Veterinary Medicines Directorate

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Post Authorisation Assessments

Stellamune Mycoplasma

•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	16 January 2015	Addition of a site for part of the manufacturing process, QC testing and batch release.
•	31 October 2014	Change to the specification of a starting material used in the manufacturing process of the active substance.
•	01 July 2013	Variation to change the name of the manufacturers responsible for active substance and the finished product.
•	24 November 2010	Variation to change the Marketing Auhtorisation Holder.
•	21 August 2008	Addition of an alternative non-ruminant PPLO Porcine Broth.
•	03 April 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-V.
•	30 September 2006	Addition of an alternative source of an excipient.
•	21 December 2005	Renewal.
•	28 June 2005	Addition of distributors.
•	08 April 2004	Renewal.
•	17 Jnuary 2000	Change to safety warnings.
•	22 December 1999	Change in shelf life of the finished product.
•	22 December 1999	Change in the shape and dimensions of the container.
•	22 December 1999	Change in the manufacturer of the veterinary medicinal product.
•	02 June 1999	Change in the potency at release (CTA).
•	17 February 1997	Variation to change the safety testing of the vaccine.