EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 9-11 September 2014

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a marketing authorisation application for **Porcilis PCV M Hyo**, from Intervet International B.V., a vaccine for the active immunisation of pigs against porcine circovirus and Mycoplasma hyopneoumoniae.

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

Equilis Prequenza, from Intervet International B.V., regarding quality changes;

Equilis Prequenza Te, from Intervet International B.V., regarding quality changes;

Equilis StrepE, from Intervet International B.V., regarding quality changes;

Fevaxyn Pentofel, from Zoetis Belgium SA, regarding quality changes;

Hiprabovis IBR Marker Live, from Laboratorios HIPRA S.A., regarding quality changes;

Circovac, Eurican Herpes 205, Ibraxion, Purevax RCCh, Purevax RCPCh, Purevax RCPCh FeLV, Vaxxitek, from MERIAL, regarding quality changes; and

STARTVAC, from Laboratorios HIPRA S.A., regarding quality changes.

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

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Withdrawal of applications

The Committee was informed of the formal notification from **MERIAL** of their decision to withdraw the application for a new marketing authorisation procedure for **Oncept Melanoma**. More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report. The document, together with the withdrawal letter from the applicant, will be published on the Agency's website in due course.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **ZOLVIX**, **Zulvac 8 Bovis** and **Zulvac 8 Ovis**. 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 **Suanovil 20 and associated names, Captalin and associated names, and generic products thereof** (spiramycin). The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC, due to concerns related to efficacy, antimicrobial resistance and withdrawal periods. The Committee adopted by majority an opinion recommending changes to the product information of the concerned products related to the indications, posology and withdrawal periods.

The Committee started a procedure for **veterinary medicinal products containing diclofenac**. The European Commission requested a scientific opinion from the Committee under Article 30(3) of Regulation 726/2004 due to concerns raised relating to the possible risks of toxicity to vultures and other necrophagous birds following exposure to veterinary medicinal products authorised in the Union containing diclofenac. In the context of this procedure the CVMP invites all interested parties such as bird conservation organisations, veterinary practitioners, the pharmaceutical industry, learned societies, governmental institutions and European Union and European Economic Area-European Free Trade Association Member States to respond to a public consultation and to submit any relevant scientific data, which may be used in preparation of the scientific opinion.

More information about the above public consultation will be published on the Agency's website.

Maximum Residue Limits

The Committee agreed to include **isotridecanol ethoxylates** and **vanillin** as new entries 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. 22). This decision followed the Committee's review of the requests 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 six separate scientific advice reports concerning:

- Initial advice on safety and efficacy issues for an antibacterial veterinary medicinal product for cattle;
- Initial advice on safety issues for an immunological product for chickens;
- Initial advice on efficacy issues for an immunological veterinary product for sheep;
- Follow up advice on quality issues for an immunostimulant veterinary medicinal product for cattle and chickens;
- Follow up advice on safety issues for an antiparasitic veterinary medicinal product for dogs;
- Follow up advice on efficacy issues for an anti-inflammatory veterinary medicinal product for dogs.

MUMS/limited market

Following the Committee's review of six requests for classification under the MUMS/limited market policy:

- The CVMP classified two veterinary medicinal products with a musculoskeletal indication in horses as MUMS/limited market but not eligible for financial incentives as they are not intended for food-producing animals.
- The CVMP classified the veterinary medicinal product with a respiratory indication in horses as MUMS/limited market but not eligible for financial incentives as an alternative product is authorised for the same target species for the same indication.
- The CVMP classified the veterinary medicinal product with a nervous system indication in horses as indicated for MUMS/limited market but not eligible for financial incentives as it is not intended for food-producing animals.
- The CVMP classified the veterinary medicinal product with a nervous system indication for dogs as not indicated for MUMS/limited market.
- The CVMP classified the veterinary medicinal product with an oncology indication for dogs as indicated for MUMS/limited market but not eligible for financial incentives as it is not intended for a food producing species.
- The Committee adopted a draft guidance document on the classification of veterinary medicinal products indicated for MUMS/limited market (EMA/CVMP/388694/2014). This document gives guidance for implementing the updated policy (EMA/308411/2014) which states the objectives of the MUMS/limited market policy. The guidance describes the procedure and the steps to be followed by the applicant and the Agency when dealing with a request for classification and updates the previous guidance given in document EMA/429080/2009-Rev.1. The guidance document has been endorsed by CVMP for a 6 week period of public consultation via the Agency website.

