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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

LETIFEND Lyophilisate and Solvent for Solution for Injection for Dogs

•	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.