7 December 2018
EMA/CVMP/818968/2018 Corr.[1]
Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 4-6 December 2018

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Kriptazen** *(halofuginone)*, from Virbac S.A., a new (generic) product for the prevention and reduction of diarrhea in new-born calves due to *cryptosporidium parvum*.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **EVANT**, from LABORATORIOS HIPRA S.A, a new vaccine for the active immunisation of chicks from 1 day of age against *coccidiosis*.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **ZULVAC BTV** (formerly ZULVAC BTV Ovis), from Zoetis Belgium SA, concerning the addition of cattle as a new food-producing target species.

The Committee adopted by consensus a positive opinion for a type II variation application for **Aivlosin** concerning changes to the summary of product characteristics to allow the use of the product in breeding chickens. The Committee also adopted by consensus a positive opinion for a type II variation application for **Galliprant** concerning quality changes.

The Committee adopted by consensus positive opinions for five grouped type II variation applications for **Aivlosin**, **Bravecto**, **Bravecto Plus**, **HALAGON** and **OSURNIA**, concerning quality changes. The Committee also adopted by consensus a positive opinion for a grouped type II variation application (subject to a worksharing procedure) for **Canigen L4** and **Nobivac L4**, concerning quality changes.

The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Ecoporc SHIGA, RESPIPORC FLU3** and **RESPIPORC FLUpan H1N1** concerning quality changes.

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

[1] The press release has been updated on 11 December to add information on the adoption of the revised mandate for CVMP Antimicrobials Working Party and to correct the name and the reference numbers some of the documents.

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

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Vectra Felis** and **Equisolon**. 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 indefinite renewal of the marketing authorisations.

The Committee adopted by consensus a final opinion for the renewal of the marketing authorisation for **Bravecto** further to the re-examination of the opinion adopted during the Committee meeting held on 9-11 October 2018. The Committee, having assessed the marketing authorisation holder's grounds for re-examination, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation. Based on pharmacovigilance grounds, the Committee concluded that a further 5-year renewal was necessary.

Scientific advice

The Committee adopted 3 separate scientific advice reports further to requests for:

- follow-up advice on safety issues for a new pharmaceutical veterinary medicinal product for a musculoskeletal disease indication in horses;
- initial advice on quality, safety and efficacy issues for a new pharmaceutical veterinary medicinal product for a musculoskeletal disease indication in dogs;
- initial advice on efficacy issues for an antiparasitic veterinary medicinal product for dogs.

Minor use, minor species (MUMS) / limited market

Following the Committee's review of 3 requests for classification under the MUMS/limited market policy, the CVMP classified:

- a product (alimentary tract and metabolism) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives in line with the Guidance on the classification of veterinary medicinal products indicated for minor use minor species MUMS/ limited market (EMA/CVMP/388694/2014);;
- a product (musculo-skeletal system) for dogs as not indicated for MUMS/limited market and was not therefore eligible for financial incentives;
- a product (immunologicals) for calves as not indicated for MUMS/limited market and was not therefore eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Coliprotec F4-F18**, **Hiprabovis IBR Marker Live**, **Porcilis Porcoli Diluvac Forte**, **Profender**, **Reconcile**, **Vectra 3D, VEPURED, Versican Plus L4, Versican Plus Pi L4, Versican Plus Pi L4 R** and **ZACTRAN** and concluded that no further action or changes to their product information were required.

The Committee reviewed the PSURs for **APOQUEL** and **Credelio**, and recommended amendments to the product information.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a new guideline on the sterilisation of the medicinal product, active substance, excipient and primary container (EMA/CHMP/CVMP/QWP/850374/2015), which provides guidance on the selection of appropriate methods of sterilisation for sterile finished products, sterile active substances, sterile excipients and sterile primary containers. The guideline replaces the document 'Decision trees for the selection of sterilisation methods' (CPMP/QWP/054/98), which is an annex to the note for guidance on development pharmaceutics (CPMP/QWP/155/96) and the document 'Decision trees for the selection of sterilisation methods' (EMEA/CVMP/065/99) which is an annex to the note for guidance: Development pharmaceutics for veterinary medicinal products (EMEA/CVMP/315/98).

The guideline together with the overview of comments (EMA/CHMP/CVMP/QWP/366428/2018) will be published on the Agency's website.

