16 June 2017
EMA/CVMP/346237/2017
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 13-15 June 2017

CVMP opinions on veterinary medicinal products

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

Exzolt (*fluralaner*), from Intervet International B.V., a new antiparasitic product for the treatment of poultry red mite in chickens;

Innovax-ND-IBD, from Intervet International B.V., a new live vaccine against Newcastle disease virus, infectious bursal disease virus and Marek's disease virus for the active immunisation of one-day-old chicks;

Suvaxyn PRRS MLV, from Zoetis Belgium SA, a new live vaccine against porcine reproductive and respiratory syndrome (PRRS) virus for the active immunisation of pigs; and

VEPURED, from Laboratorios Hipra, S.A., a new inactivated vaccine against oedema disease caused by verotoxin 2e produced by *E. coli* for the active immunisation of pigs.

The Committee adopted by consensus positive opinions for type II variation applications for **Suvaxyn Circo+MH RTU**, **Porcilis PCV** (quality changes) and **Pexion** (changes in the product information related to efficacy).

The Committee also adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **ProteqFlu**, **Purevax FeLV**, **Purevax RCP FeLV**, **Purevax RCPCh FeLV**, **Oncept IL-2**, **Proteq West Nile**, **ProteqFlu-Te** and **Purevax Rabies** concerning quality changes.

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

Maximum residue limits

The Committee agreed to include **dipropylene glycol methyl ether** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the

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

heading of excipients and adopted a revised list (EMA/CVMP/519714/2009-Rev.36). This decision followed the Committee's review of a request that had been submitted in accordance with the relevant CVMP guidance.

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

Scientific advice

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

- Initial advice on efficacy issues for a new antiparasitic veterinary medicinal product for dogs;
- Initial advice on efficacy issues for a new antiparasitic veterinary medicinal product for cats; and
- Initial advice on safety issues for a new antineoplastic veterinary medicinal product for dogs.

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 an immunological veterinary product for sea bass as indicated for MUMS/limited market and eligible for reduced data requirements. No financial incentives will apply as authorised products already exist in the EU for the indication;
- Classified an immunological veterinary product for sea bass as indicated for MUMS/limited market and eligible for reduced data requirements and financial incentives; and
- Reclassified an immunological veterinary product for sheep as indicated for MUMS/limited market and eligible for reduced data requirements and financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Canigen L4, Melovem**, **NEXGARD SPECTRA**, **Nobilis Influenza H5N2**, **Nobivac L4**, **Novaquin**, **Porcilis PCV ID**, **Sedadex**, **Versican Plus L4**, **Versican Plus Pi**, **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 also reviewed the PSUR for **Cerenia** and recommended amendments to the product information.

Concept papers, guidelines and SOPs

Novel therapies

The Committee adopted questions and answers on the following topic:

- Stem cell-based products for veterinary use: specific questions on sterility (EMA/CVMP/ADVENT/751229/2016).

The questions and answers document 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/10418/2009-Rev.9) used for electronic reporting following the yearly review and update. Implementation of the VeDDRA list in EudraVigilance Veterinary is scheduled for 1 October 2017. 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.10), and a revised call for comments on the VeDDRA standard list for EVVet (EMA/CVMP/PhVWP/123352/2004–Rev.10) were also adopted.

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

Working Parties

The Committee elected Christine Schwarz as vice-chair of the Antimicrobial 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 officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu