EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 05-07 November 2013

CVMP opinions on veterinary medicinal products

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

LEUCOFELIGEN FeLV/RCP and **LEUCOGEN** (subject to a worksharing procedure) regarding quality changes;

MS-H Vaccine regarding the DDPS; and

ZOLVIX regarding a change in wording in the SPC;

and a negative opinion for the following type II variation application:

Suvaxyn PCV regarding a change in indication.

Annual reassessment of marketing authorisations

The Committee adopted an opinion on the annual reassessment for **BLUEVAC BTV8** further to the evaluation of the data submitted by the marketing authorisation holder. The Committee recommended the continuation of the Community marketing authorisation under exceptional circumstances for the veterinary medicinal product.

Community referrals and related procedures

The Committee concluded the referral procedure for **all veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys**. The matter was referred to the Committee by the United Kingdom under Article 35 of Directive 2001/82/EC, to review indications and dosage due to concerns related to antimicrobial resistance, and withdrawal periods. The Committee adopted by consensus an opinion recommending changes to the product information of the concerned products related to indications, dosage and withdrawal periods. In addition, the Committee also recommended conditions to the terms of the marketing authorisations related to the dosing regimen for *E. coli* infections in chickens and turkeys.

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The Committee started a procedure for **all veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs**. The matter was referred to the Committee by Sweden under Article 35 of Directive 2001/82/EC, to review the treatment durations in pigs and the indication for swine dysentery (caused by *Brachyspira hyodysenteriae*).

Maximum Residue Limits

Further to a request from Ireland under Article 27(2) of Regulation (EC) No 470/2009, the Committee adopted by consensus an opinion recommending the extrapolation of the maximum residue limits (MRLs) for **triclabendazole** to milk of all ruminants (the current provisional MRL for milk expires on 1 January 2014).

Further to requests in accordance with the relevant CVMP guidance, the Committee adopted a revised list of substances considered as not falling within the scope of Regulation (EC) 470/2009 (EMA/CVMP/519714/2009-Rev.17), in order to include **propylene carbonate** as a new entry under the heading of excipients and amending the existing entry for **sodium starch glycollate** to include oral use.

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

Scientific advice

The Committee adopted one scientific advice report concerning safety and quality requirements for an anti-inflammatory product for horses.

Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR AlSap 1**, **BTVPUR AlSap 1-8**, **Cerenia**, **Equilis Prequenza**, **Equilis Prequenza Te**, **EQUIOXX**, **Hiprabovis IBR Marker Live**, **Metacam**, **Nobivac L4**, **Novem**, **Poulvac E. coli**, **Prac-tic** and **Recuvyra**, and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Immunologicals

The Committee adopted a Public statement on routes of administration of vaccines to poultry (EMA/CVMP/IWP/640481/2013). This statement clarifies the regulatory requirements for proving the safety and efficacy for the different routes of administration of immunological veterinary medicinal products in poultry.

Antimicrobials

The Committee adopted a reflection paper on the use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/SAGAM/119489/2012) following the close of the public consultation. This reflection paper has been developed to summarise current knowledge on resistance development and the potential impact of this resistance on animal and human health as detailed in a previous concept paper on the topic (EMA/CVMP/SAGAM/435644/2011). The comments received during the consultation procedure have been taken into account for the revision of the reflection paper.

The reflection paper together with the overview of comments (EMA/CVMP/AWP/257904/2013) will be published on the Agency's website.

The Committee noted a Focus Group meeting to be organised by Efficacy Working Party and Antimicrobials Working Party on the draft revision of the CVMP Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/261180/2012), which is currently in public consultation until 30 November 2013. The Focus Group meeting is scheduled for 9 December 2013, and a draft agenda (EMA/408480/2013) will be published on the Agency's website.

Working Parties

The Committee endorsed the work plans for 2014 for the CVMP Working Parties on Scientific Advice, Safety, Environmental Risk Assessment, Efficacy, Immunologicals, Antimicrobials and Pharmacovigilance as well as for the Joint CHMP/CVMP Quality Working Party.

The work plans will be available on the Agency's website.

Procedural Announcement

The Agency has reviewed current practices with regard to the preparation of timetables for pre- and post-authorisation procedures concerning marketing authorisation applications and MRL procedures and also the recommended submission dates with the aim of streamlining procedures and ensuring consistency of practice.

Whilst there will be a transitional phase for some procedures, the Agency will apply the new dates and practices for new applications and those procedures currently at Day 120 of the procedure with effect from 1 January 2014.

Applicants will continue to receive notification of the key dates for their procedures; however the timetable as such will cease to exist as a separate document and applicants will therefore be referred to the published dates for submission and procedures. Careful consideration will be given to those procedures currently around day 180 or which have recently re-started after a clock-stop.

For any queries on this please contact vet.applications@ema.europa.eu

Innovation Task Force

The scope of the European Medicines Agency's Innovation Task Force (ITF) has now been extended to cover support to veterinary medicines during the early stages of their development. Specific steps have been defined for applicants developing veterinary medicines who wish to request briefing meetings. A separate news item will be published on the Agency's website.

Publication of the CVMP agendas and minutes

Due to increased demand for transparency, the Agency has committed to publish the agendas and minutes of all its scientific committees. It is foreseen to have the first published CVMP agenda prior to the December meeting on Monday 9 December 2013.

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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