



Post Authorisation Assessments

Ubrolixin Intramammary Suspension for Lactating Dairy Cows Vm 08327/3007

• 28 April 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
• 28 September 2022	Substantial updates to an ASMF.
• 28 September 2021	Deletion of a non-significant parameter of an active substance.
• 05 February 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
• 24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
• 23 May 2019	Extension of a storage period of the active substance.
• 06 March 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
• 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.
• 30 August 2017	Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an active substance. Addition of a manufacturer of the active substance.
• 23 December 2015	Changes to DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
• 24 April 2013	Change in name of the manufacturer of the finished product.
• 24 September 2012	Renewal procedure – Ireland as RMS.
• 11 January 2012	To change the address of the MAH in Spain and Portugal.
• 11 January 2012	To change the address of the MAH in Italy.
• 23 September 2010	Addition of a manufacturing site and a milling site for the active substance. Minor change to manufacturing process of active substance.
• 23 September 2010	Change in the re-test period/storage period or

		storage conditions of the active substance.
•	23 September 2010	Change to in-process tests or limits applied during the manufacture of the finished product.
•	3 September 2010	Change in the batch size (including batch size ranges) of the finished product.