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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 06-08 March 2012

CVMP opinions on veterinary medicinal products

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

Cerenia (maropitant) to add a new target species (cats) for the 10 mg/ml solution for injection,

Improvac (GnRF analogue-protein conjugate) regarding changes to the manufacturing process.

The Committee noted the request by the marketing authorisation holder for a re-examination of the CVMP opinion on the grouped type II variation for **Nobilis IB 4-91** adopted during the February 2012 meeting.

Withdrawal of application

The applicant Oasmia Pharmaceuticals withdrew its application for a new product at day 204 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.

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Renewals of marketing authorisation

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

Community referrals and related procedures

The Committee concluded the referral procedure for **Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus and associated names** (*praziquantel, pyrantel and febantel*) from Chanelle Pharmaceuticals Manufacturing Ltd. The matter was notified to the Committee by France under Article 34 of Directive 2001/82/EC, due to divergent decisions taken by Member States resulting in discrepancies in the product information. The Committee agreed harmonised indications for the concerned products and therefore adopted by majority an opinion concluding that the marketing authorisations of Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus and associated names should be varied in order to amend the product information accordingly. No changes would be necessary to the terms of the marketing authorisations for Exitel Plus, Cazitel Plus and Prazitel Plus and associated names.

The Committee concluded the referral procedure 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 matter was referred to the Committee by the European Commission under Article 35 of Directive 2001/82/EC in order to consider appropriate measures to ensure that use of the concerned products during the non-lactating period would not lead to such residues in milk that would result in consumer exposure exceeding the acceptable daily intake (ADI) for all residues of the substances concerned.

The Committee concluded that the overall benefit-risk balance is positive for the products containing clorsulon, closantel, nitroxinil, rafoxanide or triclabendazole as a single active substance, and for the veterinary medicinal products administered as pour-on to cattle containing triclabendazole and moxidectin, subject to adequate advice concerning the use in dairy cattle in the product information.

The Committee adopted by consensus an opinion recommending changes to the product information and variations to the terms of the marketing authorisations are necessary for all veterinary medicinal products containing clorsulon, closantel, nitroxinil, rafoxanide or triclabendazole as a single active substance, and for the veterinary medicinal products administered as a pour-on to cattle containing triclabendazole and moxidectin which are subject to the referral. As the scope of the current referral was restricted to the evaluation of flukicidal substances, the second active, non-flukicidal substance contained in combination products was not assessed. Therefore no conclusion could be drawn on the need for instructions to be included in the product information of combination products, with the exception of products for which the conclusion on the flukicidal substance is that it cannot be used in dairy animals at any time.

The Committee concluded the referral procedure for **all pre-mixes for medicated feedingstuffs containing 40, 100 or 200 g tilmicosin per kg pre-mix and administered to rabbits**. The matter was referred to the Committee by the European Commission under Article 35 of Directive 2001/82/EC in order to consider the recommended dose and inclusion rates in feed for pre-mixes for medicated feedingstuffs containing 40, 100 or 200 g tilmicosin per kg pre-mix and that are administered to rabbits. The Committee concluded that overall the benefit-risk balance for the products falling under this referral is positive, subject to changes in the product information.

The Committee adopted by consensus an opinion recommending changes to the product information of the concerned products and recommending that variations are necessary to the terms of the marketing authorisations for all pre-mixes for medicated feedingstuffs that contain 40, 100 or 200 g tilmicosin per kg pre-mix and that are administered to rabbits.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the modification of the current entry in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for **prednisolone** in order to establish maximum residue limits for horses.

The Committee adopted by consensus a positive opinion recommending the modification of the current entry in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for **monensin** in bovine species in order to increase the maximum residue limits in liver and kidney.

The Committee adopted by consensus a positive opinion recommending the modification of the current entry in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for **phoxim** in order to establish harmonised maximum residue limits in the different animal species and to extrapolate these to all food producing species except fin fish.

Further to a request for re-examination of the CVMP opinion, the Committee adopted by consensus a final opinion for the modification of maximum residue limits in accordance with Regulation (EC) No 470/2009 for **neomycin**, confirming the recommendation for the increase of the MRLs for liver and kidney.

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

Scientific advice

The Committee agreed scientific advice concerning bioequivalence issues for a generic product intended for dogs.

