EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 11-13 March 2014

CVMP opinions on veterinary medicinal products

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

Versican Plus DHPPi/L4R, from **Zoetis Belgium SA**, a vaccine against canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus, leptospirosis and rabies; and

Versican Plus DHPPi/L4, from **Zoetis Belgium SA**, a vaccine against canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus and leptospirosis.

The Committee adopted by consensus a positive opinion for a type II variation application for:

AFTOVAXPUR DOE regarding the addition of a new strain to this multi-strain vaccine against foot-and-mouth disease.

The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **EQUIOXX** and **Previcox** concerning quality changes.

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

Community referrals and related procedures

The Committee considered a notification for a referral under Article 33(4) of Directive 2001/82/EC, a procedure for **AQUACOLI 2 000 000 IU/ml, Solution for use in drinking water or milk** (*colistin*) from Laboratorios Calier S.A. The matter was referred to the Committee by Spain as the reference Member State in the decentralised procedure, due to concerns raised by Poland relating to the target species. The Committee did not accept the referral procedure under Article 33(4) of Directive 2001/82/EC, on the grounds that the question to the CVMP within the referral notification is a regulatory matter and consequently not appropriate for consideration by the CVMP.

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The Committee started a procedure for **all veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses**. The matter was referred to the Committee by Denmark under Article 35 of Directive 2001/82/EC, due to concerns regarding the indications, dosing regimen and target animal safety of the above mentioned products.

Scientific advice

The Committee adopted four separate scientific advice reports concerning: initial advice on safety issues for the development of an immunological veterinary medicinal product for chickens, initial advice on quality and safety issues for an antimicrobial veterinary medicinal product for rabbits, initial advice on MRL issues for an antiparasitic medicinal product for salmon and follow-up advice on efficacy issues for an analgesic veterinary medicinal product for horses.

MUMS / limited market

Following the Committee's review of four requests for classification under the MUMS/limited market policy, which concerned a product affecting the central nervous system of rabbits, goats, horses and fish, an antiparasitic product for honey bees, a zootechnical product for cattle and a diagnostic aid product for dogs:

- The CVMP considered that the product for rabbits, goats, horses and fish was indicated for MUMS/limited market and eligible for financial incentives.
- The CVMP considered that the product for honey bees was indicated for MUMS/limited market but was not eligible for financial incentives as although it is indicated for a food-producing species an alternative product is authorised for the same target species for the same indication.
- The CVMP considered that the product for cattle was not indicated for MUMS/limited market and was not therefore eligible for financial incentives.
- The CVMP considered that the diagnostic aid product for dogs was indicated for MUMS/limited market but was not eligible for financial incentives as it is not intended for use in food-producing animals.

The Committee endorsed a clarification note concerning the financial incentives applicable to horses under the current MUMS/limited market policy (EMA/429080/2009-Rev.1). The clarification will be published as part of the question and answer document (EMEA/CVMP/370663/2009) on guidance for applicants requesting MUMS classification of products.

Pharmacovigilance

The Committee reviewed the PSURs for **Aivlosin**, **Comfortis**, **Incurin**, **Econor**, **Nobilis IB4-91**, **Procox**, **Purevax FeLV**, **Purevax Rabies**, **Recuvyra**, **Respiporc FLU3**, **Vaxxitek** and **Veraflox** and concluded that no further action or changes to their product literature were required.

The Committee adopted the Public bulletin on veterinary pharmacovigilance for 2013 summarising the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMA/781698/2013). 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 suspected adverse reactions reports and safety updates, and provides an overview of the activities and issues addressed during 2013.

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

Concept papers, guidelines and SOPs

Safety

The Committee adopted a draft concept paper on user risk assessment of topically applied products (EMA/CVMP/SWP/529692/2013) for a 3-month period of public consultation. The concept paper proposes the development of guidance to supplement the existing guideline on user safety for pharmaceutical veterinary medicinal products (EMA/CVMP/543/03-Rev.1) which provides general guidance on how user risk assessment should be conducted and reported but does not provide specific guidance on how exposure from topically administered products should be assessed.

Quality

The Committee adopted a joint CHMP/CVMP template and guidance notes for the Qualified Person's declaration concerning GMP compliance of the active substance and verification of its supply chain (EMEA/CHMP/CVMP/QWP/80360/2014) following the close of the public consultation.

The Committee adopted a joint CHMP/CVMP revised guideline on the use of near infrared spectroscopy (NIRS) by the pharmaceutical industry and the data requirements for new submissions and variations (EMEA/CHMP/CVMP/QWP/63700/2014) following the close of the public consultation. The guideline has been updated in line with developments and experience with this analytical technique, regulatory changes, and also to give some clarification on what changes to NIRS procedures would be subject to a variation application and what changes would be subject to GMP only. The guideline has been further amended to take into account comments received during a second round of public consultation.