Safety

The Committee adopted a draft revised guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/SWP/66781/2005-Rev.2) for public consultation until 31 August 2019. The guideline has been updated to take account of the extrapolation criteria to be considered by the CVMP when assessing applications for maximum residue limits (MRLs) in line with Commission Regulation (EU) 2017/880 laying down rules on the use of a MRL established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, and a MRL established for a pharmacologically active substance in one or more species for other species, in accordance with Regulation (EC) No 470/2009.

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

The Committee adopted a new guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products (EMA/CVMP/SWP/377245/2016). The purpose of this guideline is to provide a practical framework that is applicable to the identification, categorisation, qualification, and control of these mutagenic impurities, to limit potential carcinogenic risk associated with the exposure to potentially mutagenic impurities. This guideline is intended to complement VICH GL10 and VICH GL11.

The guideline together with the overview of comments (EMA/CVMP/SWP/610519/2017) will be published on the Agency's website.

Efficacy

The Committee adopted a revised guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.3). The current guideline was amended to take into account the new VICH GL52 on Bioequivalence: blood level bioequivalence study, and also comments received during the public consultation.

The guideline together with the overview of comments (EMA/CVMP/755602/2017) will be published on the Agency's website.

The Committee adopted a draft revised guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances (EMA/CVMP/EWP/755916/2016) for public consultation until 31 August 2019. The revised guideline, which aims to replace the current guideline on anticoccidials used for the therapy of coccidiosis in chickens, turkeys and geese (7AE15a), addresses both avian and mammalian species.

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

The Committee adopted questions and answers on the CVMP guideline on veterinary medicinal products controlling varroa destructor parasitosis in bees (EMA/CVMP/EWP/459883/2008). The question and answer document concerns clarification in regard to follow-up treatment (question 1) and target animal safety (question 2), and will be published on the Agency's website.

Immunologicals

The Committee adopted the revised guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza, Bluetongue and Foot-and-Mouth disease (EMA/CVMP/IWP/105506/2007-Rev.1). The revised guideline updates the existing Guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza, Bluetongue and Foot-and-Mouth disease.

The guideline together with the overview of comments (EMA/CVMP/IWP/235788/2018) will be published on the Agency's website.

The Committee also adopted revised questions and answers on the CVMP guideline data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza, Bluetongue and Foot-and-Mouth disease (EMA/CVMP/IWP/466888/2017-Rev.1).

The Committee adopted a draft guideline on requirements for the quality (production and control), safety and efficacy of allergen products for use in horses, dogs and cats (EMA/CVMP/IWP/170689/2016) for public consultation until 31 August 2019. This draft guideline provides principles and guidance for the manufacturing and quality control, safety and efficacy of allergen products of biological origin, including allergen extracts from natural source materials and allergens produced through recombinant DNA technology, used for specific immunotherapy or *in vivo* diagnosis of IgE-mediated allergic diseases for horses, dogs and cats.

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

Antimicrobial resistance

In the context of the European Commission request for an update of the previous scientific advice on the impact on public health and animal health of the use of antibiotics in animals (EMA/381884/2014) the Committee adopted a draft scientific advice on the preliminary risk profiling (EMA/CVMP/CHMP/682199/2017) for new antimicrobial medicinal products. A complementary scientific advice revising the categorisation of antimicrobials is under finalisation and will be adopted at a later meeting. The purpose of the adopted risk profiling is to provide advice on potential antimicrobial resistance public health risks at an early stage in the development of antimicrobial veterinary medicines. The advice will be submitted to the CHMP for adoption and publication for consultation until 31 March 2019.

Working parties

The Committee reviewed and adopted the revised mandate (EMA/CVMP/AWP/749774/2012-Rev.4) for the CVMP Antimicrobials Working Party (AWP) for a further period of 3 years.

Organisational matters

The Committee adopted the CVMP work plan for 2019 (EMA/CVMP/302436/2018).

The Committee re-appointed Keith Baptiste as a co-opted member to complement its expertise in antimicrobial resistance for a further 3-year mandate.

The Committee appointed Ricardo Carapeto García as a co-opted member to complement its expertise in environmental risk assessment 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 officers

Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News