Veterinary Medicines Directorate

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Post Authorisation Assessments

Tranquiline 35 mg/ml Oral Gel for Dogs

Vm 56190/3002

13 March 2026	Alignment of the product information with version 9.0* of the QRD templates.
25 February 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Change in the pharmacovigilance system master file (PSMF) location.
30 April 2025	Change outside the approved specifications limits range.
19 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
11 January 2025	Approval of mock ups.
28 June 2024	Addition of an administration device which is not an integrated part of the primary packaging.
05 October 2023	Submission of updated QP declaration to verify GMP compliance of the active substance manufacturer.
03 July 2023	Change in batch size of the finished product.
21 December 2022	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
23 February 2022	Change in the name and address of the marketing authorisation holder in Northern Ireland from Floris Animal Health Ltd., Bath House 6-8, Bath Street, Bristol, BS1 6HL, United Kingdom to Floris Holding BV, Kempenlandstraat 33 / 35, 5262 GK Vught, The Netherlands.
24 March 2021	Change of MAH from Floris Veterinaire Produkten BV, Kempenlandstraat 33 / 35, 5262 GK Vught, Netherlands to Floris Animal Health Ltd., Bath House 6-8, Bath Street Bristol BS1 6HL, United Kingdom.
17 February 2021	Changes to SPC and Product Literature following a Repeat Use procedure.
17 February 2021	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Replacement of a site where batch control/testing takes place.