European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 13 – 15 March 2007

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Suprelorin** (deslorelin acetate), from Cyton Biosciences Ltd. intended for the induction of temporary infertility in healthy, entire, sexually mature male dogs.

The Committee adopted by consensus a positive opinion under exceptional circumstances on a marketing authorisation application for **Nobilis Influenza H7N1** (inactivated whole influenza virus H7N1), from Intervet International BV, a vaccine intended for active immunisation of chickens and ducks against avian influenza type A, subtype H7. Taking into account the epidemiological situation within the EU, the assessment of the vaccine was carried out under an accelerated procedure and the opinion was adopted in 120 days.

The recommendation of the Committee with regard to this vaccine was made according to Article 39(7) of Regulation No (EC) 726/2004 for an authorisation under exceptional circumstances and subject to specific obligations and follow-up measures by the marketing authorisation holder, including enhanced pharmacovigilance measures to ensure the safe use of the product. The use of this product will be restricted to administration as part of disease control campaigns implemented by national competent authorities. A separate press release on this topic is available on the EMEA web site.

The Committee adopted by majority a positive opinion for a type II variation for **Metacam** regarding the addition of an indication for the alleviation of inflammation and pain in chronic musculo-skeletal disorders in cats.

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

The Committee adopted by consensus positive opinions for type II variations for **Equilis Prequenza** and **Equilis Prequenza Te** regarding an increase in the limit of the influenza titre and an increase in the shelf-life of the adjuvant.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **avilamycin** in Annex I of Council Regulation (EEC) No. 2377/90 for pigs, poultry and rabbits.

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

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Community Referrals

The Committee re-considered its opinion adopted on 13 September 2006 with regard to **Suramox 15% LA** (amoxicillin) and the associated invented name, **Stabox 15% LA** further to the request from the European Commission to consider new residue data made available. The Committee concluded that the new data did not allow establishment of withdrawal periods for edible tissues in cattle and pigs. Therefore the Committee adopted by consensus a revised opinion confirming its previous recommendation for the suspension of the marketing authorisations for the following reasons:

- it was not possible to establish a withdrawal period for cattle and pigs based on the data available;
- the currently established withdrawal periods for cattle and pigs are inadequate to ensure that residues do not exceed the MRLs;
- the currently authorised withdrawal periods are inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer.

The referral was initiated by Belgium under Article 35 of Directive 2001/82/EC on 28 July 2005 on the grounds that the withdrawal periods for cattle and pigs tissues were not adequately justified.

In order to consider lifting the suspension of the marketing authorisations residue depletion data allowing to establish withdrawal periods for both cattle and pigs meat and offal would be necessary.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Poulvac Flufend, Naxcel** and **Virbagen Omega** 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 revised '*Procedure for management of Periodic Safety Update Reports (PSURs) for centrally authorised products*' (SOP/V/4023). This revision enables more efficient communication on PSURs within the CVMP and with the CVMP Pharmacovigilance Working Party, when necessary, by increased use of electronic communication during assessment of PSURs. It also improves tracking of the PSUR process.

The document will be available on the EMEA web site within 2 weeks.

The Committee adopted a '*Reflection paper on criteria for requiring one additional five-year renewal of the marketing authorisation of centrally authorised products on basis of pharmacovigilance grounds'* (EMEA/430630/2006) to be forwarded to the Commission for review.

Organisational Issues

Further to the adoption of the revised CVMP rules of procedure in February 2007 the Committee noted that the document had now been endorsed by the European Commission and the EMEA Management Board. The rules of procedure were revised taking into account the new interpretation of Article 61 of Regulation (EC) No 726/2004 concerning the term of the mandate of CVMP members (EMEA/CVMP/422/04-Rev.1). In view of the new interpretation, the Committee will no longer run on a 3-year mandate, instead individual members will have their own 3-year mandate linked to the specific date of nomination.

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

The Committee adopted a revised '*Procedure for the nomination and appointment of co-opted members of the Committee for Medicinal Products for Human Use and Committee for Medicinal Products for Veterinary Use*.' The procedure was initially adopted in May 2004 and has now been revised in order to take into account the amendments introduced in the CVMP Rules of procedure concerning the term of the mandate of the members of the Committee and the experience gained during the last 3 years.

Publication of this document will follow its adoption by the Committee for Medicinal Products for Human Use (CHMP), which is foreseen for its next meeting on 19-22 March 2007.

The CVMP elected Dr Piet-Hein Overhaus from the Netherlands as the Veterinary Vice-Chair of the Joint CHMP/CVMP Quality Working Party. Dr Overhaus is a senior Pharmaceutical Assessor in the National Institute of Public Health and Environment (RIVM) and has been a member of the Quality Working Party since 1999. He will be responsible for veterinary topics in the Quality Working Party and for the liaison with the CVMP on such issues.

The Committee heard a presentation from Professor Philippe Vannier, Chairman of the EFSA Panel on Animal Heath and Animal Welfare (AHAW) concerning the functioning and organisation of EFSA. The Committee took the opportunity to discuss ways to improve communication and collaboration with EFSA and how to ensure a more efficient input of the Committee when issues of common interest are addressed by EFSA panels.

The next meeting of the CVMP will be held on 17-19 April 2007.

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http://www.emea.europa.eu