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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 13-15 July 2010

The Committee elected Dr. Johan Schefferlie from the Netherlands as its Vice-chair for a 3-year mandate.

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application under exceptional circumstances in accordance with Article 32 of Regulation (EC) No 726/2004 for **BTVPUR AlSap 2-4***, from Mérial S.A.S for active immunisation of sheep against bluetongue virus serotypes 2 and 4.

The Committee adopted by majority a positive opinion for an initial marketing authorisation application for **Veraflox*** (pradofloxacin), from Bayer Animal Health GmbH for the treatment of dogs and cats with particular infections caused by certain specified and susceptible pathogens.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **RHINISENG*** (inactivated *Bordetella bronchiseptica* strain 833CER and the recombinant Type D *Pasteurella multocida* toxin (PMTr)), from Laboratorios Hipra S.A., a vaccine against atrophic rhinitis in pigs.

The Committee adopted by majority a positive opinion for an initial marketing authorisation application under exceptional circumstances in accordance with Article 32 of Regulation (EC) No 726/2004 for **COXEVAC*** (inactivated vaccine containing *Coxiella burnetii* phase I, strain Nine Mile), from Ceva Santé Animale, intended for the active immunisation of cattle and goats to reduce infection and shedding of *Coxiella burnetii*, the causative agent of Q fever.

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The Committee adopted by consensus a positive opinion for an extension application for **Porcilis AR-T DF*** (inactivated aqueous vaccine), from Intervet International BV, concerning a new production method and some other changes which include two larger pack sizes.

The Committee adopted by consensus a final opinion, following a re-examination, for a type II variation application for **Masivet*** (masitinib) from AB Science S.A., recommending the **refusal** of the proposed variation. The variation was to extend the indication, to allow treatment of dogs with non-resectable mast cell tumours (grade 2 or 3) independent of their receptor status.

The Committee adopted by consensus a positive opinion for a type II variation application for **Advocate*** (imidacloprid and moxidectin) for a new indication for the treatment and prevention of lungworm infections in dogs, and canine demodicosis.

The Committee also adopted by consensus a positive opinion for a type II variation application for **Convenia** - change in packaging of the diluent.

* Summaries of opinions are available on the Agency's website.

Annual reassessment of marketing authorisations

The Committee adopted an opinion on the annual reassessment for **Nobilis Influenza H5N2**, further to the evaluation of the data submitted by the marketing authorisation holder. The Committee recommended the continuation of the Community marketing authorisation under exceptional circumstances for the veterinary medicinal product.

The Committee adopted an opinion on the annual reassessment for **Poulvac FluFend H5N3 RG**, further to the evaluation of the data submitted by the marketing authorisation holder. The Committee recommended the continuation of the Community marketing authorisation under exceptional circumstances for the veterinary medicinal product.

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Porcilis AR-T DF**. The Committee, having re-assessed the benefit-risk balance of this product, concluded that the quality, safety and efficacy continues to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Community referrals and related procedures

The Committee started a procedure under Article 33 (4) of Directive 2001/82/EC for **Combimox Lactating Cow Intramammary Suspension** (amoxicillin, clavulanic acid and prednisolone) from Norbrook Laboratories Ltd. The application was referred to CVMP for arbitration by the United Kingdom acting as the reference member state in a mutual recognition procedure due to concerns raised by Ireland on the basis that a failure to demonstrate equivalence with the reference product could lead to a potential serious risk to human and animal health.

The Committee started a procedure under Article 33 (4) of Directive 2001/82/EC for **Nisamox Lactating Cow Intramammary Suspension** (amoxicillin, clavulanic acid and prednisolone) from Norbrook Laboratories Ltd. The application was referred to CVMP for arbitration by the United Kingdom acting as the reference member state in a mutual recognition procedure due to concerns raised by the Netherlands on the basis that a failure to demonstrate equivalence with the reference product could lead to a potential serious risk to human and animal health.

The Committee started a procedure under Article 33 (4) of Directive 2001/82/EC for **Combisyn Lactating Cow Intramammary Suspension** (amoxicillin, clavulanic acid and prednisolone) from Norbrook Laboratories Ltd. The application was referred to CVMP for arbitration by the United Kingdom acting as the reference member state in a mutual recognition procedure due to concerns raised by France on the basis that a failure to demonstrate equivalence with the reference product could lead to a potential serious risk to human and animal health.

The Committee started a procedure for **Doxycycline 50% WSP and associated names** (doxycycline hyclate) from Dopharma Research BV. The matter was referred to the Committee by the United Kingdom under Article 34 of Directive 2001/82/EC, due to divergent decisions concerning the marketing authorisations of the product resulting in discrepancies in the summaries of product characteristics with respect to e.g. target species, indications, posology and withdrawal periods.

The Committee started a procedure for **Doxyfar 50% and associated names** (doxycycline hyclate) from Eurovet Animal Health BV. The matter was referred to the Committee by the United Kingdom under Article 34 of Directive 2001/82/EC, due to divergent decisions concerning the marketing authorisations of the product resulting in discrepancies in the summaries of product characteristics with respect to e.g. target species, indications, posology and withdrawal periods.

The Committee concluded the procedure for **Pregsure BVD and associated names** (*inactivated Bovine Viral Diarrhoea (BVD) type 1 virus*) from Pfizer Animal Health. The matter was notified to the Committee by Germany under Article 78 of Directive 2001/82/EC, due to concerns relating to animal safety following use of the vaccine in dams and development of bovine neonatal pancytopenia in calves. The Committee reviewed pharmacovigilance data, as well as epidemiological and laboratory data, and, although the aetiology of the disorder remains obscure at present and the associated risk factors have yet to be determined, the information available is sufficient to indicate a potential association with the product. Therefore, the Committee adopted by majority an opinion concluding that the marketing authorisations for Pregsure BVD and associated names should be suspended until scientific evidence is available to demonstrate that the administration of the vaccine to dams according to authorised conditions of use does not lead to an increased risk of bovine neonatal pancytopenia or that risk mitigation measures ensuring the safe use of the product can be implemented. In addition, the CVMP recommended that all batches of the product be recalled at wholesale level.

