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 21-23 January 2020

First meeting of CVMP at the permanent office of EMA in Amsterdam

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a type II variation application for **Innovax-ND-IBD** to add a new indication for mixed use with Nobilis Rismavac for the subcutaneous route of administration. The Committee also adopted by consensus a positive opinion for a type II variation application for **Rabitec** to extend the duration of immunity from 6 to 12 months.

The Committee also adopted by consensus positive opinions for a type II variation application for **Bravecto** and for a grouped type II variation application for **Clevor**, both concerning quality-related changes.

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

Maximum residue limits

The Committee agreed to include **steel shot** 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 substances that act by purely physical mechanisms and adopted a revised list (EMA/CVMP/519714/2009-Rev. 42). 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.

[1] Added paragraph on maximum residue limits

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Scientific advice

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

- Initial advice on quality and efficacy issues for a new veterinary medicinal product for musculoskeletal disorder indication in dogs;
- Initial advice on efficacy issues for a new antimicrobial veterinary medicinal product for cattle.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of two requests for classification under the MUMS/limited market policy, the CVMP classified:

- A product (musculo-skeletal system) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where 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/limited market (EMA/CVMP/388694/2014), which considers products for horses as generally not eligible.
- A product (blood and blood forming organs) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where 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/limited market (EMA/CVMP/388694/2014), which considers products for horses as generally not eligible.

Pharmacovigilance

The Committee reviewed the PSURs for **Advocate**, **Credelio**, **Metacam** and **Novem**, and recommended amendments to the product information.

The Committee reviewed the PSURs for **Activyl**, **Clomicalm**, **Evant**, **Loxicom**, **Neocolipor**, **Oxybee**, **Semintra**, **Startvac**, **Suvaxyn Circo**, **Syvazul BTV**, **Vepured**, **Versican Plus DHPPI L4** and **Zulvac SBV**, and concluded that no further action or changes to their product information were required.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a reflection paper on risk management requirements for elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/153641/2018) following the close of the public consultation. This reflection paper was developed to provide industry with guidance on the requirements to control elemental impurities in veterinary medicinal products, as a result of updates in two European Pharmacopoeia monographs. The Committee also adopted a revised version of the document addressing the implementation of risk assessment requirements to control elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/631010/2017-Rev.2).

The reflection paper together with the overview of comments (EMA/CVMP/QWP/434956/2019) as well as the revised document addressing implementation of the reflection paper will be published on the Agency's website.

Environmental Risk Assessment

The Committee adopted questions and answers in support of the guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products (EMA/CVMP/ERA/52740/2012).

Procedural Announcement

The EMA's post-authorisation guidance on editorial changes submitted within Type IA, IB and II variations has been updated and re-published as follows:

- Type IA variations, Q&A no. 15
- Type IB variations, Q&A no. 13
- Type II variations, Q&A no. 17

The equivalent questions and answer in the EMA post-authorisation guidance for human medicinal products was also updated and the revised human and vet content was presented at the joint CMDh/CMDv working party on variations. The updates clarify procedural aspects of submitting editorial changes in the different types of variation applications.

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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