14 July 2017
EMA/CVMP/411265/2017
Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 11-13 July 2017

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for type IB variation applications (subject to a worksharing procedure) for **ZULVAC 1+8 Ovis**, **ZULVAC 1+8 Bovis** and **ZULVAC 1 Bovis**, and for **ZULVAC 8 Bovis** and **ZULVAC 8 Ovis**, both concerning quality changes.

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

Community referrals and related procedures

The Committee concluded the referral procedure for **Lincocin and its associated names** (lincomycin hydrochloride) from Zoetis. The matter was referred to the Committee by the European Commission, under Article 34 of Directive 2001/82/EC, due to divergent decisions taken by Member States resulting in differences in the product information. The Committee agreed a harmonised product information for the concerned products, and 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 **Zanil and associated names, and generic products thereof** (oxyclozanide). The matter was referred to the Committee by France, under Article 35 of Directive 2001/82/EC, due to concerns related to the withdrawal periods in cattle, sheep and goats. The Committee agreed that the withdrawal periods (milk, meat and offal) for cattle, sheep and goats 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.

Scientific advice

The Committee adopted a scientific advice report further to a request for follow up advice on quality issues for a veterinary medicinal product with a musculoskeletal disease indication for horses.

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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 veterinary medicinal product with an anti-infective indication for turkeys, guinea fowls, ducks, quails, pheasants and partridges as indicated for MUMS/limited market and eligible for reduced data requirements. No financial incentives will apply as authorised products already exist in the EU for the indication.
- A veterinary medicinal product with a nervous system indication for sheep as indicated for MUMS/limited market and eligible for reduced data requirements. No financial incentives will apply as authorised products already exist in the EU for the indication.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl Tick Plus**, **Equilis StrepE**, **Equisolon**, **Nobilis IB 4-91**, **Nobilis IB Primo QX**, **Masivet**, **Osurnia**, **Vectormune ND**, **ZULVAC 1 Bovis**, **ZULVAC 1 Ovis** and **ZULVAC SBV** and concluded that no further action or changes to their product information were required. The Committee also concluded the assessment of the targeted PSUR for **Bravecto** and recommended amendments to its product information.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a reflection paper on the dissolution specification for generic solid oral immediate release products with systemic action (EMA/CHMP/CVMP/QWP/336031/2017), following the close of the public consultation. The reflection paper has been developed to address the suitability of the dissolution method and the specifications for *in vitro* dissolution of orally administered generic drug products with immediate release characteristics, and was amended to take into account comments received during its public consultation.

The reflection paper together with the overview of comments (EMA/CHMP/CVMP/QWP/257305/2017) will be published on the Agency's website.

The Committee adopted a reflection paper on the chemical structure and properties criteria to be considered for the evaluation of new active substance (NAS) status of chemical substances in marketing authorisation applications for veterinary medicinal products (EMA/CVMP/QWP/3629/2016), following the close of the public consultation. The reflection paper has been developed to provide clarifications to applicants on the elements that need to be substantiated in relation to a claim of considering an active substance as NAS.

The reflection paper together with the overview of comments (EMA/CVMP/QWP/112656/2017) will be published on the Agency's website.

The Committee adopted a questions and answers document on the following quality topic:

- Elemental impurities in veterinary medicinal products.

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

Antimicrobials

The Committee adopted a draft reflection paper on off-label use of antimicrobials in veterinary medicines (EMA/CVMP/AWP/237294/2017) for a 6-month period of public consultation. The reflection paper explores the off-label use of antimicrobials in animals providing examples, and the underlying reasons for these practices and the potential implications for animal and human health. The document addresses off-label antimicrobial use in companion animals and food-producing animals.

The Committee adopted a draft reflection paper on the use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/AWP/721118/2014) for a 3-month period of public consultation. The reflection paper critically reviews the current knowledge on the usage of aminoglycosides, resistance development and the potential impact of this resistance on animal and human health, and provides a risk profiling of aminoglycosides to enable them to be placed within the AMEG's (Antimicrobial Advice Ad Hoc Expert Group) categorisation.

The reflection papers will be published on the Agency's website.

Pharmacovigilance

The Committee adopted a revised reflection paper on promotion of pharmacovigilance reporting (EMA/CVMP/PhVWP/390033/2014-Rev.1). The reflection paper was revised to further examine issues that may be important to the pharmacovigilance promotion strategy within the regulatory network, particularly concerning food-producing animals where under-reporting of adverse events is of particular concern.

The reflection paper will be published on the Agency's website.

Novel therapies

The Committee adopted questions and answers on the following topic:

Questions and answers on allogenic stem cell-based products for veterinary use: Specific questions on extraneous agents (EMA/CVMP/ADVENT/803494/2016).

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

Working parties

The Committee endorsed the election, by the CHMP at their June 2017 meeting, of Keith Pugh as the chairperson of the Joint CHMP/CVMP Quality Working Party for a 3 year mandate.

The Committee reviewed and adopted the mandate for the CVMP Scientific Advice Working Party (SAWP-V) (EMA/CVMP/SAWP/300813/2017) for a period of 3 years.

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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