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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 14-16 May 2013

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **ProZinc** (*insulin human*) from Boehringer Ingelheim Vetmedica GmbH, for the treatment of diabetes mellitus in cats to achieve reduction of hyperglycaemia and improvement of associated clinical signs.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **AFTOVAXPUR DOE** from MERIAL, a vaccine containing a maximum of 3 inactivated, purified foot-and-mouth disease (FMD) virus strains out of 7 authorised strains. The product is indicated for active immunisation of cattle and sheep from 2 months of age and pigs from 10 weeks of age to reduce clinical signs. This is the first time that a recommendation for authorisation across the European Union has been made for a veterinary vaccine intended to reduce the clinical signs of FMD and using the multi-strain dossier approach.

More information about the above mentioned medicines, including their full indication, can be found on the Agency's website.

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

[1] Correction to the name of the marketing authorisation holder for Fiprex spot-on solution for dogs (paragraph on community referrals)

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8416
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Activyl from Intervet International BV to include a new statement in the PI related to interaction with other medicinal products,

Gripovac 3 from MERIAL relating to a quality change,

Respiporc FLU3 from IDT Biologika GmbH relating to a quality change, and

Circovac from MERIAL to register a 50 ml polypropylene bottle.

Annual reassessment of marketing authorisations

The Committee adopted an opinion on the annual reassessment for **Zulvac 1+8 Ovis**, further to the evaluation of the data submitted by the marketing authorisation holder. Since the specific obligations have been fulfilled the Committee recommended the conversion of the Community marketing authorisation from under exceptional circumstances to a normal status for this product.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Reconcile** and **ZACTRAN**. 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.

Community referrals and related procedures

The Committee started a procedure for **Norbonex 5 mg/ml pour-on solution for beef and dairy cattle** (*eprinomectin*) from Norbrook Laboratories Ltd. 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 Germany relating to a potential risk to the environment from the use of the product.

The Committee started a procedure for **Fiprex CAT 52.5 mg spot-on solution for cats, Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solution for dogs, Fiprex XL 412.5 mg spot-on solution for dogs** (*fipronil*) from Vet-Agro Trading Sp. z o.o.. The matter was referred to the Committee by the Czech Republic as the reference Member State in the mutual recognition procedure, under Article 33(4) of Directive 2001/82/EC due to concerns raised by Ireland relating to efficacy issues.

The Committee started a procedure for **Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC** (*enrofloxacin*). The matter was referred to the Committee by Spain under Article 35 of Directive 2001/82/EC due to public health interest to review the available scientific data and achieve where possible harmonised indications, posology and withdrawal periods for the products concerned.

The Committee noted a request for re-examination of the CVMP opinion adopted on 10 April 2013 in the context of a referral procedure under Article 35 of Directive 2001/82/EC for **all long acting formulations for injection containing barium selenate for all food producing species**. The procedure will be initiated once the grounds for the re-examination are submitted.

The Committee started a procedure for **Suvaxyn PCV** (inactivated vaccine) from Zoetis. The matter was notified to the Committee by the European Commission under Article 45 of Regulation (EC) No. 726/2004 due to concerns for quality and target animal safety.

Maximum Residue Limits

Further to a request in accordance with CVMP guidance on inclusion of a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, the Committee adopted a revised list (EMA/CVMP/519714/2009-Rev.15) in order to amend the entry for polymyxin B for use as an endotoxin neutralising agent in vaccines, increasing the maximum dose allowed.

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

Scientific advice

The Committee adopted three scientific advice reports concerning quality, safety and MRL requirements for a product for bees, quality and safety requirements for an immunological product for horses and safety requirements for a hormonal product for pigs.

MUMS/Limited markets

Following the Committee's review of five requests for classification under the MUMS/Limited markets policy concerning an immunological product for turkeys, an immunological product for chickens, an immunological product for horses and two anti-bacterial products for Atlantic salmon:

The CVMP considered that the immunological products for chickens and turkeys and the two products for Atlantic salmon were indicated for MUMS/Limited markets and were eligible for financial incentives and;

The CVMP considered that the immunological product for horses was indicated for MUMS/Limited markets but was not eligible for financial incentives as the market was not limited.

Pharmacovigilance

The Committee reviewed the PSURs for **Acticam**, **BTVPUR AlSap 1**, **BTVPUR AlSap 1-8**, **BTVPUR AlSap 2-4, Circovac, Hiprabovis IBR Marker Live**, **Locatim**, **Onsior**, **Oxyglobin**, **Panacur AquaSol**, **Posatex**, **Poulvac E. coli**, **SevoFlo**, **TruScient** and **Virbagen Omega**, and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/EWP/261180/2012) for a 6-month period of public consultation. The revised guideline provides more detailed information on the design and conduct of pre-clinical and clinical studies to support clinical efficacy of an antimicrobial veterinary medicinal product and also includes new considerations on claims for metaphylactic or prophylactic treatment. A focus group meeting is planned later this year to discuss the revised guideline with stakeholders. The revised guideline will replace the current CVMP guideline (EMEA/CVMP/627/2001).

The document above will be available on the Agency's website.

Quality

The Committee adopted Questions and Answers on the following quality topic:

- Co-operation between assessors and inspectors when real time release testing is applied.

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

Application of 3Rs (Replacement, Refinement and Reduction) in Regulatory Testing of Medicinal Products

The Committee adopted a recommendation to marketing authorisation holders, highlighting the need to remove the target animal batch safety test (TABST) (EMA/CHMP/CVMP/JEG-3Rs/746429/2013). The recommendation notes that in order to comply with the provisions of Directive 2010/63/EU, marketing authorisation holders must, if not yet done, update their marketing authorisations in order to remove the TABST. Guidance on the relevant actions to be undertaken was issued by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv) in its July-September 2012 and October-November 2012 reports.

Working Parties

The Committee elected Noel Joseph as vice chair of the Safety working party, Silke Hickman as vice chair of the Environmental Risk Assessment working party and Constanca Pomba as vice chair of the Antimicrobials working party for a 3-year mandate.

Organisational matters

The Committee held a meeting with interested parties on 15 May 2013 attended by representatives of the Association of Veterinary Consultants (AVC), the European Group for Generic Veterinary Products (EGGVP), the European Federation of Honey Packers and Distributors (FEEDM), 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:

- Antimicrobial resistance
- Global aspects of residues of veterinary medicinal products
- CVMP activities on injection site residues
- EMA/CVMP activities in relation to the 3Rs
- Developments for the treatment of bee diseases in the EU

The programme of the meeting can be found on the Agency web site.

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

Contact our press officers

Martin Harvey Allchurch or Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu