Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 19-21 April 2016

CVMP opinions on veterinary medicinal products

The Committee adopted by majority a positive opinion for an initial marketing authorisation application for CLYNAV, from Elanco Europe Limited, a new plasmid DNA vaccine for the active immunisation of Atlantic salmon against pancreas disease caused by salmonid alphavirus subtype 3. The product has been classified as MUMS/limited market.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for Sevocalm, from Chanelle Pharmaceuticals Manufacturing Limited, an inhalation anaesthetic (sevoflurane) for the induction and maintenance of anaesthesia in dogs.

The Committee adopted by consensus positive opinions for type II variation applications for Aivlosin to change the withdrawal period for chicken eggs, and for Metacam and AFTOVAXPUR DOE regarding quality changes. The Committee also adopted by consensus a positive opinion for a type II variation application for Versican Plus Pi/L4R and Versican Plus DHPPi/L4R (subject to a worksharing procedure) to extend the duration of immunity.

More information about the above-mentioned medicines, including their full indications, will be published on the Agency’s website.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for Emdocam, Nobilis Influenza H5N2 and Nobivac Myxo-RHD. The Committee, having reassessed 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 concluded the referral procedure for all veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally to...
food-producing species. 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 and the need to ensure responsible use of the substance in protecting animal health and limiting the possibility of future risk to public health. The Committee adopted by consensus an opinion concluding that the benefit-risk balance for the products concerned is negative as no benefit could be demonstrated of using colistin combination products over monotherapy and no feasible risk mitigation measures could be identified to address the potential risk to human health. The CVMP recommended the withdrawal of the marketing authorisations for all veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally to food producing species.

**Maximum Residue Limits**

The Committee agreed to include tris(nonylphenyl)phosphite 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. 34). This decision followed the Committee’s review of a request that has been submitted in accordance with the relevant CVMP guidance.

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

**Scientific advice**

The Committee adopted a scientific advice report further to a request for initial advice on MRL issues for a veterinary medicinal product for a respiratory indication in horses.

**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 product for a gastrointestinal indication 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 (dogs); and

- A product for a gastrointestinal indication 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 (cats).

**Pharmacovigilance**

The Committee reviewed the PSURs for APOQUEL, Bovela, BTVPUR AlSap 1, BTVPUR AlSap 1-8, Equilis Frequenza, Equilis Frequenza Te, Oxyglobin, Panacur AquaSol, Poulvac E. coli, SevoFlo, Sileo, Upcard, Versican Plus DHPPi/L4 and Zuprevo and concluded that no further action or changes to their product literature were required.

**Concept papers, guidelines and SOPs**

**Quality**

The Committee adopted a draft reflection paper on the dissolution specification for generic oral immediate release products (EMA/CHMP/CVMP/QWP/37330/2016) for a 3-month period of public
consultation. This reflection paper has been developed to address the suitability of the dissolution method and the specifications for in vitro dissolution of orally administered generic drug products with immediate release characteristics.

The reflection paper will be published on the Agency’s website.

**Efficacy**

The Committee adopted a revised reflection paper on anthelmintic resistance (CVMP/EWP/573536/2013) for a second public consultation. The reflection paper addresses the current views on issues in relation to anthelmintic resistance. The comments received during the consultation procedure have been taken into account for the revision of the reflection paper.

The reflection paper together with the overview of comments (EMA/CVMP/EWP/464714/2014) will be published on the Agency’s website.

The Committee adopted a concept paper (EMA/CVMP/EWP/707453/2015) for the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2/2007) for a 3-month period of public consultation. A revision of the current CVMP guideline is proposed following the finalisation of the VICH GL52 Bioequivalence: blood level bioequivalence study.

The concept paper will be published on the Agency’s website.

**Immunologicals**

The Committee adopted a new concept paper on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use (EMA/CVMP/IWP/867401/2015) for a 3-month period of public consultation. This concept paper has been developed to replace the CVMP Note for Guidance: DNA Vaccines Non-Amplifiable in Eukaryotic Cells for Veterinary Use (CVMP/IWP/07/98-FINAL) in order to take into account recent scientific developments and experience gained.

The concept paper will be published on the Agency’s website.

**Replacement, Reduction, Refinement of animal testing (3Rs)**

The Committee adopted a reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs (EMA/CHMP/CVMP/JEG-3Rs/164002/2016) for a 6-month period of public consultation. This reflection paper has been developed to provide an overview of the main animal tests required for the regulatory testing of veterinary medicinal products and opportunities for further improvement in the application of 3Rs (a parallel document has been developed in relation to human medicinal products).

The reflection paper will be published on the Agency’s website.

**Working Parties**

The Committee reviewed and adopted the mandate for the CVMP Pharmacovigilance working party (EMA/CVMP/PhVWP/133883/2004-Rev.5) for another period of 3 years. As this working party reports both to the Committee and the European Union Member States, the mandate will also be submitted to the Heads of Medicines Agencies – Veterinary for endorsement. The publication of the revised mandate will take place following the endorsement by the Heads of Medicines Agencies – Veterinary.
The Committee elected Jason Weeks as the chair of the CVMP Environmental Risk Assessment working party (ERAWP) for a 3-year mandate and re-elected Silke Hickmann as the ERAWP vice-chair for a further 3-year mandate.

**Organisational matters**

The Committee held a meeting with interested parties on 20 April 2016 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:

- Availability of veterinary medicines;
- Promotion of ‘Better regulation’;
- The focus on key public and animal health priorities including AMR;
- Striving for operational excellence.

**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](http://www.ema.europa.eu)

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