Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

DIB 1.0 g Vaginal Delivery System for Cattle

Vm 54400/4002

10 September 2026	Submission of a new Ph. Eur. CEP for the active substance. Submission of a new Ph. Eur. CEP for the active substance. Deletion of a Ph. Eur CEP for an active substance. (GB + NI)
08 March 2026	Change in the pharmacovigilance system master file location. (NI)
08 March 2026	Change in the pharmacovigilance system master file location. (GB)
01 March 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
01 March 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
17 December 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).
17 June 2025	Addition of a new specification parameter to the specification with its corresponding test method. (NI)
26 March 2025	Change in the specification parameters of the finished product:– Addition of a new specification parameter to the specification with its corresponding test method. (GB)
21 March 2025	Change in the address of the marketing authorisation holder. Replacement of the importer and manufacturer responsible for batch testing and sterility test. Replacement of a manufacturer responsible for batch release not including batch control or testing of a sterile or non-sterile finished product. (NI).
21 March 2025	Change in the address of the marketing authorisation holder. Replacement of the importer and manufacturer responsible for batch testing and sterility test. Replacement of a manufacturer responsible for batch release not including batch control or testing of a sterile or non-sterile finished product. (GB).
14 February 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI).
16 January 2025	Changes to the quality part of the dossier. Deletion of a test procedure for the finished product. (GB and NI).
16 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB).
09 February 2022	Repeat use to add 5 new CMS.
20 October 2021	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
01 October 2021	Replacement of a manufacturer responsible for batch release of

	the finished product. Replacement of a site where batch control/testing takes place.
11 June 2021	Change in the name and address of the Marketing Authorisation Holder from Cyton AH Biosciences GmbH, Konrad-Zuse-Ring 25, 68163 Mannheim, Germany to Syn Vet-Pharma Ireland Limited, Business Service Group, 7A Durands Court, 45 Parnell Street, Waterford X91 P381, Ireland.