



Post Authorisation Assessments

Vetflea 402 mg Spot-on Solution for Very Large Dogs

Vm 17902/5049

22 August 2025	Minor change to an approved test procedure for a finished product.
12 August 2025	Change to in-process tests or limits applied during the manufacture of the finished product.
26 June 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).
11 February 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
12 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. monograph 2869.
17 September 2018	Change in RMS from UK to HU.
11 April 2018	Increase in the shelf-life of the finished product as packaged for sale, from 24 months to 36 months for the thermoformed pipettes.
28 March 2018	Renewal - UK as RMS
30 January 2018	Deletion of a manufacturing site for the finished product.
14 June 2017	Change in the name and address of a manufacturer used in the manufacture of the active substance. Addition of a manufacturer of the active substance.
09 December 2016	Minor change in the manufacturing process of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
21 October 2015	To add an additional site of purification for the active substance.
30 July 2015	Change in the invented name of the product in Hungary and Romania only.
19 January 2015	Addition of an active substance manufacturer. Changes to the specification limits.
23 September 2014	Change to an in-process test applied during the manufacture of the finished product.
27 September 2012	Minor change in purification process of active substance, deletion of a non-significant specification parameter from the manufacturing, increase in batch size range of the active substance.
31 August 2012	Change in the primary packaging not in contact with the finished product formulation – addition of an individual blister for each pipette.