ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LETIFEND, lyophilisate and solvent for solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml vaccine contains:

Lyophilisate
Active substance:
Recombinant Protein Q from *Leishmania infantum* MON-1 ≥ 36.7 ELISA Units (EU)*
* Antigen content determined in an ELISA against an internal standard.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection.

White lyophilisate.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For active immunisation of non-infected dogs from 6 months of age to reduce the risk of developing an active infection and/or 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 in spleen and lymph nodes.

Onset of immunity: 4 weeks after vaccination.

Duration of immunity: 1 year after vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The vaccine is safe in infected dogs. Re-vaccination of infected dogs did not worsen the course of the disease (during the 2-month observation period). No efficacy has been demonstrated in these animals.

A test for the detection of Leishmania infection is recommended prior to vaccination.
The impact of the vaccine in terms of public health and control of the human infection cannot be estimated from available data.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate healthy and non-infected animals only.
De-worming of infested dogs prior to vaccination is recommended.
It is essential that measures to reduce exposure to sand-flies are employed in vaccinated animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
None.

4.6 Adverse reactions (frequency and seriousness)

After vaccination, scratching at the injection site has been observed very commonly in dogs. Spontaneous resolution of such reaction was observed within 4 hours.
Lethargy, vomiting, diarrhoea and hyperthermia following vaccination have each been reported to occur very rarely based on post-marketing safety experience. Treatment should be administered as needed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Therefore, the use is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Subcutaneous use.

Primary vaccination scheme:
A single dose of the vaccine (0.5 ml) to be administered to dogs from 6 months of age.

Re-vaccination scheme:
A single dose of the vaccine (0.5 ml) to be given annually thereafter.

Method of administration:
Reconstitute one vial of the white lyophilisate using 0.5 ml of solvent. Shake gently to give a clear solution, and administer immediately the entire content (0.5 ml) of the reconstituted product.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Following administration of a double dose, reactions are similar in nature to those observed following the administration of a single dose (see section 4.6).

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Canidae – dog – inactivated parasitic vaccines – leishmania.
ATCvet code: QI07AO01

To stimulate active immunity against disease caused by *Leishmania infantum* parasites.

Diagnostic tools designed to detect *Leishmania* antibodies (SLA or IFAT or rk-39 rapid diagnostic tests) should be suitable to enable discrimination between dogs vaccinated with this vaccine and dogs infected with *Leishmania infantum*.

The efficacy of the vaccine was demonstrated in a field study where seronegative dogs from a variety of breeds were naturally exposed to *Leishmania infantum* in zones with high infection pressure over a two year period. The data has shown that a vaccinated dog has 9.8 times less risk to develop clinical signs, 3.5 times less risk of having detectable parasites and 5 times less risk to develop clinical disease than a non-vaccinated dog.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Sodium chloride
Arginine hydrochloride
Boric acid.

Solvent:
Water for injections.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

6.3 Shelf life

Lyohilisate:

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Solvent:

Shelf life of the solvent: 5 years.
Shelf life after reconstitution according to directions: use immediately.

6.4. Special precautions for storage

Store in a refrigerator (2 ºC – 8 ºC).
Do not freeze.

6.5 Nature and composition of immediate packaging

Lyophilisate vial
Type I glass vials containing 1 dose of vaccine;
Solvent vial
Type I glass vials containing the 0.8 ml of solvent. Vials are both closed with a bromobutyl stopper and an aluminium cap.

Pack sizes:
Plastic box containing 1 vial of 1 dose of lyophilisate and 1 vial of 0.8 ml of solvent.
Plastic box containing 4 vials of 1 dose of lyophilisate and 4 vials of 0.8 ml of solvent.
Plastic box containing 5 vials of 1 dose of lyophilisate and 5 vials of 0.8 ml of solvent.
Plastic box containing 10 vials of 1 dose of lyophilisate and 10 vials of 0.8 ml of solvent.
Plastic box containing 20 vials of 1 dose of lyophilisate and 20 vials of 0.8 ml of solvent.
Plastic box containing 25 vials of 1 dose of lyophilisate and 25 vials of 0.8 ml of solvent.
Plastic box containing 50 vials of 1 dose of lyophilisate and 50 vials of 0.8 ml of solvent.
Plastic box containing 100 vials of 1 dose of lyophilisate and 100 vials of 0.8 ml of solvent.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratorios LETI, S.L.unipersonal
C/ Del Sol 5,
Polígono Industrial Norte
Tres Cantos
28760 Madrid
SPAIN
+34 91 771 17 90

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/195/001-008

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20/04/2016

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.