EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 06-08 May 2014

CVMP opinions on veterinary medicinal products

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

Versican Plus Pi, from Zoetis Belgium SA, a vaccine for dogs against canine parainfluenza virus;

Versican Plus DHPPi, from Zoetis Belgium SA, a vaccine for dogs against canine distemper virus, canine adenovirus, canine parvovirus and canine parainfluenza virus;

ERYSENG PARVO, from Laboratorios HIPRA S.A., a vaccine against porcine parvovirosis and swine erysipelas for pigs; and

ERYSENG, from Laboratorios HIPRA S.A., a vaccine against swine erysipelas for pigs.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **DRAXXIN** (*tulathromycin*), from Zoetis Belgium SA, concerning the addition of a new strength, 25 mg/ml solution for injection, for pigs.

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

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

Cerenia (*maropitant citrate*) from Zoetis Belgium SA regarding quality changes;

Metacam (*meloxicam*) from Boehringer Ingelheim Vetmedica GmbH regarding quality changes; and

Vectra 3D (*dinotefuran, pyriproxyfen* and *permethrin*) from CEVA Santé Animale regarding changes to the pharmacovigilance system.

Community referrals and related procedures

The Committee concluded the referral procedure for **all veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs**. The matter was referred to the Committee by Sweden under Article 35 of Directive 2001/82/EC, to review the treatment durations in pigs and the indication for swine dysentery (caused by *Brachyspira*

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hyodysenteriae) in order to ensure safe and effective use of the veterinary medicines and also to avoid unnecessary selection pressure for antimicrobial resistance. The Committee adopted by consensus an opinion recommending changes to the product information of the concerned products related to deletion of the indication for swine dysentery (caused by *Brachyspira hyodysenteriae*) and limiting the treatment durations for up to three weeks in pigs.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **clodronic acid** (in the form of disodium salt) in table 1 of the Annex to Regulation 37/2010 for horses with a "No MRL required" classification.

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

Further to a request from the European Commission under Article 11 of Regulation (EC) No. 470/2009, the Committee started a procedure for the review of the maximum residue limit (MRL) for **diflubenzuron** in Salmonidae in view of recent evaluations by ECHA and EFSA in the context of biocides and plant protection products and concerns relating to the genotoxic potential of the metabolite 4-chloroaniline.

Further to a request in accordance with CVMP guidance to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, the Committee adopted a revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009-Rev.18), in order to include **bentonite** as a new entry under the heading of excipients.

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

Scientific advice

The Committee adopted a scientific advice report concerning initial advice on efficacy issues for an antiparasitic product for cats.

Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR AlSap 1**, **BTVPUR AlSap 1-8**, **Cardalis**, **Cerenia**, **Circovac**, **Contacera**, **Convenia**, **Ibaflin (WD)**, **Inflacam**, **Masivet**, **Panacur AquaSol**, **Poulvac E. coli** and **Suvaxyn Aujeszky 783+O/W** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted Questions and Answers in respect to the CVMP guideline on pharmaceutical fixed combination products (EMEA/CVMP/83804/2005). The existing question and answer regarding a justification of a fixed combination has been extended, and a new question and answer has been added concerning fixed combinations of antiparasitic components.

The Questions and Answers will be published on the Agency's website.

Quality

The Committee adopted a draft Reflection paper on the use of cocrystals and other solid state forms of active substances in medicinal products (EMA/CHMP/CVMP/QWP/136250/2014) for a 3-month period of public consultation. This reflection paper has been developed to provide guidance concerning the submission requirements for cocrystals.

The reflection paper will be published on the Agency's website.

Organisational matters

The Committee held a meeting with interested parties on 7 May 2014 attended by representatives of the Association of Veterinary Consultants (AVC), the European Group for Generic Veterinary Products (EGGVP), the European Federation of Honey Packers and Distributors (FEEDM), the Federation of Veterinarians of Europe (FVE), the International Council on Animal Protection in Pharmaceutical Programs (ICAPPP) and the International Federation of Animal Health Europe (IFAH-Europe).

The topics discussed concerned:

- Improvements to the implementation of current legislation
- MRL Regulation
- Veterinary medicines for aquatic animals
- EMA/CVMP activities in relation to the 3Rs
- Developments on the availability of active substances for bees and MRLs in honey

The programme of the meeting will be published on the Agency's web site.

Procedural announcement

Dossier requirements published for the submission of marketing authorisation and maximum residue limits (MRL) applications to the European Medicines Agency (EMA) and to members of the Committee for Medicinal Products for Veterinary use (CVMP) published

The table listing the dossiers requirements for submission of marketing authorisation and MRL applications to the EMA and to CVMP members has been re-designed, streamlined and updated. The updates mention notably the recommended use of the EMA e-Submission Gateway or Web Client for submissions to the Agency. For submission to CVMP members, the update mentions those members accepting submission via the Common European Submission Portal (CESP).

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

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