EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 10-12 December 2013

CVMP opinions on veterinary medicinal products

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

Bravecto (*fluralaner*), from Intervet International B.V., a new ectoparasiticide for the treatment of flea and tick infestations in dogs; and

NexGard (*afoxolaner*), from MERIAL, a new ectoparasiticide for the treatment of flea and tick infestations in dogs.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Contacera** (*meloxicam*), from Zoetis Belgium SA to add a new strength, pharmaceutical form and a route of administration for the existing target species (horses).

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

Fevaxyn Pentofel (subject to two worksharing procedures) regarding quality changes; and

Metacam and **Novem** (subject to two worksharing procedures) regarding quality changes.

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

Renewals of marketing authorisation

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

[1] Correction to the name of the marketing authorisation holder for Fiprex spot-on solution for dogs (paragraph on community referrals)

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 concluded the referral procedure 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 solution for dogs, Fiprex XL 412.5 mg spot-on solution for dogs** (*fipronil*) from Vet-Agro Trading Sp. z o.o.. 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 an 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 in respect of 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 (MRLs)

The Committee adopted by consensus positive opinions recommending the establishment of MRLs for the following new active substances:

Cabergoline in bovine species; and

Lufenuron in fin fish.

The Committee also adopted by consensus a positive opinion recommending the modification of the existing MRLs for **lasalocid** in poultry.

Further to requests from Ireland under Article 27(2) of Regulation (EC) No. 470/2009, the Committee adopted by consensus opinions recommending final MRLs for **clorsulon** and **closantel** in milk further to the extrapoloation and establishment of provisional MRLs in milk.

Further to a request from Ireland under Article 27(2) of Regulation (EC) No. 470/2009, the Committee adopted by consensus an opinion recommending the extrapolation of the current MRLs for **rafoxanide** to bovine and ovine milk. The recommended MRL is provisional with an expiry date of 1 January 2016.

Further to a request from Germany under Article 11 of Regulation (EC) No. 470/2009, the Committee started a procedure for the review of the MRL classification for barium selenate in view of the persistence of residues at the injection site and new data on the bioavailability of residues.

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

Scientific advice

The Committee adopted five separate scientific advice reports concerning: quality, safety, efficacy and MRL issues for the development of a veterinary product for salmon, advice on bioequivalence issues for two veterinary medicinal products for cattle, follow-up advice on a MUMS product concerning quality, safety and efficacy issues for cats, and follow-up advice on efficacy issues for a product for cattle.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl Tick Plus**, **Cimalgex**, **Emdocam**, **Reconcile**, **Rheumocam**, **STARTVAC**, **Suvaxyn PCV**, **Zulvac 8 Bovis** and **Zulvac 8 Ovis** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Leucogen** and recommended amendments to the product information to include reference to the frequency of existing adverse reactions already in the product information.

Concept papers, guidelines and SOPs

Joint CVMP/CHMP AHEG on the application of the 3Rs (Replacement, Reduction, Refinement of animal testing)

The Committee adopted a concept paper on review and update of EMA guidelines to implement best practice with regard to 3Rs (EMA/CHMP/CVMP/JEG-3Rs/704685/2012) for a 3-month period of public consultation. The concept paper was developed in coordination with relevant CHMP and CVMP Working Parties to review EMA guidance documents which include reference to animal tests. Where guidance documents are found not to reflect best practice with regards to the application of 3Rs, these should be updated or a plan for their update established.

The document above will be available on the Agency's website subject to its adoption by CHMP.

Pharmacovigilance

The Committee adopted a reflection paper on pharmacovigilance communication concerning veterinary medicinal products (EMA/CVMP/PhVWP/536313/2013) following the close of the public consultation. The reflection paper has been developed to provide an overview of practises and communication tools used, outline a basic framework for veterinary pharmacovigilance communication and to improve and harmonise the approach to communication across the EU for transparent and effective transfer of pharmacovigilance information, particularly to veterinarians, health-care professionals and other users of the veterinary medicinal products.

The reflection paper together with the overview of comments received (EMA/CVMP/PhVWP/327742/2013) will be published on the Agency's website.

The Committee endorsed the draft recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products (EMA/CVMP/PhVWP/901279/2011) for release for a 6-month public consultation. The recommendation aims to provide an initial framework for the further development of signal detection in veterinary pharmacovigilance, its practical modalities, interpretation, and location in the signal management process.

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

Working Parties

The Committee re-elected Peter Ekström as chair of the CVMP Pharmacovigilance Working Party for a further 3-year mandate; and elected Esther Werner as chair of the CVMP Immunologicals working party and Eva Lander Persson as chair of the CVMP Safety working party, both for a 3-year mandate.

The Committee reviewed and adopted a revised mandate for the CVMP Scientific Advice Working Party (EMA/CVMP/SAWP/750268/2013) for another period of 3 years.

The Committee also reviewed and adopted the mandate for the CVMP Safety Working Party (EMA/CVMP/131613/2004-Rev.3) for another period of 3 years. The content of the mandate remains unchanged.

International Harmonisation

The Committee adopted a new draft VICH guideline for release for public consultation in the EU following the sign-off by the VICH Steering Committee:

- Draft VICH GL52 on Bioequivalence: blood level bioequivalence study – 6 month public consultation;

and adopted the implementation dates for the following four VICH guidelines on pharmacovigilance:

- VICH GL24 on Pharmacovigilance: management of ADRs – implementation by 31 December 2015;
- VICH GL30 on Pharmacovigilance: controlled list of terms – implementation by 31 December 2015;
- VICH GL35 on Pharmacovigilance: electronic standards for transfer of data – implementation by 31 December 2015; and
- VICH GL42 on Pharmacovigilance: data elements for submission of adverse event reports – implementation by 31 December 2015.

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

Consultation meeting on antimicrobials

The Committee noted the consultation meeting with stakeholders in the context of preparing responses to the request from the European Commission to the European Medicines Agency for scientific advice on the impact on public health and animal health of the use of antibiotics in animals. The meeting is scheduled for 28 February 2014. A draft agenda (EMA/695339/2013), information on the consultation procedure (EMA/776691/2013) and templates for the consultation will be published on the Agency's website.

Notes

1. 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 officers

Martin Harvey Allchurch or Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu