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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 13-15 February 2018

CVMP recommends changes to product information for some veterinary medicines containing enrofloxacin, to reduce development of antimicrobial resistance in target pathogens

CVMP opinions on veterinary medicinal products

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

Clevor (*ropinirole*), from Orion Corporation, eye drops, solution in single-dose container, intended for the induction of vomiting in dogs.

More information about the abovementioned medicine, including the full indication, will be published on the Agency's website.

The Committee adopted by consensus a positive opinion for a type II variation application for **Metacam** to add a non-food-producing target species (guinea pigs).

The Committee adopted by consensus a positive opinion for a type II variation application for **STARTVAC** regarding quality changes.

The Committee adopted by consensus a positive opinion for a grouped type II variation application for **ERAVAC** regarding a change to the duration of immunity and safety, as well as associated changes in the product information.

The Committee adopted by consensus a positive opinion for a type II variation application, subject to a worksharing procedure, for **Oncept IL2, Parvoduk, ProteqFlu, Proteq West Nile, ProteqFlu Te, Purevax FeLV, Purevax Rabies, Purevax RC, Purevac RCP, Purevax RCP FeLV, Purevax RCPCh, Purevax RCPCh FeLV** and **Vaxxitek HVT+IBD** concerning quality changes.

The Committee adopted by consensus a positive opinion for a type II variation application, subject to a worksharing procedure, for **Ingelvac CircoFLEX** and **Ingelvac PCV FLEX** concerning quality changes.

The Committee adopted by consensus a positive opinion for a type II variation application, subject to a worksharing procedure, for **Porcilis PCV ID** and **Porcilis M Hyo ID ONCE (also known as Porsilis**

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M Hyo ID ONCE and Porcilis M Hyo ID ONCE vakcina A.U.V.) concerning wording on associated non-mixed use.

The Committee also adopted by consensus a positive opinion for a grouped type IA, IA_{IN} and type II variation application, subject to a worksharing procedure, for **Vaxxitek HVT + IBD** (and related nationally-authorised products) concerning quality changes.

The Committee also adopted by consensus a positive opinion for a type IB variation application, subject to a worksharing procedure, for **Vaxxitek HVT + IBD** (and related nationally-authorised products) concerning quality changes.

Withdrawal of application

The Committee was informed of the formal notification from Parnell Technologies (UK) Limited of their decision to withdraw the application for an initial marketing authorisation for **Zydax**. More information about this application and the current state of the scientific assessment at the time of the withdrawal, 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 a positive opinion for the renewal of the marketing authorisation for **ProZinc**. The Committee, having re-assessed the benefit-risk balance of this product, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the indefinite renewal of the marketing authorisation.

Community referrals and related procedures

The Committee considered the grounds for re-examination of the CVMP opinion for **Girolan and its associated name Apralan** (apramycin sulfate) adopted on 5 October 2017 in the context of a referral procedure initiated under Article 34 of Directive 2001/82/EC. The matter was originally referred to the Committee by Spain due to divergent decisions taken by Member States resulting in differences in the product information. The Committee re-examined the data related to the shelf-life, which had been set at 18 months during the initial referral procedure, and recommended a two-year shelf-life for the products. The Committee agreed a harmonised product information for the concerned products and adopted by majority a final opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly.

The Committee started a procedure for **veterinary medicinal products containing 50 mg closantel per ml presented as solutions for injection for subcutaneous use in sheep**. The matter was referred to the Committee by the United Kingdom under Article 35 of Directive 2001/82/EC. This referral procedure concerns the appropriateness of withdrawal periods (meat and offal) in sheep for the aforementioned veterinary medicinal products containing closantel as a single active substance.

The Committee concluded the follow-up assessment procedure of the conditions on the marketing authorisations for **veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys** that had been applied with Commission Implementing Decision (C(2014) 1484) of 28 February 2014 in the context of a referral procedure under Article 35 of Directive 2001/82/EC for the aforementioned products. As stated in the Commission Implementing Decision (C(2014) 1484), the marketing authorisation holders were asked

to elaborate a dosage regimen aimed at limiting the development of resistance for the target pathogens. Having reviewed the relevant information submitted in 2013 (during the initial phase of the referral procedure) and the additional data provided by the marketing authorisation holders, the Committee considered that the outstanding concern over optimisation of the dosage regimen for the treatment of *E. coli* infections was not resolved. The marketing authorisation holders have not proposed a new dosage regimen or demonstrated that the current dosage regimen is optimised from a clinical perspective, or that based on pharmacokinetic-pharmacodynamic principles, it will limit the emergence of resistant sub-populations. Therefore the Committee considered that the indication for treatment of infections caused by *E. coli* susceptible to enrofloxacin in chickens and turkeys cannot remain in the product information with the currently-approved dose. The Committee adopted by majority a follow up assessment report concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly. The marketing authorisation holders were advised to contact the National Competent Authorities of the Member States as soon as possible in order to discuss the next steps for the implementation of CVMP's recommended changes to the product information.

The Committee concluded the referral procedure for **Seresto and its associated name Foresto** (*imidacloprid* and *flumethrin*) from Bayer Vital GmbH. The matter was referred to the Committee under Article 13 of Commission Regulation (EC) No. 1234/2008 by Germany as the reference Member State in the type II variation procedure due to concerns raised by the United Kingdom relating to a potential serious risk to animal health. The Committee adopted by consensus an opinion concluding that the objections raised by the United Kingdom should not prevent the granting of the variation to the terms of the marketing authorisations, subject to changes in the product information.

Maximum residue limits

The Committee adopted by consensus a positive opinion recommending the extension of maximum residue limits, in accordance with Regulation (EC) No 470/2009, for **paromomycin** to chicken eggs. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the established MRLs for paromomycin in chicken eggs to eggs of other poultry species.

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

The Committee agreed to include **methacrylic acid - ethyl acrylate copolymer** 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. 38). 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.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of a request for reclassification under the MUMS/limited market policy, the CVMP:

- Reclassified a veterinary medicinal product (immunologicals) for ferrets as intended for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as the product is intended for use in non-food-producing species.

Pharmacovigilance

The Committee reviewed the PSURs for **Aivlosin, Bovela, Coliprotec F4**, **Econor, Fortekor Plus, Eravac, Eurican Herpes, Proteq Flu** and **Proteq Flu Te** and concluded that no further action or changes to their product information were required.

The Committee also reviewed the PSURs for **Versican Plus L4, Versican Plus PiL4** and **Versican PiL4R** and recommended amendments to their product information.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a draft guideline on manufacture of the veterinary finished dosage form (EMA/CVMP/QWP/798401/2015) for a 6-month period of public consultation. The guideline, which replaces the veterinary note for guidance on the manufacture of the finished dosage form (EMEA/CVMP/126/95), has been updated to reflect the requirements as laid down in the current legislation (Directive 2001/82/EC and its Annex I). It also addresses current manufacturing practices in terms of complex supply chains and worldwide manufacture.

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

Replacement, Reduction and Refinement of animal testing (3Rs)

The Committee endorsed the Biennial Report 2016 – 2017 of the CVMP/CHMP Working Group on the Application of the 3Rs in Regulatory Testing of Medical Products (J3RsWG). The report is aimed at informing pharmaceutical companies and the public of the EMA activities in relation to "3Rs".

The document above will be published on the Agency's website after its adoption by the CHMP which is foreseen for their February meeting next week.

Notes

1. 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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