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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 12-13 October 2010

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a marketing authorisation application under exceptional circumstances in accordance with Article 39(7) of Regulation (EC) No 726/2004 for **BTVPUR AlSap 1** (Bluetongue virus serotype 1 antigen) from Merial for the active immunisation of sheep and cattle to prevent viraemia and to reduce clinical signs caused by bluetongue virus serotype 1.

The Committee adopted by consensus a positive opinion for a marketing authorisation application under exceptional circumstances in accordance with Article 39(7) of Regulation (EC) No 726/2004 for **BTVPUR AlSap 1-8** (Bluetongue virus serotypes 1 and 8 antigens) from Merial for the active immunisation of sheep and cattle to prevent viraemia and to reduce clinical signs caused by bluetongue virus serotypes 1 and 8.

The Committee adopted by consensus a positive opinion for an extension application for a new pharmaceutical form (oral powder) of the existing marketing authorisation for **Econor** (valnemulin) from Novartis Animal Health GmbH Austria for the treatment of swine dysentery, clinical signs of Porcine Proliferative Enteropathy (ileitis) and Swine Enzootic Pneumonia.

The Committee adopted by consensus a positive opinion for a type II variation for **Circovac** (inactivated porcine circovirus type 2) concerning the addition of piglets as a new target category.

Summaries of these opinions are available on the Agency's website.

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

Halocur (halofuginone) - introduction of a new manufacturer of the active substance;

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Improvac (gonadotropin releasing factor (GnRF) analogue-protein conjugate) - extension of the shelf life of the active substance (the conjugate);

Zulvac 8 Bovis and **Zulvac 8 Ovis** (inactivated bluetongue virus, serotype 8) **-** introduction of a revised pharmacovigilance system following the transfer of the marketing authorisation to a new marketing authorisation holder.

MUMS / Limited markets

The Committee reviewed four requests for classification under the MUMS/limited markets policy, which concerned:

- a product for a respiratory indication in horses, where the CVMP considered that the product was indicated for MUMS/Limited market and was eligible for financial incentives;
- an immunological product for wild boar where the CVMP considered that the product was indicated for MUMS/Limited market and was eligible for financial incentives;
- an immunological product for pigs where the CVMP considered that the product did not fall within the scope of the MUMS policy;
- topical antibiotic treatment for dogs where the CVMP considered that the product was not indicated for MUMS and was not eligible for financial incentives as the market was not limited.

Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR AlSap 8**, **Halocur**, **Improvac**, **Leucofeligen FeLV/RCP**, **Leucogen**, **Naxcel**, **Palladia**, **Porcilis PCV**, **Promeris** and **Promeris Duo** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a Question and Answer document on the microbiological quality of veterinary premixes containing excipients of natural origin (EMA/CVMP/QWP/565528/2010) which clarifies the limits for microbiological quality considered appropriate for such products.

The Committee adopted a Question and Answer document on rubber stopper testing (EMA/CVMP/QWP/565529/2010) which clarifies the requirements for large multi-dose injectables with rubber stoppers that might be punctured a very large number of times.

The Committee adopted a Question and Answer document on veterinary powders for use in drinking water (EMA/CVMP/QWP/574579/2010). This document addresses whether such products should be authorised if they do not fully dissolve, and remain in solution, in drinking water of the usual pH range without the addition of other pH adjusting substances.

The Committee adopted a Question and Answer document which clarifies the regulatory issues concerning whether or not it is permitted to authorise a multi-dose (parenteral) veterinary medicinal product for use both as an intramuscular injection and also an intramammary preparation (EMA/CVMP/QWP/565531/2010).

The Committee also adopted a Question and Answers document on post-approval change management protocols (EMA/CHMP/CVMP/QWP/586330/2010). This document sets out some general principles on the content and future use of these protocols (introduced under the new Variations Regulation).

The Committee adopted a Question and Answer document on Variation B.II.b.4 (change of batch size of the finished product) (EMA/CHMP/CVMP/QWP/586385/2010) which clarifies what is understood by "manufactured by complex manufacturing processes" in this Variation category.

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

Working Parties

The Committee reviewed and adopted a mandate for the CVMP Scientific Advice Working Party for period of 3 years. No changes were introduced to the document.

The Committee adopted the work plans for 2011 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 and the CVMP Scientific Advisory Group on Antimicrobials. In addition, the Committee agreed on priorities for the working parties.

The work plans and priorities will be available on the Agency's website.

Organisational matters

The Committee appointed the following four co-opted members to complement its expertise:

- Wilhelm Schlumbohm as an expert in quality with specific interest in quality assessment of veterinary medicinal products and holds competence in new technologies such as process analytical technologies and "quality by design".
- Christian Friis as an expert in residue metabolism and pharmacokinetics and has significant experience in assessment of data contained in MRL applications, including aspects relating to biocides.
- Boris Kolar as an expert in environmental risk assessment and also has a background in toxicology.
- Rory Breathnach as a veterinarian with significant expertise in large and small animal clinical practice with regard to specific therapeutic areas, such as dermatology, and has experience in conduct of clinical trials.

The mandates of these four co-opted members start on 6 November 2010.

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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