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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 19–21 June 2018

First stem cell-based veterinary medicine recommended for marketing authorisation

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Cortacare** (*hydrocortisone aceponate*), from Ecuphar NV, a cutaneous spray solution, intended for symptomatic treatment of inflammatory and pruritic dermatoses in dogs.

The Committee adopted by majority a positive opinion for an initial marketing authorisation application for **Arti-Cell Forte** (chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells), from Global Stem cell Technology NV, a suspension for injection for horses intended for the reduction of mild to moderate recurrent lameness associated with non-septic joint inflammation. The product has been classified as MUMS/limited markets.

The Committee adopted by majority a negative opinion for **Horse Allo 20** (allogeneic mesenchymal stem cells from horse adipose tissue), from Centauri Biotech SL, which was proposed for treatment of osteoarthritis in adult horses.

The Committee adopted by consensus a negative opinion for **LONGRANGE** (*eprinomectin*), from MERIAL, which was proposed for treatment and control of specified parasites in cattle.

The Committee adopted by consensus a positive opinion for a type II variation application for **BTVPUR** to add a new serotype, BTV2, for sheep and cattle.

The Committee adopted by consensus a positive opinion for a type II variation application (subject to a worksharing procedure) for **LEUCOGEN**, **LEUCOFELIGEN FeLV/RCP** and **Nobivac LeuFel**, to modify the duration of immunity.

The Committee adopted also by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Circovac** and **EQUIOXX**, regarding quality changes.

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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 authorisations for **Vectra 3D**. 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.

Scientific advice

The Committee adopted two scientific advice reports further to requests for:

- initial advice on quality, safety and efficacy issues for an immunological veterinary medicinal product for dogs;
- initial advice on safety and efficacy issues for an antiparasitic veterinary medicinal product for dogs.

Minor use, minor species (MUMS)/limited market

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

- Classified a product (antiparasitic products, insecticides and repellents) for honey bees as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as authorised products already exist in the EU for the proposed indication.
- Classified 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.

Pharmacovigilance

The Committee reviewed the PSURs for **Credelio, DRAXXIN, Exzolt, Innovax NB-IBD, Porcilis PCV ID**, **Sileo, Stronghold, Trifexis, ZULVAC 8 Bovis** and **ZULVAC 8 Ovis,** and concluded that no further action or changes to their product information were required.

Concept papers, guidelines and SOPs

Antimicrobials

The Committee adopted a revised reflection paper on the use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/AWP/721118/2014), following the close of the public consultation. The reflection paper has been developed to critically review the current knowledge on the usage of aminoglycosides, resistance development and the potential impact of this resistance on animal and human health.

The reflection paper together with the overview of comments (EMA/CVMP/AWP/726389/2017) will be published on the Agency's website.

Immunologicals

The Committee adopted a draft revised guideline on the use of adjuvanted veterinary vaccines (EMA/CVMP/IWP/315887/2017) for a 6-month period of public consultation. The revised guideline, which aims to replace the 'Note for Guidance on the use of adjuvanted veterinary vaccines' (EMA/CVMP/IWP/043/97), was developed to outline the information which should be included for the adjuvant in the marketing authorisation application of an immunological veterinary medicinal product.

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

Pharmacovigilance

The Committee adopted the CVMP combined **VeDDRA list of clinical terms** for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/PhVWP/10418/2009-Rev10), following the yearly review and update. Implementation of the VeDDRA list in EudraVigilance Veterinary is provisionally scheduled for 1 October 2018.

The Committee also adopted the revised **guidance notes on the use of VeDDRA terminology** for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007-Rev.11).

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

The Committee adopted updates to the questions and answers on the following topics:

- Adverse event reporting (EMA/CVMP/PhVWP/145186/2013);
- Preparation, management and assessment of periodic safety update reports (PSURs) (EMA/CVMP/PhVWP/126661/2009).

The questions and answers documents will be published on the Agency's website.

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

The Committee adopted the Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken (EMA/CHMP/CVMP/3Rs/677407/2015), following the close of the public consultation. The purpose of this review was to ensure that EMA guidelines do not make reference to animal tests that are no longer considered appropriate and to provide an update on the work undertaken and the guidelines that have been updated as a result of this review.

The document together with the overview of comments (EMA/CHMP/CVMP/3Rs/731086/2016) will be published on the Agency's website.

The Committee adopted a reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs (EMA/404979/2018) following the close of the public consultation. The reflection paper, which has been developed as a follow up to the guideline on regulatory acceptance of 3R (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012), provides an overview of the main animal tests required for the regulatory testing of veterinary medicinal products. The document also includes information on opportunities for limiting animal testing that can already be implemented, where appropriate, as well as information on opportunities that may become available in the future.

The reflection paper together with the overview of comments (EMA/CHMP/CVMP/3Rs/731924/2016) 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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