EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 2-4 June 2015

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **UpCard** (*torasemide anhydrous*), from Vétoquinol SA, a veterinary medicinal product for the treatment of clinical signs related to congestive heart failure in dogs.

The Committee adopted by consensus a positive opinion for a grouped type II variation application for **COXEVAC**, concerning quality changes.

The Committee adopted by consensus a positive opinion for a type II variation application for **Poulvac E. coli** (vaccine) to include an additional route of administration.

The Committee adopted by consensus a positive opinion for a type IB variation application, subject to a worksharing procedure, for the Bluetongue virus vaccines **BTVPUR AlSap 8**, **BTVPUR AlSap 1-8**, **BTVPUR AlSap 2-4** and **BTVPUR AlSap 1**, concerning quality changes.

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

Renewals of marketing authorisations

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **COXEVAC** (after re-examination) and **BTVPUR AlSap 2-4**. 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.

Community referrals and related procedures

The Committee started a procedure for **Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys** (*amoxicillin*) from Eurovet Animal Health B.V. The matter was referred to the Committee by the United Kingdom as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by Denmark related to

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demonstration of bioequivalence of the product with the reference product and prudent use advice in the product information.

The Committee concluded the referral procedure for **Coglapix suspension for injection for pigs** (*Actinobacillus pleuropneumoniae* strains serotype 1 and 2) from CEVA-Phylaxia Veterinary Biologicals Co. Ltd. The matter was referred to the Committee by Hungary as the reference Member State in the mutual recognition procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by Italy related to the efficacy of the product. The Committee adopted by majority an opinion concluding that the objections raised by Italy during the mutual recognition procedure should not prevent the granting of a marketing authorisation subject to changes in the product information regarding the indication for use and immunological properties of the product.

Maximum Residue Limits

The Committee agreed to include **monophosphoryl lipid A (MPL)** as a new entry 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.29). This decision followed the Committee's review of a request that had been 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 safety issues for an antiparasitic veterinary medicinal product for cats;
- Initial advice on quality issues for an antiparasitic veterinary medicinal product for dogs; and
- Initial advice on safety issues for an antiparasitic veterinary medicinal product for cattle.

MUMS/limited market

Following the Committee's review of a request for classification under the MUMS/limited market policy, the CVMP classified an immunological product for pigeons as indicated for MUMS/limited market. The product is eligible for reduced data requirements, where applicable, and for financial incentives as it is indicated for a food-producing species and no alternative product is authorised for the same target species.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl Tick Plus**, **ECOPORC SHIGA**, **Emdocam**, **Equilis Te**, **Kexxtone**, **Nobilis Influenza H5N2**, **ProZinc**, **Stronghold**, **Suprelorin**, **Suvaxyn PCV**, **Ypozane**, **ZULVAC 1 Bovis**, **ZULVAC 1 Ovis**, **ZULVAC 8 Bovis**, and **ZULVAC 8 Ovis**, and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Environmental Risk Assessment

The Committee adopted a new concept paper on the testing strategy and risk assessment for plants in Phase II of the environmental risk assessment for veterinary medicinal products

(EMA/CVMP/ERA/698394/2014) for a 3-month period of public consultation. This concept paper has been prepared to address the need to develop a guideline on the strategy for plant testing in the Phase II environmental risk assessment for the terrestrial compartment. The proposed guideline will incorporate guidance already available in the existing reflection paper in this topic (EMA/CVMP/ERA/147844/2011), and provide additional guidance on how and when to conduct a tier based assessment for plants for those substances that form high amounts of non-extractable residues or transformation products in manure.

Pharmacovigilance

The Committee adopted the CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/90241/2009) used for electronic reporting following the yearly review and update. Implementation of the VeDDRA list in EudraVigilance Veterinary is scheduled for 1 October 2015. The guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007) were also adopted.

Quality

The Committee adopted a reflection paper on the use of cocrystals of active substances in medicinal products (EMA/CHMP/CVMP/QWP/284008/2015) and overview of comments (EMA/CHMP/CVMP/QWP/230826/2015) following the close of the public consultation. This reflection paper presents the current considerations of EU regulators regarding different aspects concerning the use of cocrystals of active substances in medicinal products, for either human or veterinary use.

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

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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