European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 13 – 15 February 2007

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Slentrol** (dirlotapide), from Pfizer Ltd. intended as an aid in the management of overweight and obesity in adult dogs.

The summary of opinion is available on the EMEA web site: http://www.emea.europa.eu

The Committee adopted by consensus a positive opinion for a Type II variation for **Nobivac Piro** regarding an introduction of "dose equivalent" instead of "ml" as unit for the antigen content in the antigenic mass assay.

The Committee adopted by consensus a positive opinion for a Type II variation for **Nobivac Piro** regarding introduction of an additional site for production of the active ingredients (*Babesia canis* and *Babesia rossi* Soluble Parasite Antigen).

Following the withdrawal by Pfizer Ltd. of their application for a new indication for **Draxxin** for the treatment of bovine interdigital necrobacillosis associated with *Bacteroides melaninogenicus*, *Bacteroides nodosus* and *Fusobacterium necrophorum*, the Committee adopted a Questions and Answers document on this withdrawal which will be published on the EMEA website (EMEA/CVMP/58270/2007). The notification of the withdrawal of the application will also be published on the EMEA website.

The documents will be available on Monday 19 February 2007 on the EMEA web site: http://www.emea.europa.eu

Maximum Residue Limits

Following the CVMP recommendation for the establishment of MRLs for **oxytetracycline** in honey, the European Commission raised concerns in respect to the theoretical exceeding of the ADI for oxytetracycline and requested the CVMP to review the safety assessment of the substance with the view to amend the ADI. The Committee, having considered the matter, concluded that on the basis of the data available there are no sufficient scientific grounds that would allow modifying the current ADI. The Committee acknowledged that the current exceeding of the ADI was not optimal but considered that it was not associated with any hazard to the safety of the consumer.

Further to a request for clarification from a company, the Committee agreed the current entry in Annex II of Council Regulation 2377/90 for benzoyl benzoate was incorrect and should be amended to indicate benzyl benzoate. The recommendation for amendment of the Annex would be forwarded to the European Commission.

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Community Referrals

The Committee concluded the referral procedure for **Doxyprex 100 mg/g Premix** for medicated feedingstuff for pigs (doxycycline hyclate) from Industrial Veterinaria S.A. The procedure was referred to the Committee by the Reference Member State in the Mutual Recognition Procedure, Spain, under Article 33 of Directive 2001/82/EC due to concerns raised by the Concerned Member State, Germany, that the efficacy of the product was not sufficiently substantiated in the dossier. The Committee adopted, by consensus, an opinion concluding that the efficacy was sufficiently demonstrated in view of the entire available data and that there were no concerns that the product would represent a potential serious risk to animal health. The product's claim has been modified based on the risk/benefit analysis to "For the treatment and prevention of porcine respiratory disease caused by *Pasteurella multocida* and *Bordetella bronchiseptica*, susceptible to doxycycline, when disease has been diagnosed in the herd". The opinion will now be forwarded to the European Commission.

Scientific advice

The Committee agreed on scientific advice regarding:

- safety issues for a new antimicrobial for pigs and chickens
- preclinical and clinical development of an oncology product for dogs
- clinical development of a product to treat congestive heart failure in dogs
- quality issues and clinical development of a product for bone fractures in dogs.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Aivlosin**, **Econor**, **Previcox**, **Eurifel RCP FeLV** and **Purevax RC**, **Purevax RCCh**, **Purevax RCP**, **Purevax RCP FeLV**, **Purevax RCPCh** and **Purevax RCPCh FeLV**, and concluded that no further action or changes to the product literature of the products were required.

The Committee adopted the EMEA public bulletin on veterinary pharmacovigilance for 2006 summarising the EMEA activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMEA/CVMP/PhVWP/73213/2007). Annual public bulletins on veterinary pharmacovigilance are being produced by the EMEA with the intention to improve communication to all stakeholders, but particularly to veterinary health professionals, on the surveillance of the safety of veterinary medicines in the EU. The bulletin includes descriptive statistics on suspected adverse reactions reports and safety updates, and provides an overview of the activities and issues addressed during 2006.

The document will be available on Monday 19 February 2007 on the EMEA web site: http://www.emea.europa.eu

Antimicrobial resistance

The Committee adopted a public statement on the use of (fluoro)quinolones in food-producing animals in the European Union: development of resistance and impact on human and animal health" (EMEA/CVMP/SAGAM/184651/2005). The paper takes into account the comments received during the public consultation of the preceding reflection paper on this issue. The document critically reviews information on the use of fluoroquinolones in food-producing animals in the EU, its effect on the development of resistance to this category of antimicrobial agents in bacterial species that are of importance for human and animal health, and the potential impact on human and animal health.

It includes also a set of actions recommended by the CVMP to Member States and different stakeholders. In particular the document was the basis for the standard precautionary phrases for inclusion in the SPCs for (fluoro)quinolones which were forwarded to the Heads of Medicines Agencies (Veterinary) and Industry for implementation.

An overview of the comments received during the public consultation of this guideline will be published on the EMEA website.

The documents will be available on Monday 19 February 2007 on the EMEA web site: http://www.emea.europa.eu

International harmonisation

Following sign-off by the VICH Steering Committee at its 19th meeting on 24-25 January 2007, the Committee adopted the following revised VICH guidelines:

- VICH GL3(R) Stability testing of new veterinary drug substances and medicinal products (EMEA/CVMP/VICH/899/99-Rev.1). This guideline is a revision of the guidance on the core stability data package required for registration of a new drug substance or medicinal product.

- VICH GL10(R) Impurities in new veterinary drug substances (EMEA/CVMP/VICH/837/99-Rev.1). This revised guideline concerns the content and qualification of impurities in new drug substances intended to be used for new veterinary medicinal products produced by chemical synthesis.

- VICH GL11(R) Impurities in new veterinary medicinal products (EMEA/CVMP/VICH/838/99-Rev.1). This revised guideline is complementary to that described above but concerns the content and qualification of impurities in new veterinary medicinal products produced from chemically synthesised new drug substances not previously registered in a region or member state.

These three guidelines will all be implemented by January 2008.

The documents will be available on Monday 19 February 2007 on the EMEA web site: http://www.emea.europa.eu

The Committee prepared comments to the Codex Circular letter 2006/38-AMR including proposals for the work for the Codex Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance. The Committee agreed that priority should be given to the work on antimicrobials used for growth promotion.

Availability – Minor Uses and Minor Species

The Committee considered two requests that the requirements defined in the relevant CVMP guidelines on data requirements for veterinary medicinal products intended for minor uses or minor species should be applied in relation to proposed applications for Community Authorisations. The Committee agreed that the guidelines were not applicable in relation to a proposed application for a product for the treatment of epilepsy in dogs and that they were in relation to a proposed application for an oncology product for dogs.

Regulatory Issues

The Committee adopted a guideline on *"Monitoring of compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections"* (EMEA/INS/PhV/47075/2005). This guideline describes the expectations of the competent authority on the pharmacovigilance system of a marketing authorisation holder, and sets out criteria for the arrangement and conduct of monitoring of these systems. The document will be submitted to the European Commission for review.

The next meeting of the CVMP will be held on 13-15 March 2007.

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This press release and other documents are available on the Internet at the following address:
http://www.emea.europa.eu