

14 February 2014
EMA/CVMP/54452/2014
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 11-13 February 2014

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Parvoduk**, from Merial, a vaccine for the active immunisation of Muscovy ducks to reduce weight loss and lesions of Muscovy duck parvovirus and Derzsy's disease and, in the absence of maternally derived antibodies, to also prevent mortality.

The Committee adopted by consensus a positive opinion for a type II variation application for **Profender** from Bayer Animal Health GmbH regarding a quality change.

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

Annual reassessment of marketing authorisations under exceptional circumstances

The Committee adopted an opinion on the annual reassessment for the blue tongue virus vaccine **BTVPUR Alsap 2-4**, further to the evaluation of the data addressing the specific obligations of the marketing authorisation granted under exceptional circumstances submitted by the marketing authorisation holder. Since the specific obligations for BTVPUR Alsap 2-4 are now fulfilled the Committee recommended the conversion of the Community marketing authorisation to normal status for this product.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Improvac** and **Equilis StrepE**. 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 **Resflor solution injectable** (*florfenicol*, *flunixin*) from Intervet International B.V. The matter was referred to the Committee under Article 13(1) of Commission Regulation (EC) No 1234/2008 by France as the reference Member State in the 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 started a procedure for **Ubrolexin intramammary suspension for lactating dairy cows** (*cephalexin*, *kanamycin*) from Boehringer Ingelheim Vetmedica GmbH. The matter was referred to the Committee under Article 13(1) of Commission Regulation (EC) No 1234/2008 by Ireland as the reference Member State in the variation procedure, due to concerns raised by the Czech Republic relating to the extended duration of treatment for mastitis caused by *Staphylococcus aureus*.

Scientific advice

The Committee adopted five separate scientific advice reports concerning: quality, safety and efficacy issues for the development of a musculoskeletal product for horses; safety and efficacy issues for the development of an oncology product for dogs; safety (MRL) and efficacy issues for the development of an antimicrobial product for sheep; safety issues for the development of an antiparasitic product for dogs and safety issues for the development of an oncology product for dogs.

Pharmacovigilance

The Committee reviewed the PSURs for **BLUEVAC BTV8**, **Bovilis BTV8**, **Canileish**, **Comfortis**, **ECOPORC SHIGA**, **Ibraxion**, **Netvax**, **Nobivac Myxo-RHD**, **ZULVAC 1+8 Bovis** and **ZULVAC 1+8 Ovis** and concluded that no further action or changes to their product information were required.

The Committee also reviewed the PSUR for **Suprelorin** and recommended amendments to the product information to include reference to a new special warning in the product information.

Concept papers, guidelines and SOPs

Antimicrobials

The Committee re-adopted the reflection paper on the use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/AWP/119489/2012-Rev.1) previously adopted following the close of the public consultation. This reflection paper was revised to take into account the comments from two stakeholders and updated data on sales of antimicrobials.

The reflection paper together with the overview of comments (EMA/CVMP/AWP/257904/2013) will be published on the Agency's website.

Working Parties

The Committee re-elected Gesine Hahn as chair of the Efficacy Working Party for a further 3-year mandate.

The Committee reviewed the work plan for 2014 for the CVMP Working Party on Immunologicals. The revised work plan will be available on the Agency's website.

International harmonisation

The Committee adopted a new draft VICH guideline for release for public consultation in the EU following the sign-off by the VICH Steering Committee:

- Draft VICH GL53 on electronic exchange of documents: file format requirements – 6 month public consultation.

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

Procedural announcement

The Agency has recently updated its document on Recommended Submission Dates for applications (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004957.pdf).

This update harmonises practices with the current practice for medicinal products for human use and provides more detailed information on the procedures, giving an overview of the procedural timelines with the anticipated dates for circulation of the various procedural documents.

As more detail is now being made available to all parties, individual procedural timetables will not be sent during the procedure; rather applicants will be guided to the published timetables.

For any queries on this please do not hesitate to contact vet.applications@ema.europa.eu.

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

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu