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EMA/CVMP/72976/2017
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 14-16 February 2017

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for initial marketing authorisation applications for:

Credelio (*lotilaner*), from Elanco Europe Ltd, a new antiparasitic product for the treatment of flea and tick infestations in dogs;

Zulvac BTV Ovis, from Zoetis Belgium SA, a new bluetongue vaccine for the active immunisation of sheep; and

CYTOPOINT (*lokivetmab*), from Zoetis Belgium SA, a new monoclonal antibody product for the treatment of atopic dermatitis in dogs.

The Committee adopted by consensus a positive opinion for a type II variation application for **BTVPUR** regarding quality changes.

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

Scientific advice

The Committee adopted four separate scientific advice reports further to a request for:

- Initial advice on quality and safety issues for a new immunological product for dogs;
- Initial advice on efficacy issues for a new veterinary medicinal product for a cardiovascular condition in dogs;
- Follow up advice on efficacy issues for a new veterinary medicinal product for the treatment of blood and blood forming organs in dogs; and
- Follow up advice on efficacy issues for a new veterinary medicinal product acting on the nervous system in dogs.

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Minor use, minor species (MUMS)/limited market

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

- Classified a veterinary medicinal product with a cardiovascular indication in cats as not indicated for MUMS/limited market and, therefore, not eligible for reduced data requirements;
- Classified an immunological product in sheep as not indicated for MUMS/limited market and, therefore, not eligible for reduced data requirements; and
- Classified a veterinary medicinal product with an alimentary tract and metabolism indication in horses as indicated for MUMS/limited market and eligible for reduced data requirements. No financial incentives will apply as according to the MUMS policy, products for horses are generally not eligible for fee incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Bovalto Ibraxion**, **Coliprotec F4**, **Econor**, **Evalon**, **FORTEKOR PLUS**, **Fungitraxx**, **Imrestor**, **Incurin**, **Previcox**, **ProteqFlu**, **ProteqFlu-Te**, **Vaxxitek HVT-IBD** and **ZULVAC 1+8 Bovis** and concluded that no further action or changes to their product information were required.

The Committee also reviewed the PSURs for **Canigen L4 & Nobivac L4** and recommended amendments to their product information.

The Committee adopted the bulletin on veterinary pharmacovigilance for 2016 summarising the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMA/568976/2016). Annual public bulletins on veterinary pharmacovigilance are published by the Agency with the intention to improve communication to all stakeholders, but particularly to veterinary health professionals, on the surveillance of the safety of veterinary medicines in the EU. The bulletin includes descriptive statistics on suspected adverse reactions reports and safety updates, and provides an overview of the activities and issues addressed during 2016.

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

Concept papers, guidelines and SOPs

Safety

The Committee adopted a draft guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products (EMA/CVMP/SWP/377245/2016) for a 6-month period of public consultation. The guideline was developed to provide a practical framework that is applicable to the identification, categorisation, qualification, and control of these mutagenic impurities to limit potential carcinogenic risk.

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

Environmental risk assessment

The Committee adopted a draft guideline on assessing the toxicological risk to human health and the environment from veterinary pharmaceuticals in groundwater (EMA/CVMP/103555/2015) for a 6-month period of public consultation. The guideline provides a methodology for performing an assessment of the risk to human health and aquatic ecosystems.

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

Pharmacovigilance

The Committee adopted the draft revised recommendation for the basic surveillance of Eudravigilance Veterinary (EVVet) data for centrally authorised products (EMA/CVMP/PhVWP/171122/2016/Rev.1) for a 6-month period of public consultation. The main aim of the revision was to improve the overall pharmacovigilance surveillance process, where possible, by integrating periodic safety update report (PSUR) evaluation and signal detection processes based on EVVet data and using risk-based principles. The recommendation is applicable for veterinary medicinal products (VMPs) authorised via the centralised procedure only.

The Committee adopted a risk management strategy for feline and canine vaccines with regard to potential presence of the replication competent feline endogenous retrovirus RD114 (EMA/CVMP/IWP/592652/2014). The strategy has been developed to provide direction for risk management with regard to the potential presence of replication competent RD114 in feline and canine vaccines. This strategy responds to the CVMP opinion from 2010 pursuant to Article 30(3) (EMA/CVMP/433418/2010) concerning RD114. The benefit-risk balance of the affected vaccines remains unchanged and strongly favours continued use of these vaccines. No evidence of an actual risk has been identified for this quality issue but it is considered necessary to bring existing and new vaccines into line with the requirements that are now in place.

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

Regulatory

Further to the adoption by CVMP in January and subsequent adoption by CMDv at their January meeting, a new question and answer document on the information to be included in section 5.1 of the SPC on pharmacodynamic properties for pharmaceutical products (EMA/CVMP/757903/2016) has been published on the Agency's website within the section on product information (subsection 'Reference document and guidelines').

Working parties

The Committee re-elected Jean-Claude Rouby as chair of the CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT) and elected Elisabeth Begon as vice-chair of the CVMP Pharmacovigilance Working Party (PhVWP-V) for a 3-year mandate.

International harmonisation

The Committee adopted the following draft VICH guideline for release for a 5-month period of public consultation in the EU following the sign-off by the VICH Steering Committee:

- VICH GL56: Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods

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

Organisational issues

The CVMP adopted a new guidance document for applicants on oral explanations (EMA/CVMP/519444/2016).

Procedural announcement

CVMP outcome communications

From 1 February 2017, the European Medicines Agency (EMA) changed its process for communicating outcomes from the Committee for Medicinal Products for Veterinary Use (CVMP) to applicants, marketing authorisation holders (MAHs) and the European Commission.

EMA now extends submission of CVMP outcome communications in electronic-only format to all types of procedures, adopting the approach implemented progressively by EMA scientific committees over the past few years. Addressees, i.e. applicants, MAHs and the European Commission, will no longer receive any hard copies of documents for any procedures related to veterinary medicines.

At the same time, and in further alignment with the practices implemented by other EMA scientific committees, CVMP outcomes and related communications will no longer bear a signature and will be sent to addressees as a word file (.doc) via Eudralink - the European medicines regulatory network's secure file-transfer system.

The date when the Eudralink message is opened by addressees for the first time will be considered as the day of the receipt of the document attached to the Eudralink message, for the purpose of calculating procedural timelines in accordance with Directive (EC) 2001/82/EC. Eudralink automatically records this date as "accessed by" without a need for acknowledgement of receipt or other active response action by the addressee.

Applicants and marketing authorisation holders are advised to download and archive the attached documents promptly upon receipt, and to note that Eudralink preserves file attachments only for up to 90 days. EMA will retain a read-only version of the electronic documentation in its electronic archives.

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

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