7 November 2014
EMA/CVMP/651488/2014
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 4-6 November 2014

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **NEXGARD SPECTRA** (*afoxolaner/milbemycin oxime*), from MERIAL, a new antiparasitic product for dogs.

The Committee adopted by consensus positive opinions for the following type IB variation applications (subject to worksharing procedures) for:

ZULVAC 1 Bovis, **ZULVAC 8 Bovis**, **ZULVAC 1+8 Bovis**, **ZULVAC 1 Ovis**, **ZULVAC 8 Ovis** and **ZULVAC 1+8 Ovis**, from Zoetis Belgium SA, regarding quality changes; and

Purevax RCPCh FeLV, **Purevax FeLV** and **Purevax RCP FeLV**, from MERIAL, regarding quality changes.

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

Annual reassessment of marketing authorisations under exceptional circumstances

The Committee adopted opinions on the annual reassessments for two immunological products **COXEVAC** and **BLUEVAC BTV8**, further to the evaluation of the data submitted by the marketing authorisation holders. The Committee recommended the conversion of the community marketing authorisation from under exceptional circumstances to a normal status for COXEVAC as the specific obligations have been fulfilled, and the continuation of the community marketing authorisation under exceptional circumstances for BLUEVAC BTV8.

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

Community referrals and related procedures

The Committee started a procedure for **Coglapix vakcina A.U.V. suspension for injection for pigs** (*Actinobacillus pleuropneumoniae* strains serotype 1 and 2) from CEVA-Phylaxia Veterinary Biologicals Co. Ltd. The matter was referred to the Committee by Hungary as the reference Member State in the mutual recognition procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by Italy related to efficacy which may present a potential serious risk to animal health.

The Committee concluded the referral procedure for **all veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses**. The matter was referred to the Committee by Denmark under Article 35 of Directive 2001/82/EC, due to concerns regarding the indications, dosing regimen and target animal safety of the above mentioned products. The Committee agreed harmonised indications and dosing regimen, thereby also addressing the concerns on target animal safety for these veterinary medicinal products, and adopted by consensus an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **propyl 4-hydroxybenzoate and its sodium salt** in all food producing species. These two substances were previously covered by the entry for food additives with a valid E-number in table 1 of the annex to Regulation (EU) No 37/2010 with a 'No MRL required' classification. However as a result of EFSA's 2004 re-evaluation of parabens with E numbers E214-E219, and the subsequent suspension of the E-numbers for propyl 4-hydroxybenzoate and its sodium salt, these substances were no longer covered by the entry for food additives.

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **virginiamycin** in chickens. Furthermore, the Committee agreed to extrapolate these maximum residue limits to poultry.

The Committee adopted by consensus a revised positive opinion, recommending the establishment of a maximum residue limit for **tylvalosin** in chicken eggs and the extrapolation of this maximum residue limit to poultry eggs. This followed the request by the European Commission for the CVMP to review its previous opinion and in particular, if possible, to retain a sufficient portion of the ADI for future use. This revised opinion reconfirms the Committee's conclusions and provides additional clarifications for its recommendation.

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

Scientific advice

The Committee adopted four separate scientific advice reports concerning:

- Initial advice on safety and efficacy issues for an anti-inflammatory veterinary medicinal product for cows;
- Initial advice on MRL issues for a hormonal veterinary medicinal product for pigs;
- Initial advice on quality issues for an immunological veterinary medicinal product for dogs; and
- Follow-up advice on safety issues for an anti-inflammatory veterinary medicinal product for dogs.

MUMS/limited market

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

- an immunological product for pigs as not indicated for MUMS/limited market; and
- an anti-parasitic product for dogs as indicated for MUMS/limited market. No financial incentives as the product is not intended for food-producing animals.

Pharmacovigilance

The Committee reviewed the PSURs for **Acticam**, **BTVPUR AlSap 1**, **BTVPUR AlSap 1-8**, **Cardalis**, **Cerenia**, **Contacera**, **Equilis Prequenza**, **Equilis Prequenza Te**, **Hiprabovis IBR Marker Live**, **Inflacam**, **LEUCOFELIGEN FeLV/RCP**, **MELOXIDYL**, **Panacur AquaSol**, **Porcilis ColiClos**, **Poulvac E. coli**, **Prac-tic**, **ProZinc**, **Trifexis** and **TruScient** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a concept paper recommending the drafting of a new guideline on data requirements for the prevention of transmission of canine and feline vector-borne diseases (EMA/CVMP/EWP/309734/2014) for a 3-month period of public consultation. The intended guideline is aimed to provide guidance on the specific study design to demonstrate the prevention of transmission of vector-borne diseases, which is not available at present.

Immunologicals

The Committee adopted a guideline on data requirements for changes to the strain composition of authorised equine influenza vaccines in line with the OIE requirements (EMA/CVMP/IWP/97961/2013) following the close of the public consultation. The guideline provides guidance on the data requirements to support modifications to authorised, equine influenza vaccines based on recommendations from the OIE Expert Surveillance Panel on Equine Influenza Vaccine Composition.

Availability of medicines

The Committee adopted a concept paper for the revision of the CVMP guidelines on data requirements for veterinary medicinal products for minor use minor species (MUMS) (EMA/CVMP/505827/2014) for a 3-month period of public consultation. The intention is to review current MUMS guidelines in view of experience gained and also taking into account the latest revised policy, so that the available guidance is in line with current knowledge and best practice. In addition further clarification to applicants in terms of applicability to particular products.

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

Working Parties

The Committee endorsed the work plans for 2015 for the CVMP Working Parties on Scientific Advice, Safety, Environmental Risk Assessment, Efficacy, Immunologicals, Antimicrobials and Pharmacovigilance as well as for the Joint CHMP/CVMP Quality Working Party and the Joint CVMP/CHMP ad hoc expert group on the application of 3Rs in regulatory testing of medicinal products.

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

International harmonisation

The Committee adopted the revised VICH guideline GL23(R) on safety: Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing: genotoxicity testing (EMA/CVMP/VICH/526/2000) for implementation in the EU following the sign-off by the VICH Steering Committee at step 6 of the VICH procedure.

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

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 36608427

E-mail: press@ema.europa.eu