EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 9-11 November 2010

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a marketing authorisation application for **Hiprabovis IBR Marker Live** (a live vaccine against infectious bovine rhinotracheitis (IBR)) from Laboratorios Hipra S.A. for the active immunisation of cattle to prevent clinical signs of IBR and to reduce field virus excretion.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Rheumocam** (meloxicam), from Chanelle Pharmaceuticals Manufacturing Limited to include a 15 mg/ml oral suspension for horses.

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

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

Improvac (gonadotropin releasing factor (GnRF) analogue-protein conjugate) – addition of a behavioural claim and a warning on anaphylactoid-like reactions in the product information;

Metacam (meloxicam) – change of the composition of the finished product, change in qualitative composition of the immediate packaging and change outside the range of the currently approved pack sizes of the finished product;

Netvax (vaccine for necrotic enteritis in chickens) **-** change in the manufacturing process of the finished product and change to in-process tests applied during the manufacture of the finished product deleting a redundant final product test (sterility);

Netvax (vaccine for necrotic enteritis in chickens) **-** change to in-process tests applied during the manufacture of the active substance to revise the upper inactivation limit for the production of *C. perfringens* type A toxoid.

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Community referrals and related procedures

The Committee started a referral procedure for **Baytril 10% oral solution and associated names** (enrofloxacin) from Bayer Plc with the objective to harmonise the summary of product characteristics for this product in those Member States where it is authorised. The matter was notified to the Committee by the United Kingdom under Article 34 of Directive 2001/82/EC, due to divergent decisions concerning the marketing authorisations of the product resulting in discrepancies between Member States in the summaries of product characteristics with respect to e.g. target species, indications, posology and withdrawal periods.

Maximum Residue Limits

The Committee also adopted a positive opinion recommending the establishment of provisional maximum residue limits for **triclabendazole** in milk of all ruminants. The opinion follows the assessment of a request from the Irish Medicines Board to the European Medicines Agency under Article 9.1b of Regulation (EC) No. 470/2009 concerning the establishment of maximum residues limits for substances intended for use under Article 11 of Directive 2001/82/EC (the "cascade"). The Irish Medicines Board had expressed serious concerns over potential animal welfare problems resulting from the lack of available treatments for immature fluke in dairy cattle and sheep, which is a consequence of the absence of an MRL for this substance in milk. The Irish Medicines Board therefore requested an urgent opinion of the Committee on the matter.

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

MUMS / Limited markets

The Committee reviewed a request for classification under the MUMS/limited markets policy, which concerned a pharmaceutical product for treatment of an ophthalmic condition in dogs and the CVMP considered that the product was indicated for MUMS but was not eligible for financial incentives as an alternative authorised product already exists for the same indication.

Pharmacovigilance

The Committee reviewed the PSUR for **Advocate** and recommended amendments concerning the nature and frequency of adverse reactions already included in the product literature. The Committee also reviewed the PSURs for **Equilis Te**, **EQUIOXX and Previcox oral paste for horses**, **Gripovac 3**, **Meloxidyl**, **Onsior**, **Porcilis Porcoli**, **Prac-Tic** and **RESPIPORC FLU3** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a Concept paper for a guideline on the demonstration of palatability of veterinary medicinal products (EMA/CVMP/EWP/81987/2010) for a 3-month period of public consultation. This concept paper has been developed to provide applicants and regulators with guidance on how to demonstrate compliance for oral formulations.

The Committee adopted a revised Guideline on veterinary medicinal products controlling *Varroa destructor parasitosis* in bees (EMA/CVMP/EWP/459883/2009) and overview of comments (EMA/324712/2010). The guideline has been revised following public consultation.

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

Safety

The Committee adopted a Guideline on data to be provided in support of a request to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/516817/2009) and the overview of comments received on the draft guideline (EMA/CVMP/513604/2010). The guideline has been revised following public consultation.

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

Immunologicals

The Committee adopted a Public statement on the number of tests required to control for complete inactivation in inactivated vaccines (EMA/596708/2010). This statement clarifies that from a scientific perspective the IWP/CVMP consider that, in most cases, a single test to confirm complete inactivation, carried out at the stage after inactivation when detection of any residual live antigen is most likely, should give sufficient assurance of complete inactivation and compliance with the pharmacopoeial standard.

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

Antimicrobials

The Committee adopted a Reflection paper on the use of macrolides, lincosamides and streptogramins (MSL) in food-producing animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/SAGAM/741087/2009) for a 3-month period of public consultation. This reflection paper addresses the use of macrolides, lincosamides and streptogramins and provides recommendations for prudent use.

The document 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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