EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 February 2016
EMA/CVMP/864727/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Evalon

Common name: Coccidiosis vaccine (live) for chickens

On 18 February 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Evalon, suspension and solvent for oral spray, intended for active immunisation of chickens to reduce clinical signs (diarrhoea), intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria acervulina, Eimeria brunetti, Eimeria maxima, Eimeria necatrix and Eimeria tenella*. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

Evalon is a live attenuated parasitic vaccine against coccidiosis in chickens (ATCvet code QI01AN01) containing sporulated oocysts as active substances from *Eimeria acervulina* (strain 003), *Eimeria brunetti* (strain 034), *Eimeria maxima* (strain 013), *Eimeria necatrix* (strain 033) *and Eimeria tenella* (strain 004).

The benefits of Evalon are its prophylactic immunisation of chickens, used as layers or breeders, against five major disease-causing coccidia to reduce clinical signs (diarrhoea), intestinal lesions and oocysts output. Chickens can be vaccinated from 1 day of age with the onset of immunity established 3 weeks after vaccination. Duration of immunity is 60 weeks after vaccination covering the entire laying period, in an environment that permits the recycling of oocysts in vaccinated birds.

Evalon is well tolerated at the recommended dose.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Evalon and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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