Veterinary Medicines Directorate

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Post Authorisation Assessments

Endofluke 100 mg/ml Oral Suspension

Vm 50146/5009

12 August 2026	Replacement of a primary packaging site of a non-sterile finished product.
22 July 2026	Replacement of a secondary packaging site of the finished product. Replacement of a manufacturing site responsible for batch release and batch control of the finished product. Up to 10-fold increase compared to the originally approved batch size of the finished product.
22 July 2026	Replacement of a manufacturing site for part of the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product.
18 December 2025	Submission of a new CEP for the manufacture of an active substance.
23 April 2025	Alignment of the product information with version 9.0* of the QRD templates.
17 November 2023	Update of the registered QC testing site for the finished product. (NI)
17 November 2023	Submission of an updated certificate of suitability. Submission of an updated certificate of suitability. Submission of an updated certificate of suitability. (NI)
06 October 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer. (GB) Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer. (GB) Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer. (GB)
16 June 2023	Change in the specification parameters or limits of the immediate packaging of the finished product. (NI)
23 June 2023	Change of address of quality testing site for finished product. (GB)
20 May 2022	Tightening of specification limits of the immediate packaging of the finished product. Tightening of specification limits of the immediate packaging of the finished product. Tightening of specification limits of the immediate packaging of the finished product.
14 October 2021	Changes to the labelling and package leaflet.
30 March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability

	for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
23 February 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
22 August 2019	Change in the name of control testing site. Change in the name and address of a manufacturer of the finished product, also responsible for batch release. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
19 October 2018	Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
10 January 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
21 August 2017	Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product. Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product.
16 December 2016	Minor change in the manufacturing process of the finished product.
02 September 2016	Addition of a new value pack for the finished product.
28 October 2015	Change in the dimension limits of the finished product. Addition of a specification parameter.
07 August 2015	Change in the name & address of the manufacturer of the active substance. Change in the manufacturer of a starting material.
03 April 2014	Change to the specification parameters for the finished product.
06 November 2013	Change to the milk withdrawal period for cattle.
28 October 2013	Addition of a 5 litre pack size.
22 February 2013	Update to withdrawal period on the SPC and Product literature
16 March 2012	Change of manufacturer of the active substance
05 August 2010	Submission of an updated Active Substance Master File (ASMF)
20 January 2010	Minor change to manufacturing process of the finished product
07 January 2010	Change of batch size of finished product
03 December 2009	Extension to add Sheep as a target species
10 June 2008	Renewal
23 August 2007	Change of name of manufacturer of the active substance