Post Authorisation Assessments

Adequan IM 500mg/5ml Solution for Injection

Vm 36483/4002

•	02 April 2019	Change in RMS from UK to FR.
•	19 January 2015	Change to the MAH, from Novartis to Daiichi Sankyo Altkirch SARL.
•	16 January 2014	Change in address of the MAH in Portugal.
•	04 July 2013	Change of address for the Marketing Authorisation Holder (MAH) in France.
•	28 March 2013	Change of address for the MAH in Denmark, Finland, Norway and Sweden.
•	31 March 2011	Deletion of a manufacturer of the finished product responsible for QC testing and replacement of the manufacturer of secondary packaging.
•	24 March 2011	Change of the product name in Austria and Germany from Adequan 500mg/g ml Injektionslosung fur Pferde (Austria) and Adequan Vet., injektionsvaeske, oplosning (Germany) to Adequan IM 500 mg/5 ml
•	03 August 2010	Change of MAH and distributor from Janssen-Cilag Ltd to Novartis Animal Health UK Ltd
•	11 February 2010	Renewal
•	29 May 2009	Change of MAH address in Germany only.
•	06 March 2009	Change of name for the manufacturer of the active substance, minor changes to a test on the finished product and replacement of the manufacturing site for secondary packaging.
•	28 March 2008	Change to the manufacture of the finished product, specification and test methods. Change to the primary packaging.
•	27 February 2008	Change in the address of the MAH.
•	28 January 2008	Increase in the batch size of the finished product from 100L to 200L and 460L
•	04 December 2006	Change of the releasing site of the primary packaged product.
•	30 June 2005	Change in the name of the manufacturer.
•	17 March 2005	Renewal
•	13 March 2002	Submission of TSE Certificate
•	25 October 1999	Mutual Recognition procedure. UK as RMS. CMS's Austria, Belgium, Denmark, Germany, Greece, Spain, France, Italy, Luxembourg, Netherlands and Portugal.