Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Advocin 180, 180mg/ml, Solution for Injection for Cattle

Vm 42058/3008

•	06 October 2023	One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.
•	17 January 2023	Deletion of a test procedure for the finished product. Deletion of a manufacturer of the finished product. Deletion of a manufacturer of the finished product.
•	29 March 2022	Deletion of manufacturing site for an active substance. Extension of a re-test period of the active substance.
•	15 December 2021	Addition to a test procedure for an excipient.
•	08 January 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	08 January 2020	Replacement of a site for the manufacture of the active substance intermediate.
•	07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	06 September 2018	Addition of a site where batch control/testing takes place. Replacement of a manufacturer responsible for batch release of the finished product. Addition of a secondary packaging site of the finished product. Addition to a test procedure for the finished product. Changes to a test procedure for the finished product. Decrease in batch size range of the finished product. Addition of an in-process control test. Addition of a manufacturing site of the finished product.
•	24 July 2018	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	08 August 2017	Tightening of specification limits of an active substance used in the manufacturing process of the active substance. Changes to a test procedure (including replacement * or addition*) for the active substance. Change in the specification parameters and/or limits of the immediate packaging of the active substance. Additional manufacturer of the active substance only for synthesis.

•	18 July 2017	Change in the name of the manufacturer of the finished product
•	14 October 2015	To add a site of secondary packaging for the finished product. To add a new batch range for the finished product. To add a site of manufacture and primary packaging for the finished product.
•	05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure.
•	06 March 2015	Updates to the SPC and product literature.
•	10 December 2014	Change in the name of a site responsible for manufacturing and batch control and release of the finished product.
•	20 December 2013	Change to test procedures for the finished product.
•	30 October 2013	Addition of a finished product manufacturer responsible for batch release. Update to the QPPV contact details.
•	22 October 2013	Change to the name of the MAH in Austria, Belgium, France and Luxembourg only.
•	16 August 2013	Change in distributor and MAH from Pfizer Limited to Zoetis UK Limited.
•	13 April 2012	Change to in process tests applied during the manufacture of the finished product.
•	20 March 2012	Change in product packaging components.
•	13 February 2012	Change to the name of the MAH in Spain only.
•	16 June 2011	Change to the name of the MAH in Poland only.
•	04 March 2010	Change in test procedure on the finished product.
•	27 April 2009	Change in test procedure on the finished product.
•	29 December 2008	Addition of a statement on use of fluoroquinolones to the SPC.
•	12 May 2008	Repeat use procedure.
•	15 May 2006	Renewal.
•	09 May 2006	Change of marketing authorisation holder (MAH) in Portugal only.
•	12 August 2005	Addition of a new therapeutic indication.
•	07 July 2005	Addition of a distributor.
•	25 October 2004	Change of name and address of a manufacturer.
•	06 August 2003	Addition of a new route of administration.
•	11 July 2002	Change of supplier of an intermediate in the manufacturing process of the active substance.