



Post Authorisation Assessments

Amflee 67 mg Spot-on Solution for Small Dogs

Vm 01656/4087

16 May 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
20 April 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
19 February 2026	Alignment of the product information with version 3.0 & 9.0* of the QRD templates.
29 September 2025	Change of Distributor from: Unidrug Distribution Group Limited, Amber Park 1, 2, 3 and 5 Berristow Lane, South Normanton, Alfreton, Derbyshire, DE55 2FH; Centaur Services Limited, Centaur House, Torbay Road, Castle Cary, Somerset, BA7 7EU; Movianto UK Limited, 1A Progress Park, Elstow, Bedford, Bedfordshire, MK42 9XE; National Veterinary Services Limited, Unit 4, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW; Potter Logistics Limited, Charleywood Road, Knowsley Industrial Park, Liverpool, L33 7SG; Henry Schein UK Holdings Limited, Medcare North, Centurion Close, Gillingham Business Park, Gillingham, Kent, ME8 0SB to: KRKA UK Ltd, Thames House, Waterside Drive, Langley, SL3 6EZ, United Kingdom.
30 June 2025	Change in the address of a manufacturer of the finished product. (NI).
28 May 2025	Change in the address of a finished product manufacturer. (GB).
10 January 2025	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (GB and NI).
05 November 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).
24 December 2021	Minor change in the manufacturing process of the finished product.
18 August 2021	Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Deletion of manufacturing site for an active substance.
21 December 2020	Increase in the shelf-life of the finished product as packaged for sale, from 30 months to 36 months.
03 March 2020	Renewal – UK as CMS.
08 March 2019	Change in the contact details of the QPPV of an existing

	pharmacovigilance system as described in the DDPS.
09 March 2018	Change in RMS from UK to DE.
22 February 2018	Change in contact details for local representative.
03 March 2016	Addition of a site of manufacture for the active substance