



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 7-9 July 2015

CVMP opinions on veterinary medicinal products

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

Novaquin (*meloxicam*), from Le Vet Beheer B.V., a veterinary medicinal product for the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses;

Porcilis PCV ID, from Intervet International B.V., a vaccine for the active immunisation of pigs from three weeks of age to reduce viraemia, virus load in organs and lymphoid tissues and virus shedding caused by porcine circovirus type 2 infection; and

Vectormune ND, from CEVA-Phylaxia Veterinary Biologicals Co. Ltd., a vaccine for the active immunisation of 18-day-old embryonated chicken eggs or day-old broiler chickens to reduce mortality and clinical signs caused by Newcastle disease virus, and to reduce mortality, clinical signs and lesions caused by Marek's disease virus.⁴

The Committee adopted by majority a positive opinion for an initial marketing authorisation application for **FORTEKOR PLUS** (*pimobendan/benazepril*), from Elanco Europe Ltd. (formerly Novartis Healthcare A/S), a veterinary medicinal product for the treatment of congestive heart failure due to atrioventricular valve insufficiency or dilated cardiomyopathy in dogs.

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

Advocate regarding the addition of a new indication for dogs; and quality changes for **Hiprabovis IBR Marker Live**, **Ingelvac CircoFLEX** and **Oxyglobin**, as well as for a work-sharing procedure for **Purevax RCPCh**, **Purevax RCPCh FeLV** and **Suvaxyn CSF Marker**.

More information about the above mentioned medicines will be published on the Agency's website.



Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **BTVPUR AISap 1**, **BTVPUR AISap 1-8** and **Meloxoral**. 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 the marketing authorisations.

Community referrals and related procedures

The Committee started a procedure under Article 78 of Directive 2001/82/EC for **Closamectin pour-on solution and associated names** (*ivermectin/closantel*) from Norbrook Laboratories Limited. The matter was referred to the Committee by France following suspension of the marketing authorisation for 'Closamectin Pour-on Solution pour bovins' further to the evaluation of pharmacovigilance data related to animal health concerns.

Maximum Residue Limits

The Committee agreed to include **n-ethylglucamine** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients and adopted a revised list (EMA/CVMP/519714/2009-Rev.30). This decision followed the Committee's review of a request that had been submitted in accordance with the relevant CVMP guidance.

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

Scientific advice

The Committee adopted two separate scientific advice reports concerning:

- Initial advice on safety issues for an otologic veterinary medicinal product for dogs; and
- Follow up advice on efficacy issues for a cardiovascular product for dogs.

MUMS/limited market

Following the Committee's review of four requests for classification under the MUMS/limited market policy, the CVMP classified:

- An immunological product for chickens and turkeys as not indicated for MUMS/limited market and therefore not eligible for financial incentives, since the specific indication claimed was not considered to be a minor use.
- An immunological product for chickens as not indicated for MUMS/limited market and therefore not eligible for financial incentives, since the specific indication claimed was not considered to be a minor use.
- An anti-parasitic veterinary medicinal product for dogs as indicated for MUMS/limited market and eligible for reduced data requirements. As the product is indicated for a non-food producing species, it is not eligible for financial incentives.
- An immunological product for pigs as not indicated for MUMS/limited market and therefore not eligible for financial incentives, since the specific indication claimed was not considered to be a minor use.

Pharmacovigilance

The Committee reviewed the PSURs for **BLUEVAC BTV8, Bovilis BTV8, Bravecto, COXEVAC, NexGard, Proteq West Nile, Purevax Rabies, Purevac RC, Purevax RCP, Purevax RCP FeLV, Purevax RCPCh, Purevax RCPCh FeLV, RevitaCAM, RHINISENG** and **Semintra** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSURs for **Nobivac L4** and **Pexion** and recommended amendments to the product information.

Concept papers, guidelines and SOPs

Antimicrobials

The Committee adopted a new concept paper for the development of a reflection paper on the use of extended-spectrum penicillins in animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/AWP/37203/2015) for a 3-month period of public consultation. The concept paper highlights the need to prepare a reflection paper to elaborate on the use of these substances in veterinary medicines and their potential public and animal health risks.

Immunologicals

The Committee adopted a draft revised guideline on requirements for the production and control of immunological veterinary medicinal products (EMA/CVMP/IWP/206555/2010-Rev.1) for a 6-month period of public consultation. The guideline, which provides guidance on the requirements that are not covered by Directive 2001/82/EC, the European Pharmacopoeia (Ph. Eur.) and relevant VICH guidelines, is under revision to include the approach to demonstrate freedom from extraneous agents as part of the production and control of immunological veterinary medicinal products for mammalian species and finfish.

In addition, the Committee adopted a draft reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products (EMA/CVMP/IWP/251741/2015) for a 6-month period of public consultation. The reflection paper describes examples of suitable cells and methods for testing for freedom from a range of extraneous agents, based on available data on seeds assessed and approved as part of marketing authorisation applications in the European Union.

Quality

The Committee adopted a concept paper (EMA/CVMP/QWP/360463/2015) on the need for revision of the veterinary note of guidance on manufacture of the finished dosage form for a 3-month period of public consultation. The concept paper was developed to address the need to update and revise the note for guidance to cover the current variety of manufacturing practices.

The Committee adopted a concept paper (EMA/CVMP/QWP/107359/2015) on the need for a single veterinary note for guidance on the chemistry of active substances for a 3-month period of public consultation. The concept paper was developed to address the need to update and revise the guidance available for the chemistry of both new and existing active substances to reflect changes in legislation, recent developments and other guidance.

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

Procedural announcement

Mandatory use of electronic application forms (eAFs) for centralised procedure applications from 1 July 2015

The use of the eAFs is now mandatory for all human and veterinary medicines centralised procedure applications (initial marketing authorisation applications, variations, renewals). The eAFs are available from the [eAF webpage](#) on the eSubmission website. Updated word application forms have been published on the EudraLex website (see [Eudralex Volume 6 of the Notice to Applicants](#).) to reflect the mandatory usage of eAFs for the centralised procedure.

A news item on the mandatory use of eAF has also been published on the [Agency website](#).

Publication of validation checklists for initial marketing authorisation applications for immunologicals and pharmaceuticals

Validation checklists used by the Agency to validate initial marketing authorisation applications for immunological and pharmaceutical veterinary medicinal products have been published on the [Agency website](#). Applicants are invited to use them as a means to review their submissions in advance.

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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