Veterinary Medicines Directorate

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Post Authorisation Assessments

Boviseal 2.6 g Intramammary Suspension for Cattle (Dairy Cows)

•	15 October 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	01 October 2019	Change in the name and address of the manufacturer of the finished product.
•	29 August 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.
•	18 December 2018	Change in RMS from UK to FR.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	08 November 2017	Renewal – UK as RMS.
•	27 September 2017	Replacement of a supplier of packaging components or devices. Change in the name of a manufacturer of the active substance used in the manufacture of the active substance. Change in the name of a manufacturer of the active substance used in the manufacture of the active substance. Deletion of irradiation site for gamma irradiation. To harmonise the dossier across EU.
•	05 May 2015	Change to the QPPV contact details.
•	28 February 2014	Change of name of the product in Belgium.
•	11 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS.
•	01 August 2013	Change in the name of the product in France only from Teatseal 2.6 g intramammary suspension for cattle (dairy cows) to Mamiseal 2.6 g intramammary suspension for cattle (dairy cows).
•	23 January 2013	Copycat – Informed Consent procedure.
•	18 January 2013	Change of name of the product in Austria and Belgium. (Under previous MAH).