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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 14-16 March 2017

CVMP opinions on veterinary medicinal products

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

Ingelvac PCV FLEX, from Boehringer Ingelheim Vetmedica GmbH, a vaccine for the active immunisation of pigs against porcine circovirus type 2 (PCV2); and

Zeleris (*florfenicol* and *meloxicam*), from CEVA Santé Animale, a fixed combination product for cattle.

The Committee adopted by majority a positive final opinion for an initial marketing authorisation application for **RESPIPORC FLUpan H1N1**, from IDT Biologika GmbH, an inactivated viral vaccine for active immunisation of pigs against swine influenza caused by pandemic subtype H1N1, further to the re-examination of the opinion adopted during the Committee meeting held on 6-8 December 2016.

The Committee adopted by consensus positive opinions for the extension of the existing authorisations for:

Novem, from Boehringer Ingelheim Vetmedica GmbH, concerning the addition of a new strength (40 mg/ml) solution for injection for cattle; and

ZACTRAN, from MERIAL, concerning the addition of a new food-producing species (sheep).

The Committee adopted a positive opinion for a type II variation application to add a new therapeutic indication for **NEXGARD SPECTRA**. The Committee also adopted by consensus positive opinions for type II variation applications for **Bravecto**, **ProZinc** and **Stronghold** regarding quality changes.

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

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Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Poulvac E. coli** and **Suprelorin**. 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 follow-up assessment procedure of the conditions on the marketing authorisations for **veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys** that have been applied with Commission Implementing Decision (C(2014) 1484) of 28 February 2014 in the context of a referral procedure under Article 35 of Directive 2001/82/EC for the aforementioned products. Background information regarding the referral procedure, concerned products and details about the conditions is published on the Agency's website.

The Committee concluded the referral procedure for **veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for use in target species cattle.** The matter was referred to the Committee by Germany, under Article 35 of Directive 2001/82/EC, due to concerns related to the withdrawal periods in cattle (meat and offal) set for the aforementioned products. The Committee adopted by consensus an opinion concluding that in the absence of appropriate residue depletion data, a withdrawal period for meat and offal derived from treated cattle cannot be set. The Committee recommended the refusal of the granting of the marketing authorisation for the target species cattle and the variation of the existing marketing authorisations in order to remove any reference to the target species cattle for veterinary medicinal products containing methylprednisolone hydrogen succinate.

The Committee concluded the referral procedure for **veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma* spp.** The matter was referred to the Committee by Finland, under Article 35 of Directive 2001/82/EC, due to concerns related to the efficacy of tylosin in the treatment of bovine mastitis caused by *Mycoplasma* spp. The Committee adopted by consensus an opinion concluding that in the absence of pre-clinical or clinical data, and in light of the current scientific knowledge, the indication for treatment of bovine mastitis caused by *Mycoplasma* spp. with veterinary medicinal products containing tylosin that are administered parenterally is not effective. The Committee recommended variations to the terms of the marketing authorisations for veterinary medicinal products containing tylosin that are administered parenterally in order to remove the indications 'bovine mastitis caused by *Mycoplasma* spp.' or 'bovine mastitis caused by *Mycoplasma bovis*' from the product information.

The Committee considered the grounds for re-examination of the CVMP opinion for **veterinary medicinal products containing zinc oxide to be administered orally to food producing species**, adopted on December 2016, in the context of a referral procedure initiated under Article 35 of Directive 2001/82/EC. The Committee concluded that the recommendations included in their initial opinion should be maintained. The matter had been referred to the Committee by the Netherlands and France under Article 35 of Directive 2001/82/EC due to concerns related to potential risk to the environment and increase of prevalence of antibiotic resistant bacteria from the use of products containing zinc oxide. The Committee concluded that overall the benefit-risk balance for the products concerned by this referral is negative, as the benefits of zinc oxide for the prevention of diarrhoea in pigs do not outweigh the risks for the environment. The CVMP acknowledged that there is a risk of co-

selection for resistance associated with the use of zinc oxide but, at the present time, that such risk is not quantifiable. The Committee adopted by consensus a final opinion recommending the refusal of the granting of the marketing authorisations and the withdrawal of the existing marketing authorisations for veterinary medicinal products containing zinc oxide.

Maximum Residue Limits

The Committee agreed to include **polyoxyethylene cetyl ethers** 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. 35). This decision followed the Committee's review of a request submitted in accordance with the relevant CVMP guidance.

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

Scientific advice

The Committee adopted one scientific advice report further to a request for initial advice on safety and efficacy issues for a new immunological product for cats.

Minor use, minor species (MUMS) / limited market

Following the Committee's review of two requests for classification under the MUMS/limited market policy, the CVMP classified:

- A veterinary medicinal product with a genito-urinary system and sex hormones indication in rabbits as indicated for MUMS/limited market and eligible for reduced data requirements. No financial incentives will apply as authorised products already exist in the EU for the indication; and
- An immunological product intended for use in rabbits as indicated for MUMS/limited market and eligible for reduced data requirements. No financial incentives will apply as authorised products already exist in the EU for the indication.

Pharmacovigilance

The Committee reviewed the PSURs for **Comfortis**, **LETIFEND** and **Porcilis Pesti** and concluded that no further action or changes to their product information were required. The Committee also reviewed the PSUR for **Equisolon** and recommended amendments to the product literature.

Concept papers, guidelines and SOPs

Environmental Risk Assessment

The Committee adopted a guideline on the plant testing strategy for veterinary medicinal products (EMA/CVMP/ERA/689041/2015) following the close of the public consultation. The guideline replaces the reflection paper published on this topic in 2012 (EMA/CVMP/ERA/147844/2011), and provides additional options for a higher tier assessment for plants.

The guideline together with the overview of comments (EMA/CVMP/ERA/8138/2017) will be published on the Agency's website.

Notes

1. 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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