EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 February 2016
EMA/CVMP/4233/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

LETIFEND

Common name: Canine leishmaniasis vaccine (recombinant protein)

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 LETIFEND, lyophilisate and solvent for solution for injection, intended for active immunisation against leishmaniasis in dogs. The applicant for this veterinary medicinal product is Laboratorios LETI, S.L.unipersonal.

LETIFEND is an immunological medicinal product containing the recombinant protein Q from *Leishmania infantum* MON-1 (ATCvet code QI07A) as active substance.

The benefits of LETIFEND are its prophylactic immunisation of non-infected dogs from 6 months of age to reduce the risk of developing an active infection and/or a clinical disease after exposure to *Leishmania infantum*. The efficacy of the vaccine was demonstrated in a field study where dogs were naturally exposed to *Leishmania infantum* in zones with high infection pressure over a two year period.

In laboratory studies including experimental challenge with *Leishmania infantum*, the vaccine reduced the severity of the disease, including clinical signs and parasite burden when compared to non-vaccinated dogs.

Onset of immunity is established at 28 days after vaccination and duration of immunity is established for 1 year after vaccination.

The most common side effect is scratching at the injection site after vaccination; spontaneous resolution of such reaction was observed within 4 hours.

The appropriate CVMP guidelines on data requirements for immunological veterinary medicinal products intended for minor use minor species (MUMS)/limited market (EMA/CVMP/IWP/123243/2006-Rev.2) have been applied when assessing the application.

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

[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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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 LETIFEND and therefore recommends the granting of the marketing authorisation.