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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 3-5 June 2014

CVMP opinions on veterinary medicinal products

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

Osurnia (*terbinafine / florfenicol / betamethasone acetate*), from Novartis Santé Animale S.A.S., an ear gel for treatment of otitis externa in dogs;

Versican Plus L4, from Zoetis Belgium SA, a vaccine for dogs against leptospirosis;

Versican Plus Pi/L4, from Zoetis Belgium SA, a vaccine for dogs against canine parainfluenza and leptospirosis; and

Versican Plus Pi/L4R, from Zoetis Belgium SA, a vaccine for dogs against canine parainfluenza, leptospirosis and rabies.

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

ProteqFlu, from Mérial regarding quality changes; and

ProteqFlu-Te, from Mérial regarding quality changes.

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 a positive opinion for the renewal of the marketing authorisation for **Palladia**. 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.

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Community referrals and related procedures

The Committee started a procedure under Article 35 of Directive 2001/82/EC for **all veterinary medicinal products containing colistin to be administered orally** and intended for use in food producing species. The matter was referred to the Committee by the European Commission in order to give its opinion on the measures that need to be taken to ensure the prudent use of colistin in food-producing animals across the EU and to minimise potential risks with the use of the identified products.

Maximum Residue Limits (MRLs)

The Committee adopted by consensus an opinion recommending the extension of the time period applying to the provisional MRLs for **eprinomectin** in ovine and caprine species. The provisional MRLs for eprinomectin in ovine and caprine species expire on 1 July 2014 and a two year extension is now recommended.

The Committee adopted by consensus a positive opinion recommending the extension of MRLs for **tulathromycin** to ovine and caprine species.

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

Further to a request from the European Commission under Article 11 of Regulation (EC) No. 470/2009, the Committee started at its May meeting a procedure for the review of the previous opinion for the establishment of MRLs for **diflubenzuron** in *Salmonidae* in view of recent evaluations by European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA) and concerns relating to the genotoxic potential of the metabolite 4-chloroaniline. In the context of this review the CVMP invites all interested parties such as the pharmaceutical industry, learned societies, governmental institutions and European Union and European Economic Area-European Free Trade Association Member States to submit any relevant scientific data, which may be used in the review.

More information about the above call for scientific data will be published on the Agency's website.

The Committee agreed to include **benzethonium chloride** 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. 21). 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 a scientific advice report concerning initial advice on safety and efficacy issues for an anti-infective product for cows.

MUMS/limited market

Following the Committee's review of a request for classification under the MUMS/limited market policy, which concerned an immunological product for sheep, the CVMP considered that the product was indicated for MUMS/limited market but was not eligible for financial incentives, as although it is indicated for a food-producing species an alternative immunological product is authorised for the same target species for the same indication.

Pharmacovigilance

The Committee reviewed the PSURs for **Ecoporc Shiga**, **Equilis Te**, **Gonazon (WD)**, **Kexxtone**, **Melovem**, **Nobilis Influenza H5N2**, **Onsior**, **ProZinc**, **Rheumocam**, **Suprelorin**, **Trifexis**, **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

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

The Committee adopted a concept paper proposing the development of a guideline on transferring quality control methods validated in collaborative trials to a product/laboratory specific context (EMA/CHMP/CVMP/JEG-3Rs/94304/2014) for a 3-month period of public consultation. The proposed guidance, which focuses on improving implementation of validated 3Rs methods for quality control purposes, will clarify the requirements for industry and assessors will encourage consistent regulatory criteria and decisions and will promote compliance with Directive 2010/63/EU.

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

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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