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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 09-11 April 2013

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Equilis West Nile** from Intervet International B.V. a vaccine for the active immunisation of horses against West Nile virus to reduce clinical signs of disease and lesions in the brain and to reduce viraemia.

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

Cardalis from Ceva Sante Animale to confirm the palatability of the tablets and modify the pharmaceutical form and

Contacera from Pfizer Limited regarding the change of its composition.

More information about the above mentioned medicines, including their full indication, can be found on the Agency's website.

Annual reassessment of marketing authorisations

The Committee adopted by consensus opinions on the annual reassessments for **Zulvac 8 Ovis** and **Zulvac 8 Bovis**, further to the evaluation of the data submitted by the marketing authorisation holder. Since the specific obligations have been fulfilled the Committee recommended the conversion of the Community marketing authorisations from under exceptional circumstances to a normal status for these two products.

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

Renewals of marketing authorisation

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

Community referrals and related procedures

The Committee started a procedure for **all veterinary medicinal products containing altrenogest to be administered orally to pigs and horses**. The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC, due to concerns relating to a potential serious risk to the environment from the use of the products.

The Committee started a procedure for **Cydectin TriclaMox pour-on solution for cattle** (*moxidectin and triclabendazole*) (marketing authorisation holder, Zoetis). The matter was referred to the Committee under Article 13 of Regulation (EC) No. 1234/2008 by France as the reference Member State in the type II variation procedure, due to concerns raised by Belgium relating to the efficacy of the product against lice species.

The Committee concluded the referral procedure for **all long acting formulations for injection containing barium selenate for all food producing species**. The matter was notified to the Committee by Germany under Article 35 of Directive 2001/82/EC, due to concerns on safety of residues. The Committee adopted, by majority, an opinion concluding that benefit-risk balance for the products concerned is negative as following treatment at recommended doses barium selenate remains at injection sites for long time periods after treatment and consequently consumption of injection site residues could pose a significant risk to human health. The CVMP recommended the suspension of the marketing authorisations for long acting formulations for injection containing barium selenate for all food producing species.

The Committee concluded the referral procedure for **STRENZEN 500/125 mg/g powder for use in drinking water for pigs** (*amoxicillin trihydrate and potassium clavulanate*) (applicant Novartis Animal Health d.o.o.). The matter was referred to the Committee by the Czech Republic as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC due to concerns raised by the United Kingdom and the Netherlands relating to a potential risk to the environment from use of the product. The Committee adopted by consensus an opinion concluding that the objections raised by the United Kingdom and the Netherlands during the decentralised procedure should not prevent the granting of the marketing authorisation for STRENZEN 500/125 mg/g powder for use in drinking water for pigs.

The Committee noted a request for re-examination of the CVMP opinion adopted on 7 March 2013 in the context of a referral procedure under Article 13(2) of Commission Regulation (EC) No 1234/2008 for **Soludox 500 mg/g powder for use in drinking water for pigs and chickens and associated names** (*doxycycline hyclate*). The procedure will be initiated once the grounds for the re-examination are submitted.

Safety of Residues

Further to a request in accordance with CVMP guidance to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, the Committee adopted a revised list of substances to include polyoxyethylene (40) sorbitol septaoleate.

The document will be available on the Agency's website.

Scientific advice

The Committee adopted three scientific advice reports concerning quality requirements for an immunological product for poultry, efficacy requirements for a cardiovascular product for cats and whether an excipient can be considered as not falling within the scope of Regulation (EC) No 470/2009.

MUMS/Limited markets

Following the Committee's review of three requests for classification under the MUMS/Limited markets policy concerning an immunological product for horses, a product with an endocrine indication for dogs and a product with an alimentary indication in cats, the CVMP considered that the product for cats was not indicated for MUMS/Limited market and was not eligible for financial incentives; that the product for dogs was indicated for MUMS/Limited market and was eligible for financial incentives; the product for horses was indicated for MUMS but was not eligible for financial incentives as the market was not limited.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl**, **Aivlosin**, **Equip WNV**, **Improvac**, **Inflacam**, **Masivet**, **Meloxoral**, **MS-H vaccine**, **Palladia**, **Porcilis ColiClos**, **Porcilis AR-T DF** and **Zuprevo** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Safety - Environmental Risk Assessment

The Committee adopted a draft Concept paper on assessing the toxicological risk to humans and the environment of veterinary pharmaceuticals in groundwater (EMA/CVMP/ERA/718229/2012) for consultation for a 2-month period of public consultation. The concept paper was developed to provide further technical support to the implementation of the VICH guidelines GL6 and GL38 on the environmental risk assessment (ERA) of veterinary medicinal products. The concept paper gives guidance on the methodology to use when performing the groundwater risk assessment. The methodology should consider both the risk for human health resulting from residues of veterinary medicinal products in groundwater and the risk to the environment.

The document above will be available on the Agency's website.

Immunologicals

The Committee adopted a draft Guideline on the compliance of authorised equine influenza vaccines with OIE requirements (EMA/CVMP/IWP/97961/2013) for a 6-month period of public consultation. The guideline was developed to replace the Note for Guidance: Harmonisation of requirements for equine influenza vaccines – Specific requirements for substitution or addition of a strain or strains (EMEA/CVMP/112/98-FINAL). The guideline provides guidance on the data requirements to support modifications to authorised, equine influenza vaccines based on recommendations from the OIE Expert Surveillance Panel on Equine Influenza Vaccine Composition.

The document above will be available on the Agency's website.

Pharmacovigilance

The Committee adopted Questions and Answers on the following topics:

- Serious non-fatal adverse events and reporting rules
- PSUR preparation, management and assessment and
- Adverse event reporting

The Questions and Answers will be published on the Agency's website.

Statement on the presence of residues of phenylbutazone in horsemeat

Further to the European Commission's request dated 28 February 2013, the Committee endorsed the joint statement from the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) on the presence of residues of phenylbutazone in horsemeat. Once formally adopted by both agencies and sent to the Commission, the joint statement will be published on the EMA and EFSA websites on 15 April 2013.

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