11 July 2014
EMA/CVMP/382972/2014
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 8–10 July 2014

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Nobilis IB Primo QX** (lyophilisate and solvent for suspension), from **Intervet International B.V.**, a vaccine for the active immunisation of chickens from one day-old onwards in order to reduce respiratory signs of infectious bronchitis.

The Committee adopted by consensus a positive opinion for a type II variation application for **COXEVAC** from **CEVA Santé Animale** regarding quality changes.

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

The Committee noted the formal notification from **Nexcyon Pharmaceuticals Ltd** of their decision to withdraw the application for an initial marketing authorisation for **Enthryv**. More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report. The document, together with the withdrawal letter from the applicant will be published on the Agency's website in due course.

Renewals of marketing authorisations

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8416
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Community referrals and related procedures

The Committee was informed of the formal notification from Boehringer Ingelheim Vetmedica GmbH of their decision to withdraw the type II variation application for **Ubrolexin intramammary suspension for lactating dairy cows** (*cephalexin, kanamycin*). The matter was referred to the Committee under Article 13(1) of Commission Regulation (EC) No 1234/2008 by Ireland as the reference Member State in the variation procedure, due to concerns raised by the Czech Republic relating to the extended duration of treatment for mastitis caused by *Staphylococcus aureus*. Given the withdrawal, the Committee considered the procedure closed.

Maximum Residue Limits

The Committee adopted by consensus positive opinions recommending the establishment of maximum residue limits for:

- **Hexaflumuron** in fin fish;
- **Gamithromycin** in porcine species; gamithromycin is currently included in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 with maximum residue limits established for bovine species;
- **Methylprednisolone** in horses; methylprednisolone is currently included in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 with maximum residue limits established for bovine species;
- **Tylvalosin** in eggs; tylvalosin is included in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 with maximum residue limits established for porcine species and poultry.

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **doxycycline** in rabbits. Furthermore, the Committee agreed to extrapolate the maximum residue limits already established in bovine, porcine and poultry species, and now recommended in rabbits, to all food producing species.

The Committee adopted by consensus a positive opinion recommending the establishment of final maximum residue limits for **tulathromycin** in bovine and porcine species following the recommendation of provisional (amended) maximum residue limits in October 2013.

More information about the above recommendations will be published on the Agency's website.

Scientific advice

The Committee adopted three separate scientific advice reports concerning:

- An initial advice on efficacy issues for a new fixed combination veterinary medicinal product for pigs;
- An initial advice on safety and efficacy issues for a new fixed combination veterinary medicinal product for cows; and
- An initial advice on bioequivalence issues for a gastrointestinal veterinary medicinal product for horses.

Antimicrobial resistance: advice on the use of antibiotics

Further to the request from the Commission for scientific advice on the impact on public health and animal health of the use of antibiotics in animals and the answer to the first question on July 2013, the Committee has now adopted draft answers to the 3 remaining questions[1]. The answers will also be considered by the CHMP at their meeting on 21-24 July 2014. Following adoption by the CHMP the answers will be published for public consultation until 30 September 2014. The final answers are foreseen for adoption by CVMP and CHMP in November 2014 and submission to the European Commission, as requested, by December 2014.

MUMS/limited market

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

- The CVMP considered that the immunological product for rainbow trout was indicated for MUMS/limited market and was eligible for financial incentives.
- The CVMP considered that the antibacterial product for homing pigeons was indicated for MUMS/limited market but was not eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl**, **Bovilis BTV8**, **COXEVAC**, **DRAXXIN, Emdocam**, **Equilis Prequenza Te**, **Equilis Prequenza**, **Equilis StrepE**, **Melosus**, **Nobivac L4**, **Proteq West Nile**, **Purevax Rabies**, **RevitaCAM**, **RHINISENG**, **Semintra**, **Zulvac 1 Bovis**, and **Zulvac 1 Ovis** concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a draft guideline on demonstration of palatability of veterinary medicinal products (EMA/CVMP/EWP/206024/2011) following the close of the public consultation. The guideline takes into account comments received during the public consultation as outlined in the overview of comments (EMA/CVMP/EWP/67168/2014). The guideline provides recommendations regarding the design, conduct, and evaluation of studies for the demonstration of palatability of veterinary medicinal products intended for oral individual or group animal treatment.

Antimicrobials

The Committee adopted a concept paper proposing the development of a 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/158821/2014), for a 3-month period of public consultation. The proposed reflection paper will critically review recent information on the use of aminoglycosides in food producing and companion animals in the EU.

[1] See http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142070.pdf

Pharmacovigilance

The Committee adopted the CVMP combined **VeDDRA list of clinical terms** for electronic reporting of suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/PhVWP/377918/2014) following the yearly review and update of the standard list.

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/382972/2014-Rev.7).

The implementation of the standard list in EudraVigilance Veterinary is tentatively scheduled for 1 October 2014.

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

Working Parties

The Committee endorsed the re-election, by the CHMP at their June 2014 meeting, of Jean-Louis Robert as the chairperson of the Joint CHMP/CVMP Quality Working Party for a further 3 year term.

Notes

1. 'MUMS' stands for minor use minor species.
2. 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 7418 8427

E-mail: press@ema.europa.eu