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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 11-13 April 2012

CVMP opinions on veterinary medicinal products

The Committee adopted, by consensus, positive opinions for initial marketing authorisation applications for:

Poulvac E. Coli, from Pfizer Limited, a vaccine for the active immunisation of chickens to reduce mortality and lesions associated with *E. coli serotype 078*, and

Porcilis ColiClos, from Intervet International B.V., a vaccine for the passive immunisation of piglets against *E. Coli and C. perfringens*.

More information about the above mentioned medicines, including their full indication, can be found on the Agency's website.

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

Convenia to add a new smaller presentation,

Advocate regarding changes to the manufacturing process, and

Equip WNV regarding changes to the manufacturing site.

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Withdrawal of application

The applicant New A Innovation Limited B.V. withdrew its application for a new product at day 180 of the procedure before the CVMP could finalise its opinion.

In accordance with the Agency's reflection paper on publication of withdrawals of marketing authorisation applications for veterinary medicinal products (EMEA/CVMP/42558/2006-Rev.1), the withdrawal letter and a withdrawal public assessment report (WEPAR) will be published on the Agency's website shortly.

Community referrals and related procedures

The Committee started a procedure for **all injectable and pour-on veterinary medicinal products containing doramectin that are intended for use in mammalian food producing species**. The matter was notified to the Committee by the Netherlands under Article 35 of Directive 2001/82/EC, due to concerns relating to withdrawal periods and environmental risk mitigation measures.

The Committee concluded the referral procedure for **Hipralona ENRO-S and its generics** (enrofloxacin). The matter was referred to the Committee by France under Article 35 of Directive 2001/82/EC in order to consider the benefit/risk balance of the products. The Committee adopted, by majority, an opinion concluding that the overall benefit-risk balance for the products concerned by this referral is positive and no changes in the product information were considered necessary.

The Committee noted a request for re-examination of the CVMP opinion adopted on 8 March 2012 in the context of a referral procedure under Article 35 of Directive 2001/82/EC for **all veterinary medicinal products containing active substances belonging to the class of flukicides for which no MRL has been established in milk and which are intended for use in ruminants producing milk for human consumption.** The procedure will be initiated once the grounds for the re-examination have been submitted.

Maximum Residue Limits

The Committee adopted, by consensus, a positive opinion recommending the establishment of maximum residue limits (MRLs) for **diclazuril** in poultry.

The Committee adopted, by consensus, a positive opinion for **double stranded RNA homologous to viral RNA coding for part of the coat protein and part of the intergenic region of Israel Acute Paralysis Virus** concluding that the establishment of maximum residue limits in bees is not necessary for the protection of public health and recommending its inclusion in table 1 of Commission Regulation No. 37/2010 of 22 December 2009.

The Committee adopted, by consensus, a positive opinion recommending the establishment of provisional maximum residue limits (MRLs) for **eprinomectin** in ovine and caprine species.

More information about the above recommendations for establishment of MRLs can be found on the Agency's website.

Scientific advice

The Committee agreed two scientific advice reports; on clinical development of an antimicrobial for cattle; and on quality, safety and clinical development of an immunological veterinary medicinal product for use in swine.

MUMS / Limited markets

Following the Committee's review of one request for classification under the MUMS/ Limited markets policy, which concerned a veterinary medicinal product for horses, the CVMP considered that the veterinary medicinal product for horses was indicated for MUMS/Limited market and was eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR Alsap 2-4, CERTIFECT, Equip WNV, Masivet, Netvax, Palladia, PRILACTONE** and **Rabigen SAG2** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Econor** and recommended the following amendments to the product literature: addition of new special warnings; addition of a new special precaution for use in animals and humans (to wear gloves when handling the product); and inclusion of new information concerning pharmacodynamic properties.

Concept papers, guidelines and SOPs

Immunologicals

The Committee adopted a Guideline on requirements for the production and control of immunological veterinary medicinal products (EMA/CVMP/IWP/206555/2010) following the close of the public consultation. The guideline has been amended to take into account comments received during public consultation. The guideline provides guidance on important items related to the quality, safety and efficacy parts of the marketing authorisation dossier that are not sufficiently defined in the requirements of the existing texts.

Quality

The Committee adopted some Questions and Answers on the **Uniformity of Dosage Units** following recent information that a harmonised approach (in the regions, EU, US, Japan) will not be possible from 1 January 2013 as had been envisaged. This document will replace several of the Q&As on this topic which were published on the Agency's website in previous years and give guidance to both industry and assessors on how to now demonstrate compliance with the Ph. Eur. with regard to the uniformity of dosage units.

Regulatory issues

The Committee endorsed the standard operating procedure in accordance with Article 78 of Directive 2001/82/EC, related to **pharmacovigilance measures** for veterinary medicinal products authorised in the European Union (SOP/V/4025). The SOP was developed to ensure effective management of Article 78 procedures in a harmonised and transparent manner.

The Committee also noted the revised SOP on referrals in accordance with the provisions of Articles 34 and 35 of Directive 2001/82/EC, related to veterinary medicinal products authorised in the European

Union (SOP/V/4024). In the revised SOP, new templates have been applied and the procedure has been updated to reflect minor procedural changes and now includes the workflow of the re-examination process.

A question and answer document on issues which are usually addressed in discussions or correspondence with applicants/marketing authorisation holders during referrals regarding veterinary medicinal products to the CVMP has been published on the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000124.jsp&mid=WC0b01ac0580522957.

All the documents above will be available on the Agency's website.

Other

Workshop on vaccine development against the Schmallenberg virus

The European Medicines Agency held a one-day workshop on 10 April 2012 to discuss issues related to the development of inactivated vaccines against the Schmallenberg virus.

Bringing together members of the Committee and its Immunologicals Working Party as well as European experts from academia and industry, the workshop included discussions of the latest epidemiological developments of the Schmallenberg virus as well as feedback from both regulators and industry on the experiences and challenges related to vaccines produced in response to avian influenza and bluetongue outbreaks. The workshop also discussed how the lessons learnt can be considered in the context of vaccine development for the Schmallenberg virus.

The outcomes from this workshop will be posted in a separate press release on the Agency's website.

Procedural Announcements by the Agency

The Agency will shortly be publishing a separate procedural announcement regarding electronic submissions for veterinary medicinal products and MRL applications. These should be fully compliant with the requirements of the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product as of 1 June 2012.

The Agency will also shortly be publishing a separate procedural announcement regarding a revision of the application form for the establishment of maximum residue limits (MRLs) to bring it in line with Regulation (EC) No. 470/2009 of the European Parliament and of the Council of 6 May 2009.

Notes

1. 'MUMS' stands for minor use minor species.
2. 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

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