16 January 2015
EMA/CVMP/601/2015
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 13-15 January 2015

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Coliprotec F4**, from Prevtec Microbia GmbH, a vaccine for the active immunisation of pigs against enterotoxigenic F4-positive *Escherichia coli*.

The Committee adopted by consensus a positive opinion for a grouped extension application for the existing authorisation for **Stronghold** (*selamectin*), from Zoetis Belgium SA, concerning the addition of a new strength for dogs and a new strength for cats.

The Committee adopted by consensus a negative opinion for **Lodipressin** which was intended for the treatment of systemic arterial hypertension in cats.

The Committee adopted by consensus positive opinions for the following type II variation applications:

Acticam regarding quality changes;

Bluevac BTV8 regarding quality changes;

ERYSENG PARVO regarding quality changes;

Metacam and **Novem** (subject to a worksharing procedure) regarding quality changes; and

Purevax RCPCh, Purevax RCP, **Purevax RC**, **Purevax RCPCh FeLV** and **Purevax RCP FeLV** (subject to a worksharing procedure) regarding quality changes.

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

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

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **sisapronil** in bovine species. Furthermore, the Committee agreed to extrapolate these maximum residue limits to caprine species.

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

The Committee agreed to include **alcohols**, **C9-11**, **ethoxylated substances** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients and adopted a revised list (EMA/CVMP/519714/2009-Rev. 25). 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 two separate scientific advice reports concerning:

- Follow up advice on safety issues for an oncology product for dogs; and
- Follow up advice on efficacy issues for an anti-parasitic product for cats.

MUMS/limited market

Following the Committee's review of a request for classification under the MUMS/limited market policy, the CVMP classified an immunological product for rainbow trout as indicated for MUMS/limited market. As the product is indicated for a food-producing species and no alternative vaccine is authorised for the same target species for the same indication, it is eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Bovilis BTV8**, **Bravecto**, **Equisolon**, **Kexxtone**, **RevitaCAM**, **Suvaxyn PCV**, **ZULVAC 1 Bovis** and **ZULVAC 1 Ovis** and concluded that no further action or changes to the product information were required.

The Committee also reviewed the PSUR for **Pexion** and recommended amendments to the product information.

Concept papers, guidelines and SOPs

Antimicrobials

The Committee adopted a reflection paper on the risk of antimicrobial resistance transfer from companion animals (EMA/CVMP/AWP/401740/2013) following the close of the public consultation. This reflection paper has been developed to address the selection in companion animals of multidrug-resistant bacteria that could carry risks for public health and its possible transmission from companion animals to humans. The comments received during the consultation procedure have been taken into account for the revision of the reflection paper.

The reflection paper, together with the overview of comments (EMA/CVMP/89283/2014), will be published on the Agency's website.

Safety

The Committee adopted a guideline on risk characterisation and assessment of MRLs for biocides used in animal husbandry (EMA/CVMP/90250/2010) following the public consultation. The guideline has been amended to take into account comments received from stakeholders and describes a revised approach for determining whether an MRL evaluation is needed.

Immunologicals

The Committee adopted a draft revised guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus (BVDV) (EMA/CVMP/IWP/205351/2006-Rev.1) for a 3-month period of public consultation. The guideline was revised to remove the provision for an *in vivo* test, with the view to ensuring best practice with regard to implementation of 3R (Replacement, Reduction and Refinement) principles further to the end of consultation in 2014 on the concept paper on review and update of EMA guidelines to implement best practice with regard to 3Rs in regulatory testing of medicinal products (EMA/CHMP/CVMP/JEG-3Rs/704685/2012). The guideline outlines the procedure to be followed by the competent authorities when a batch of a vaccine is suspected to be contaminated with bovine viral diarrhoea virus.

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

Working Parties

The Committee elected Jean-Claude Rouby as chair of the Ad Hoc Group on Novel Veterinary Therapies (ADVENT) for a 2-year mandate.

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 3660 8427

E-mail: press@ema.europa.eu