Veterinary Medicines Directorate

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Post Authorisation Assessments

Tulieve 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep

Vm 02000/4441

July 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
19 January 2025	Minor changes to an approved test procedure for starting material used in the manufacturing process of the active substance. (NI)
19 January 2025	Minor changes to an approved test procedure for starting material used in the manufacturing process of the active substance. (NI)
19 January 2025	Minor changes to an approved test procedure for active substance. (NI)
22 November 2024	Extension of the re-test period for an active substance. Minor change to the restricted part of an Active Substance Master File.
22 November 2024	Minor changes to an approved test procedure for active substance. Minor changes to an approved test procedure for starting material used in the manufacturing process of the active substance. Minor changes to an approved test procedure for starting material used in the manufacturing process of the active substance.
27 October 2024	Deletion of obsolete specification parameters of an excipient. Deletion of obsolete specification parameters of an excipient. (NI)
01 August 2024	Deletion of obsolete specification parameters of an excipient. (GB)
02 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
14 November 2023	Minor changes to an approved test procedure for the finished product. (NI)
15 June 2023	Minor changes to an approved test procedure for the finished product.
28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
15 March 2022	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
20 July 2021	Tightening of specification limits of the finished product.
11 May 2021	Addition of a new specification parameter with its corresponding

	test method of an active substance. Increase in batch size of active substance or intermediate used in the manufacturing process of the active substance. Minor change to the restricted part of an Active Substance Master File.
27 April 2021	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 24 months.