EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 9-11 February 2010

CVMP Opinions on Veterinary Medicinal Products

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

ProteqFlu Te – alignment of the product's specifications with the shelf-life;

Draxxin – addition of a 250 ml vial size for pigs for Draxxin 100 mg/ml solution for injection;

Suvaxyn PCV – change in the testing method for sterility of the formulation;

Loxicom – addition of a new pharmaceutical form (oral suspension) for cats.

The Committee was informed of the formal notification from Pfizer Animal Health of their decision to withdraw the extension application for a new target species (horses) for **Naxcel.** More information about this extension application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report. The document, together with the withdrawal letter from the applicant will be published on the Agency's website in due course.

Community Referrals

The Committee concluded the referral procedure for all strengths of water soluble powders and oral solutions containing **doxycyline hyclate** indicated for use in poultry intended to be administered via drinking water. The matter was referred to the CVMP by the United Kingdom, under Article 35 of Directive 2001/82/EC, due to concerns that differences in the posology and indications may present a potential serious risk to public and animal health. Whilst noting that the conditions of use of these veterinary medicinal products varied throughout the Union, the Committee did not identify emerging risks to human or animal health arising as a result of this disharmony and did not therefore recommend changes to the conditions of use. However, due to the known prevalence of resistance to this antimicrobial, changes to the Summary of Product Characteristics (SPCs) of the relevant products

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

were recommended to reflect the principles for prudent use. Therefore the Committee adopted by majority an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the SPC, Package Leaflet and Labelling by inclusion of appropriate standard prudent use statements in line with recommendations of the CVMP revised guideline on the SPC for antimicrobial products and inclusion of additional information regarding the correct administration of the products concerned.

The Committee concluded the referral procedure for veterinary medicinal formulations containing **colistin** at 2MIU/ml and intended for administration via drinking water to any food producing species. The matter was referred to the CVMP by the United Kingdom, under Article 35 of Directive 2001/82/EC, on the basis that it is in the interest of the Union to consider concerns that differences in the posology and withdrawal period may present a potential serious risk to public and animal health. The Committee agreed harmonised conditions of use and withdrawal periods (where applicable) for the concerned products and therefore adopted by consensus an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the Summary of Product Characteristics (SPC), Package Leaflet and Labelling.

Scientific Advice

The Committee agreed two separate scientific advice requests, one for the development of a new anti-viral product for fish as a MUMS product and one for bioequivalence studies for the development of a pharmaceutical product for dogs.

MUMS/Limited markets

The Committee reviewed four requests for classification under the new MUMS/limited markets policy which commenced on 1 September 2009. The first two requests concerned a pharmaceutical with a zootechnical use in ferrets and also the same active substance in dogs for urinary incontinence. The request for ferrets was classified as MUMS but not considered eligible for financial incentives however the product for dogs was not considered as minor use. The other two requests concerned cardiovascular products for use in cats which was classified as MUMS and considered eligible for financial incentives.

The Committee reviewed two requests for appeal; one for an immunological in cats and upheld the previous decision that the indication is not a minor use; the second request was for a product for bees where the product is considered as MUMS however, due to issues with the establishment of an MRL for this substance, no decision on eligibility for financial incentives can be given at this time.

Pharmacovigilance

The Committee reviewed the PSURs for **Aivlosin**, **BTVPUR Alsap 8**, **Circovac**, **Meloxivet**, **Rabigen SAG2** and **Trocoxil** and concluded that no further action or changes to the products' literature were required.

The Committee adopted the Public bulletin on veterinary pharmacovigilance for 2009 summarising the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMA/CVMP/PhVWP/729768/2009). Annual public bulletins on veterinary pharmacovigilance are published by the Agency 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 2009.

The document will be available on the Agency web site:
http://www.ema.europa.eu/htms/vet/phvwp/bulletins.htm

Concept Papers, Guidelines and SOPs

General

The Committee adopted a list of products for sampling and testing in the Agency's 2011 sampling and testing programme (EMA/INS/S&T/55227/2010). The list was developed in accordance with a risk-based approach. The Agency manages annual sampling and testing programmes pursuant to Article 57r of Regulation (EC) 726/2004 in collaboration with the European Directorate for the Quality of Medicines and Healthcare (EDQM) and the network of national Official Medicines Control Laboratories. Further information is available on the Agency web site:
http://www.ema.europa.eu/Inspections/Samptest.html

The Committee adopted a revised Standard Operating Procedure (SOP) on Evaluation procedure for applications and requests for the establishment of Maximum Residue Limits (MRLs) under Articles 3,9, 10 and 15 of Regulation (EC) 470/2009 (SOP/EMA/85634/2006-Rev.1) to take into account the new MRL Regulation (Regulation (EC) No 470/2009).

The document will be available on the Agency web site:
http://www.ema.europa.eu/htms/general/sop/sop.htm#Vets

Quality

The Committee adopted a "*Concept paper on the need for revision of the guideline on stability testing for applications for variations to a marketing authorisation*" (EMA/63033/2010-CONSULTATION) for a 2-month period of public consultation. The guideline requires revision because of recent changes to the underlying variations legislation.

The concept paper will be available on the Agency's website (at:
http://www.ema.europa.eu/htms/vet/vetguidelines/quality.htm) after its adoption by the CHMP which is foreseen for their February meeting next week.

The Committee also adopted several Questions and Answers concerning stability issues of pharmaceutical bulk products used in the manufacture of drug products (EMEA/CHMP/CVMP/QWP/80386/2010). These aim to clarify the information to be provided in marketing authorisation applications, for veterinary or human use, in order to support the storage and/or transportation of bulk products during manufacturing processes.

The publication of these Questions and Answers on the Agency's website
http://www.ema.europa.eu/Inspections/qwp/list.htm) will follow their adoption by the CHMP which is foreseen for their February meeting next week.

Immunologicals

The Committee adopted a "*Reflection paper on data requirements for swine influenza vaccines against pandemic (H1N1) 2009 influenza*" (EMA/CVMP/IWP/58879/2010). This reflection paper has been developed in response to the threat of outbreaks of pandemic H1N1 infection in pigs within Europe and to address some specific concerns relating to the development of vaccines intended to protect

against the pandemic H1N1 infection. This paper does not undergo a formal consultation but comments are welcome by 31 May 2010.

The document will be available on the Agency web site:
http://www.ema.europa.eu/htms/vet/vetguidelines/immunologicals.htm

Environmental Risk

The Committee adopted a draft "*Guideline on degradation of veterinary medicinal products in manure*" (EMA/CVMP/ERA/430327/2009-CONSULTATION) for a 6-months period of public consultation. The guideline is related to the possibility of referring the predicted environmental concentration of Phase I of the environmental risk assessment (ERA). The guideline is intended to provide guidance on the design and interpretation of studies on the transformation of veterinary medicinal products in manure, which could then be used in preparation of the ERA by the applicant and in the evaluation of the studies by the Competent Authorities.

The document will be available on the Agency web site:
http://www.ema.europa.eu/htms/vet/vetguidelines/safety.htm

Notes

1. 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