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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP)

Meeting of 7-9 October 2014

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Bovela**, containing modified live bovine viral diarrhoea virus type 1 and modified live bovine viral diarrhoea virus type 2, from Boehringer Ingelheim Vetmedica GmbH, a vaccine for the active immunisation of pregnant cattle against bovine viral diarrhoea virus.

The Committee adopted by consensus a positive opinion for a type II variation application for **ZACTRAN**, from Mérial, regarding quality changes.

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

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Gripovac 3** and **Respiporc flu3**. 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 started a procedure for **Gutal 1000 g/kg for medicated feeding stuff for pigs** (zinc oxide) from Huvepharma NV. 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 France and the Netherlands relating to a potential risk to the environment from use of the product.

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The Committee concluded the referral procedure for **Resflor solution injectable** (florfenicol and flunixin) from Intervet International B.V. The matter was referred to the Committee under Article 13 of Commission Regulation (EC) No 1234/2008 by France, as the reference Member State in the type-II-variation procedure, due to concerns raised by Denmark and Germany relating to the addition of *Mycoplasma bovis* as a target organism for this veterinary medicinal product. The Committee adopted by majority an opinion concluding that the objections raised by Denmark and Germany during the variation procedure should not prevent the granting of the variation to the terms of the marketing authorisation for Resflor solution injectable.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the modification of the maximum residue limit classification for basic aluminium salicylate and the establishment of provisional maximum residue limits in bovine tissues and milk, in accordance with Regulation (EC) No 470/2009. Furthermore, the Committee agreed to extrapolate these provisional maximum residue limits to caprine species, *Equidae* and rabbits.

More information about the above recommendation will be published on the Agency's website.

The Committee agreed to include cytosine-phosphate-guanine 23877 as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, and adopted a revised list (EMA/CVMP/519714/2009-Rev. 23). This decision followed the Committee's review of a request that had been submitted in accordance with the relevant CVMP guidance.

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

MUMS/limited market

Following the Committee's review of six requests for classification under the MUMS/limited market policy, the CVMP classified:

- a veterinary medicinal product with an indication for mastitis in cattle as indicated for MUMS/limited market, but not eligible for financial incentives as an alternative product is authorised for the same target species for the same therapeutic indication;
- a veterinary medicinal product with an indication for a protozoal disease in dogs as not indicated for MUMS/limited market;
- a veterinary medicinal product with an immunological indication for mink as MUMS/limited market, but not eligible for financial incentives as it is not intended for food-producing animals;
- two veterinary medicinal products with anthelminthic indications in cats as not indicated for MUMS/limited market; and
- a veterinary medicinal product with an oncology indication in dogs as MUMS/limited market but not eligible for financial incentives, as it is not intended for food producing animals.

Pharmacovigilance

The Committee reviewed the PSURs for **Aivlosin**, **Apoquel**, **BTVPUR Alsap 2-4**, **Certifect**, **Equioxx** and **Previcox**, **Leucogen**, **MS-H Vaccine**, **Oncept IL-2**, **ProMeris, ProMeris Duo** and **Vectra 3D** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSURs for **Nobivac Myxo-RHD, Pexion,** and **Recuvyra** and recommended amendments to the product information.

Concept papers, guidelines and SOPs

Environmental Risk Assessment

The Committee adopted a revised guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicines (EMA/CVMP/ERA/52740/2012), following the close of the public consultation, for a second 3-month public consultation. The guideline outlines the criteria for PBT/vPvB assessment for veterinary medicinal products and explains how these, under the guidance developed for industrial chemicals under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation, should be interpreted for veterinary medicinal products and what testing strategy should be followed to complete the PBT assessment. The second public consultation was considered appropriate as the guideline now provides more details than the first draft and a new section on the assessment of products containing a PBT substance has been added.

The document above will be published on the Agency's website. The compilation of comments received during the first public consultation will be published after the November CVMP meeting.

Efficacy / Antimicrobials

The Committee adopted revised Questions and Answers in relation to the SPC guideline on antimicrobials (EMA/CVMP/414812/2011-Rev.1) providing the following revised definitions:

- definition of the term 'treatment';
- definition of the term 'metaphylaxis'; and
- definition of the term 'prevention'.

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

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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