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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 05-07 February 2013

CVMP opinions on veterinary medicinal products

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

Meloxidolor (*meloxicam*) from Le Vet Beheer B.V., an anti-inflammatory and anti-rheumatic product for dogs, cats, cattle, pigs and horses.

ECOPORC Shiga from IDT Biologika GmbH, a vaccine for the active immunisation of piglets to reduce the mortality and clinical signs of oedema disease.

The Committee adopted by consensus a positive opinion for extension and variation applications of the existing authorisations for:

Equilis Prequenza (*vaccine against equine influenza*) from Intervet International B.V., concerning a replacement of a strain and other changes in the quality of the product.

Equilis Prequenza Te (*vaccine against equine influenza and tetanus*) from Intervet International B.V., concerning a replacement of a strain and other changes in the quality of the product.

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

Annual reassessment of marketing authorisations

The Committee adopted opinions on the annual reassessments for **BTVPUR AlSap 1** and **BTVPUR AlSap 1-8**, further to the evaluation of the data submitted by the marketing authorisation holder.

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Since the specific obligations have been fulfilled the Committee recommended the conversion of the Community marketing authorisations from under exceptional circumstances to a normal status for these two products.

Community referrals and related procedures

Further to the request of the European Commission following the consultation of the Standing Committee on Veterinary Medicinal Products, the Committee re-considered its opinion on the referral procedure **for Nuflor Swine Once 450mg/ml solution for injection** (florfenicol) adopted on 13 June 2012. The Committee, having reviewed the issues raised, revised the opinion and adopted by majority an opinion concluding that the application does not comply with Article 13 of Directive 2001/82/EC and consequently does not satisfy the criteria for marketing authorisation in respect to efficacy. Therefore the Committee recommended the refusal of the granting of the marketing authorisation and the suspension of the existing marketing authorisations for Nuflor Swine Once 450 mg/ml solution for injection. The matter was initially referred to the Committee by Germany as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC due to concerns raised by Denmark relating to the efficacy of the product.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for diclazuril in rabbits.

More information about the above recommendation can be found on the Agency's website.

The Committee adopted a revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009-Rev.13) following consideration of several requests during the last months. The changes concern: modification of the maximum dose restriction for the excipient denatonium benzoate; inclusion of the substances PPG-2 myristyl ether propionate and polybutene under the heading 'Excipients'; introduction of a new heading 'Biologically active constituents' with a new entry for 'stem cells'.

More information about the above recommendation can be found on the Agency's website.

Scientific advice

The Committee responded to three separate scientific advice requests concerning safety data requirements for an anti-viral product for cats, efficacy data requirements for an anti-inflammatory product for cats and for a diuretic product for dogs.

MUMS/Limited markets

Following the Committee's review of three requests for classification under the MUMS/Limited markets policy, which concerned an oncology product for horses and a product with digestive indications and an antibiotic both for dogs; the CVMP considered that the product for horses was indicated for MUMS/Limited market and was eligible for financial incentives and that one product for dogs was indicated for MUMS but was not eligible for financial incentives as authorised products already exist for these indications.

Pharmacovigilance

The Committee reviewed the PSURs for **BLUEVAC BTV8**, **Bovilis BTV8**, **Coxevac**, **Netvax, Nobivac Myxo-RHD**, **Profender**, **Purevax Rabies**, **RHINISENG**, **ZULVAC 1+8 Bovis** and **ZULVAC 1+8 Ovis** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Suprelorin** and recommended changes to Section 4.4 of the SPC to amend a special warning already included in the product literature.

The Committee adopted the Public bulletin on veterinary pharmacovigilance for 2012 summarising the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMA/CVMP/PhVWP/717241/2012). 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 adverse events and safety updates, and provides an overview of the activities and issues addressed during 2012.

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

Concept papers, guidelines and SOPs

Quality

The Committee adopted a revision to the joint CHMP/CVMP guidance document Annexes to: CPMP/ICH/283/95 Impurities: Guideline for Residual Solvents & CVMP/VICH/502/99 Guidelines on Impurities: Residual Solvents (CPMP/QWP/450/03-Rev.1 and EMEA/CVMP/511/03-Rev.1). Annex I of the document on specifications for Class 1 and Class 2 residual solvents in active substances had a sentence relating to Class 2 solvents, which was the source of confusion, but has now been amended for clarification.

The document above will be published on the Agency's website after its adoption by the CHMP.

Pharmacovigilance

The Committee adopted a draft Reflection paper on pharmacovigilance communication concerning veterinary medicinal products (EMA/CVMP/PhVWP/536313/2011) for a 3-month period of public consultation. The reflection paper has been developed to provide an overview of practises and communication tools used, outline a basic framework for veterinary pharmacovigilance communication and improve and harmonise the approach to communication across the EU for transparent and effective transfer of pharmacovigilance information, particularly to veterinarians and other health-care professionals and other 'users' of the veterinary medicinal products.

The reflection paper will be published on the Agency's website.

The Committee adopted a draft revised Recommendation on harmonising the approach to causality assessment for adverse events to veterinary medicinal products (EMA/CVMP/PhVWP/552/2003–Rev.1) for a 3-month period of public consultation. The former causality assessment guideline was renamed as a recommendation and the content revised for consistency with Volume 9B of The Rules Governing Medicinal Products in the European Union and to improve a harmonised approach for causality assessment.

The recommendation will be published on the Agency's website.

Procedural announcement

Further to the decision by the European Pharmacopoeia (Ph. Eur.) Commission of April 2012 to delete the target animal batch safety test (TABST) from the Ph. Eur. for nearly all veterinary vaccines with effect from 1 April 2013, it has been agreed to follow a notification procedure for centralised veterinary medicinal products whereby marketing authorisation holders will inform us in writing of the products for which they will withdraw the TABST in line with the Ph. Eur. requirements, the products for which the TABST will be renamed a residual toxicity test and the date on which the changes will be implemented (before 1 April 2013).

Marketing authorisation holders and other stakeholders have been contacted and invited to notify the Agency in writing before 1 April 2013 of the products concerned.

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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