The Committee concluded the referral procedure for **Suvaxyn PCV** (*inactivated vaccine*) from Fort Dodge Animal Health. The matter was notified to the Committee by the European Commission under Article 45 of Regulation (EC) No. 726/2004 due to concerns relating to a suspected potential for incomplete inactivation of the vaccine strain. The Committee adopted by consensus an opinion concluding that the marketing authorisation for the product should be suspended until appropriate resolution of the issues by the marketing authorisation holder.

The Committee concluded the referral procedure for **Flexicam 1.5 mg/ml Oral Suspension for Dogs** (*meloxicam*) from Dechra Veterinary Products A/S. The matter was notified to the Committee by the European Commission under Article 45 of Regulation (EC) No 726/2004 due to concerns regarding the quality of the product. The Committee adopted by consensus an opinion concluding that the marketing authorisation of the product should be suspended until appropriate resolution of the issues by the marketing authorisation holder.

The Committee received information from representatives of IFAH Europe in relation to their consideration of the request from the Executive Director of the Agency for an opinion under Article 30(3) of Regulation (EC) No. 726/2004 on the potential presence of retrovirus RD114 in live attenuated vaccines produced on cell lines of feline origin.

Scientific advice

The Committee agreed four separate scientific advice requests concerning; the establishment of a maximum residue limit for a veterinary medicinal product in bees; quality and MRL requirements for an anti-parasitic for sheep; quality and safety requirements for a vaccine for chickens; safety and efficacy requirements for an anti-hypertensive in cats.

MUMS / Limited markets

The Committee reviewed two requests for classification under the MUMS/limited markets policy, which concerned a vaccine against an infectious disease in sheep and goats. The CVMP considered that the products were indicated for MUMS however they were not deemed eligible for financial incentives due to the existence of currently authorised products for the same indication in the same target species.

Pharmacovigilance

The Committee reviewed the PSURs for, **Dexdomitor**, **Flexicam**, **Ingelvac CircoFLEX**, **Loxicom**, **Poulvac Flufend H5N3 RG**, **ProteqFlu**, **ProteqFlu-Te**, **Reconcile** and **Vaxxitek HVT+IBD** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Convenia** and recommended an amendment of the information included in the product literature concerning the indication for use.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted the following standard lists used for electronic reporting of suspected adverse reactions following the yearly review and update*:*

- CVMP combined **VeDDRA list of clinical terms** for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009-Rev.2)
- **List of species and breeds** for electronic reporting of suspected adverse reactions in veterinary pharmacovigilance (EMA/CVMP/553/03-Rev.5);

The Committee adopted the revised **guidance notes on the use of VeDDRA terminology** for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007-Rev.3 and a revised **call for comments on standard lists for EudraVigilance Veterinary** (EMA/123352/2004-Rev.5);

The implementation of the standard lists in EudraVigilance Veterinary is provisionally scheduled for 6 December 2010.

The standard lists and related standard documents will be published on the Agency's web site.

Efficacy

The Committee adopted a revised **Guideline on the conduct of bioequivalence studies for veterinary medicinal products** (EMA/CVMP/330382/2007-Rev.2) and Overview of comments (EMA/CVMP/330382/2007). The guideline has been revised following public consultation. In view of major changes, in particular to the annex of the document, the Committee agreed on a second public consultation of 3 months.

In view of the few comments received during the public consultation of the revised **Guideline on demonstration of target animal safety and efficacy of veterinary medicinal products intended for use in farmed finfish** (EMEA/CVMP/EWP/459868/2008-CONSULTATION), the Committee agreed to extend the deadline for public consultation for another 3 months.

The documents will be published on the Agency's web site.

Quality

The Committee adopted a Guideline on setting specifications for related impurities in antibiotics (EMA/CHMP/CVMP/QWP/199250/2009) for a 6 month-period of public consultation. The guideline has been developed to provide guidance on how specifications for related substance in antibiotics that are fermentation products or semi-synthetic substances derived from fermentation products, and therefore not within the scope of the (V)ICH, guidelines should be set.

The document will be published on the Agency's web site.

Environmental Risk Assessment

The Committee adopted a **Concept paper on assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicine** (EMA/CVMP/ERAWP/389867/2010) for a 2-month public consultation. This concept paper is intended as the first step to developing guidance on how PBT/vPvB veterinary medicinal products should be assessed and what testing strategy should be followed in the light of test requirements of the VICH guidelines.

The Committee adopted an update of the **Questions and Answers (Q&A) document on the implementation of CVMP guideline on Environmental Impact Assessment for veterinary medicinal products in support of the VICH guidelines GL6 (PHASE I) and GL38 (PHASE II)** (EMEA/CVMP/ERA/172074/2008-Rev.2). This Q&A document includes three new answers to questions on the application of the above mentioned guidance.

The document will be published on the Agency's web site.

Regulatory matters

1. The Committee agreed on responses to the questions posed by the European Commission on how to put in place a simpler legal framework, safeguarding public and animal health while increasing the competitiveness of companies as part of the public consultation launched by the European Commission on Better regulation of veterinary pharmaceuticals. These responses will be provided via the Commission website. The Committee adopted in addition a separate document containing its analysis of the functioning of the current veterinary legislation and proposals for its evolution to provide clarification on its views and additional areas for consideration by the European Commission (EMA/CVMP/38660/2010). This document will be published on the Agency's website.

Notes

2. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website.

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