man for treatment of multi-resistant organisms, with particular emphasis on colistin an tigicycline; the appropriateness of classifying veterinary antibiotics according to their use (first, second line, etc); whether or not it is appropriate to incentivise the development of novel antibiotics for veterinary use; and finally, the need or not to restrict the use of currently authorised antibiotics in veterinary medicine. Each aspect has its own timeline and further information will be released on the EMA website as agreement is reached on the approach to be adopted.

Pharmacovigilance

The Committee reviewed the periodic safety update reports for **CaniLeish, Porcilis PCV, Procox, Suvaxyn PCV and Veraflox** and concluded that no further action or changes to their product information were required.

Working Parties

The Committee re-elected Piet-Hein Overhaus as Vice-chair of the Joint CHMP/CVMP Quality Working for a 3-year mandate.

International harmonisation

The Committee adopted four VICH guidelines for implementation in the EU following the sign-off by the VICH Steering Committee at step 6:

- GL 34 on Biologicals: Testing for the detection of Mycoplasma contamination
- GL 35 on Pharmacovigilance: Electronic standards for transfer of data
- GL 50 on Biologicals: Harmonisation of criteria to waive Target Animal Batch Safety Testing (TABST) for inactivated vaccines for veterinary use
- GL 51 on Quality: Statistical evaluation of stability data

The guidelines will be published on the Agency's website.

Organisational matters

The CVMP meeting was followed by a European Medicines Agency / IFAH-Europe Info Day on 7- 8 March 2013 under the theme "The Latest Developments in Scientific Review, Legislation and Marketing Authorisation Procedures".

Procedural Announcement on the
Pre-Accession Linguistic Checking Procedure for the Croatian language

Applicants and Marketing Authorisation Holders are reminded of the need to include Croatian language versions in their product information for procedures leading to a Commission Decision from 1 July 2013 onwards (i.e. for procedures having an opinion from the April 2013 CVMP onwards).

Guidance documents are available at Croatian Pre Accession Lingusitic Check; if you have any queries on this please contact grd@ema.europa.eu.

Notes

1. 'MUMS' stands for minor use minor species.
2. 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