Veterinary Medicines Directorate

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Post Authorisation Assessments

Rompun Dry Substance 500 mg Powder and Solvent for Solution for Injection

•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	18 November 2015	Update of a manufacturing site address for secondary assembly only.
•	20 June 2013	Addition of a finished product manufacturing site.
•	11 June 2012	Change of name of the manufacturer of the active substance.
•	06 July 2011	Increase in shelf life of finished productfrom 4 years to 5 years.
•	22 February 2011	Change of distributor.
•	24 November 2010	Addition of a manufacturing site for part of the manufacture of the finished product.
•	07 September 2010	Increase in shelf life of finished product from 3 to 4 years.
•	07 September 2010	Change in specification of the finished product.
•	17 November 2009	Addition of precautionary statements to Section 4.5ii of the SPC and package leaflet.
•	19 February 2009	Change in the name of the active substance manufacturer and semi-finished product manufacturer.
•	22 May 2008	Changes to the SPC regarding horse withdrawal period.
•	02 January 2008	Renewal.
•	13 December 2006	Addition of a finished product test.
•	25 October 2006	Correction of an error in section 4.9 of the SPC.
•	04 October 2006	Change in composition of the solvent.
•	04 October 2006	Change to the stopper of a vial.
•	14 June 2006	Changes to the SPC and product literature to bring them into line with new legislation.
•	07 January 2005	Change in the name/addressof the active substance manufacturer.
•	23 December 2004	Change of address of the manufacturer of dosage form.
•	29 September 2004	Change of withdrawal period for horse meat.
•	03 February 2004	Change of MAH address.
•	21 November 2003	Renewal.
•	21 March 2003	Change of release and shelf life finished product specifications.
•	17 January 2003	Change of release and shelf-life finished product specification.
•	27 July 1998	Renewal
•	24 April 1997	Further information regarding safety warnings.