Veterinary Medicines Directorate

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Post Authorisation Assessments

Lactovac Suspension for Injection

•	23 July 2021	Update of the SPC/Product Information according to the latest QRD template.
•	04 June 2020	Repeat Use Application to add 11 new member states.
•	15 January 2020	Changes to a test procedure (including replacement) for the active substance.
•	12 December 2019	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	27 November 2019	Replacement of a test procedure for an excipient.
•	27 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	02 October 2018	Changes in the manufacturing process of the active substances. Changes in the manufacturing process of the active substance. Changes in the manufacturing process of the active substance.
•	09 January 2018	Change in the RMS from the UK to IE.
•	23 January 2017	Changes to a test procedure (including replacement) for a starting material. Changes to a test procedure (including addition) for the active substance. Change in the specification limits of the finished product.
•	31 March 2016	Increase to the shelf-life of the active substances.
•	05 May 2015	Change to the QPPV contact details.
•	15 January 2015	Increase to the shelf-life of the active substances.
•	17 April 2014	Change in the invented name of the veterinary medicinal product in Italy and Poland only.
•	17 April 2014	Change in name of manufacturer of the active substance.
•	17 January 2014	Change in manufacturer of a starting material / intermediate used in the manufacturing process of the active substance and addition of a test procedure used in the manufacturing process of the active.
•	17 October 2013	Change to in-process tests applied during the manufacture of the finished product and change in the manufacturing process of the finished product.
•	11 October 2013	Variation to change the name of the finished product manufacturer responsible for Batch Release.
•	31 July 2013	Transfer of Marketing Authorisation Holder and

		Distributor. Editorial change to the distributor address.
•	06 June 2012	Variation to change the contact details of the Qualified Person for Pharmacovigilance.
•	23 June 2011	Variation to change the name and address of the Spanish Marketing Authorisation Holder office.
•	11 April 2011	Variation to change the finished product manufacturing site.
•	04 August 2010	Replacement of Master Seed.
•	10 June 2010	Variation to change the legal category from POM-V to POM-VPS.
•	23 April 2010	Renewal.
•	02 April 2009	Change in the Marketing Authorisation Holder and Distributor.
•	22 June 2006	Update the SPC/Labelling to bring in line with the Veterinary Regulations, 2005. Change in the legal category from POM to POM-V.
•	29 November 2005	Change of distributor.
•	09 February 2005	New EUDE.
•	17 March 2004	Renewal.
•	23 January 2004	Changes to present an additional safety study.
•	06 June 2003	Variation to change section of SPC.
•	09 December 2002	Transfer of Manufacturing Site
•	09 December 2002	Transfer of Batch Control site.
•	09 December 2002	Transfer of Manufacturing site for Filling.
•	11 January 2001	Additional packaging site of
•	31 May 2000	Additional Quality Control testing site.
•	09 March 2000	Change in the name and address of Marketing Authorisation Holder.