Pharmacovigilance

The Committee reviewed the PSURs for **Flexicam**, **Meloxoral**, **Porcilis AR-T DF**, **Suvaxyn PCV** and **ZOLVIX**, and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Activyl Tick Plus**, and recommended amendments to the product information to add new adverse reactions.

Concept papers, guidelines and SOPs

Safety

The Committee adopted a draft guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (EMA/CHMP/CVMP/SWP/169430/2012), following the close of the public consultation and the workshop with stakeholders held on 30 September 2013. The guideline describes a toxicological approach to be used as part of the process of determining whether or not active substances and medicinal products need to be manufactured in dedicated facilities, and has been amended following comments received during the public consultation.

The guideline will be reviewed by the Agency's Guidelines Consistency Group and discussed at the GMP/GDP Inspectors Working Group before being published on the Agency's website.

Joint CVMP/CHMP AHEG on the application of the 3Rs (Replacement, Reduction, Refinement of animal testing) in regulatory testing of medicinal products

The Committee adopted a draft guideline on regulatory acceptance of 3Rs testing approaches (EMA/CHMP/CVMP/JEG-3/Rs/450091/2012) for a 6-month period of public consultation. The guideline describes the process for submission and evaluation of a proposal for regulatory acceptance of 3Rs testing approaches for use in the development and quality control of human and veterinary medicinal products.

The guideline will be published on the Agency's website after their adoption by CHMP.

Organisational matters

The Committee finalised the preparation of the Informal CVMP and Joint CVMP/CMDv meetings to be held under the Italian Presidency of the EU, on 22-23 September 2014. The discussions will focus on:

- Availability of medicines: fish diseases, emergency animal diseases
- Future of pharmacovigilance
- Multinational assessment teams
- National guidelines on blood products
- Alternatives to antimicrobials
- Revised veterinary legislation

Procedural announcement

Changes in fee processing for type IA variations as of 1 January 2015

Background

The European Medicines Agency has been conducting a systematic review of its processes and procedures since 2013. To date, this review has focused predominantly on procedures related to human medicinal products. Now that the implementation plan for human products is well under way, the Veterinary Division has started to review the procedures related to veterinary medicine to identify where best practice now in place in the human domain can be applied directly, or adapted, to the veterinary domain. The first procedures to be optimised relate to the initiation of financial transactions

for variations. The objective of the exercise is to streamline procedures by ensuring that each application is processed only once. As of 1 June 2011, fees for type IA variations formally became due at the start of the 30-day procedure but, to date, this requirement has not been strictly applied for veterinary medicines and applicants have generally been provided with the opportunity to rectify deficient applications without charge.

New process

The Agency has been moving towards charging the fee for all type IA variations entirely on the basis of the information provided in the application form as received and irrespective of the final outcome of the procedure.

Applicants are therefore encouraged to ensure that the information contained in the application form is complete and correct. Applications found to be erroneous after the start of the procedure will lead to the rejection of the variation but the fee due will still apply. There is no validation in the case of type IA variations and therefore the procedure starts on the day following receipt by the Agency of the notification from the marketing-authorisation holder.

Please note therefore that the applicable type IA fee will still be charged for applications that are withdrawn after the start of the procedure.

In the case of type IA variations that are grouped with other variations or extensions with a validation step, or are part of worksharing procedures, the Agency will charge the appropriate fee following conclusion of the validation of the application. The current rules for charging of fees will continue to apply. The appropriate fee will be charged for all applications for type IA variations affecting one or multiple products, irrespective of whether all variations are approved or there is a partial or complete negative outcome.

In order to allow applicants to become familiar with this new approach to the existing procedure, the Agency will continue to provide applicants with the opportunity to rectify deficiencies in applications until 31 December 2014. After this time fees will become due following receipt by the Agency of the notification from the applicant.

Similar streamlining will be progressively implemented for all variation procedures that involve a fee to applicants. Applicants will be informed of the timelines for implementation in similar procedural announcements.

New formatted table template to be used in selected veterinary procedural submission cover letters

As announced on the new item published on the EMA website on 23 July 2014, a new formatted table template for use in selected veterinary procedural submission cover letters is available since July 2014. This template can be found on EMA website under: Veterinary regulatory, Pre-authorisation, Application guidance.

The formatted table template is intended to systematically structure and label key information concerning the procedure in a comprehensive summary.

A similar approach has been followed for medicines for human uses since 2011. The experience gained proves that the template improves and streamlines the administrative processes both for the Agency and the applicant.

Applicants are invited to send any questions regarding the procedural amendments to the Agency via the vet.applications@ema.europa.eu mailbox.

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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