Veterinary Medicines Directorate

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Post Authorisation Assessments

Nefotek 100 mg/ml Solution for Injection for Cattle, Horses and Pigs

Vm 32509/4008

•	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.