

Post Authorisation Assessments

Amatib 800 mg/g Oral Powder for Pigs and Chickens Vm 01656/3070

20 March 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
18 June 2024	One-off alignment of the product information with version 9.0 of the EU QRD templates.
03 May 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
30 January 2023	Updated certificate of suitability from an already approved manufacturer.
12 August 2022	Updated certificate of suitability from an already approved manufacturer.
04 June 2021	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
21 April 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
18 September 2020	Renewal – UK as CMS.
02 September 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
11 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
22 February 2018	Change in contact details for local representative.
23 May 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Change in the specification limits of an excipient.
02 February 2017	Change in pack size of the finished product.
09 November 2016	Change in dimensions of the container (immediate packaging)