



## Post Authorisation Assessments

### Api-Bioxal 632.7 mg/g Bee-hive Powder Vm 23101/4001

08 March 2026	Change in the pharmacovigilance system master file (PSMF) location. Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
16 December 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI).
03 December 2025	Change in pack size of the finished product. Change in the specification parameters and/or limits of the finished product. Change in the specification parameters and/or limits of the finished product. Change in the manufacturing process of the finished product. Changes in the composition (excipients) of the finished product.
20 February 2025	Alignment of the product information with version 9.0* of the QRD templates.
24 June 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
02 August 2021	Update of Summary of Product Characteristics and product literature to reflect current QRD template.
04 March 2020	Repeat Use application to add 1 new member state.
08 January 2020	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
22 February 2017	Repeat Use application to add 5 new member states
14 June 2016	Renewal – UK CMS
19 January 2016	Addition of a new specification parameter of an active substance and of the finished product.