Veterinary Medicines Directorate

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Post Authorisation Assessments

Closiver 5 mg/ml and 200 mg/ml Pour-on Solution for Cattle

•	19 June 2019	Changes to the withdrawal period of the veterinary medicinal product.
•	03 June 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS
•	03 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	12 March 2019	Change in RMS from UK to ES.
•	17 April 2018	Minor changes to an approved test procedure of the finished product.
•	25 January 2017	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product
•	26 October 2016	Additional safety warnings added to the SPC.
•	07 October 2016	Submission of a new certificate of suitability.
•	22 June 2016	Renewal – UK RMS
•	24 July 2015	Submission of an updated certificate of suitability.
•	25 September 2014	Change of QPPV and update to the DDPS.
•	05 September 2014	Change to the distributor address.
•	22 November 2013	Change to update the withdrawal periods on the SPC and product literature following an EU Directive.
•	14 December 2012	Updated Ph. Eur. Certificate of Suitability from an already approved manufacturer of an active substance, submission of a new Ph. Eur. Certificate of Suitability from a new manufacturer of an active substance, updated Ph. Eur. Certificate of suitability from an already approved manufacturer of an active substance.
•	08 November 2012	To add a single neck dispensing bottle, to add additional target animals safety warnings and dosing guide to the SPC, change of shelf-life from 1 year to 18 months.
•	28 September 2012	Addition of safety warnings to SPC and labelling.