EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 16-18 February 2016

CVMP opinions on veterinary medicinal products

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

Evalon, from LABORATORIOS HIPRA, S.A., a live attenuated parasitic vaccine to stimulate active immunity in chickens against coccidiosis; and

Letifend, from Laboratorios LETI, S.L.U., a vaccine containing a recombinant protein for the active immunisation of non-infected dogs against leishmaniasis.

The Committee adopted by consensus a positive opinion for an extension of the existing marketing authorisation for **Poulvac E. coli**, from Zoetis Belgium SA, concerning the addition of a new food-producing species (turkeys).

The Committee adopted by consensus positive opinions for a type II variation application for **Bravecto** regarding quality changes and for a grouped type II variation application for **BTVPUR AlSap 1-8** to establish a multi-strain dossier and to add a new serotype BTV4. The Committee also adopted by majority a positive opinion for a type II variation application for **DRAXXIN** to add a new indication for use in swine respiratory disease.

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 positive opinions for the renewal of the marketing authorisations for **CERTIFECT**, **Zulvac 1 Bovis** and **Zulvac 1 Ovis**. The Committee, having re-assessed 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.

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Community referrals and related procedures

The Committee started a procedure for **all 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.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **hydrocortisone aceponate** in bovine species. Furthermore, the Committee agreed to extrapolate these MRLs to all ruminants and equine species.

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

The Committee agreed to include **poly(lactic-co-glycolic acid)** and **polydimethyl siloxane dimethylvinyl terminated** as new entries 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. 33). This decision followed the Committee's review of requests that have been submitted in accordance with the relevant CVMP guidance.

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

MUMS/limited market

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

- An antiseptic/anaesthetic veterinary medicinal product for goats as indicated for MUMS/limited market and eligible for reduced data requirements and financial incentives.
- An oncology veterinary medicinal product 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).

Pharmacovigilance

The Committee reviewed the PSURs for **Aivlosin**, **CaniLeish**, **Coliprotec F4**, **Comfortis**, **Equisolon**, **Fungitraxx**, **Recocam** and **Zulvac 1+8 Bovis** and concluded that no further action or changes to their product literature were required.

Antimicrobial resistance

Following the request from the European Commission to update the 2013 advice on the use of colistin in animals by 30 June 2016, the Committee agreed on a timetable for the update. The timetable includes a short period for a call for scientific data (29 February – 15 March 2016). Once adopted by the CVMP and CHMP, the draft revised opinion will be subject to a short period of consultation, anticipated for the end of May/beginning of June 2016.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a revised draft guideline on the conduct of efficacy studies for intramammary products for use in cattle (EMA/CVMP/344/1999-Rev.2) for a second three-month period of public consultation. The revised guideline provides guidance on the conduct of efficacy studies and their evaluation for veterinary medicinal products that are administered via the teat canal to cattle.

Following comments received during the first consultation procedure, a new annex on biowaivers has been included in the guideline.

The revised draft guideline will be published on the Agency's website.

Environmental Risk Assessment

The Committee adopted a new reflection paper on the authorisation of veterinary medicinal products containing (potential) Persistent Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) substances (EMA/CVMP/448211/2015) for a three-month period of public consultation. The reflection paper discusses the approach to the assessment of (potential) PBT and vPvB substances in veterinary medicinal and other products (chemicals, biocides, plant protection products). The reflection paper addresses the issues for consideration in the evaluation of veterinary medicinal products containing such substances under the current legislation and also the need for new legal provisions.

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

Quality

The Committee adopted a draft guideline on the sterilisation of the medicinal product, active substance, excipient and primary container (EMA/CHMP/CVMP/QWP/850374/2015) for a three-month period of public consultation. The guideline was developed to replace the (separate) human and veterinary notes for guidance on manufacture of the finished dosage form and the guidance on the selection of sterilisation methods currently provided for in the annexes to the (separate) human and veterinary development pharmaceutics guidelines.

The draft guideline will be published on the Agency's website.

The Committee adopted a new reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances (EMA/CVMP/QWP/3629/2016) for a three-month period of public consultation. This reflection paper has been developed to describe the chemical structure and properties criteria to be taken into account to qualify a chemical active substance as a new active substance, as well as the required elements to be submitted by applicants.

The reflection paper will be published on the Agency's website after its adoption by the CMDv.

The Committee adopted **Questions and Answers** (Q&A) on the following quality and efficacy/antimicrobials topics:

- On the data requirements for sterilisation processes of primary packaging material subsequently used in an aseptic manufacturing process; and
- A new Question and Answer relating to the SPC guideline for antimicrobials, in regard to suitable pack sizes for antimicrobials.

The Questions and Answers will be published on the Agency's website.

Novel therapies

The Committee agreed for the release of two problem statements prepared by the CVMP Ad hoc Expert Group on Novel Therapies (ADVENT) on novel therapy topics for a 2-month public consultation, further to their adoption. The problem statements provide the basis for development of guidance on the following novel therapy topics:

- Monoclonal antibodies intended for veterinary use; and
- Sterility in relation to stem cell products intended for veterinary use.

The consultation is used as a means to further facilitate identification of additional pertinent questions relevant to each particular topic. The aim is to take comments received into account for developing guidance in the form of Questions and Answers (Q&A).

The problem statements will be published on the Agency's website.

Working Parties

The Committee elected Stefan Scheid as vice-chair of the CVMP Safety working party for a 3-year mandate.

International harmonisation

The Committee adopted two revised VICH guidelines for release for public consultation in the EU following the sign-off by the VICH Steering Committee:

- VICH GL50: Revised guideline on Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use; and
- VICH GL55: Revised guideline on Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use.

The guidelines will be published on the Agency's website.

Organisational matters

The Committee adopted the CVMP Work Plan for 2016. This first annual work plan highlights the priority areas for the Committee in the coming year.

The work plan for 2016 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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