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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 08–10 April 2015

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Sileo** (*dexmedetomidine hydrochloride*), from Orion Corporation, a veterinary medicinal product for the alleviation of acute anxiety and fear associated with noise in dogs.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Cerenia** (*maropitant citrate*), from Zoetis Belgium S.A., concerning the addition of a new route of administration (intravenous use) for the solution for injection for dogs and cats.

The Committee adopted by consensus positive opinions for type II variation applications for quality changes for **Gripovac 3, RESPIPORC FLU3** and **RHINISENG** as well as for a work-sharing procedure for **Suvaxyn PCV**, **Equip WNV** and **Poulvac E.coli**.

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

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Bovilis BTV8**, **COXEVAC** and **Equilis Te**. 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 concluded a procedure concerning the risk to the consumer resulting from the use of **lidocaine** in food producing species. The procedure responds to the request from the Netherlands for the Committee to give a scientific opinion under Article 30 of Regulation (EC) No. 726/2004 due to concerns relating particularly to new scientific data on the metabolite 2,6-xylidine. The Committee

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adopted by consensus an opinion responding to the specific questions raised by the Netherlands, and concluded that the existing regulatory provisions with regard to the use of the substance in horses ensure that the risk for consumers resulting from potential exposure to residues of lidocaine from treated animals is negligible. With regard to off-label use of lidocaine in cattle and pigs under Article 11 of Directive 2001/82/EC the Committee concluded that the existing regulatory provisions concerning the minimum withdrawal period also ensure that the risk to the consumer from potential exposure to residues in meat is negligible. In relation to residues that may occur in milk following off-label use of lidocaine, current provisions cannot rule out the possibility that consumers could be exposed to lidocaine residues and consequently appropriate communication with veterinarians was recommended in order to ensure that an adequate interval of time is allowed to elapse between the administration of lidocaine and the taking of milk for human consumption. As part of the same procedure, the Committee was asked for its opinion on the consumer safety of xylazine. The Committee concluded that, based on the existing regulatory provisions, the use of xylazine in cattle and horses represents a negligible risk to consumer safety.

The opinion and assessment report will be published on the Agency's website.

Maximum Residue Limits

The Committee agreed to include **bis(2,6-diisopropylphenyl)carbodiimide, pine wood flour and polyvinyl chloride homopolymer** 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.27). This decision followed the Committee's review of the requests 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 a scientific advice report concerning initial advice on MRL issues for an anaesthetic veterinary product for *equidae*.

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 a fish species as indicated for MUMS/limited market. The product is eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as an alternative vaccine is authorised for the same target species for the same indication.

Pharmacovigilance

The Committee reviewed the PSURs for **APOQUEL**, **BTVPUR Alsap 2-4**, **Oncept IL-2**, **Palladia**, **Panacur AquaSol**, **Porcilis ColiClos**, **Posatex**, **PRILACTONE**, **Vectra Felis**, 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 **Rabigen SAG2** and recommended amendments to the product information.

Antimicrobials

The Committee initiated discussions on the request from the European Commission for a joint EFSA and EMA scientific opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety. The European Commission requests, inter alia, to review and assess the measures that have been, or are being taken, to reduce the use of antimicrobials in animal husbandry in the EU, review recent scientific developments in the area of possible alternatives to the use of antimicrobials in animal husbandry in the EU and to assess the impact of such alternatives, and to recommend options to reduce antimicrobial usage in animal husbandry. The impact on public health, animal health and welfare will be taken into account for the preparation of the opinion. The deadline provided by the European Commission for the delivery of the opinion is 20 December 2016. The mandate will be published on the Agency website. Dialogue will now take place between EMA and EFSA on the practical arrangements for the preparation of this opinion.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted the draft recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products (EMA/CVMP/PhVWP/901279/2011) and overview of comments (EMA/CVMP/PhVWP/459562/2014) following the close of the 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 documents will be published on the Agency website following adoption by Heads of Medicines Agencies - Veterinary.

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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