18 March 2016
EMA/CVMP/169459/2016
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 15-17 March 2016

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for type II variation applications for **Profender** to add a therapeutic indication and for **Aftovaxpur DOE** to change the vaccination schedule.

The Committee adopted by majority a positive final opinion for an extension of the existing authorisation application for **Bravecto** (fluralaner), from Intervet International B. V., concerning the addition of a new pharmaceutical form (spot-on solution) for dogs and a new target species (cats) for this spot-on formulation, further to the request for a re-examination of the negative opinion adopted during the Committee meeting held on 8-10 December 2015.

More information about the above mentioned medicines, including their full indication, 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 **MS-H Vaccine** and **Proteq West Nile**. 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 concluded the referral procedure for **CattleMarker IBR Inactivated emulsion for injection for cattle** (*Infectious bovine rhinotracheitis (IBR) vaccine*) from Zoetis Belgium SA. The matter was referred to the Committee by Belgium as the reference Member State in the mutual recognition procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by Germany relating to a potential serious risk to animal health. The Committee adopted by majority an opinion concluding that the objections raised by Germany during the mutual recognition procedure should not prevent the granting of the marketing authorisation subject to conditions concerning risk mitigation and surveillance measures.

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Scientific advice

The Committee adopted three separate scientific advice reports concerning:

- Initial advice on quality, safety and efficacy issues for a diagnostic veterinary medicinal product for pigs;
- Initial advice on quality, safety and efficacy issues for a genito-urinary veterinary medicinal product for cattle; and
- Initial advice on efficacy issues for a genito-urinary veterinary medicinal product for cattle.

MUMS/limited market

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

- A cardiovascular veterinary medicinal product for cats as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in a non-food producing species (cats).
- A gastro-intestinal veterinary medicinal product for dogs as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in a non-food producing species (dogs).
- An anti-parasitic veterinary medicinal product for pigeons as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in racing pigeons not intended for human consumption.

Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR Alsap 2-4**, **CERTIFECT, Dicural, EQUIP WNV**, **Meloxidolor**, **Oncept IL-2**, **Parvoduk**, **Pexion, Porcilis ColiClos**, **Porcilis PCV M Hyo**, **Procox**, **ProteqFlu**, **ProteqFlu-Te**, **Versican Plus DHPPi/L4R** and **VIRBAGEN OMEGA** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Quality

The Committee noted the revised note for guidance on limitations to the use of ethylene oxide in the manufacture of medicinal products (EMEA/CVMP/271/01-Rev.1). This note for guidance is now applicable to veterinary medicinal products only.

Environmental Risk Assessment

The Committee adopted a reflection paper on poorly extractable and/or non-radiolabelled substances (EMA/CVMP/ERA/349254/2014) following the close of the public consultation. This reflection paper, which was developed to present a pragmatic approach on how to deal with substances which are difficult to extract from soil, proposes a number of options to applicants on how to perform OECD TG 307 studies when the extraction efficiency (recovery) of the substance in soil is lower than the minimum required for validating the test results.

The reflection paper together with the overview of comments (EMA/CVMP/169459/2016) will be published on the Agency's website.

The Committee adopted Questions and Answers on the following quality topic:

- Mixtures of active pharmaceutical ingredients with one or more excipients.

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

Working Parties

The Committee elected M. O'Grady's as the veterinary vice-chair of the joint CHMP/CVMP Quality working party for a 3-year mandate.

Procedural announcement

Mandatory use of Gateway for veterinary submissions as of 1 January 2017

Since 1 March 2014 the use of the eSubmission Gateway / Web Client has been mandatory for the submission to the European Medicines Agency (the Agency) of all applications through the centralised procedure related to human medicinal products using the electronic Common Technical Document (eCTD) submission format. On 1 April 2014 the Agency extended the use of the eSubmission Gateway and the Web Client to all veterinary medicines submissions including veterinary referrals.

For veterinary procedures, submissions on physical media (CD/DVD) or by Eudralink have continued to be accepted as an alternative method to use of the Gateway as an interim measure, although applicants have been encouraged to register to use the eSubmission Gateway or the free web-based Web Client solution as soon as possible.

In co-operation with representatives from the human and veterinary pharmaceutical industry, the Agency is now engaging in further development of systems to support electronic submission of applications by means of the eCollaboration programme which forms Programme 3 of the EU Telematics Strategy. As part of this programme, in 2016 the Agency is carrying out activities aimed at simplifying eSubmission through Gateway / Web Client. Following this, it is the Agency's intention to make submissions via Gateway / Web Client mandatory for all documentation related to veterinary centralised procedures from 1 January 2017.

As a first milestone in the step-wise progression towards this goal, the Agency is preparing a new pilot release of the Gateway system on 23 May 2016. This release will introduce a new functionality enabling less manual input and more automation, thanks to a user-friendly interface based on an XML delivery file technology, with pre-filtered submission data that will remove the current need for a complex file-naming convention. For more details, see the below statement of intent for use of XML delivery files for submissions via Gateway / Web Client.

Further information on these developments will be provided throughout the year via the relevant eSubmission channels and consultative groups with information on timelines for the specific changes and training arrangements for the industry.

Related information

- Statement of intent for use of xml delivery files for submissions via Gateway / Web Client
- Use of eSubmission Gateway / Web Client extended to new procedure types from 1st of April 2014
- eSubmission Gateway and Web Client
- eSubmission Registration
- eSubmission Web Client
- electronic Application Forms

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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