Veterinary Medicines Directorate

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Post Authorisation Assessments

Folltropin 700 IU Powder and Solvent for Solution for Injection

Vm 08007/4145

•	15 December 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI) Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	09 December 2022	Change in test procedure for the finished product.
•	04 August 2021	Minor change to an approved test procedure for the active substance. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
•	11 February 2021	Minor change in the manufacturing process of the active substance. Deletion of manufacturing site for an active substance.
•	05 March 2019	Addition of a site where batch testing takes place. Change of a test procedure for the active substance. Change of a test procedure for the finished product.
•	28 August 2018	Change in the address of the marketing authorisation holder from Vetoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northants, NN12 7LS.
•	16 July 2018	Minor changes to an approved test procedure of the finished product Addition of a site where batch control/testing takes place
•	15 May 2018	Changes to the quality control testing arrangements for the active substance. Change in the manufacturer used in the manufacturing process of the active substance.
•	29 December 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	25 September 2017	Deletion of a non-significant parameter used in the manufacturing process of the active substance. Deletion of a non-significant parameter used in the

		manufacturing process of the active substance. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Change in the specification for the active substance.
•	07 September 2017	To harmonise the Product Information in all concerned Member States
•	07 August 2017	Change in the name and address of the manufacturer of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product
•	15 November 2016	Change in test procedure for active substance.
•	01 August 2016	Change in the re-test period/storage period of the active substance.
•	27 June 2016	Change in a test procedure for the finished product. Replacement a manufacturing site for secondary packaging of the finished product. Replacement of quality control testing site for the finished product.
•	13 April 2016	Replacement* or addition* of a site where batch control/testing takes place Decrease in batch size range of the finished product. Replacement* / addition* of a manufacturing site of the finished product
•	15 January 2015	Change in the name and/or address of a manufacturer Change in the name and/or address of a manufacturer/importer of the finished product Change to importer, batch release arrangements and quality control testing of the finished product Deletion of a manufacturing sites
•	21 December 2015	Introduction of a new Pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	09 October 2015	Change in legal entity & distributor details and updates to labelling.
•	13 January 2015	Addition of a site for secondary packaging and batch release for the finished product.
•	07 November 2014	Change in the names of active substance and finished product manufacturing sites and a change to the primary packaging not in contact with the finished product formulation.
•	26 April 2013	Changes (Safety/Efficacy) to a veterinary medicinal product.
•	03 April 2013	Change in the test procedure for the finished product. Change in the batch release and quality control testing arrangements.
•	21 January 2013	Grouped variation to: tighten the in-process testing fill volumes, to remove virus testing from the vial specification, and to tighten the moisture specification.

•	27 September 2012	Repeat Use – Comment.
•	16 February 2012	Change in the manufacturing process of the finished product.
•	24 January 2012	Introduction of a new pharmacovigilance system.
•	17 January 2012	Change in the manufacturing process of the active substance.
•	23 December 2011	Change in the name of the manufacturer of the active substance.
•	09 November 2011	Change in the manufacturing process of the active substance.
•	07 July 2011	Change to the test procedure of the finished product from 36 to 48 months.
•	10 December 2010	Change in the shelf-life of the finished product.
•	25 November 2010	Change to the test procedure of the finished product.
•	19 November 2010	Change to the test procedure of the finished product, change to the manufacturing process of the active substance.
•	19 November 2010	Change to the test procedure of the finished product, change to the manufacturing process of the active substance.
•	03 November 2010	Changes in the test procedure and specification parameters of the finished product.
•	30 July 2010	Renewal.
•	16 July 2010	Change in the test procedure for the preparation of the active substance
•	09 July 2010	Change in the specification parameters of excipients, change to comply with the Ph. Eur. Change in the test procedure for the active substance
•	06 May 2010	Change in the batch size of the finished product.
•	10 March 2010	Change in the address of the Marketing Authorisation Holder.
•	23 February 2007	Change of distributor.
•	05 March 2007	Tightening of specification limits.
•	22 February 2007	Minor change to approved biological test.
•	18 February 2007	Shelf life extension.
•	16 July 2006	Variation to change a manufacturer.
•	02 June 2006	Minor change to approved test on finished product.
•	02 June 2006	Minor change to approved test on finished product.