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 March 2010

CVMP Opinions on Veterinary Medicinal Products

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

Vaxxitek HVD+IBD - addition of a new presentation and clarification on compatibility statements in the product literature.

Improvac - extension of the re-testing period for a peptide used in the preparation of the conjugate.

Improvac - extension of the shelf life for diphtheria toxoid used in the preparation of the conjugate.

Renewals of Marketing Authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Naxcel** and **Ibaflin**. The Committee, having re-assessed the benefit-risk balance of the products, concluded that the quality, safety and efficacy of the products continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations.

Community Referrals

The Committee concluded the referral procedure for **Tiamutin premix** and associated names (tiamulin fumarate). The matter was referred to the CVMP by Belgium and Ireland, under Article 34 of Directive 2001/82/EC, due to divergent decisions concerning the marketing authorisations of the product resulting in discrepancies in the summaries of product characteristics (SPCs). The Committee agreed harmonised indications, posology and withdrawal periods 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 product literature accordingly.

The Committee considered the grounds for re-examination of the CVMP opinion for all veterinary medicinal formulations containing **quinolones including fluoroquinolones** intended for use in food-

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producing species adopted on 11 November 2009 in the context of a referral procedure initiated under Article 35 of Directive 2001/82/EC. The Committee concluded that the recommendation included in their previous opinion should be maintained. However, the scientific conclusions presented in Annex II of the opinion were amended to reflect the amendments in the CVMP assessment report following consideration of the grounds for re-examination of the opinion. The Committee adopted by consensus the final opinion recommending the amendment of the marketing authorisations for the concerned veterinary medicinal products in order to include in the SPC and package leaflet the prudent use warnings recommended in the CVMP *reflection paper on the use of Fluoroquinolones in food-producing animals – Precautions for use in the SPC regarding prudent use guidance*, for those products where such warnings are currently not included or are out of line.

Scientific Advice

The Committee agreed three scientific advice requests. The first concerned quality issues for the development of a pharmaceutical product for cows. The second request concerned the pharmacological activity of an excipient incorporated into a pharmaceutical product for sheep. The third request concerned biosimilarity with a reference product along with quality, safety and efficacy requirements for the development of a pharmaceutical product for dogs.

MUMS/Limited markets

The Committee reviewed a request for classification under the new MUMS/limited markets policy which commenced on 1 September 2009. The request concerned an immunological product for dogs. The CVMP considered that the product was indicated for MUMS/Limited market and was eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Duvaxyn WNV**, **Nobilis Influenza H5N2** and **Nobilis Influenza H7N1** and concluded that no further action or changes to the products' literature were required.

Antimicrobial resistance

The Committee prepared comments to the European Commission staff working paper of the services of the Commission on antimicrobial resistance, currently under public consultation. The CVMP supports the need for further coordination of activities on the area of AMR by all concerned stakeholders.

Concept Papers, Guidelines and SOPs

Immunologicals

The Committee adopted a **Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)** (EMA/CVMP/IWP/105506/2007) following the close of public consultation**.** This guideline applies to new applications for authorisation of vaccines defined in multi-strain dossiers and variations concerning the addition or replacement of strains of inactivated vaccines intended for use against avian influenza (AI), Bluetongue (BT) and Foot-and-mouth disease (FMD). It describes the requirements that should be presented in the analytical, safety and efficacy part of the multi-strain dossier. The guideline will come into effect on 1 October 2010.

The Committee endorsed a **Recommendation on the submission of multi-strain dossier applications for vaccines against avian influenza, bluetongue and foot-and-mouth disease** (EMA/CVMP/IWP/43283/2010). This document deals with the procedural issues of applications for multi-strain authorisations and will be published together with the above-mentioned guideline.

The Committee adopted a **Guideline on data requirements to support in-use stability claims for veterinary vaccines** (EMA/CVMP/IWP/250147/2008) following the close of public consultation. This guideline outlines the data requirements which should be provided in support of claims for in-use stability of veterinary vaccines. The guideline will come into effect on 1 October 2010.

The Committee adopted a **Reflection paper on the demonstration of a possible impact of maternally derived antibodies on vaccine efficacy in young animals** (EMA/CVMP/IWP/439467/2007). This reflection paper gives an example of data that should be provided when a vaccine is intended to be used in young animals which potentially have maternally derived antibodies.

The Committee adopted a **Reflection paper on control of the active substance in the finished product for immunological veterinary medicinal products (IVMPs)** (EMA/CVMP/IWP/582970/2009). The aim of this reflection paper is to discuss the different methods currently used for control of the active substance in the finished product and their features, difficulties associated with the validation of these tests, problems arising from the use of *in vivo* tests and the possibility of an alternative *in vitro* approach for batch testing. This paper does not undergo a formal consultation but comments are welcome by 31 May 2010.

The guidelines with their overview of comments and the reflection papers will be published on the Agency web site:

http://www.ema.europa.eu/htms/vet/vetguidelines/immunologicals.htm

Safety

The Committee adopted a revised **Guideline on user safety for pharmaceutical veterinary medicinal products** (EMA/CVMP/543/03-Rev.1), having taken the comments raised during the public consultation into consideration. The guideline was revised with the aim of improving the overall clarity of the document. The guideline will come into effect on 1 October 2010.

The guideline with the overview of comments will be published on the Agency web site:

http://www.ema.europa.eu/htms/vet/vetguidelines/safety.htm

Working Parties

The Committee re-elected P.-H. Overhaus as the Veterinary Vice-Chair of the Joint CHMP/CVMP Quality Working Party and endorsed the election by the Scientific Advisory Group on Antimicrobials for K. Törneke as the Chairperson, both for a 3-year mandate.

Organisational matters

The CVMP meeting was followed by a European Medicines Agency / IFAH-Europe Info Day on 11-12 March 2010 under the theme “The latest developments in scientific review, legislation and marketing authorisation procedures”.

The programme of the meeting can be found on the Agency web site:
http://www.ema.europa.eu/meetings/conference.htm

Adjusted fees for application to the EMA to come into effect on 1st April 2010

Applicants are reminded that the European Commission is in the process of adopting a regulation adjusting the fees payable to the EMA in line with inflation and amending Council Regulation (EC) No 297/95. It is expected that the adopted Commission Regulation will be published shortly.

Details of the revised fees will be published shortly thereafter, in the section Guidelines on fees payable to the European Medicines Agency:
http://www.ema.europa.eu/htms/general/admin/fees/feesfaq.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

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