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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 11-13 January 2011

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a marketing authorisation application for **CaniLeish** from Virbac S.A., a vaccine for the active immunisation of Leishmania in dogs against Leishmania infection containing as active ingredient *Leishmania infantum* excreted secreted proteins.

The Committee adopted by consensus a positive opinion for a marketing authorisation under exceptional circumstances for an application for **ZULVAC 1+8 Ovis** from Pfizer Limited, a vaccine for the active immunisation of sheep for the prevention of viraemia caused by Bluetongue Virus serotypes 1 and 8, containing inactivated Bluetongue virus, serotypes 1+8.

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

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Flexicam 5 mg/ml solution for injection**. 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.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of a maximum residue limit for **methylprednisolone** in milk.

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Methylprednisolone is currently included in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010, as amended, with maximum residue limits established for cattle tissues and a provisional maximum residue limit for milk expiring on 1 July 2011.

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

Further to a request of the European Commission under Article 11 of Regulation (EC) 470/2009, the Committee started a procedure for the revision of the of maximum residue limits for ivermectin in order to consider the possibility of establishing a maximum residue limit in muscle. The request from the Commission aims at facilitating the monitoring of residues in case where the full carcass is not available and only muscle is available for analysis.

Scientific advice

The Committee agreed scientific advice concerning safety and clinical requirements for an ectoparasiticide product intended for dogs and cats.

MUMS / Limited markets

Following the Committee's review of 2 requests for classification under the MUMS/limited markets policy, concerning a product indicated for use as an anthelmintic in certain birds and an antimicrobial product indicated for use in cats and dogs. The CVMP considered that:

- the anthelmintic product was indicated for MUMS/Limited markets but was not eligible for financial incentives as authorised products already exist for the indication

- the antimicrobial product was not indicated for MUMS/Limited market and was not eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for, **Aivlosin**, **Incurin**, **Loxicom** and **Nobilis IB4-91** and concluded that no further action or changes to their product literature were required. The Committee also reviewed the PSUR for **Zubrin** and recommended amendment of the product literature concerning the inclusion of a new adverse reaction.

Concept papers, guidelines and SOPs

Antimicrobial Resistance

The Committee adopted a revised Reflection paper on meticillin-resistant *Staphylococcus pseudintermedius* (MRSP) (EMA/CVMP/SAGAM/736964/2009) following the end of the public consultation. This reflection paper has been developed to address a sudden emergence of meticillin-resistant *Staphylococcus pseudintermedius* (MRSP) in dogs and cats mainly due to clonal spread. The document considers the risks to animal and human health derived from MRSP and makes recommendations for action. The reflection paper has been revised to take into account the comments received.

The document and the overview of comments will be published on the Agency's web site.

CVMP Working Parties

The Committee elected Gesine Hahn as the new chairperson of the Efficacy Working Party for a 3-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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