



Post Authorisation Assessments

Apistan 10.3% w/w Bee Hive Strip Vm 61437/3000

28 April 2026	Addition of a manufacturer responsible for batch release.
03 February 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Change in the pharmacovigilance system master file (PSMF) location.
05 November 2025	Change of legal entity of the Marketing Authorisation Holder, in NI only, from Vita (Europe) Ltd, Vita House, London Street, Basingstoke, Hampshire, RG21 7PG to Vita Bee Health Limited, 1 Castlewood Avenue, Rathmines, Dublin, D06 H685, Ireland.
15 October 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI) Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
13 February 2025	Addition of a manufacturer responsible for batch release. (GB)
13 February 2025	Addition of a secondary packaging site of a finished product. (GB)
16 January 2025	Addition of a secondary packaging site of a finished product. (NI)
10 September 2021	Change in the address of a manufacturer of the finished product, also responsible for batch release.
25 March 2020	Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release of the finished product. Addition of a secondary packaging site of the finished product.
12 February 2020	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
20 December 2018	Change in RMS from UK to SE.
31 July 2018	Replacement of a secondary packaging site of the finished product.
05 April 2018	Renewal – UK as RMS
27 November 2014	Change in address of a manufacturer of the finished product. Change in the name and address of an importer of the finished product. Change in the name and address of the batch release site. Change in the name and address of the site responsible for batch control testing. Addition of a manufacturing site for part of the manufacturing process of the finished product.
14 November 2014	Removal of 'Do not store above 25°C' storage condition.

09 August 2012	Changes to the DDPS that do not impact the Pharmacovigilance system
02 August 2012	Change to the manufacturing site of the active substance and change in the manufacturing process of the active substance. Minor change in specifications of the active substance and minor changes to test procedures for the active substance.
26 August 2011	MRP procedure – UK as RMS.
14 December 2010	Changes to bring the SPC and Product Literature in line with new legislation.
17 July 2006	Renewal.
29 October 2004	Change of MAH address and change to the name of a manufacturer of the active substance.