Veterinary Medicines Directorate

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Post Authorisation Assessments

Ovuplant 2.1 mg Implantation Tablets for Horses (Mares)

•	19 March 2020	Change in the name of a manufacturer of the active substance.
•	23 May 2019	Change to importer, batch release arrangements and quality control testing of the finished product.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	01 August 2018	Change in the RMS from UK to IE.
•	29 July 2016	Mock-ups approved.
•	29 June 2016	Change in the address of the Marketing Authorisation Holder.
•	24 Feb 2011	Changes to an existing pharmacovigilance system as described in DDPS.
•	15 December 2010	Change of distributor.
•	17 June 2010	Renewal.
•	02 July 2009	Change of Marketing Authorisation Holder.
•	10 January 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	23 November 2006	Pre-irradiation of pack by gamma irradiation.
•	25 October 2006	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	25 October 2006	Minor change in the manufacture of the finished product.
•	04 October 2006	Change of distributor.
•	03 October 2006	Change in test procedure of the finished product.
•	05 August 2005	Change in specification of the active substance.
•	05 August 2005	Change in test procedure of active substance.
•	10 June 2005	Withdrawal period (decrease).