EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 08-10 April 2014

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for:

Vectra Felis (dinotefuran/pyriproxyfen) from **Ceva Santé Animale**, an ectoparasiticide for the treatment and prevention of flea infestations in cats.

The Committee adopted by consensus a positive opinion for a type II variation application for:

RESPIPORC FLU3 regarding quality changes.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **LEUCOFELIGEN FeLV/RCP**, **LEUCOGEN**, **Melovem** and **Suvaxyn PCV**. The Committee, having re-assessed the benefit-risk balance of these products, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations.

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

Community referrals and related procedures

The Committee concluded the referral procedure for **Linco-Spectin 100 and its associated names** (*lincomycin* and *spectinomycin*) from Zoetis. The matter was referred to the Committee by Belgium, under Article 34 of Directive 2001/82/EC, due to divergent decisions taken by Member States resulting in discrepancies in the product information. The Committee agreed to harmonised product information for the concerned 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.

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

The Committee concluded the referral procedure for **Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names** (*enrofloxacin*) from Bayer Animal Health. The matter was referred to the Committee by France, under Article 34 of Directive 2001/82/EC, due to divergent decisions taken by Member States resulting in discrepancies in the product information. The Committee agreed harmonised product information for the concerned products, and adopted by majority an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly.

The Committee concluded the referral procedure for **Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC** (*enrofloxacin*). The matter was referred to the Committee by Spain under Article 35 of Directive 2001/82/EC due to public health interest to review the available scientific data and achieve where possible harmonised indications, posology and withdrawal periods for the concerned products, in order to have safe and effective veterinary medicines and also to avoid unnecessary selection pressure for antimicrobial resistance. The Committee adopted by majority an opinion recommending changes to the product information of the concerned products related to the harmonisation of the indications, posology and withdrawal periods.

The Committee considered the grounds for re-examination of the CVMP opinion for **Fiprex CAT 52.5 mg spot-on solution for cats, Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solutions for dogs and Fiprex XL 412.5 mg spot-on solution for dogs** (*fipronil*), from Vet-Agro Trading Sp. z o.o., adopted on 11 December 2013 in the context of a referral procedure initiated under Article 33(4) of Directive 2001/82/EC. The matter was referred to the Committee by the Czech Republic as the reference Member State in the mutual recognition procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by Ireland relating to efficacy. The Committee adopted by majority a final opinion concluding that the application does not meet the requirements laid down by Article 13a of Directive 2001/82/EC and consequently does not satisfy the criteria for marketing authorisation with respect to efficacy. Therefore, the Committee recommended the refusal of the granting of the marketing authorisations and the suspension of the existing marketing authorisations for the above mentioned veterinary medicinal products.

Maximum Residue Limits

Further to a request from Germany, under Article 11 of Regulation (EC) 470/2009, for the Committee to review the previous opinion on **barium selenate** in light of new scientific information that could have an impact on the consumer risk assessment, the Committee adopted by consensus an opinion recommending the modification of the current entry in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for barium selenate. The recommendation restricts the use of the substance to non-injectable administration.

More information about the above recommendation can be found on the Agency's website.

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) 470/2009 (EMA/CVMP/519714/2009-Rev19), in order to include **di-polyethylene glycol-6 ester of oleic acid** as a new entry under the heading of excipients.

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

Scientific advice

The Committee adopted two separate scientific advice reports concerning initial advice on quality, safety and efficacy issues for a musculoskeletal veterinary medicinal product for dogs, which is a parallel scientific advice with the US FDA-CVM, and a follow-up advice on efficacy issues for a cardiovascular veterinary medicinal product for dogs.

MUMS/limited market

Following the Committee's review of four requests for classification under the MUMS/limited market policy, which concerned an immunological product for dogs, an immunological product for cats, an oncology medicinal product for dogs, and an immunological product for foxes and raccoon dogs, the CVMP considered that the four products were indicated for MUMS/limited market but were not eligible for financial incentives as they are not intended for use in food-producing animals.

Pharmacovigilance

The Committee reviewed the PSURs for **Apoquel**, **BTVPUR AlSap 2-4**, **Certifect**, **Equip WNV, Improvac**, **MS-H vaccine**, **Oncept IL-2**, **Palladia**, **Porcilis ColiClos**, **Porcilis Pesti**, **Posatex**, **TruScient** and **Zuprevo** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Comfortis** and recommended amendments to the product information to add new adverse reactions.

Concept papers, guidelines and SOPs

Quality

The Committee adopted Questions and Answers on the following quality topics:

- The acceptability of two different appearances for a single strength tablet in a single marketing authorisation; and
- Particles originating from the container-closure system.

Efficacy

The Committee adopted a draft reflection paper on anthelmintic resistance (EMA/CVMP/EWP/573536/2013) for a 3-month period of public consultation. This reflection paper has been developed to address the current views on issues in relation to anthelmintic resistance.

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

Procedural announcement

Revised pre-submission guidance for marketing authorisation applications for veterinary medicinal products published

The pre-submission guidance for applications for centralised marketing authorisations for veterinary medicinal products, published by the Agency, has been updated recently. The Agency reviews its guidance continuously and this major revision updates all aspects of the pre-submission guidance with up-to-date links to more detailed webpages, which it is hoped will be of help to users. The main changes concern the procedures and timelines for the notification of intended applications (previously called 'letter of intent') and appointment of rapporteur and co-rapporteur, the procedure for requests for eligibility for the centralised procedure, guidance regarding the Active Substance Master File (ASMF) procedures, new guidance on pre-submission meetings and the Innovation Task Force for use for veterinary medicines.

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