Veterinary Medicines Directorate

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Post Authorisation Assessments

Compagel Gel for Horses

Vm 08327/4293

•	08 June 2023	Change(s) in the name of a qualified person for pharmacovigilance (QPPV). (NI) Introduction of a summary of the PSMF. (NI)
•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	08 July 2021	Replacement of a test procedure for the finished product.
•	24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	24 September 2019	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	06 March 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 January 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	07 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	23 May 2018	Change in the specification limits of the finished product.
•	22 February 2013	Renewal procedure – Germany as RMS.
•	15 June 2012	Submission of a new certificate of suitability for a new manufacturer of an active substance.
•	15 June 2012	Submission of an updated certificate of suitability for an already approved manufacturer of an active substance.
•	15 June 2012	Submission of an updated certificate of suitability for an already approved manufacturer of an active substance.
•	12 January 2012	Change in the immediate packaging of the finished product.

•	12 March 2010	To submit a new European Pharmacopoeia certificate of suitability.