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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 5-7 May 2015

CVMP opinions on veterinary medicinal products

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

Innovax-ILT, from Intervet International B.V., a vaccine for the active immunisation of chickens against infectious laryngotracheitis (ILT) and Marek's disease (MD); and

Canigen L4, from Intervet International B.V., a vaccine for the active immunisation of dogs against *Leptospira*.

The Committee adopted by consensus a positive opinion for a type II variation application for **Nobivac L4** regarding quality changes.

The Committee adopted by consensus a negative final opinion for an initial marketing authorisation application for **Lodipressin** (amlodipine), from Le Vet Beheer B.V, a product which was intended for the treatment of systemic arterial hypertension in cats, further to the request for a re-examination of the negative opinion adopted during the Committee meeting held on 13-15 January 2015.

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 **RHINISENG**. 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 concluded the referral procedure for **Gutal 1000 g/kg for medicated feeding stuff for pigs** (zinc oxide) from Huvepharma NV. The matter was referred to the Committee by the United Kingdom, as the reference Member State in the decentralised procedure under Article 33(4) of Directive 2001/82/EC, due to concerns raised by France and the Netherlands relating to a potential risk to the environment from use of the product. The Committee adopted by majority an opinion concluding that the objections raised by France and the Netherlands during the decentralised procedure should not prevent the granting of a marketing authorisation subject to changes in the product information recommending risk mitigation measures.

The Committee started a procedure for **all veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry**. The matter was referred to the Committee by Belgium under Article 35 of Directive 2001/82/EC, to review indications and dosing regimen due to concerns related to antimicrobial resistance, and withdrawal periods of the aforementioned products.

The Committee started a procedure for **all veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally**. The matter was referred to the Committee by the European Commission under Article 35 of Directive 2001/82/EC, due to concerns related to antimicrobial resistance.

Maximum Residue Limits

The Committee adopted by majority a positive opinion recommending the inclusion of **purified semi-solid extract from *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts)** in table 1 of the Annex to Regulation (EU) No 37/2010 with a "No MRL required" classification for honey.

Further to a request from the European Commission under Article 11 of Regulation (EC) No 470/2009 for the review of the MRL for **diflubenzuron** due to concerns relating to the genotoxic potential of the metabolite 4-chloroaniline, the Committee adopted by consensus an opinion recommending the modification of the current entry in table 1 (Allowed substances) of the Annex to Regulation (EU) No 37/2010 for diflubenzuron in *Salmonidae*, amending the existing MRL to a provisional one, pending provision of additional residue data.

The Committee adopted by consensus a final opinion for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 for **sisapronil**, further to a request for a re-examination of the opinion adopted during the Committee meeting held on 13-15 January 2015.

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

The Committee agreed to include **diethylhexyladipate** 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. 28). 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 four separate scientific advice reports concerning:

- Initial advice on quality, safety and efficacy issues for a veterinary medicinal product with a musculoskeletal indication for horses;
- Initial advice on safety issues for a veterinary medicinal product with an alimentary indication for cats;
- Follow up advice on safety and efficacy issues for a veterinary medicinal product with a musculoskeletal indication for horses; and
- Follow up advice on quality and efficacy issues for a veterinary medicinal product for treatment of anaemia in dogs.

MUMS/limited market

Following the Committee's review of five requests for classification under the MUMS/limited market policy:

- The CVMP classified an immunological product for rabbits as indicated for MUMS/limited market. The product is eligible for reduced data requirements, where applicable, and for financial incentives as it is indicated for a food-producing species and no alternative vaccine is authorised for the same target species.
- The CVMP classified a gastrointestinal veterinary medicinal product for dogs as indicated for MUMS/limited market. The product is eligible for reduced data requirements, where applicable, but not eligible for financial incentives as it is not indicated for a food-producing species.
- The CVMP classified an anti-inflammatory veterinary medicinal product for horses as indicated for MUMS/limited market. The product is eligible for reduced data requirements, where applicable, but not eligible for financial incentives as alternative products are authorised for the same target species for the same indication.
- The CVMP reviewed a previous classification where new information was provided for an ant-parasitic veterinary medicinal product for cats and classified the product as indicated for MUMS/limited market. The product is eligible for reduced data requirements, where applicable, but not eligible for financial incentives as it is not indicated for a food-producing species.
- The CVMP classified an immunological product for turkeys and chickens as indicated for MUMS/limited market. The product is eligible for reduced data requirements, where applicable, but not eligible for financial incentives as alternative vaccines are authorised for the same target species for the same indication.

Pharmacovigilance

The Committee reviewed the PSURs for **Broadline**, **BTVPUR Alsap 1**, **BTVPUR Alsap 1-8**, **Cardalis**, **Cerenia**, **Circovac**, **Contacera**, **Equilis Prequenza**, **Equilis Prequenza Te**, **ERYSENG**, **ERYSENG PARVO**, **Melosus**, **Poulvac E. coli**, **Slentrol, Trifexis**, **TruScient** and **Vectra 3D** and concluded that no further action or changes to their product literature were required.

Organisational matters

The Committee held a meeting with interested parties on 6 May 2015 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 concerned:

- Application of 3R principles in the authorisation of medicines
- Building blocks for an improved pharmacovigilance system
- How to avoid duplication and redundancy of environmental risk assessment within the EU authorisation system
- SPC harmonisation – focus on withdrawal periods
- Response preparation to CVMP consultations
- Progress on VICH GL52 on bioequivalence: blood level bioequivalence study

The programme of the meeting will be published on the Agency's website.

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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