European Medicines Agency
Veterinary Medicines and Inspections

EMEA/CVMP/216890/2005
London, 15 July 2005

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 12 to 13 July 2005

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for six type II variations for the **Purevax** range (Purevax RC, Purevax RCCh, Purevax RCP, Purevax RCPCh FeLV, Purevax RCPCh, Purevax RCP FeLV) to increase the batch size of the freeze dried component of the vaccines.

The Committee also adopted by consensus a positive opinion for a type II variation for **Nobilis IB4-91** regarding a change of stabilizer for freeze-drying.

Maximum Residue Limits

The Committee adopted by majority a positive opinion recommending the inclusion of **firocoxib** in Annex III of Council Regulation (EEC) No. 2377/90 for horses.

The Committee adopted by consensus a positive opinion recommending the inclusion of ***Piceae turiones recentes extractum*** **(spruce-tip extract)** in Annex II of Council Regulation (EEC) No. 2377/90 for all food producing species and for oral use only.

The Committee adopted by consensus a positive opinion recommending the inclusion of **tosylchloramide sodium** in Annex II of Council Regulation (EEC) No. 2377/90 for horses for topical use only.

The Committee adopted by consensus an opinion recommending the extrapolation of the current MRL for **dihydrostreptomycin** to all ruminants further to a request from a company. This recommendation was made in accordance with the review of the risk assessment approach for the establishment of maximum residue limits with the aim of establishing a more pragmatic approach in securing the provision of medicines for treating animals.

The Summary opinions are available on the EMEA web site: http://www.emea.eu.int

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Community Referrals

The European Commission has suspended the Standing Committee of Veterinary Medicinal Products procedure ("comitology" procedure) regarding the Community referral for Micotil 300 (Tilmicosin). In accordance with Article 38(2) of Directive 2001/82/EC, the Committee is now requested to assess the new safety data having been made available and consequently to further consider any appropriate revision of its initial opinion.

The referral for Micotil 300 had been initiated in May 2004 by France under Article 35 of Council Directive 2001/82/EC in the interest of the Community to investigate concerns regarding user safety. The Committee had finalised its opinion at its December 2004 meeting concluding that the benefits of Micotil under appropriate use as detailed in the revised user safety warnings outweigh the potential risks to the user, especially in conjunction with the additional measures recommended by the Committee.

Scientific Advice

The Committee adopted advice on the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) concerning clinical development of a product for the treatment of atopic dermatitis in dogs.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Aivlosin**, **Nobivac Bb, Nobilis OR inac, Proteq Flu, Proteq Flu-Te** and **Previcox** and concluded that no further action or changes to the product literature of the products were required.

Concept Papers, Guidelines and SOPs

Pharmacovigilance

The Committee adopted a concept paper for a guideline on veterinary Periodic Safety Update Report (PSUR) assessment for release for a 2-month period of public consultation (EMEA/CVMP/PhVWP/145320/2005-CONSULTATION). The concept paper highlights the need for guidance on harmonised PSUR requirements and assessment in order to ensure consistent evaluation across the EU.

Immunologicals

The Committee adopted a revised guideline on requirements and controls applied to bovine serum used in the production of immunological veterinary medicinal products (EMEA/CVMP/743/00-Rev.1) following a 6-month period of public consultation. The guideline will be effective from 1 January 2006.

The documents will be available on Monday 18 July 2005 on the EMEA web site:
http://www.emea.eu.int

Quality

The Committee adopted a revised Joint CHMP/CVMP guideline on the Quality of herbal medicinal products/traditional herbal medicinal products (EMEA/CVMP/814/00-Rev.1) for release for a 2-month period of public consultation. The guideline was revised in order to take into account the provisions of the new Human legislation for traditional herbal medicinal products. Publication of this

joint guideline will follow its adoption by the CHMP, which is forseen for their next meeting on 25-28 July 2005.

International harmonisation

The Committee appointed Dr Johan Schefferlie (The Netherlands) as EU expert to the newly agreed VICH topic Expert Working Group on metabolism and residue kinetics. Dr Stefan Scheid (Germany) will be topic leader for the guideline.

Regulatory issues

The Committee reviewed certain aspects of the implementation of the new legislation for the authorisation of veterinary medicinal products and agreed draft guidelines and reflection papers to be referred to the Commission:

- Guideline on Renewals in the centralised procedure;
- Reflection paper on the EPAR Summary for the public;
- Reflection paper on the Publication of withdrawal.

These guidelines and reflection papers will be reviewed by the European Commission before release for consultation.

The next meeting of the CVMP will be held on 6-8 September 2005

CVMP Secretariat
Veterinary Medicines and Inspections Unit
This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int