Veterinary Medicines Directorate

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Post Authorisation Assessments

Cosecure Cattle Bolus Continuous Release Intraruminal Device

Vm 18584/4000

•	25 January 2024	Change in the address of a manufacturer the active substance. (NI)
•	25 July 2023	Change in the address of a manufacturer the active substance.
•	09 February 2023	Change from PVC to R.PET trays for the immediate packaging of the finished product.
•	03 February 2023	Change from PVC to R.PET trays for the immediate packaging of the finished product.
•	27 January 2023	Change in address of quality control testing site for the finished product.
•	07 December 2022	Change in address of quality control testing site for the finished product.
•	23 February 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 February 2021	Change in the name/address of a manufacturer used in the manufacture of the active substance. Change in the name/address of a manufacturer used in the manufacture of the active substance. Addition of a manufacturer responsible for batch release including batch control/testing. Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an active substance.
•	24 September 2019	Introduction of a new pharmacovigilance system.
•	01 May 2018	Change in RMS from UK to IE.
•	11 April 2017	Minor change to an approved test procedure for the active substance. Minor change to an approved test procedure for an excipient. Minor changes to an approved test procedure of the finished product. Deletion of a non-significant specification parameter of an excipient.
•	08 January 2016	To add a new active substance manufacture
•	16 December 2015	Changes in the composition (excipients) of the finished product.
•	16 December 2015	Change in the manufacturing process of the finished product.
•	24 September 2014	Labelling approved.
•	06 August 2014	Change to the distributor details.
•	31 January 2011	Renewal.

•	19 January 2007	Addition of a manufacturer of an active substance. Minor change to the manufacture of the finished product.
•	16 June 2005	Mutual Recognition Procedure, UK as RMS.
•	19 February 2004	Addition of manufacturers of an active substance. Changes to the manufacturing process of the finished product. Change of specification of excipients.
•	14 March 2003	Addition of indication regarding improving fertility.