MUMS / Limited markets

Following the Committee's review of three requests for classification under the MUMS/Limited markets policy, which concerned an immunological for turkeys, an anti-inflammatory for dogs and a musculoskeletal treatment for horses

- the CVMP considered that the musculoskeletal indication in horses was indicated for MUMS/Limited markets and was eligible for financial incentives;

- the CVMP considered that the anti-inflammatory indication in dogs was indicated for MUMS/Limited markets and was eligible for financial incentives;

- the CVMP considered that the immunological for turkeys was indicated for MUMS/Limited markets but was not eligible for financial incentives as authorised products already exist for the indication.

Pharmacovigilance

The Committee reviewed the PSURs for **Acticam, Aivlosin, CaniLeish, Eurican Herpes 205, Loxicom, Meloxoral, Previcox chewable tablets, Procox, Trocoxil, Veraflox** and **ZOLVIX** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a draft revised **guideline on process validation** (EMA/CHMP/CVMP/QWP/70278/2012-Rev.1) for a 6-month period of public consultation. This draft revision introduces clarification on how new opportunities can be taken when enhanced process understanding, coupled with risk management tools under an efficient quality management system, have been applied to manufacturing processes.

The Committee adopted some Questions and Answers on **Post Approval Change Management Protocols** (EMA/705532/2011) following end of consultation. This document gives guidance to both industry and assessors on how to handle (optional) Post Approval Change Management Protocols.

The documents above will be available on the Agency's website after their adoption by the CHMP which is foreseen for their next meeting (13-15 March 2012).

Environmental Risk Assessment

The Committee adopted a new reflection paper on **mitigation measures related to the environmental risk assessment of veterinary medicinal products testing** (EMA/CVMP/ERA/409328/2010) following the close of the public consultation. This reflection paper has been developed to address a critical review of the adequacy/appropriateness of risk mitigation measures included in current marketing authorisations of veterinary medicinal products. The comments received during the consultation procedure have been taken into account for the revision of the reflection paper.

Immunologicals

The Committee adopted a new concept paper on the need of revision of the Note for Guidance on the **Harmonisation of requirements for equine influenza vaccines** – Specific requirements for substitution or addition of a strain or strains (EMA/CVMP/IWP/4199/2012) for consultation for a 2 - month period of public consultation. The concept paper has been developed because a revision of the Note for Guidance is required to provide guidance on the data requirements necessary to support the deletion,substitution or addition of viral strains to meet OIE recommendations for equine influenza vaccines in order to encourage vaccine manufacturers to update the equine influenza strains in their vaccines so that horses are adequately protected against circulating strains.

Working Parties

The Committee reviewed and adopted the revised **mandate for the CVMP Pharmacovigilance Working Party** (EMA/CVMP/PhVWP/133883/2004-Rev.3). No significant changes were made to the content of the mandate however editorial and formatting improvements were introduced as part of the routine three-yearly revision of the document. As this Working Party reports both to the Committee and the EU Member States, the mandate will also be submitted to the Heads of Medicines Agencies - Veterinary for endorsement. The publication of the mandate will take place following the endorsement by the Heads of Medicines Agencies – Veterinary.

The document will be available on the Agency's website.

The CVMP agreed to organise a **workshop** with vaccine manufacturers to be held on 10 April 2012. This workshop is aimed to discuss approaches to facilitate the process whereby the European Union can have prompt access to safe and effective inactivated **vaccines** against **Schmallenberg virus** (SBV) should a decision be taken at a future date that vaccination should form part of control measures against this rapidly emerging disease within the Union.

International activities

The Committee discussed the CCRVDF discussion documents on extrapolation of MRLs for veterinary medicinal products to additional species and tissues and on the Policy for the establishment of MRLs or other limits in honey and agreed reflections and comments that are intended to be used as basis for preparing an EU position on these topics in preparation of the 20th CCRVDF meeting to be held on 7-10 May 2012 in Puerto Rico. The Committee had agreed already at its February 2012 meeting considerations and conclusions regarding the proposed draft Codex MRLs at step 3 for discussion at the 20th CCCRVDF meeting which will be used in preparation of the EU position on these MRLs.

The Committee also agreed CVMP comments on the WHO/FAO report proposing changes to the way JECFA assesses exposure to residues of veterinary drugs, which will be submitted to the WHO/FAO.

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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