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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 9-11 December 2014

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for initial marketing authorisation applications for:

Suvaxyn CSF Marker, from Zoetis Belgium SA, a vaccine for the active immunisation of pigs against classical swine fever virus; and

Zulvac SBV, from Zoetis Belgium SA, a vaccine for the active immunisation of cattle and sheep to prevent viremia associated with infection by Schmallenberg virus. The product has been classified as MUMS/limited market.

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

Easotic, regarding quality changes;

Equip WNV, regarding quality changes;

LEUCOFELIGEN FeLV/RCP and LEUCOGEN, (subject to a worksharing procedure) regarding ranking of adverse reactions; and

Purevax RCPCh, **Purevax RCP**, **Purevax RC**, **Purevax RCPCh FeLV**, **Purevax RCP FeLV**, (subject to a worksharing procedure) regarding the extension of the duration of immunity.

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

Withdrawal of applications

The Committee was informed of the formal notification from **New A Innovation (NL) Limited B.V.** of their decision to withdraw the application for a new marketing authorisation for **Oxapex**. More information about this application and the current state of the scientific assessment at the time of the

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withdrawal will be made available in a public assessment report. The document, together with the withdrawal letter from the applicant, will be published on the Agency's website in due course.

Community referrals and related procedures

The Committee concluded the referral procedure for **all veterinary medicinal products containing colistin to be administered orally**. The matter was referred to the Committee by the European Commission under Article 35 of Directive 2001/82/EC, in order to give its opinion on the measures that need to be taken to ensure the prudent use of colistin in food producing animals across the EU and to minimise potential risks with the use of the identified products following the scientific advice. The Committee agreed a harmonised indication, a limitation of the duration of treatment up to 7 days and warning sentences on prudent use. 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.

The Committee concluded a procedure **concerning the risk to vultures and other necrophagous bird populations in the European Union in connection with the use of veterinary medicinal products containing the substance diclofenac**. The procedure responds to the request from the European Commission for the Committee to give a scientific opinion under Article 30 of Regulation (EC) No. 726/2004 due to concerns raised relating to the possible risks of toxicity to vultures and other necrophagous birds following exposure to veterinary medicinal products authorised in the Union containing diclofenac. The Committee adopted by consensus an opinion concluding that a risk has been identified for vultures feeding on carcasses of livestock that have been treated with diclofenac 10 or fewer days before their death and certain scenarios have been identified in which vultures could be exposed to contaminated carcasses. Therefore, the CVMP is of the opinion that additional risk management measures are needed and efforts should focus on determining suitable and effective risk management measures, particularly applicable for those scenarios for which a risk has been identified.

The CVMP has sent its opinion to the European Commission. The opinion and assessment report are available on the Agency's website. For further information please see separate press release.

Maximum Residue Limits

The CVMP was informed of the outcome of the written procedure for the review of the MRL status of **potassium selenate**, **sodium selenate** and **sodium selenite** in all food producing species, requested by the European Commission under Article 11 of Regulation (EC) 470/2009.The opinion was adopted by consensus on 4 December 2011, recommending the maintenance of the existing entries in Table 1 of the Annex to Commission Regulation (EU) No 37/2010.

The above recommendation will be published on the Agency's website.

The Committee agreed to include **phosphodiester oligodeoxynucleotides** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients and adopted a revised list (EMA/CVMP/519714/2009-Rev. 24). This decision followed the Committee's review of a request that had been submitted in accordance with the relevant CVMP guidance.

The revised list will be published on the Agency's website.

Scientific advice

The Committee adopted three separate scientific advice reports concerning:

- Initial advice on safety and efficacy issues for an antiparasitic veterinary medicinal product for cattle;
- Initial advice on quality issues for an anti-inflammatory veterinary medicinal product for horses; and
- Follow up advice on efficacy issues for an immunological veterinary medicinal product for horses.

Antimicrobial resistance: advice on the use of antibiotics

Further to the request from the Commission for scientific advice on the impact on public health and animal health of the use of antibiotics in animals and the answer to the first question on July 2013, the Committee has now adopted the final answers to the 3 remaining questions[1]. The questions are related to the ranking of antimicrobials, new classes of veterinary antimicrobials and risk mitigation options for antimicrobials which are authorised as veterinary medicinal products. The answers will also be considered by the CHMP at their meeting on 15-18 December 2014. Following adoption by the CHMP the final answers will be submitted to the European Commission.

MUMS/limited market

Following the Committee's review of three requests for classification under the MUMS/limited market policy, the CVMP classified:

- An immunological product for dogs as indicated for MUMS/limited market. The product is not eligible for financial incentives as it is not indicated for food-producing animals;
- An immunological product for rabbits as indicated for MUMS/limited market. The product is not eligible for financial incentives as there are alternative products authorised; and
- An oncology product for dogs as indicated for MUMS/limited market. The product is not eligible for financial incentives as it is not indicated for food-producing animals.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl Tick Plus**, **BROADLINE**, **CORTAVANCE**, **ECOPORC SHIGA**, **Gripovac 3**, **Nobivac L4**, **PIRSUE**, **Reconcile**, **RESPIPORC FLU3**, **Rheumocam**, **Semintra**, **ZULVAC 8 Bovis** and **ZULVAC 8 Ovis** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Immunologicals

The Committee adopted a draft reflection paper on the replacement of cell lines used for the production of immunological veterinary medicinal products (EMA/CVMP/IWP/37620/2014) for a 3-month period of public consultation. This reflection paper has been developed to outline the data requirements for marketing authorisation holders to replace the cell line as host system for production of immunological veterinary medicinal products without significant changes to the production process and maintaining finished product specifications.

[1] See http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142070.pdf

The Committee adopted a draft reflection paper on the use of heat treatment to inactivate retrovirus RD114 in live immunological veterinary medicinal products (EMA/CVMP/IWP/37924/2014) for a 3-month period of public consultation. This reflection paper has been developed to outline the data requirements for marketing authorisation holders to introduce a heat treatment to inactivate retroviruses in the active substance for the production of live viral vaccines for immunological veterinary medicinal products and to show the absence of negative impact of this treatment on the immunological veterinary medicinal product.

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

Working Parties

The Committee established a new *ad hoc* Expert Group on Veterinary Novel Therapies (ADVENT) and adopted a mandate and rules of procedure for this group (EMA/CVMP/ADVENT/630299/2014). In recent years the Agency has observed an increased interest in therapies that are entirely new to the veterinary domain (novel therapies) and sufficient experience of providing advice with respect to such novel therapies has now been gained to identify the need for a dedicated expert group in this area. ADVENT consists of experienced regulatory scientists with a wide knowledge on the scientific aspects of veterinary pharmaceutical and immunological products and also on regulation of veterinary medicinal products. ADVENT will be assisted by specialised topic groups as needed and a work plan for identification of topic areas will be adopted in early 2015.

The document above 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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