Veterinary Medicines Directorate

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Post Authorisation Assessments

Nifencol 300 mg/ml Solution for Injection for Cattle and Pigs

Vm 32509/4011

•	23 January 2024	Incorporation of SPC and product literature changes subsequent to the Article 83 referral for products including NMP.
•	31 July 2023	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	06 July 2023	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	02 October 2019	Changes to the labelling or package leaflet.
•	20 November 2018	Renewal - UK as CMS.
•	08 May 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	28 February 2018	Repeat Use application to add 5 new member states
•	06 September 2017	Minor change to an approved test procedure for the starting material used in the manufacturing process of the active substance. Change in the manufacturer of the active substance where no Ph. Eur. Certificate of Suitability is part of the approved dossier. Minor change to the restricted part of an Active Substance Master File.
•	15 December 2016	Deletion of a non-significant specification parameter of the finished product. Change in the specification limits of the finished product.
•	25 July 2014	To replace the manufacturer of the finished product, also responsible for primary and secondary packaging, batch control and batch release. To change the batch of the finished product. To add a new package size. To change one of the test procedures for the finished product.