Veterinary Medicines Directorate

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Post Authorisation Assessments

Aurofac Granular 100mg/g Premix for Medicated Feeding Stuff

Vm 42058/4007

•	18 May 2024	Change in qualitative or quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product.
•	03 April 2024	Submission of an updated CEP for the manufacture of an active substance.
•	08 April 2021	Minor changes to an approved test procedure of the finished product.
•	21 December 2020	Deletion of manufacturing site for an active substance.
•	21 August 2020	Change in the address of the MAH, from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited,1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	23 October 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	08 August 2017	Deletion of a test procedure for the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Change in the specification limits of the finished product.
•	11 April 2017	Minor change in the manufacturing process of the finished product.
•	31 March 2015	Submission of updated Ph. Eur. Certificates of Suitability.
•	17 April 2014	Addition of a site for batch testing.
•	12 June 2013	Change in distributor details. Change in legal entity. Change in name/address of the manufacturer of the finished product, including quality control sites
•	03 August 2012	Change of name of manufacturer of the finished product
•	19 December 2011	Changes to an existing pharmacovigilance system as described in the DDPS
•	10 August 2011	Change of MAH and distributor
•	15 June 2011	Change of QPPV and deputy QPPV
•	21 April 2010	Deletion of laying birds from list of target species
•	11 March 2010	Renewal
•	17 February 2010	Submission of updated Ph. Eur. Certificate of Suitability for the active substance Addition of a manufacturer of the active substance Addition of a manufacturer for part of the manufacturing process

•	20 November 2008	Changes to bring the SPC and Product Literature in line with new legislation
•	23 September 2008	Change to batch size of the finished product
•	02 May 2007	Increase in shelf life from 2 to 3 years
•	14 June 2006	Increase of withdrawal period in laying hens producing eggs for human consumption to 4 days
•	10 May 2006	Change of address of the MAH Change in name of manufacturer of the finished product
•	27 February 2006	Increase in shelf life from 18 months to 2 years