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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 14-16 July 2020

CVMP adopts recommendations for the extension of maximum residue limits for lidocaine to porcine and bovine species

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus two positive opinions for two initial marketing authorisations for **Increxxa** from Elanco GmbH and **Tulinovet** from VMD N.V. (*tulathromycin*), two generic products for the treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease and treatment of the early stages of infectious pododermatitis in sheep.

The Committee adopted by consensus a positive opinion for a marketing authorisation for **Mhyosphere PCV ID** from Laboratorios Hipra, S.A, a new vaccine for the active immunisation of pigs against porcine enzootic pneumonia and porcine circovirus type 2 related diseases.

The Committee also adopted by consensus a positive opinion for a marketing authorisation for **Innovax-ND-ILT** from Intervet International B.V., a new vaccine for the active immunisation of one-day-old chicks or embryonated chicken eggs against Newcastle disease, avian infectious laryngotracheitis and Marek's disease.

The Committee adopted by consensus positive opinions for three grouped type II variations applications for **Aivlosin**, **Posatex** and **UpCard** concerning the implementation of quality-related changes. The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Panacur AquaSol** concerning the implementation of quality-related changes.

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

Renewals of marketing authorisations

The Committee adopted by consensus two positive opinions for the renewal of the marketing authorisations for **Imrestor** and **Suvaxyn Circo + MH RTU**. 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 for **injectable veterinary medicinal products containing vitamin A for use in food producing species**. The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC. This referral concerns the appropriateness of the current withdrawal periods (milk, meat and offal) in food producing species for injectable veterinary medicinal products containing vitamin A, as well as the appropriateness of user safety warnings.

The Committee started a procedure for **modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines**. The matter was referred to the Committee by the European Commission under Article 35 of Directive 2001/82/EC. This referral concerns potential risk management measures that could protect animal health and limit the risk of recombination between PRRS viruses, including PRRS vaccine strains.

The Committee concluded the referral procedure for **Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof**. The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC due to concerns relating to the appropriateness of the withdrawal periods in pigs. The Committee agreed that the withdrawal periods for meat and offal derived from treated pigs should be amended to ensure consumer safety. The Committee also recommended a maximum injection volume per injection site. The Committee adopted by consensus an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly.

The Committee concluded the referral procedure for **Betamox LA 150 mg/ml suspension for injection and associated names, and generics products thereof**. The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC due to concerns relating to the appropriateness of the withdrawal periods in cattle, sheep and pigs. The Committee agreed that the withdrawal periods for milk, meat and offal derived from treated cattle and for meat and offal derived from treated sheep and pigs should be amended to ensure consumer safety. The Committee also recommended maximum injection volumes per injection site for cattle, sheep and pigs. The Committee adopted by consensus an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly.

Maximum residue limits

The Committee adopted by consensus two positive opinions recommending the extension of maximum residue limits (no MRL required) for **lidocaine** to porcine and the establishment of numerical MRLs for bovine species. Lidocaine is currently included in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 with a 'No MRL required' entry for equine species.

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

Scientific advice

The Committee adopted two scientific advice reports further to requests for:

- initial advice on quality, safety and efficacy issues for a new veterinary medicinal product for musculoskeletal disorder indication in dogs;
- follow-up advice on efficacy issues for a product for cats.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of a request for re-examination of a classification under the MUMS/limited market policy, the CVMP did not classify a product (ATCvet classification: antineoplastic and immunomodulating agents) as indicated for MUMS/limited market and the product was not therefore eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl Tick Plus**, **Cardalis** and **Onsior**, and concluded that changes to their product information were required. The Committee also reviewed the PSURs for **Equilis Prequenza**, **Equilis Prequenza Te**, **Eravac**, **Exzolt**, **Innovax ND IBD**, **Sedadex**, **Suvaxyn Circo**, **Suvaxyn PRRS MLV** and **UpCard**, and concluded that no further action or changes to their product information were required.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted an update to questions and answers on adverse event reporting (EMA/CVMP/PhVWP/145186/2013 – Rev. 4).

Novel therapies

The Committee adopted questions and answers (EMA/CVMP/ADVENT/791717/2016) on evaluation of target animal safety for stem cell products for veterinary use.

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

Working parties

The Committee re-elected Esther Werner as chair of the CVMP Immunologicals Working Party for a 3-year mandate and appointed a new panel of members under the revised mandate, objectives and rules of procedure for the CVMP Immunologicals Working Party (EMA/CVMP/IWP/208689/2004).

Regulation (EU) 2019/6

Further to the request from the European Commission related to implementing measures under Article 106(6) of Regulation (EU) 2019/6, the Committee adopted a scientific problem analysis and recommendations to ensure a safe and efficient oral administration of veterinary medicinal products via routes other than medicated feed. The document will be sent to the European Commission and published on the Agency's website in due course.

The Committee adopted a draft concept paper on criteria for the application of Article 40(5) of Regulation (EU) 2019/6 (EMA/CVMP/340959/2020) for a two-month period of public consultation. Article 40(5) provides for additional periods of protection for part of the technical documentation under specific conditions. The aim of the concept paper is to gain stakeholder input in order to develop a reflection paper which will consider the state of knowledge in the fields defined by the legal provision, for example criteria concerning reduction of antimicrobial and antiparasitic resistance, and. types of product development that could meet the criterion of improving the benefit-risk balance of the veterinary medicinal product.

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

Procedural Announcement

The EMA's pre-submission guidance for veterinary medicinal products has been updated with a new question and answer concerning information to be provided with the marketing authorisation application regarding GMP compliance. From 1 August 2020 applicants for veterinary medicinal products are requested to provide a declaration in the cover letter of their marketing authorisation applications stating that the information related to Good Manufacturing Practice is correct and is consistent throughout the dossier. For further details see Question and answer no. 40 published on the Agency's website.

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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