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Press Office

**Press release**

# Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 7 - 9 February 2012

## CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for type II variation applications for:

**Masivet** (masitinib mesylate) to register an alternative active substance manufacturer,

**Masivet** (masitinib mesylate) to extend the shelf-life and change the storage conditions of the finished product.

**MS-H Vaccine** (*Mycoplasma synoviae* strain MS-H live attenuated thermosensitive) to add an alternative supplier of packaging material and a minor modification to a test method

**Nobilis IB4-91** (Live attenuated avian Infectious Bronchitis Virus (IBV) variant strain 4-91, to include vaccination at day old for layers and breeders.

**Purevax Rabies** (Rabies recombinant canarypox virus (vCP65)) to extend the duration of immunity afforded by the vaccine and the vaccination scheme.

## Annual reassessment of marketing authorisations

The Committee adopted by consensus positive opinions on the annual reassessments for the two bluetongue virus vaccines authorised under exceptional circumstances **BTVPUR AlSap 1** and **BTVPUR AlSap 1-8** further to the evaluation of the data submitted by the marketing authorisation holder in accordance with the conditions for the marketing authorisations. The Committee recommended the

[1] The update concerns the paragraph on Scientific Advice.

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continuation of the Community marketing authorisations under exceptional circumstances for these veterinary medicinal products.

## Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Slentrol**. 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 indefinite renewal of the marketing authorisations.

## Community referrals and related procedures

The Committee concluded the procedure for **Prontax 10mg/ml solution for injection for cattle, sheep and pigs** and associated names (doramectin) from Pfizer Limited. The matter was referred to the CVMP by Ireland as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by the Netherlands and France, relating to the environmental risk assessment, and due to concerns raised by the Netherlands, relating to the withdrawal period in cattle. The Committee adopted by majority an opinion concluding that the objections raised by the Netherlands and France should not prevent the granting of a marketing authorisation subject changes in the product information recommending risk mitigation measures and a withdrawal period of 70 days for cattle.

The Committee concluded the procedure for **Prontax 5mg/ml pour-on solution for cattle** and associated names (doramectin) from Pfizer Limited. The matter was referred to the CVMP by Ireland as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by the Netherlands and France, relating to the environmental risk assessment. The Committee adopted by consensus an opinion concluding that the objections raised by the Netherlands and France should not prevent the granting of a marketing authorisation subject changes in the product information recommending risk mitigation measures.

## Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits (MRLs) for **sodium salicylate** in turkeys. This recommendation follows resolution of the outstanding issues identified by the Committee in its opinion recommending the establishment of provisional MRLs.

More information about the above recommendation for establishment of MRLs, can be found on the Agency's website.

The Committee adopted a revised list of substances considered as not falling within the scope of Regulation (EC) 470/2009 (EMA/CVMP/519714/2009), in order to include acetone under the heading of excipients.

More information about the above recommendation can be found on the Agency's website.

## Scientific advice

The Committee agreed three separate scientific advice reports; on clinical development of an antimicrobial for rabbits; on safety and clinical development of a cardiovascular product for dogs; and follow-up scientific advice concerning the safety and clinical development of an ophthalmic product for dogs.

# Pharmacovigilance

The Committee reviewed the PSURs for **Bluevac BTV8**, **BTVPUR AlSap 8**, **Cimalgex**, **Slentrol** and **Zulvac 1+8 Ovis** and concluded that no further action or changes to their product literature were required.

The Committee adopted the Public bulletin on veterinary pharmacovigilance for 2011 summarising the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMA/CVMP/PhVWP/987984/2011). Annual public bulletins on veterinary pharmacovigilance are published by the Agency with the intention to improve communication to all stakeholders, but particularly to veterinary health professionals, on the surveillance of the safety of veterinary medicines in the EU. The bulletin includes descriptive statistics on suspected adverse reactions reports and safety updates, and provides an overview of the activities and issues addressed during 2011.

The document above will be available on the Agency's website.

# Concept papers, guidelines and SOPs

### Safety

The Committee adopted a draft Concept paper introducing a review and update of existing EU guidelines on residues studies to bring these into line with the VICH metabolism and residues guidelines VICH 46-49 (EMA/CVMP/SWP/878228/2011) for release for a 3-month consultation. The concept paper was developed to review and update EU residues guidance to bring these into line with the new VICH metabolism and residues kinetics guidelines (GL46-49) and to develop a reference document that directs applicants and assessors to the most relevant residues guidelines.

The document above will be available on the Agency's website.

### Pharmacovigilance

The Committee adopted a revised Reflection paper on risk management plans for centrally authorised veterinary medicinal products (EMA/CVMP/126726/2007-Rev.1) following the close of the public consultation. This Reflection paper has been developed to evaluate the effect and value of the recommendations concerning risk management systems. The Committee considered that further guidance regarding risk management plans for centrally authorised veterinary medicines is not required at the current time. The comments received during the consultation procedure have been taken into account for the finalisation of the reflection paper.

The reflection paper together with the overview of comments (EMA/CVMP/697961/2011) will be available on the Agency's website.

### Other

The Committee endorsed a revised list of target species (EMA/899273/2011), which is a comprehensive and standardised list of all target species terms being in use by the EU regulatory community. The use of the standard terms is promoted to allow for easy exchange and analysis of the information in the different EU telematics systems.

The document above will be available on the Agency's website.

PROCEDURAL ANNOUNCEMENT

To further streamline procedures, the Agency is discontinuing the sending of paper copies of opinions to applicants and marketing authorisation holders after adoption of opinions and after conclusion of other procedures. Electronic copies will continue to be sent as normal.

## 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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