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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 06-08 December 2016

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Stronghold Plus** (*selamectin/sarolaner*), from Zoetis Belgium SA, a new antiparasitic product for cats.

The Committee adopted by majority a positive opinion for an extension of the existing marketing authorisation for **EQUIOXX**, from MERIAL, concerning the addition of a new pharmaceutical form (chewable tablets).

The Committee adopted by consensus a negative 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.

The Committee adopted by consensus positive opinions for type II variation applications for **Aivlosin** and **Broadline** regarding quality changes.

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

Community referrals and related procedures

The Committee concluded the referral procedure for **veterinary medicinal products containing zinc oxide to be administered orally to food producing species**. The matter was 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 adopted by consensus an opinion concluding 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 risk is not quantifiable. The Committee therefore

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recommended the refusal of the granting of the marketing authorisations and the withdrawal of the existing marketing authorisations for veterinary medicinal products containing zinc oxide.

Scientific advice

The Committee adopted one scientific advice report further to a request for initial advice on MRL issues for a new veterinary medicinal product for broilers.

Minor use, minor species (MUMS)/limited market

The Committee adopted three revised guidelines concerning data requirements for pharmaceutical veterinary medicinal products intended for minor use and minor species following the close of the public consultation, on:

- Quality (EMEA/CVMP/QWP/128710/2004);
- Safety and residues (EMEA/CVMP/66781/2005); and
- Efficacy and target animal safety (EMEA/CVMP/EWP/117899/2004)

The documents together with the overview of comments (EMA/CVMP/QWP/472725/2016, EMA/CVMP/SWP/523387/2016 and EMA/CVMP/EWP/523421/2016) will be published on the Agency's website.

Following the Committee's review of a request for classification under the MUMS/limited market policy, the CVMP classified an indication for an anti-parasitic veterinary product for dogs as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in a non-food producing species.

Pharmacovigilance

The Committee reviewed the PSURs for **ECOPORC SHIGA**, **ERYSENG**, **ERYSENG PARVO**, **Innovax-ILT**, **Kexxtone**, **NEXGARD SPECTRA**, **Porcilis PCV ID**, **ProZinc**, **Suvaxyn PCV**, **UpCard**, **Versican Plus L4**, **Versican Plus Pi, Versican Plus Pi/L4R, ZACTRAN**, **ZULVAC 8 Bovis**, **ZULVAC 8 Ovis** and **ZULVAC SBV**, and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSURs for **Easotic**, **Loxicom** and **Rheumocam**, and recommended amendments to their product literature.

Antimicrobial resistance

The Committee adopted by majority a **joint EMA and EFSA 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 (RONAFA)** (EMA/CVMP/570771/2015) on the basis of advice provided by a dedicated advisory group. The opinion reviews the measures that have been taken in the EU to reduce the use of antimicrobials in animal husbandry and includes recommendations on how to reduce antimicrobial use, including setting of targets, good farm management, alternative production systems and alternatives to the use of antimicrobials. The opinion will initially be published in the EFSA Journal at the beginning of 2017 and later on the EMA website.

Concept papers, guidelines and SOPs

Quality

The Committee adopted questions and answers on the following quality topics:

- Removal of a general heavy metals test from a specification;
- Improving the understanding of normal operating ranges, proven acceptable ranges, design spaces and normal variability of process parameters.

Efficacy

The Committee adopted a concept paper for the revision of the CVMP guideline on veterinary medicinal products for zootechnical purposes (EMA/CVMP/EWP/707573/2015) for a 3-month period of public consultation. The revision is proposed to take account of 3R principles/animal welfare issues, and to clarify requirements in regard to oestrus synchronisation protocols.

The Committee adopted a concept paper for the revision of the CVMP guideline on veterinary medicinal products for fluid therapy in case of diarrhoea (EMA/CVMP/EWP/707299/2015) for a 3-month period of public consultation. The revision is proposed based on the 3R review (use of a negative control group), and also to provide more detailed and relevant information regarding the selection of control groups, taking quality aspects of the study. Furthermore, a broadening of the scope could be considered to include recommendations on clinical efficacy and safety evaluation for different types of fluid therapy and for different disease conditions.

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

Immunologicals

The Committee adopted a revised guideline on requirements for the production and control of immunological veterinary medicinal products (EMA/CVMP/IWP/206555/2010-Rev.1) following comments received during the public consultation. The guideline, which provides guidance on the requirements that are not covered by Directive 2001/82/EC, the European Pharmacopoeia (Ph. Eur.) and relevant VICH guidelines, has been revised to include the approach to demonstrate freedom from extraneous agents as part of the production and control of immunological veterinary medicinal products for mammalian species and finfish.

The Committee adopted a reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products (EMA/CVMP/IWP/251741/2015) following comments received during the public consultation. The reflection paper provides examples of suitable cells and methods for testing for freedom from a range of extraneous agents, based on available data on seeds assessed and approved as part of marketing authorisation applications in the European Union.

The documents together with the overview of comments (EMA/CVMP/IWP/74071/2016 and EMA/CVMP/IWP/65876/2016) will be published on the Agency's website.

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

The Committee adopted a guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012) following comments received during the public consultation. The guideline describes the process for submission and evaluation of a proposal for regulatory acceptance of 3Rs testing approaches for use in the development and quality control of human and veterinary medicinal products. The guideline aims to

encourage stakeholders and authorities to initiate, support and accept development and use of 3Rs testing approaches.

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

VICH

The committee adopted the following VICH guideline, following the sign-off by the VICH Steering Committee:

- VICH GL54: Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD) (EMA/CVMP/VICH/699251/2010)

The guideline will be implemented by EU Member States by 30 November 2017.

General

The Committee adopted an implementation plan for QRD template v.8.1 for the centralised procedure (EMA/827463/2016).

The document will be published on the section of the Agency's website relating to product information templates.

The Committee adopted guidance in the form of a question and answer document on the requirements for changing the classification from prescription-only status to non-prescription status for products authorised via the centralised procedure.

The document will be published under the post-authorisation guidance on the Agency's website.

Working Parties

The Committee re-elected Eva Lander Persson as chair of the CVMP Safety Working Party and Esther Werner as chair of the CVMP Immunologicals Working Party for a further three-year mandate. The Committee also elected Lisbet Vesterager Borge as chair of the CVMP Pharmacovigilance Working Party for a three-year mandate.

The Committee endorsed the work plans for 2017 for the CVMP working parties on scientific advice, safety, environmental risk assessment, efficacy, immunologicals, antimicrobials and pharmacovigilance as well as for the joint CHMP/CVMP quality working party, joint CHMP/CVMP working group on the application of the 3Rs (J3RsWG) and the ad hoc veterinary expert group on novel therapies (ADVENT).

The work plans will be published on the Agency's website.

The Committee adopted a revised mandate (EMA/CHMP/CVMP/JEG-3Rs/442724/2012-Rev.1) for the formation of a joint CVMP/CHMP working group on the application of the 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (J3RsWG). The J3RsWG replaces the joint CVMP/CHMP expert group on the application of the 3Rs (JEG 3Rs).

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

Organisational matters

The Committee adopted the CVMP work plan for 2017, which highlights the priority areas for the Committee in the coming year.

The work plan for 2017 will be published on the Agency's website.

Notes

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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