EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 February 2015
EMA/CVMP/60802/2015
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 10-12 February 2015

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Metacam** (*meloxicam*), from Boehringer Ingelheim Vetmedica GmbH, concerning the addition of a new strength for cattle and horses.

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

Suvaxyn PCV regarding quality changes;

NexGard regarding changes to the SPC; and

Zuprevo regarding a new indication and changes to the SPC.

The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Novem** and **Metacam** (*meloxicam*) concerning quality changes.

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

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the extension of maximum residue limits for **diethylene glycol monoethyl ether** to poultry. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate these maximum residue limits to all food producing species.

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

The Committee agreed to include **polyethylene glycol-8 beeswax** and **octadecenoyloxyethyl–heptadecenyl-hydroxyethylimidazolinium chloride (DOTIM)** as new entries 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. 26). This decision

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

followed the Committee's review of requests submitted in accordance with the relevant CVMP guidance.

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

Scientific advice

The Committee adopted three separate scientific advice reports concerning:

- Initial advice on efficacy issues for a cardiovascular veterinary medicinal product for dogs;
- Initial advice on MRL issues for an antiparasitic veterinary medicinal product for pigs; and
- Follow up advice on safety issues for an immunostimulant veterinary medicinal product for cattle and chickens.

MUMS/limited market

Following the Committee's review of a request for classification under the MUMS/limited market policy, the CVMP classified a product for pigs intended for making a medical diagnosis as indicated for MUMS/limited market. The product is eligible for financial incentives as it is indicated for food-producing animals and no alternative test is authorised.

Pharmacovigilance

The Committee reviewed the PSURs for **Aivlosin**, **CaniLeish**, **Comfortis**, **Econor**, **Meloxidolor**, **Previcox**, **ProteqFlu**, **ProteqFlu-Te**, **Recocam**, **ZULVAC 1+8 Bovis** and **ZULVAC 1+8 Ovis** and concluded that no further action or changes to their product literature were required.

The Committee adopted the public bulletin on veterinary pharmacovigilance for 2014 summarising the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMA/CVMP/793263/2014). A total of 11.900 adverse event reports were received in 2014 relating to the exposure of centrally authorised products. The significant upward trend in reporting is continued with, on average, a yearly increase of 35% adverse event reporting since 2011. This confirms the increased awareness of reporting by veterinarians and the increased efforts by regulators to control compliance by industry. Further to the analysis of the data, recommendations were made to amend the product literature for 6 products. The report also contains detailed feedback on the outcome of the analysis of the overall data performed by the expert bodies during 2014, including information on issues that require further monitoring.

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

Concept papers, guidelines and SOPs

Antimicrobials

The Committee adopted a revised guideline for the demonstration of **efficacy** for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/EWP/261180/2012) for a second public consultation for a period of 3 months. The revised guideline provides more detailed information on the design and conduct of pre-clinical and clinical studies to support clinical efficacy of an antimicrobial veterinary medicinal product and also includes new considerations on claims for metaphylactic or

prophylactic treatment. The draft revised guideline takes into account comments received during the first public consultation as indicated in the overview of comments (EMA/CVMP/EWP/737951/2013).

The Committee adopted a draft new guideline on the **assessment of the risk** to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals (EMA/CVMP/AWP/706442/2013) for a 6-month period of public consultation. The guideline provides advice with regard to applications for marketing authorisations for antimicrobial veterinary medicinal products on the data required and the methodology to be used for performing an assessment of the risk to public health from antimicrobial resistance due to use of the product. The guideline addresses the risk of possible transmission of antimicrobial resistance by the foodborne route or through direct contact with treated animals.

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

Quality

The Committee adopted a Question and Answer document on the following quality topic:

- Plastic containers for eye drops.

The document will be published on the Agency's website after its adoption by the CHMP.

International harmonisation

The Committee adopted two revised VICH guidelines for implementation in the EU following the sign-off by the VICH Steering Committee:

- VICH GL48(R): Revised guideline on Studies to Evaluate the Metabolism and Residues Kinetics of Veterinary Drugs in Human Food-producing Animals: Market Residue Depletion Studies to establish Product Withdrawal Periods;
- VICH GL49(R): Revised guideline on Studies to Evaluate the Metabolism and Residues Kinetics of Veterinary Drugs in Human Food-producing Animals: Validation of Analytical Methods used in Residue Depletion Studies.

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

Procedural announcement

With effect from Monday 16 February 2015, the Agency will not require a hard copy of the cover letter accompanying applications submitted via Eudralink (the cover letter will still be required to be included in the electronic submission's dossier). This change affects submission of post-authorisation procedures where the Agency has previously required that a hard copy be submitted in order to officially start the procedure.

Where applications are submitted by CD or DVD, the hard copy cover letter will still be required.

Please note that the recommended submission method for the Agency is the EMA e-submission Gateway/Web Client; for submissions via the Gateway no hard copy of the cover letter has been required since April 2014.

For further details on electronic submissions please see the following link: http://esubmission.ema.europa.eu/tiges/vetesub.htm.

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