EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 8-10 September 2015

CVMP opinions on veterinary medicinal products

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

Zycortal (*desoxycortone*), from Dechra Limited, a veterinary medicinal product for use as replacement therapy for mineralocorticoid deficiency in dogs with primary hypoadrenocorticism (Addison's disease);

Simparica (*sarolaner*), from Zoetis Belgium SA, a veterinary medicinal product for the treatment of flea, tick and sarcoptic mange infestations in dogs; and

Suvaxyn Circo+MH RTU, from Zoetis Belgium SA, a vaccine for the active immunisation of pigs against porcine circovirus type 2 and *Mycoplasma hyopneumoniae* infection.

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

Aivlosin, **Eurican Herpes 205**, **Gripovac 3**, **Ingelvac CircoFLEX**, **RESPIPORC FLU3**, **SevoFlo**, **STARTVAC** and **ZULVAC SBV** regarding quality changes;

As well as for work-sharing procedures for:

Circovac, **Eurican Herpes 205**, **Ibraxion**, **Purevax RCPCh FeLV** and **Purevax RCPCh**;

NexGard and **NexGard Spectra**; and

Versican Plus DHPPi/L4R, **Versican Plus Pi/L4R**, **Versican Plus Pi/L4**, **Versican Plus DHPPi/L4**, **Versican Plus DHPPi** and **Versican Plus Pi**.

More information about the above mentioned medicines 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 **Hiprabovis IBR Marker Live**. The Committee, having re-assessed the benefit-risk balance of the

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product, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Community referrals and related procedures

The Committee started a procedure for **Denagard 45% and associated names** (*tiamulin hydrogen fumarate*) (marketing authorisation holder Novartis). The matter was referred to the Committee by Germany, under Article 34 of Directive 2001/82/EC due to divergent decisions taken by Member States resulting in discrepancies in the product information.

Scientific advice

The Committee adopted five separate scientific advice reports concerning:

- Initial advice on quality, safety and efficacy issues for an immunological product for pigs;
- Initial advice on quality and efficacy issues for an immunological product for pigs;
- Initial advice on quality issues for a veterinary medicinal product with a reproductive indication for cattle;
- Initial advice on efficacy issues for a veterinary medicinal product for an antiparasitic product for dogs; and
- Initial advice on efficacy issues for an immunological product for cattle, sheep and pigs.

MUMS/limited market

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

- An anti-inflammatory veterinary medicinal product for horses as indicated for MUMS/limited market and eligible for reduced data requirements. As an alternative product is already authorised for the same target species for the same indication, it is not eligible for financial incentives.
- An endocrine veterinary medicinal product for horses not intended for human consumption as indicated for MUMS/limited market and eligible for reduced data requirements. As the product is indicated for a non-food producing species, it is not eligible for financial incentives.
- An anti-epileptic veterinary medicinal product for dogs as indicated for MUMS/limited market and eligible for reduced data requirements. As the product is indicated for a non-food producing species, it is not eligible for financial incentives.
- An anti-inflammatory veterinary medicinal product for horses as not indicated for MUMS/limited market and therefore not eligible for financial incentives, since the specific proposed indication was not considered to be a minor use/limited market.

Pharmacovigilance

The Committee reviewed the PSURs for **Fungitraxx**, **Meloxidolor**, **Meloxoral**, **Nobilis IB 4-91**, **Parvoduk**, **Porcilis AR-T DF**, **Porcilis PCV M Hyo**, **Recuvyra**, **Versican Plus DHPPi/L4** and **Versican Plus DHPPi/L4R** and concluded that no further action or changes to their product literature were required.

The Committee reviewed the post authorisation safety study (PASS) for **Parvoduk** and recommended amendments to the product literature.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a revised Question and Answer on complex manufacturing processes.

Environmental Risk Assessment

The Committee adopted a guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products (EMA/CVMP/ERA/52740/2012), following the close of the second public consultation. The guideline provides guidance on how PBT/vPvB are assessed in accordance with the guidance developed for industrial chemicals under the Regulation (EC) No 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), taking into account the scientific data/information expected to be available for veterinary medicinal products. The guideline also addresses general principles on how veterinary medicinal products containing a PBT substance should be further assessed within the context of the environmental risk assessment and benefit-risk assessment of the product concerned. The comments received during the consultation procedure have been taken into account for the revision of the guideline (EMA/CVMP/ERA/74265/2015).

Immunologicals

The Committee adopted a draft concept paper on requirements for the production and control of allergen products for use in animals (EMA/CVMP/IWP/351882/2015) for a 3-month period of public consultation. The concept paper was developed to revise the existing CVMP/IWP Guideline on allergen products, 'Specific Requirements for the Production and Control of Allergen Products (7BIm11a, volume 7)' in order to reflect the recent developments and scientific progress in this area.

The Committee adopted a revised guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus (BVDV) (EMA/CVMP/IWP/205351/2006-Rev.1) following the close of the public consultation. The guideline was revised to remove the provision for an *in vivo* test, with the view to ensuring best practice with regard to implementation of 3Rs (Replacement, Reduction and Refinement) principles. The guideline outlines the procedure to be followed by the competent authorities when a batch of a vaccine is suspected to be contaminated with bovine viral diarrhoea virus. The comments received during the consultation procedure have been taken into account for the revision of the guideline (EMA/CVMP/IWP/342158/2015).

The Committee adopted a reflection paper on the use of heat treatment to inactivate endogenous retroviruses in live immunological veterinary medicinal products (EMA/CVMP/IWP/37924/2014) following the close of the public consultation. This reflection paper has been developed to outline the data requirements for marketing authorisation holders to introduce a heat treatment to inactivate retroviruses in the active substance for the production of live viral vaccines for immunological veterinary medicinal products and to show the absence of negative impact of this treatment on the immunological veterinary medicinal product. The comments received during the consultation procedure have been taken into account for the revision of the reflection paper (EMA/CVMP/IWP/254504/2015).

The Committee adopted a reflection paper on the replacement of cell lines used for the production of immunological veterinary medicinal products (EMA/CVMP/IWP/37620/2014) following the close of the public consultation. This reflection paper has been developed to outline the data requirements for marketing authorisation holders to replace the cell line as host system for production of immunological

veterinary medicinal products without significant changes to the production process and maintaining finished product specifications. The comments received during the consultation procedure have been taken into account for the revision of the reflection paper (EMA/CVMP/IWP/254498/2015).

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

VICH

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

- VICH GL52: Bioequivalence: blood level bioequivalence study (EMA/CVMP/VICH/751935/2013)

The guideline will be implemented by EU Member States by 31 August 2016. As a consequence, the respective CVMP guideline on the "Conduct of bioequivalence studies for veterinary medicinal products" (CVMP/016/2000 Rev. 2) will be revised accordingly.

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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