22 January 2016
EMA/CVMP/11490/2016
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 19-21 January 2016

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for type II variation applications for **Nobilis IB4-91** and **Panacur AquaSol** regarding quality changes.

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Zuprevo**. 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 renewal of the marketing authorisation.

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

Community referrals and related procedures

The Committee started a procedure for **all veterinary medicinal products containing gentamicin presented as solutions for injection for cattle and pigs**. The matter was referred to the Committee by Belgium under Article 35 of Directive 2001/82/EC due to concerns related to the withdrawal periods set for the aforementioned products.

Scientific advice

The Committee adopted three separate scientific advice reports concerning:

- Initial advice on quality issues for an immunological product for cats;
- Initial advice on efficacy issues for an immunological product for cattle and pigs; and
- Follow up advice on efficacy issues for a hormonal product for pigs.

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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 for a haematopoietic condition as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in a non-food-producing species (cats).
- An oncology veterinary medicinal product as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in a non-food-producing species (dogs).

The Committee adopted four draft revised guidelines on data requirements for veterinary medicinal products intended for MUMS/limited market for a six-month period of public consultation. After almost 10 years in use it is considered necessary to review these guidelines, to ensure that the current guidance is in line with experience gained and best practice in terms of setting appropriate data requirements for this type of product.

Quality (EMA/CVMP/QWP/128710/2004 – Rev.1)

Safety (EMA/CVMP/SWP/66781/2005 – Rev.1)

Efficacy (EMA/CVMP/EWP/117899/2004 – Rev.1)

Immunologicals (EMA/CVMP/IWP/123243/2006 – Rev.3).

The documents will be published on the Agency's website.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl**, **Bovilis BTV8**, **Bravecto**, **Econor**, **Ingelvac CircoFLEX**, **NexGard**, **Nobilis IB4-91**, **Nobilis IB Primo QX**, **Semintra** and **ZULVAC SBV** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSURs for **Kexxtone**, **Nobivac L4**, **Profender** and **Zolvix** and recommended amendments to their product literature.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a draft concept paper (EMA/CVMP/11490/2016) for the revision on the guideline for the conduct of pharmacokinetic studies in target animal species (EMEA/CVMP/133/99-Final) for a three-month period of public consultation. The concept paper proposes that the guideline is revised in order to consider the scientific developments over the years (e.g. population kinetics, pharmacokinetic/pharmacodynamic (pk/pd) modelling), and also recent considerations on best practice for the implementation of 3Rs (replacement, reduction, refinement).

Efficacy and Antimicrobials

The Committee adopted a revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/627/01-Rev.1) following the close of the public consultation. The revised guideline together with the overview of comments (EMA/CVMP/EWP/374087/2015) received during public consultation provides more detailed information on the design and conduct of pre-clinical and clinical studies to support clinical efficacy of an antimicrobial veterinary medicinal product, and also includes new considerations on claims for metaphylactic or prophylactic treatment.

The documents will be published on the Agency's website.

Notes

1. 'MUMS' stands for minor use minor species.
2. 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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