EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2013
EMA/CVMP/494034/2013
Press Office

Press release

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

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Comfortis** (*spinosad*), from Eli Lilly and Company Limited concerning the addition of a new tablet strength of 180 mg with two presentations for dogs and cats.

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

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

CERTIFECT regarding safety changes and amendments introduced to the product literature;

Convenia regarding manufacturing;

Equip WNV regarding the addition of a new indication;

Gripovac 3 regarding quality changes;

Improvac regarding quality and manufacturing; and

RESPIPORC FLU3 regarding quality changes.

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Annual reassessment of marketing authorisations

The Committee adopted opinions on the annual re-assessment for **Zulvac 1+8 Bovis** and **Coxevac**, further to the evaluation of the data submitted by the marketing authorisation holders. Since the specific obligations for Zulvac 1+8 Bovis have been fulfilled the Committee recommended the conversion of the Community marketing authorisation from under exceptional circumstances to a normal status for this product. The Committee recommended the continuation of the Community marketing authorisations under exceptional circumstances for Coxevac.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Onsior** and **Easotic**. 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.

Maximum Residue Limits

Further to the adoption of an opinion recommending the establishment of a maximum residue limit (MRL) for **ivermectin** in muscle in all mammalian food producing species together with the reference to a residue level to be considered for the injection site, the European Commission requested the CVMP to review its opinion and in particular to consider alternatives to the recommended inclusion of an injection site residue limit in Table 1 of the Annex to Regulation (EU) No. 37/2010. The Committee, having reviewed the previous opinion and having considered the available options, agreed to revise its recommendation and adopted, by consensus, a revised positive opinion recommending the establishment of MRLs for **ivermectin** in all mammalian food producing species without reference to injection site residues in Regulation (EU) No. 37/2010. Information on residue levels at the injection site, to be taken into account for the establishment of withdrawal periods, is now provided in the European public MRL assessment report (EPMAR), which will be published following adoption of the MRLs by the European Commission and their publication in the Official Journal of the European Union.

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

Scientific advice

The Committee adopted five separate scientific advice reports concerning: safety and efficacy requirements for a veterinary medicinal product for dogs; quality, safety and MRL requirements for an antimicrobial veterinary medicinal product for lactating dairy cows; efficacy requirements for an anti-inflammatory veterinary medicinal product for horses; MRL requirements for an excipient used in an antiparasitic veterinary medicinal product for cattle, and efficacy requirements for an immunological veterinary medicinal product for sheep and cattle.

MUMS / Limited markets

Following the Committee's review of three requests for classification under the MUMS/Limited markets policy, which concerned an antimicrobial product for rabbits, an immunological product for chickens, and a product for horses

- The CVMP considered that the product for rabbits was indicated for MUMS but was not eligible for financial incentives as an alternative product is authorised for the same target species for the same indication and the market does not appear to be limited.
- The CVMP considered that the product for chickens was indicated for MUMS/Limited markets and would be eligible for financial incentives.
- The CVMP considered that the product for horses was indicated for MUMS but was not eligible for financial incentives as alternative products for the same target species and for the same indication are available.

Pharmacovigilance

The Committee reviewed the PSURs for **Acticam**, **Advocate**, **BTVPUR AlSap 2-4**, **Dicural**, **Halocur**, **Inflacam**, **Porcilis ColiClos**, **Procox**, **Proteq Flu**, **Veraflox** and **Zuprevo** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSURs for **Activyl** and **Equilis StrepE** and recommended amendments to the product information to add new adverse reactions.

The Committee additionally reviewed the PSUR for **Porcilis AR-T DF** and recommended amendments to the product information to add new adverse reactions and to modify the precautions for use during pregnancy, lactation or lay.

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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