



## Post Authorisation Assessments

For details of post authorisation assessments prior to 1<sup>st</sup> January 2021,  
please refer to the [EMA](#) website.

### LETIFEND Lyophilisate and Solvent for Solution for Injection for Dogs Vm 44009/5000

• 31 March 2023	Approval of mock-ups.
• 16 March 2023	Change in test procedure for the active substance.
• 16 August 2022	Extension of the storage period of the active ingredient from 3 to 4 years.
• 29 March 2022	Change(s) in the SPC, Labelling or Package Leaflet intended to implement the outcome of a PSUR.
• 15 September 2021	Increase in the shelf-life of the finished product as packaged for sale, from 3 years to 4 years.
• 01 September 2021	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS
• 12 July 2021	Change in the name and/or address of the manufacturer of the finished product. Change in the name and/or address of a manufacturer of the finished product, also responsible for batch release.
• 16 June 2021	Change in the name of the marketing authorisation holder from: Laboratorios LETI, S.L. unipersonal, C/ Del Sol 5, Polígono Industrial Norte, Tres Cantos, 28760, Madrid, SPAIN to: LETI Pharma, S.L.U., C/ Del Sol 5, Polígono Industrial Norte, Tres Cantos, 28760, Madrid, SPAIN.