Veterinary Medicines Directorate

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Post Authorisation Assessments

Spirovac
Vm 60021/3062

26 February 2025	Change in legal entity of MA holder in NI only to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood, Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland.
23 January 2025	G.I.18 update of product information to v9.
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 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
19 June 2018	Changes to a test procedure for the finished product.
17 January 2018	Change in the RMS from the UK to IE.
02 September 2016	Deletion of a test procedure for the finished product.
11 May 2016	Change in immediate packaging of the finished product. Deletion of a manufacturing sites (for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier).
03 May 2016	Repeat Use application to add one new Member State
10 November 2015	Renewal UK as RMS
05 May 2015	Change in the QPPV contact details.
03 July 2014	Extension to the shelf life for the active substance.
17 February 2014	Mutual recognition repeat use procedure – UK RMS.
06 December 2013	Changes to the safety/efficacy warnings on the SPC and Product Literature.
11 October 2013	Change in the name and address of the Marketing Authorisation Holder.
10 October 2013	Grouped variation to change the name of the active substance manufacturer, change the name of the manufacturer responsible for finished product and batch release, change the name of the manufacturer responsible for finished product (not including batch release), and to change the QPPV details.
31 July 2013	Variation to transfer the Marketing Authorisation Holder and distributor address.
09 August 2012	Variation to introduce a DDPS.
17 October 2011	Renewal (UK as RMS).
08 April 2011	Variation to change the address of the Marketing Authorisation Holder.
17 November 2010	Variation to change the finished product test procedure.
04 June 2010	Change of legal category from POM to POM-VPS.
24 March 2010	Addition of a manufacturer.

10 June 2009	MRP (UK as RMS).
10 June 2009	Manufacturing method (product).
12 September 2007	Change in the shelf life of the finished product.
17 May 2007	Variation to the SPC.
17 May 2007	Variation to the SPC.
16 May 2007	Variation to the SPC.
20 March 2007	Variation to introduce re-testing of vaccine.
17 November 2007	Replacement of additional manufacturing site.
15 August 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
28 October 2005	Reviewed Marketing Authorisation.