EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 14-16 January 2014

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for initial marketing authorisation applications for:

Fungitraxx (*itraconazole*), from Avimedical B.V., an antifungal product for treatment of aspergillosis and candidiasis in identified species of ornamental birds. The product has been classified as MUMS/limited markets; and

Equisolon (*prednisolone*), from LE VET B.V., an anti-inflammatory product for use in horses with recurrent airway obstruction in combination with environmental control. The product has been classified as MUMS/limited markets.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Panacur AquaSol** (fenbendazole), from Intervet International B.V., concerning the addition of a new target species (chickens).

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

The Committee adopted by consensus a positive opinion for the type II variation application for **MS-H vaccine** from Pharmsure Ltd regarding quality changes.

The Committee was informed of the formal notification from Eco Animal Health of their decision to withdraw the extension application for a new indication for Aivlosin 42.5 mg/g Premix for chickens. More information about this extension application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report. The document, together with the withdrawal letter from the applicant will be published on the Agency's website in due course.

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Annual reassessment of marketing authorisations under exceptional circumstances

The Committee adopted an opinion on the annual reassessment for the blue tongue virus vaccine **Bovilis BTV8**, further to the evaluation of the data addressing the specific obligations of the marketing authorisation granted under exceptional circumstances submitted by the marketing authorisation holder. Since the specific obligations for Bovilis BTV8 are now fulfilled the Committee recommended the conversion of the Community marketing to a normal status for this product.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **BTVPUR AlSap 8** and **Loxicom**. The Committee, having re-assessed the benefit-risk balance of these products, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations.

Community referrals and related procedures

The Committee concluded the referral procedure for **Norbonex 5 mg/ml pour-on solution for beef and dairy cattle** (*eprinomectin*) from Norbrook Laboratories Ltd. 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 Germany relating to a potential risk to the environment from the use of the product. The Committee adopted by consensus an opinion concluding that the objections raised by Germany during the decentralised procedure should not prevent the granting of the marketing authorisation for Norbonex 5 mg/ml pour-on solution for beef and dairy cattle.

The Committee noted a request for re-examination of the CVMP opinion adopted on 11 December 2013 in the context of a referral procedure initiated under Article 33(4) of Directive 2001/82/EC for **Fiprex CAT 52.5 mg spot-on solution for cats**, **Fiprex S 75 mg spot-on solution for dogs**, **Fiprex M 150 mg spot-on solution for dogs**, **Fiprex L 300 mg spot-on solution for dogs** and **Fiprex XL 412.5 mg spot-on solution for dogs** (*fipronil*). The procedure will be initiated once the grounds for the re-examination are submitted.

Maximum Residue Limits

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 considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009-Rev.18), in order to include **2-[2-(dodecyloxy)ethoxy]ethanol** and **polyoxyethylene (9) lauryl ether** as new entries under the heading of excipients. The document will be available on the Agency's website.

Scientific advice

The Committee adopted four separate scientific advice reports concerning: efficacy issues for the development of a gastrointestinal product for horses; two separate requests for efficacy issues for oncology products for dogs and follow-up advice on safety issues for a musculoskeletal product for horses.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl**, **Cardalis**, **Clomicalm**, **Gripovac 3**, **Kexxtone**, **Loxicom**, **Melosus**, **Neocolipor**, **Pexion**, **Proteq West Nile**, **RevitaCAM**, **Semintra**, **Zulvac 1 Bovis** and **Zulvac 1 Ovis** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a revised guideline on the conduct of efficacy studies for non-steroidal anti-inflammatory drugs (NSAID) (EMA/CVMP/EWP/513162/2013) following the close of public consultation. The current guideline was revised to provide clearer information and guidance on trial design and conduct, as well as on reporting standards for efficacy studies submitted in support of an application to authorise a new NSAID, or to vary the indications of an already authorised NSAID..

Quality

The Committee adopted a revised guideline on process validation (EMA/CHMP/CVMP/QWP/70278/2012-Rev.1) following the close of public consultation. This revision introduces clarification on how new opportunities can be taken when enhanced process understanding, coupled with risk management tools under an efficient quality management system, have been applied to manufacturing processes.

The Committee adopted a revised guideline on stability testing for applications for variations to a marketing authorisation (EMA/CHMP/CVMP/QWP/441071/2011) following the close of public consultation. The existing guideline was revised to take into account the changes introduced in the amending Directive 2009/53/EC, in the new variations regulation (Commission Regulation (EC) No 1234/2008) and in the variations classification guideline (Commission Communication 2010/C 17/01).

The Committee adopted a revised Question and Answer on the following quality topic:

- Limits for microbiological quality for premixes for medicated feeding stuffs which contain excipients of natural origin. The revision is to bring the document in line with the updated European Pharmacopoeia General Chapter 5.1.4 “Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use” and the updated Pharmacopoeia Monograph “Premixes for medicated feeding stuffs for veterinary use”.

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

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