15 May 2017
EMA/CVMP/268972/2017
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 10-12 May 2017

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for type II variation applications for **Broadline** (addition of new parasite species in the indications) and for **Nobivac Bb** and **Vaxxitek HVT+IBD** (quality changes). The Committee also adopted by majority a positive opinion for a type II variation application for **Activyl** (change in the legal status) for the target species dogs.

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

Community referrals and related procedures

The Committee concluded the referral procedure for **veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses**. The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC, due to concerns that moxidectin may have persistent, bioaccumulative and toxic (PBT) properties, and consequently a potential serious risk to the environment may arise from the use of products containing the substance. The Committee adopted by consensus an opinion concluding that based on data from laboratory studies moxidectin fulfils the criteria for a PBT substance, and that the use of veterinary medicinal products containing the substance is posing a risk to aquatic and sediment organisms and to dung fauna. The Committee further concluded that these products are effective and an important therapeutic option in the treatment of internal and external parasites in cattle, sheep and horses; therefore in order to reduce and prevent as far as possible the identified risks for aquatic and sediment organisms and dung fauna, the Committee recommended risk mitigation measures and warnings to be included in the product information. The Committee further concluded that a targeted sampling in the environment following the use of veterinary medicinal products as a pour-on solution containing 5 mg moxidectin per ml or as a solution for injection containing 100 mg moxidectin per ml in beef cattle on pasture is necessary in order to obtain a better understanding of the actual environmental exposure, and, consequently, recommended conditions to the terms of the marketing authorisations. The Committee concluded that overall the benefit-risk balance for the products concerned by this referral is positive, subject to changes in the product information and conditions to the marketing authorisations.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **bromelain** in table 1 of Annex to Regulation (EU) No 37/2010 with a "No MRL required" classification for porcine species.

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

Scientific advice

The Committee adopted one scientific advice report further to a request for an initial advice on quality, safety and efficacy issues for a veterinary medicinal product with a musculoskeletal disease indication for horses.

Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR**, **BTVPUR Alsap 1**, **Cardalis**, **Convenia**, **Equilis Prequenza**, **Equilis Prequenza Te**, **Eryseng**, **Eryseng Parvo**, **Innovax ILT**, **Onsior**, **Porcilis ColiClos, Poulvac E. coli**, **Sileo**, **Suvaxyn Aujeszky 783 + O/W**, **Trifexis**, **UpCard**, **Velactis**, **ZULVAC 8 Bovis** and **ZULVAC 8 Ovis** and concluded that no further action or changes to their product information were required. The Committee also reviewed the PSUR for **Simparica** and recommended amendment to the product information.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted a reflection paper on non-spontaneous adverse event reports (literature, internet and social media) for veterinary medicinal products (EMA/CVMP/PhVWP/357539/2015) following the close of public consultation. The reflection paper outlines aspects of handling of adverse events reported in peer-reviewed literature and other non-spontaneous sources e.g. on the internet. The comments received during the consultation procedure have been taken into account for the revision of the reflection paper.

The reflection paper together with the overview of comments (EMA/CVMP/PhVWP/615063/2016) will be published on the Agency's website.

Environmental Risk Assessment

The Committee endorsed for publication a reflection paper on the authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances (EMA/CVMP/448211/2015) after adoption in April 2017 following the close of the public consultation and subsequent adoption by the Heads of Medicines Agencies (HMA). The reflection paper discusses the approach to the assessment of (potential) PBT and vPvB substances in veterinary medicinal and other products (chemicals, biocides, plant protection products), and also addresses the issues for consideration in the evaluation of veterinary medicinal products containing such substances under the current legislation and also the need for new legal provisions. The comments received during the consultation procedure have been taken into account for the revision of the reflection paper.

The reflection paper together with the overview of comments (EMA/CVMP/401418/2016) will be published on the Agency's website.

Working Parties

The Committee elected Nathalie Bridoux as vice-chair of the CVMP Efficacy Working Party (EWP-V) for a 3-year mandate.

Notes

1. 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 3660 8427

E-mail: press@ema.europa.eu