



## Post Authorisation Assessments

### Nefotek 100 mg/ml Solution for Injection for Cattle, Horses and Pigs Vm 32509/4008

29 December 2025	Deletion of the manufacturing site and responsible for batch release for the finished product.
05 February 2025	Change in the Address of the Marketing Authorisation Holder from C/ Les Corts, 23 08028 Barcelona, Spain, to Gran Via Carles III, 98, 7 <sup>a</sup> 08028 Barcelona, Spain. (GB & NI)
11 October 2022	Submission of an updated Ph. Eur. certificate of suitability
01 July 2021	Changes to the labelling and/or package leaflet.
03 December 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
18 May 2018	Changes to the labelling and/or package leaflet. Change in distributor details from Vetpharma Animal Health, S.L, Les Corts, 23, 08028 Barcelona, Spain to Bimeda, A division of Cross Vetpharm Group (UK) Ltd, Bryn Cefni Industrial Park, Langefni, Anglesey, LL77 7XA.
08 May 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
25 April 2017	Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a secondary packaging site of the finished product. Changes to a test procedure for the finished product. Decrease in batch size range of the finished product. Addition of a manufacturing site of the finished product.
14 December 2016	Renewal - UK as CMS.
24 February 2015	Addition of a local representative, deletion of a distributor, and approval of mock-ups.
14 July 2014	Repeat use procedure.
30 April 2014	To update the Ph. Eur Certificate of Suitability for an approved manufacturer.