



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 12-14 June 2012

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an extension of the existing marketing authorisation for:

Inflacam (*meloxicam*), from Chanelle Pharmaceuticals Manufacturing Limited concerning the addition of a new strength 5 mg/ml solution for injection for dogs and cats. This product is a duplicate of Rheumocam 5mg/ml solution for injection; and

Dexdomitor (*dexmedetomidine*), from Orion Corporation concerning the addition of a new strength of 0.1 mg/ml *dexmedetomidine hydrochloride*.

More information about the above mentioned medicines, including their full indications, can be found on the Agency's website.

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

Fevaxyn Pentofel, regarding the replacement of a reference vaccine batch in an immunological test method,

Gripovac 3, regarding the manufacturing process of the active substance, and

RESPIPORC FLU3, regarding the manufacturing process of the active substance.

The Committee adopted by consensus a positive opinion for a type II variation application subject to a worksharing procedure for:

Ingelvac CircoFLEX, regarding the amendment to the product information of Ingelvac CircoFLEX and Ingelvac MycoFLEX to reflect the mixing instructions with regard to simultaneous use based on the 'headspace' concept, and



ZULVAC 1 Ovis, ZULVAC 8 Ovis, ZULVAC 1+8 Ovis, regarding the change to the dimensions of stoppers.

Renewals of marketing authorisation

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

Community referrals and related procedures

The Committee concluded the referral procedure for **Nuflor 300 mg/ml solution for injection for cattle and sheep** (*florfenicol*) from Intervet International BV. The matter was referred to the Committee 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 Denmark relating to the efficacy of the product in sheep. The Committee adopted by consensus an opinion concluding that the objections raised by Denmark during the decentralised procedure should not prevent the granting of a marketing authorisation subject to changes in the product information recommending clarifications regarding the treatment dose and treatment interval for sheep.

The Committee concluded the referral procedure for **Nuflor Swine Once 450 mg/ml solution for injection** (*florfenicol*) from Intervet International BV. The matter was referred to the Committee by Germany as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by Denmark relating to the efficacy of the product. The Committee adopted by majority an opinion concluding that the objections raised by Denmark during the decentralised procedure should not prevent the granting of a marketing authorisation subject to a condition on the marketing authorisations.

The Committee concluded the referral procedure for **Baytril 10% oral solution and associated names** (*enrofloxacin*) from Bayer Animal Health GmbH. The matter was referred to the Committee by the United Kingdom under Article 34 of Directive 2001/82/EC, due to divergent decisions taken by Member States resulting in discrepancies in the product information. The Committee agreed harmonised product information for the concerned products and adopted by majority an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly and subject to a condition on the marketing authorisations concerning the target species rabbits.

The Committee considered the grounds for re-examination of the CVMP opinion for **all veterinary medicinal products containing active substances belonging to the class of flukicides for which no MRL has been established in milk and which are intended for use in ruminants producing milk for human consumption** adopted on 8 March 2012 in the context of a referral procedure initiated under Article 35 of Directive 2001/82/EC. The Committee concluded that the recommendations included in their previous opinion should be maintained.

The matter was referred to the Committee by the European Commission under Article 35 of Directive 2001/82/EC in order to consider appropriate measures to ensure that use of the concerned products during the non-lactating period would not lead to such residues in milk that would result in consumer exposure exceeding the acceptable daily intake (ADI) for all residues of the substances concerned.

The Committee concluded that the benefit-risk balance is positive for the products containing clorsulon, closantel, nitroxinil, rafoxanide or triclabendazole as a single active substance, and for the veterinary

medicinal products administered as pour-on to cattle, containing triclabendazole and moxidectin, subject to adequate advice concerning the use in dairy cattle in the product information.

The Committee adopted by consensus a final opinion recommending changes to the product information and variations to the terms of the marketing authorisations for all veterinary medicinal products containing clorsulon, closantel, nitroxinil, rafoxanide or triclabendazole as a single active substance, and for the veterinary medicinal products administered as pour-on to cattle, containing triclabendazole and moxidectin, which are subject to the referral. As the scope of the referral was restricted to the evaluation of flukicidal substances, the second active, non-flukicidal, substance contained in combination products was not assessed. Therefore, no conclusion could be drawn on the need for instructions to be included in the product information of combination products, with the exception of products for which the conclusion on the flukicidal substance is that it cannot be used in dairy animals at any time.

Maximum Residue Limits

Further to a request for re-examination of the CVMP opinion, the Committee adopted by consensus a final opinion for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 for **prednisolone** in horses with a revised recommendation for the maximum residue limit in fat.

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

Scientific advice

The Committee agreed four separate scientific advice requests concerning: quality, safety and efficacy requirements for an oncology veterinary medicinal product for dogs; safety and efficacy requirements for a diuretic veterinary medicinal product for dogs; quality, safety and efficacy requirements for a dermatology product for dogs; and efficacy requirements for an ectoparasiticide for dogs and cats.

MUMS / Limited markets

Following the Committee's review of two requests for classification under the MUMS/ Limited markets policy, which concerned one product with an indication for analgesia in horses and a separate immunological product for sheep and goats;

- the CVMP considered that the product for horses was indicated for MUMS but was not eligible for financial incentives as an alternative authorised product for the same indication already exists.
- the CVMP considered that the immunological product was indicated for MUMS/Limited market and was eligible for reduced financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Cimalgex, Circovac, Gripovac 3, Melosus, Melovem, Onsiar, RESPIPORC FLU3, Rheumocam, Ypozane, ZACTRAN, ZULVAC 8 Bovis, ZULVAC 8 Ovis** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a revised Guideline on the active substance master file procedure (EMA/CVMP/134/02-Rev.3 /CHMP/QWP/277/02-Rev.3) following the close of the public consultation. The guideline has been further revised to introduce the concepts of a unique version of an ASMF for one active substance valid for the whole EU/EEA, and consequently one assessment report for it recognised by all EU Competent Authorities, and support the ASMF Working Group in their initiatives to improve the ASMF procedure across the European Regulatory Network.

The Committee adopted a new Guideline on setting specifications for related impurities in antibiotics (EMA/CHMP/CVMP/QWP/199250/2009) following the close of the public consultation. The guideline has been developed to provide guidance on how specifications for related substances in antibiotics, which are fermentation products or semi-synthetic substances derived from fermentation products, should be set and has been amended to take into account comments received during public consultation.

The documents above will be available on the Agency's website after their adoption by the CHMP (foreseen for their June 2012 meeting).

Immunologicals

The Committee adopted a revised new Guideline on requirements for the production and control of immunological veterinary medicinal products (EMA/CVMP/IWP/206555/2010) following the close of the public consultation and initial adoption of the guideline in April 2012. This guideline provides information on items to be considered for the production and control of all immunological veterinary medicinal products (IVMPs). The guideline outlines important items related to the quality, safety and efficacy parts of the marketing authorisation dossier that are not clearly defined in the requirements of Annex I to Directive 2001/82/EC and the European Pharmacopoeia.

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

Pharmacovigilance

The Committee adopted the following standard list used for electronic reporting of suspected adverse reactions following the yearly review and update:

- CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009-Rev.4)

The Committee adopted the revised guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007-Rev.5) and a revised call for comments on standard lists for EudraVigilance Veterinary (EMA/123352/2004-Rev.6)

The implementation of the standard list in EudraVigilance Veterinary is provisionally scheduled for 1 October 2012.

The documents above will be available 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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