EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 16-18 June 2020

CVMP adopts a draft strategy on antimicrobials 2021-2025

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a grouped type II variation application for **Bluevac BTV8** to add the strains BTV1 and BTV4 into the vaccine.

The Committee adopted by consensus a positive opinion for a type IB variation application for **Stronghold Plus** and **Felisecto Plus** (*selamectin/sarolaner*) to correct the translations of product information.

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 positive opinions for the renewal of the marketing authorisations for **Simparica** and **Zycortal**. 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 **Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection and associated names, and generic products thereof**. The matter was referred to the Committee by France under Article 35 of Directive 2001/82/EC due to concerns relating to the appropriateness of the withdrawal periods in cattle. The Committee agreed that the withdrawal periods for cattle meat and offal should be amended to provide assurance for consumer safety. 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.

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The Committee adopted by majority a corrigendum of the opinion adopted on 20 May 2020 on the procedure under Article 45 of Regulation (EC) No. 726/2004 for **Suvaxyn PRRS MLV** from Zoetis Belgium SA. In the corrected opinion, a sentence was reinstated in the product information.

Maximum residue limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **bupivacaine** in bovine.

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

The Committee agreed to include **natural crystalline graphite** 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. 44). 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 classification under the MUMS/limited market policy, the CVMP classified a product (immunological) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as it is intended for use in non-food producing species.

The Committee also reclassified a product (systemic hormonal preparation) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, when applicable. The product is not eligible for financial incentives in line with the Guidance on the classification of veterinary medicinal products indicated for minor use minor species MUMS/limited market (EMA/CVMP/388694/2014) as according to the MUMS policy, products for horses are generally not eligible for fee incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Purevax FeLV** and **Vectra 3D,** and recommended amendments to the product information. The Committee also reviewed the PSURs for **Comfortis**, **Credelio**, **Innovax ILT**, **Masivet**, **Melovem**, **Nasym**, **Osurnia**, **ProZinc**, **Sileo**, **Ubac** and **Zactran**, and concluded that no further action or changes to their product information were required.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a new guideline on water for pharmaceutical use (EMA/CHMP/CVMP/QWP/496873/2018), further to its adoption by CHMP at their May 2020 meeting. It replaces the Note for guidance on quality of water for pharmaceutical use (EMEA/CVMP/115/01). This guideline takes into account comments received during public consultation and addresses changes in some European Pharmacopoeia monographs (water for injections – revised, water for preparation of extracts – new, water highly purified – deleted) as well as current expectations for the minimum acceptable quality of water used in the manufacture of active substances and medicinal products for human and veterinary use.

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

Antimicrobials

The Committee adopted the draft CVMP strategy on antimicrobials 2021-2025 (EMA/CVMP/179874/2020) for a 3-month period of public consultation. In the context of this strategy, the focus of the CVMP's activities regarding antimicrobials over the next five years will be on supporting the effective implementation of those provisions in the Regulation (EU) 2019/6 that take forward the EU's One Health Action Plan against antimicrobial resistance (AMR). Proposed actions address measures embedding the responsible use of antimicrobials in veterinary medicine, the protection of public and animal health from the risk of AMR and support to the development of new antimicrobials and their alternatives.

Immunologicals

The Committee adopted questions and answers on management of extraneous agents in immunological veterinary medicinal products (EMA/CVMP/IWP/669993/2019).

The Committee adopted a revised mandate, objectives and rules of procedure for the CVMP Immunologicals Working Party (EMA/CVMP/IWP/208689/2004).

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

Regulatory

Further to the request from the European Commission, the Committee adopted scientific recommendations for implementing measures under Article 57(4) of Regulation (EU) 2019/6 on veterinary medicinal products regarding the format of the data to be collected on antimicrobial medicinal products used in animals.

The documents will be sent to the European Commission and published on the Agency's website in due course.

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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