

## Post Authorisation Assessments

### **Fiprotec 268 mg Spot-On Solution for Large Dogs** Vm 41941/4003

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| 30 April 2025    | Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)  |
| 22 February 2022 | Changes to the labelling and/or package leaflet.   |
| 20 May 2020      | Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.<br>Addition of a manufacturer of the active substance.   |
| 08 August 2019   | Renewal- UK as CMS.  |
| 24 July 2018     | Change in RMS from UK to NL.   |
| 14 June 2018     | Change of distributor from Beaphar B.V., Drostenkamp 3, 8101 BX Raalte, The Netherlands to Beaphar UK Ltd, Rook Tree Farm, Withersfield Road, Great Wrating, Suffolk, CB9 7HD  |
| 29 March 2018    | Change in type of container for the finished product.<br>Change in type of container for the finished product.<br>Change in the number of units (e.g. tablets, ampoules, etc.) in a pack within the range of the currently approved pack sizes of the finished product.<br>Changes to the package leaflet. |
| 09 February 2018 | Increase in batch size (including batch size range*) of the finished product.<br>Addition of a manufacturer responsible for importation batch release including batch control/testing.<br>Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.                             |
| 28 June 2016     | Change in the SPC, labelling or package leaflet due to new data.   |
| 04 June 2015     | Change in distribution category.   |
| 20 May 2015      | Updates to SPC and product labelling, including the removal of flea allergy dermatitis claim.<br>Change in pack size of the finished product.  |