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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 17-19 April 2018

CVMP adopts new guideline on user safety of topically applied veterinary medicines

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Dany's BienenWohl** (*oxalic acid dihydrate*) powder and solution for bee-hive dispersion, an informed consent application from Dany Bienenwohl GmbH, intended for the treatment of varroosis in honey bees. The product has been classified as MUMS/ limited markets. In an informed consent application, reference is made to an authorised medicine and the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure.

The Committee adopted by consensus a positive opinion for an extension to the existing marketing authorisation for **Credelio** (*lotilaner*) from Elanco Europe Ltd, to add further, lower tablet strengths of 12 mg and 48 mg, for the treatment of flea and tick infestations in a new target species (cat).

The Committee adopted by consensus positive opinions for type II variation applications for **Porcilis ColiClos** and **Vectormune ND** concerning quality changes.

The Committee also adopted by consensus a positive opinion for a type II variation application (subject to a worksharing procedure) for **Oncept IL-2, Parvoduk, ProteqFlu, Proteq West Nile, ProteqFlu Te, Purevax FeLV, Purevax Rabies, Purevax RC, Purevac RCP, Purevax RCP FeLV, Pu8revax RCPCh, Purevax RCPCh FeLV, Vaxxitek HVT+IBD** concerning quality changes.

Withdrawal of application

The Committee was informed of the formal notification from Vita (Europe) Limited of their decision to withdraw the application for an initial marketing authorisation for **HopGuard Gold**. More information about this application and the current state of the scientific assessment at the time of the withdrawal, together with the withdrawal letter from the applicant, will be published on the Agency's website in due course.

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 a positive opinion for the renewal of the marketing authorisation for **AFTOVAXPUR DOE**. The Committee, having re-assessed the benefit-risk balance of this product, 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 (no post-marketing safety information) the Committee concluded that a further 5-year renewal was necessary.

Community referrals and related procedures

The Committee started a procedure under Article 30(3) of Regulation (EC) No 726/2004, to prepare a scientific opinion on the need for inclusion of a maximum limit for histamine in the active substance and/or finished product specifications for **gentamicin-containing** medicinal products for parenteral administration to horses. The matter was referred to the Committee by the Executive Director of the Agency in connection with adverse reactions seen in horses, which are considered to be linked to histamine residues present in the active substance, following use of gentamicin solution for injection.

Scientific advice

The Committee adopted a scientific advice report further to a request for an initial advice on safety issues for a pharmaceutical veterinary medicinal product for cats.

Minor use, minor species (MUMS)/limited market

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

- Classified a veterinary medicinal product (immunologicals) for pigs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as an authorised product exists in the EU for the indication.
- Classified a veterinary medicinal product (immunologicals) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as it is intended for use in non-food producing species.
- Did not classify a veterinary medicinal product (antiparasitic products, insecticides and repellents) for dogs as indicated for MUMS/limited market.
- Did not classify a veterinary medicinal product (alimentary tract and metabolism) for dogs as indicated for MUMS/limited market.

Pharmacovigilance

The Committee reviewed the PSURs for **Oncept IL-2**, **Palladia**, **SevoFlo**, **Simparica** and **Zeleris**, and concluded that no further action or changes to their product information were required.

The Committee reviewed the PSUR for **Pexion**, and recommended amendments to the product information.

The Committee discussed adverse reactions reported after accidental eye exposure to **Osurnia** and agreed on a written communication from Elanco Europe Ltd to be circulated to veterinarians and other

healthcare professionals regarding this issue. More information will be published on the Agency's website.

Concept papers, guidelines and SOPs

Safety

The Committee adopted a new guideline on user safety of topically administered veterinary medicinal products (EMA/CVMP/SWP/721059/2014). The guideline provides specific guidance and advice on how user risk assessments should be conducted for such products, and should be used in conjunction with the 'Guideline on user safety for pharmaceutical veterinary medicinal products' (EMA/CVMP/543/03-Rev.1).

The guideline together with the overview of comments (EMA/CVMP/SWP/30675/2017) will be published on the Agency's website.

The Committee adopted Questions and Answers (EMA/CHMP/CVMP/SWP/246844/2018) on implementation of risk-based prevention of cross contamination in production related to the 'Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities'. The Questions and Answers support the parent guideline by providing clarifications relating to the setting of health based exposure levels and their use.

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

Safety and Environmental Risk Assessment

The Committee adopted a new guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater (EMA/CVMP/ERA/103555/2015). The guideline provides a methodology for performing a risk assessment for human health and for aquatic ecosystems of residues of veterinary medicinal products in groundwater.

The guideline together with the overview of comments (EMA/CVMP/ERA/609438/2017) will be published on the Agency's website.

Efficacy and Antimicrobials

The Committee adopted a revised guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/383441/2005-Rev.1.) for a 5-month period of public consultation. The guideline, which was developed to encourage optimal use and to minimise selection of antimicrobial resistance, was revised in order to improve consistency of the SPCs for antimicrobial products in the EU Member States.

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

Working parties

The Committee elected Stefan Scheid as chair of the CVMP Safety Working Party 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

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