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 May 2012

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Cardalis** tablets (benazepril and spironolactone), from Ceva Santé Animale, indicated for the treatment of congestive heart failure caused by chronic degenerative valvular disease in dogs.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation for **Nobivac L4**, from Intervet International BV, a vaccine that contains inactivated Leptospira strains and which is indicated for the active immunisation of dogs to reduce infection and/or urinary excretion caused by Leptospira strains.

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 final opinion, following a re-examination of a type II variation opinion for **Nobilis IB 4-91** (Live attenuated avian Infectious Bronchitis Virus (IBV) variant strain 4-91) to include vaccination of 1 day old future layers and breeders.

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

Improvac relating to a starting material;

Oxyglobin regarding the introduction of a new detailed description of the pharmacovigilance system (DDPS).

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Renewals of marketing authorisation

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

Community referrals and related procedures

The Committee started a 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 started a procedure for **Micotil 300 Injectie and its associated names** (tilmicosin) from Eli Lilly Nederland, Elanco Animal Health. The matter was referred to the Committee by the Netherlands under Article 34 of Directive 2001/82/EC, due to divergences amongst the nationally authorised SPCs for the above-mentioned product.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **monepantel** in ovine and caprine milk.

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.10), in order to include dimethyldioctadecylammonium bromide under the heading of excipients.

More information about the above recommendations can be found on the Agency's website.

Scientific advice

The Committee agreed scientific advice on the clinical development of an antibiotic veterinary medicinal product for pigs.

MUMS / Limited markets

Following the Committee's review of two requests for classification under the MUMS/Limited markets policy, the CVMP considered that a product with a cardiovascular indication in cats was indicated for MUMS/Limited market and was eligible for financial incentives and that the second product with a CNS indication for mice and rats was also indicated for MUMS/Limited market and was eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR AlSap 1, BTVPUR AlSap 1-8, Cerenia, Equilis Te, EQUIOXX and Previcox oral paste, Hiprabovis IBR Marker Live, Improvac, LEUCOFELIGEN FeLV/RCP, LEUCOGEN, MS-H vaccine, Posatex, Slentrol** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Porcilis AR-T DF** and recommended the addition of a new adverse reaction in the product literature.

The Committee also reviewed the PSUR for **Zuprevo** and recommended the addition of a new adverse reaction and the addition of a special precaution for use in the product literature.

Organisational matters

The Committee held a meeting with interested parties on 15 May 2012 attended by representatives of European Group for Generic Veterinary Products (EGGVP), Federation of Veterinarians of Europe (FVE), International Council on Animal Protection in Pharmaceutical Programs (ICAPPP) and the International Federation of Animal Health Europe (IFAH-Europe).

The topics discussed concerned:

- Antimicrobial resistance
- Review of the veterinary legislation
- The Agency's transparency initiatives
- EMA/CVMP activities in relation to the 3Rs
- Developments on MRLs and Reference Points for Action for honey

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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