7 December 2017
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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 5–7 December 2017

CVMP adopts revised guidance on use of pictograms and QR codes in packaging for veterinary medicinal products

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Suvaxyn Circo**, from Zoetis Belgium SA, a new vaccine for the active immunisation of pigs to reduce viral load in blood and lymphoid tissues and faecal shedding caused by porcine circovirus type 2 (PCV2).

The Committee adopted by consensus a positive opinion for a type II variation application for **ZACTRAN** to add a new therapeutic indication. The Committee also adopted by consensus positive opinions for type II variation applications for **Easotic** and **RESPIPORC FLUpan H1N1** concerning quality changes.

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

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Ecoporc SHIGA**. 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 indefinite renewal of the marketing authorisation.

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:

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- A product (musculo-skeletal system) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as according to the MUMS policy, products for horses are generally not eligible for fee incentives.
- A product (nervous system) for cats and dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as the product is intended for use in a non-food-producing species.
- A product (immunologicals) for sea bass and gilt-head (sea) bream 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.

Pharmacovigilance

The Committee reviewed the PSURs for **CORTAVANCE, Gripovac 3, Innovax-ILT, Meloxidyl, Osurnia, Pirsue, RESPIPORC FLU3, Sedadex, Sileo, Suvaxyn PCV, UpCard** and **ZACTRAN,** and concluded that no further action or changes to their product information were required.

The Committee also reviewed the PSURs for **LEUCOFELIGEN FeLV RCP, Versican Plus DHPPi,** and **Versican Plus Pi** and recommended amendments to their product information. In addition, with regard to **Canigen L4 and Nobivac L4** the Committee requested a targeted PSUR on all adverse event reports involving death.

The Committee also recommended changes to the product information for **Improvac** and **Metacam** following surveillance of adverse event reports.

Concept papers, guidelines and SOPs

Scientific Advice

The Committee adopted revised guidance for companies requesting scientific advice (EMA/CVMP/SAWP/172329/2004).

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

Quality

The Committee adopted the final guideline on the chemistry of active substances for veterinary medicinal products (EMA/CVMP/QWP/707366/2017) which replaces the 'Note for guidance on chemistry of new active substances' (EMEA/CVMP/541/03/Final) and 'Chemistry of active substances' (3AQ5a), and covers new and existing active substances in a single document.

The Committee adopted guidance on a phased implementation of requirements to control elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/631010/2017) which aims to provide a pragmatic approach for the implementation of Ph. Eur. requirements in relation to the control of elemental impurities in veterinary medicinal products.

The Committee adopted Questions and Answers on in-use shelf life for solid dose forms in multidose containers.

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

Efficacy

The Committee adopted a concept paper for the revision of the guideline on the summary of product characteristics for anthelmintics (EMA/CVMP/EWP/158889/2017) for release for a 3-month period of public consultation. The revision of the guideline (EMEA/CVMP/EWP/170208/2005) is being proposed in view of concerns regarding to resistance development, and in order to clarify some aspects that are currently not adequately addressed in the current guideline.

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

Novel therapy groups and related issues

The Committee adopted Questions and Answers on monoclonal antibodies for veterinary use.

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

Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

The Committee adopted a statement of the CVMP position on the ethical use of animals in the testing, development and manufacture of veterinary medicines. The statement will be published on the Agency's website.

The Committee adopted a recommendation to marketing authorisation holders, highlighting recent measures in the veterinary field to promote reduction, refinement and replacement (3Rs) measures described in the European Pharmacopoeia.

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

Regulatory matters

The Committee adopted the revised QRD guidance on the use of approved pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP) and decentralised procedures (DCP)(EMA/776723/2017) following the public consultation. The guidance was revised in light of the consultation comments and to improve clarity of the process.

The Committee adopted QRD procedural guidance on Quick Response (QR) codes in the labelling and package leaflet of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised procedures (DCP) and national procedures (EMA/364980/2017). The applicant's request form for a QR code is appended to the guidance.

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

Working parties

The Committee adopted the work plans for 2018 for the CVMP Working Parties on Scientific Advice, Safety, Environmental Risk Assessment, Efficacy, Antimicrobials, Immunologicals, Pharmacovigilance as well as for the CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT), the Joint CHMP/CVMP Quality Working Party and the Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG).

The Working Party work plans will be published on the Agency's website.

Organisational matters

The Committee adopted the CVMP work plan for 2018, which highlights the priority areas for the Committee in the coming year. The activities outlined in the work plan for 2018 as well as in the CVMP

Working Parties work plans have been agreed in view of preparation for the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

The CVMP work plan for 2018 will be published on the Agency's website.

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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