Veterinary Medicines Directorate

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Post Authorisation Assessments

Excenel Flow, 50 mg/ml, Suspension for Injection for Pigs and Cattle

Vm 42058/5151

12 December 2024	Change in batch size of intermediate used in the manufacturing process of the active substance.
03 February 2022	Change in the address of an intermediate used in the manufacture of the active substance. Deletion of manufacturing site for an intermediate. Deletion of manufacturing site for an intermediate. Change in the manufacturer of an intermediate used in the manufacturing process of the active substance.
08 January 2020	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.
17 May 2019	Deletion of a supplier of packaging components or devices Deletion of a supplier of packaging components or devices
07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
17 April 2018	Update the ASMF.
20 September 2017	Deletion of manufacturing site for an active intermediate. Deletion of manufacturing site for an active intermediate. Deletion of manufacturing site for an active intermediate.
05 April 2017	Deletion of manufacturing sites for batch release. Deletion of a manufacturing site for batch control testing.
16 February 2017	To update the SPC and product information in line with the outcome of a repeat use renewal procedure.
26 January 2016	Change to in-process limits applied during filling.
15 January 2016	Change in the name and/or address of a manufacturer/importer of the finished product
06 November 2015	Change in the immediate packaging of the finished product.
05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
23 December 2014	Change in test procedure for the finished product.
31 March 2014	Minor change in the manufacturing process of the finished product.
28 February 2014	Addition of a testing/control site for the finished product.
30 October 2013	Grouped variation to change the active substance manufacturer, the addition of a finished product manufacturer, and to change the QPPV contact details.
22 October 2013	Change in the name and address of the MAH in Austria,

	Belgium, France and Luxembourg only.
10 October 2013	Increase of shelf life.
21 August 2013	Variation to modify a packaging component.
21 August 2013	Variation to change the invented name of the product.
08 August 2013	Variation to change the Marketing Authorisation holder and distributor.
13 June 2013	Grouped variation to change the formulation of the finished product, make changes to the manufacturing process, make changes to the excipient and finished product specifications, and reduce the withdrawal periods for pigs and cattle. Update of ATC Vet Code and the addition of a pack size.
13 July 2012	Variation to update the EU QPPV details.
25 May 2012	Addition of a site for batch release.
16 April 2012	Variation to update the SPC and Product Literature.
23 March 2012	Variation to increase the retest period for the active substance.
13 February 2012	Grouped variation to change the name of the Marketing Authorisation Holder.
04 July 2011	Repeat Use Comm.
27 September 2010	Manufacturer (active).
09 October 2009	Variation to change the manufacture of active/active component and addition of a manufacturer.
21 July 2008	Minor changes in the manufacture of the finished product.
19 November 2007	Replacement of a manufacturing site.
24 August 2007	Renewal.