



## Post Authorisation Assessments

### Vetflea 67 mg Spot-on Solution for Small Dogs

Vm 17902/4021

|   |                   |                                                                                                                                                                                               |
|---|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| • | 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.<br>Addition of a manufacturer of the active substance.                                      |
| • | 09 December 2016  | Minor change in the manufacturing process of the finished product.<br>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.<br>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.                                                    |