Veterinary Medicines Directorate

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Post Authorisation Assessments

Tribrissen 48% Suspension for Injection

•	26 May 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	05 April 2017	Change in the name of the manufacturer of the finished product. Submission of an updated certificate of suitability. Submission of an updated certificate of suitability.
•	24 April 2015	Submission of a new Ph. Eur. Certificate of Suitability. Addition of new specification parameters.
•	13 January 2014	Change in the finished product test procedure.
•	13 January 2014	Change in the specification parameters/limits of the finished product.
•	20 August 2013	Variation to update the European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	20 June 2012	Grouped variation to change the Marketing Authorisation Holder and distributor.
•	21 February 2012	Variation to change the name of the active substance manufacturer.
•	23 November 2010	Variation to change the name of the site of finished product manufacture.
•	22 May 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	08 November 2006	Renewal.
•	26 March 2003	Renewal.
•	05 December 2002	Increase in the finished product withdrawal period.
•	30 November 2001	Change in the QC Procedures.
•	22 May 2001	Variation concerning a change in the active substance manufacturer.
•	12 January 1998	Variation concerning a change in the name and address of the PL/ATC Holder.
•	02 December 1996	Renewal.