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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 5–7 September 2017

CVMP opinions on veterinary medicinal products

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

Oxybee (*oxalic acid dihydrate*), from Dany Bienenwohl GmbH, a powder and solution for bee-hive dispersion for honey bees;

Nobivac Leufel, from Virbac, a new inactivated vaccine indicated for the active immunisation of cats against feline leukaemia; and

Bovilis Blue-8, from Intervet International B.V., a new inactivated vaccine against bluetongue virus serotype 8, indicated for the active immunisation of sheep and cattle.

The Committee adopted by consensus positive opinions for type II variation applications for **NEXGARD SPECTRA, Reconcile, RESPIPORC FLU3** and **RHINISENG** concerning quality changes, and for **Simparica** to add new indications.

The Committee adopted by consensus a positive opinion for a type II variation application, subject to a worksharing procedure, for **Eurican Herpes 205**, **Purevax RCPCh**, **Bovalto Ibraxion**, **Purevax RCP FeLV**, **Purevax RC**, **Purevax RCP**, **BTVPUR AlSap 2-4**, **BTVPUR**, **Parvoduk and Purevax RCPCh FeLV (and products authorised via MRP/DCP/purely-nationally)** concerning quality changes.

The Committee also adopted by consensus positive opinions for two type IB variation applications (subject to worksharing procedures) for **Fevaxyn Pentofel (and a purely-nationally authorised product)** concerning 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 a positive opinion for the renewal of the marketing authorisation for **Contacera**. 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 indefinite renewal of the marketing authorisation.

Community referrals and related procedures

The Committee started a procedure for **Seresto and its associated name Foresto** (*imidacloprid and flumethrin*) (marketing authorisation holder, Bayer Vital GmbH). The matter was referred to the Committee under Article 13 of Regulation (EC) No. 1234/2008 by Germany as the reference Member State in the type II variation procedure, due to efficacy concerns raised by the United Kingdom relating to the addition of a new indication for dogs.

Scientific advice

The Committee adopted five scientific advice reports further to requests for:

- Initial advice on safety and efficacy issues for a new pharmaceutical veterinary medicinal product for a cardiovascular condition in cats;
- Initial advice on MRL issues for a new pharmaceutical veterinary medicinal product acting on the nervous system of sheep;
- Initial advice on MRL issues for a new pharmaceutical veterinary medicinal product for an alimentary tract condition in horses;
- Initial advice on efficacy issues for a new pharmaceutical veterinary medicinal product acting on the nervous system of horses;
- Follow up advice on safety issues for a new immunological veterinary medicinal product for a respiratory condition in cattle.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of requests for four classifications and four reclassifications, under the MUMS/limited market policy, the CVMP:

- Classified a veterinary medicinal product (antineoplastic and immunomodulating agents) for dogs as not indicated for MUMS/limited market.
- Classified a veterinary medicinal product (antineoplastic and immunomodulating agents) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements. No financial incentives will apply as it is intended for use in non-food producing species (dogs).
- Classified a veterinary medicinal product (genito-urinary system and sex hormones) for pigs (sows) 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.
- Classified a veterinary medicinal product (nervous system) for sheep (lambs) 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 indications.

- Reclassified two veterinary medicinal products (musculo-skeletal system) for horses as indicated for MUMS/limited market and eligible for reduced data requirements. No financial incentives will apply as according to the MUMS policy, products for horses are generally not eligible for fee incentives.
- Reclassified a veterinary medicinal product (nervous system) for horses as indicated for MUMS/limited market and eligible for reduced data requirements. No financial incentives will apply as according to the MUMS policy, products for horses are generally not eligible for fee incentives.
- Reclassified a veterinary medicinal product (immunological) for cattle as indicated for MUMS/limited market and eligible for reduced data requirements, and confirmed that it remains eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **ERAVAC, LETIFEND, Meloxidolor, Recuvyra (WD),** and **ZOLVIX**, and concluded that no further action or changes to their product information were required.

The Committee also reviewed the PSURs for **Bovela** and **Versican Plus DHPPi** and recommended amendments to their product information.

Concept papers, guidelines and SOPs

Immunologicals

The Committee adopted a draft revised guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), bluetongue (BT) and foot-and-mouth disease (FMD) (EMA/CVMP/IWP/105506/2007-Rev.1) for a 6-month period of public consultation. The guideline has been revised in order to take into account some additional issues identified since it came into effect in 2010 and the experience gained during assessment of recent applications for marketing authorisations.

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

The Committee also adopted Questions and Answers to address the topics raised by stakeholders that are not specifically addressed within the revised guideline itself.

Antimicrobials

The Committee adopted a Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food producing animals. The joint opinion provides a list of harmonised outcome indicators to assist European Union Member States in assessing their progress in reducing the use of antimicrobials and antimicrobial resistance (AMR) in both humans and food-producing animals. The proposed indicators have been selected on the basis of data collected by Member States at the time of publication.

Once the opinion is adopted by the above mentioned Agencies it will be sent to the EC and will be published on the Agencies' website in the second half of October 2017.

Organisational matters

The Committee held a meeting with Interested Parties on 6 September 2017 attended by representatives of the Association of Veterinary Consultants (AVC) the European Group for Generic Veterinary Products (EGGVP), the Federation of Veterinarians of Europe (FVE), the International

Council on Animal Protection in Pharmaceutical Programs (ICAPPP) and the International Federation of Animal Health Europe (IFAH-Europe).

The topics discussed related to the following themes:

- 2nd EC action plan on Antimicrobial resistance (AMR) and CVMP strategy on AMR;
- Pilot Project Harmonisation and Optimisation of Veterinary Antimicrobials (PPHOVA);
- Persistent, bioaccumulative and toxic (PBT) assessments;
- Quality issues specific to veterinary medicines;
- Update on work related to the 3Rs;
- Brexit preparedness;
- Impact of referrals on ongoing procedures.

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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