Veterinary Medicines Directorate

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Post Authorisation Assessments

Ubrolexin Intramammary Suspension for Lactating Dairy Cows

•	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.