EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 15-17 June 2010

The Committee elected Dr Anja Holm from Denmark as its Chair for a 3-year mandate. The Committee also re-elected Dr Rory Breathnach as the Chair of the Scientific Advice Working Party for a further 3-year mandate.

CVMP opinions on veterinary medicinal products

The Committee adopted by majority a positive opinion for an initial marketing authorisation application under exceptional circumstances for **Bovilis BTV 8** (*inactivated Bluetongue virus, serotype 8, clone 1*), from Intervet International BV. Bovilis BTV 8 is an inactivated vaccine for sheep and cattle against Bluetongue virus serotype 8.

The Committee adopted by consensus a positive opinion for an extension application for **Meloxidyl** (*meloxicam*), from Ceva Santé Animale, concerning the addition of a new strength (0.5 mg/ml oral suspension for cats).

The summary opinions are available on the Agency web site:
http://www.ema.europa.eu/htms/vet/opinion/opinintro.htm

The Committee adopted by consensus a positive opinion for a type II variation application for the marketing authorisation of **Porcilis Pesti** (*vaccine against classical swine fever*), from Intervet International BV, regarding amendments to the base used for pH adjustment and also a change in the shelf life from 36 months to 12 months.

Following the Committee's opinion regarding the afore-mentioned type II variation for **Porcilis Pesti** the Committee considered that the requirements for lifting of the suspension of the marketing authorisation were satisfactorily addressed by the submission of data to support an appropriate shelf-life and results of investigations into the cause of a reduced shelf life. Therefore the Committee adopted by consensus an opinion recommending the lifting of the suspension of the marketing authorisation of 20 February 2009 for Porcilis Pesti.

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Community referrals and related procedures

The Committee started a procedure for **Suvaxyn PCV** (*inactivated vaccine*) from Fort Dodge Animal Health. The matter was notified to the Committee by the European Commission under Article 45 of Regulation (EC) No. 726/2004 due to concerns relating to the inactivation of the vaccine strain.

Scientific advice

The Committee agreed five separate scientific advice requests concerning; the establishment of a maximum residue limit for a pharmaceutical product in cows; the establishment of a maximum residue limit for an anti-bacterial active substance in sheep; the safety and efficacy requirements for an anti-viral veterinary medicine for cats; quality and efficacy requirements for a vaccine for horses; clinical development for a pharmaceutical product against mastitis in cows.

MUMS / Limited markets

Following the Committee's review of a request for classification under the MUMS/limited markets policy, which concerned a product for fungal infections in different bird species (all minor species), the CVMP considered that the product was indicated for MUMS/Limited market and was eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Circovac**, **Equilis Prequenza**, **Equilis Prequenza Te**, **Equilis Te**, **Locatim**, **Nobilis Influenza H5N2**, **Profender**, **Startvac**, **Suprelorin** and **Zactran** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Improvac** and recommended the inclusion of information on new adverse reactions in the product literature.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a Question and Answer document on GMP compliance documentation that should be submitted in case of sterilisation of an active substance (EMA/CHMP/CVMP/QWP/300039/2010). This document clarifies the GMP and regulatory requirements for active substance manufacturers performing sterilisation and/or aseptic handling processes.

The document will be published on both the Quality Working Party and Good Manufacturing Practice (GMP) parts of the Agency's website after its adoption by the CHMP (foreseen for their June meeting).

Organisational matters

The Committee held a meeting with the interested parties on 16 June 2010 attended by representatives of International Federation of Animal Health Europe (IFAH-Europe), International Council on Animal Protection in Pharmaceutical Programs (ICAPPP), Association of Veterinary Consultants (AVC), European Group for Generic Veterinary Products (EGGVP) and the European Federation of Honey Packers and Distributors (F.E.E.D.M).

The topics discussed concerned:

- Update on EMA/CVMP activities in relation to reduction of animal testing (3Rs)
- Update from CVMP on proposals to be made to the review of veterinary medicines legislation
- Reflection on preparation of future EMA/IFAH-Europe Info Days
- European Medicines Agency Road Map to 2015.

Notes

1. 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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