The Committee adopted a joint CHMP/CVMP concept paper for the establishment of a guideline on the selection of sterilisation processes for drug products (EMA/CHMP/CVMP/QWP/53392/2014) for a 3-month period of public consultation. This concept paper has been developed to address the need for a revision of the guidance on the selection of sterilisation methods currently provided for in the annexes to the (separate) human and veterinary development pharmaceutics guidelines.

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

- Limits for unspecified impurities for active substances used in veterinary medicinal products; and
- The stability of generics versus the innovator product.

The documents above will be available on the Agency's website in due course.

Working Parties

The Committee re-elected Dr. Fredrik Hultén from the Swedish Medical Products Agency as vice-chair of the Efficacy Working Party for a 3-year mandate.

The Committee endorsed the revised work plans for 2014 for the CVMP working parties on efficacy and safety, as well as for the Joint CVMP/CHMP ad hoc expert group on the application of the 3Rs in regulatory testing of medicinal products to update the listing of the on-going/planned work.

The revised work plans will be available on the Agency's website.

Organisational matters

The CVMP meeting was followed by a European Medicines Agency / IFAH-Europe Info Day on 13-14 March 2014 under the theme "The latest developments in scientific review, legislation and marketing authorisation procedures".

Procedural announcements

eSubmission matters

EMA eSubmission Gateway / Web Client

The Agency is pleased to announce that the EMA eSubmission gateway/web client will be extended to all veterinary medicines submissions, including veterinary referrals, from 1 April 2014. This follows requests to make the facility available as soon as possible to the veterinary sector ensuring secure transmission of dossiers.

Submissions on physical media (CD/DVD) (and eudralink for post-authorisation submissions) will continue to be accepted as an alternative method for the time being. It is however essential that applicants only use one method of submission and do not submit duplicate submissions with a physical media (CD/DVD) or eudralink, as these might cause a delay in the processing of the electronic submission.

It should be noted that the use of the gateway/web client does not mean that the applicants can stop sending copies to CVMP members. Dossier requirements for rapporteurs and co-rapporteurs/CVMP remain in place until further notice. The dossier requirements for CVMP members are being updated to take into account those Member States who can accept submission via the Common European Submission Portal (CESP) for applications for the centralised procedure.

A webinar on the use of the gateway/web client for veterinary applications will be held on 24 March 2014 (register here) and will be made available online shortly afterwards.

The EMA Q&A on e-submission will be revised accordingly.

Electronic applications form (eAF)

Updated eAFs for veterinary marketing authorisation applications, variations and renewals have been published on the e-submission website (http://esubmission.ema.europa.eu/eaf/index.html); these updates take into account comments received to improve the use of the forms. The use of these electronic formats is recommended.

The forms have now incorporated controlled terminology, including the facility to choose the active substance from a drop-down reference list. An on-line form to request a new active substance or other term has been published (eAF term request form).

It is hoped that these improvements will facilitate the completion of the forms. Please send any feedback on the use of the forms or queries to eAF@ema.europa.eu.

Revised checking process of mock-ups of outer carton, immediate labelling and package leaflet in the centralised procedure for veterinary medicinal products

The Agency has developed a revised mock-up checking process based on the following general principles:

Before marketing the product and after receipt of opinion/Commission decision:

- There is no requirement to submit mock-ups systematically. Instead, the applicant/marketing authorisation holder (MAH) is responsible to ensure that their packaging is correct from the outset. A mock-up checklist will be available shortly, summarising critical labelling elements and providing guidance to assist applicants in checking their mock-ups.
- The Agency will not routinely perform checks of mock-ups but will instead institute random post-authorisation checks (as per current guideline possibilities). This new approach is to ensure that all mock-ups may be checked, rather than only those specifically submitted for checking.
- It is the responsibility of the applicant/MAH to ensure that their mock-ups and subsequent packaging are in conformity with the adopted opinion and the decision text. The veterinary medicinal product may therefore be marketed once the applicant is satisfied that their packaging is in line with all the requirements. The applicant/MAH does not need to seek confirmation from the Agency that their mock-ups are acceptable.
- Upon receipt of a specific request from the Agency to submit their mock-ups, any applicant should be in a position to provide such mock-ups of the requested packaging and will be asked to deal with any observed issues that could be highlighted during the specific review by the Agency.

The relevant guidance is being revised accordingly.

This new process will be implemented from 1 April 2014.

For any queries on any of these points please do not hesitate to contact vet.applications@ema.europa.eu.

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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