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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 06-08 November 2012

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation for **Kexxtone** continuous-release intraruminal device for cattle (*monensin*) from Eli Lilly and Company Limited. The product is intended for the reduction of the incidence of ketosis in the periparturient dairy cow/heifer, which is expected to develop ketosis.

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

The Committee adopted by consensus a positive opinion for an extension and variation applications for the existing authorisation for **Comfortis** (*spinosad*) from Eli Lilly and Company Limited to add cats as a new target species and to add lower tablet strengths.

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

Equip WNV regarding the addition of a manufacturing site,

Procox regarding the addition of a new indication for the treatment of *Trichuris vulpis* (mature adults),

RHINISENG regarding a quality change,

Metacam regarding the addition of a new indication for dehorning in calves,

Novem regarding the addition of a new indication for dehorning in calves,

Inflacam regarding a quality change,

and **Rheumocam** regarding a quality change.

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The Committee adopted by consensus a positive final opinion further to re-examination of one aspect of the opinion for a grouped type II variation application for **Onsior** regarding the addition of new indications. The changes agreed are for the solution for injection to add an indication for the treatment of pain and inflammation associated with orthopaedic surgery in cats (including repeated use post-surgery) and for the tablet formulation the reduction of moderate pain and inflammation associated with orthopaedic surgery in cats. Additional warnings were included in the product literature following the PSUR assessment.

The Committee adopted by consensus a negative opinion for a type II variation application for **Naxcel** regarding the addition of a new indication for the treatment of bovine respiratory disease for the cattle presentation.

The Committee was informed of the formal notification from Novartis of their decision to withdraw the extension application for a new target species (goats) for **ZOLVIX**. 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.

Annual reassessment of marketing authorisations

The Committee adopted opinions on the annual reassessment for **Bovilis BTV8** and **BLUEVAC BTV8**, further to the evaluation of the data submitted by the marketing authorisation holders. The Committee recommended the continuation of the Community marketing authorisations under exceptional circumstances for these veterinary medicinal products.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Advocate** and **Ingelvac CircoFLEX**. 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 **Melosolute 40 mg/ml solution for injection for cattle, pigs and horses** (*meloxicam*) (marketing authorisation holder, CP-Pharma Handelsgesellschaft mbH) in relation to the target species pigs. The matter was referred to the Committee by the Netherlands as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC due to concerns raised by Ireland and the United Kingdom relating to demonstration of bioequivalence of the product with the reference product for the target species pigs. The Committee adopted by consensus an opinion concluding that the application does not comply with Article 13 of Directive 2001/82/EC and that a positive benefit-risk balance cannot be established for the target species pigs. Therefore the Committee recommended the refusal of the granting of the marketing authorisation for Melosolute 40 mg/ml solution for injection for the target species pigs.

The Committee started a procedure for **Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names** (*enrofloxacin*) (marketing authorisation holder, Bayer Animal Health). The matter was referred to the Committee by France, under Article 34 of Directive 2001/82/EC due to divergent decisions taken by Member States resulting in discrepancies in the product information.

The Committee started a procedure for **all veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys**. The matter was referred to the Committee by the United Kingdom under Article 35 of Directive 2001/82/EC, to review indications, dosage and withdrawal periods due to concerns related to antimicrobial resistance.

The Committee started a procedure for **Soludox 500 mg/g powder for use in drinking water for pigs and chickens** (*doxycycline hyclate*) (marketing authorisation holder, Eurovet Animal Health BV). The matter was referred to the Committee under Article 13 of Regulation (EC) No. 1234/2008 by the United Kingdom as the reference Member State in the variation work-sharing procedure, due to concerns raised by the Netherlands relating to a potential risk to human health resulting from the proposed withdrawal period for chickens.

Scientific advice

The Committee agreed two separate scientific advice requests concerning safety requirements for an antimicrobial product for swine, bovine and poultry and safety and efficacy requirements for a product for the treatment of a haematological condition in dogs.

MUMS / Limited markets

Following the Committee's review of three requests for classification under the MUMS/Limited markets policy, which concerned a zootechnical product for rabbits, a product indicated for a gastrointestinal indication in dogs and an ectoparasiticide for bees; the CVMP considered that all three products were indicated for MUMS/Limited markets but were not eligible for financial incentives as authorised products already exist for the specific indications.

Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR AlSap 1**, **Cerenia**, **Comfortis**, **Equilis StrepE**, **Hiprabovis IBR Marker Live**, **Panacur AquaSol** and **Posatex** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **CaniLeish** and recommended amendments to the product information to add new adverse reactions.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a draft guideline on demonstration of palatability of veterinary medicinal products (EMA/CVMP/EWP/206024/2011-CONSULTATION) for a 6-month period of public consultation. The guideline was developed to provide recommendations regarding the design, conduct, and evaluation of studies for the demonstration of palatability of veterinary medicinal products intended for oral individual or group animal treatment.

The Committee adopted a draft revised guideline on conduct of efficacy studies for non-steroidal anti-inflammatory drugs (NSAID) (EMA/CVMP/EWP/1061/2011-CONSULTATION) for a 6-month period 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. This guideline is a revision of the original guideline on the topic (EMA/CVMP/237/01-FINAL).

Safety

The Committee adopted a guideline on the approach to establish a pharmacological ADI (EMA/CVMP/SWP/355689/2006) taking into account the comments received during the public consultation. The guideline provides guidance on when to establish a pharmacological ADI and on the pharmacological studies and endpoints to be addressed in order to establish a pharmacological ADI.

The Committee adopted a draft guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (EMA/CHMP/CVMP/SWP/169430/2012-CONSULTATION) to be published for a 6-month period of public consultation following its adoption by the CHMP. The guideline proposes a toxicological approach to be used as part of the process of determining whether or not active substances and medicinal products need to be manufactured in dedicated facilities.

Immunologicals

The Committee adopted a draft guideline on the requirements for combined vaccines and association of immunological veterinary medicinal products (EMA/CVMP/IWP/594618/2010-CONSULTATION) taking into account the comments received during the public consultation. The guideline has been developed to provide guidance on the data requirements to support authorisation of combined vaccines and a claim for the use of two or more IVMPs, each with its own separate marketing authorisation, in association with one another. Since the guideline has been revised substantially the Committee agreed to publish this guideline for a second, 2-month consultation period.

The Committee adopted a draft table of extraneous agents to be tested for in relation to the Guideline on Requirements for the Production and Control of Immunological Veterinary Medicinal Products (EMA/CVMP/IWP/105112/2011-CONSULTATION) for consultation for a 6-month period of public consultation. This table has been developed to include a detailed list of agents which must be taken into account when considering what testing for extraneous agents is appropriate.

The documents above will be published on the Agency's website.

Working Parties

The Committee endorsed the work plans for 2013 for the CVMP Working Parties on Scientific Advice, Pharmacovigilance, Efficacy, Safety, Immunologicals and Environmental Risk Assessment as well as for the Joint CHMP/CVMP Quality Working Party.

The work plans will be published on the Agency's website.

Organisational

The Committee elected Keith Baptiste as the co-opted member in the area of antimicrobials and antimicrobial resistance for a three-year mandate.

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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