

## **Post Authorisation Assessments**

## Anarthron 100 mg/ml Solution for Injection for Dogs Vm 15519/4002

| • | 12 May 2022      | Minor changes to an approved test procedure of the finished product.<br>Increase in batch size (from 50 litres, or 5,000 vials to 400 litres, or 40,000 vials) of the finished product   |
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| • | 01 April 2021    | Change in the QPPV of an existing pharmacovigilance<br>system as described in the DDPS.<br>Change in the contact details of the QPPV of an existing<br>pharmacovigilance system as described in the DDPS.<br>Change of the back-up procedure of the QPPV of an<br>existing pharmacovigilance system as described in the<br>DDPS. |
| • | 01 July 2014     | Deletion of a manufacturing site.  |
| • | 17 May 2013      | Renewal.   |
| • | 17 May 2012      | Change in address of Marketing Authorisation Holder.   |
| • | 20 October 2011  | To change the active ingredient manufacturer.  |
| • | 13 October 2011  | To change the stopper used for sealing.  |
| • | 13 October 2011  | To change the storage conditions.  |
| • | 13 October 2011  | To change the shelf life (in-use) from 28 days to 3 months.  |
| • | 19 May 2011      | To update the Detailed Description of the Pharmacovigilance System.  |
| • | 19 May 2011      | To change the QPPV.  |
| • | 22 December 2010 | To change the Marketing Authorisation Holder from Forte Healthcare Limited to Arthropharm (Europe) Ltd.  |
| • | 09 November 2010 | Repeat Use Procedure.  |
| • | 05 February 2009 | Variation to add Eurovet Animal Health B.V. as an additional manufacturing site and an additional site of batch control and release.   |
| • | 20 January 2009  | Variation to add Eurovet Animal Health B.V. as an additional site of batch control and release.  |