



## Post Authorisation Assessments

### Neoprinil Pour-on 5 mg/ml Pour-on Solution for Cattle Vm 05653/4177

•	24 May 2023	Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance:– up to 10-fold increase compared to the originally approved batch size.
•	24 May 2023	Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier: - Extension or introduction of a re-test period/storage period supported by real time data.
•	27 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	14 February 2019	Renewal UK as CMS
•	14 February 2018	Addition of a manufacturer of the active substance.
•	20 September 2017	Change in shape or dimensions of the container or closure (immediate packaging)
•	18 December 2015	Change in the shelf-life from 2 years to 3 years Minor changes to images on SPC and labelling
•	27 October 2015	Tightening of the test limits of the contents of the active substance.
•	14 October 2015	Change in the manufacturing process of the finished product. Changes in the manufacturing process of the active substance.
•	17 April 2015	Change to the in-use shelf-life of the pouches from 1 year to 2 years.
•	13 February 2015	Change in dimensions of the container. Addition of a site for batch control/testing.