Veterinary Medicines Directorate

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Post Authorisation Assessments

Aurofac Granular 250 mg/g Premix for Medicated Feeding Stuff

Vm 42058/4006

•	12 March 2024	Updated CEP submitted for the manufacture of an active substance.
•	27 September 2022	Change in the qualitative/quantitative composition of the immediate packaging.
•	08 April 2021	Minor changes to an approved test procedure of the finished product. 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	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	23 October 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 April 2017	Minor change in the manufacturing process of the finished product.
•	02 December 2015	Addition of an alternative batch size for the finished product.
•	20 April 2015	Change to the QPPV contact details.
•	11 February 2015	Submission of updated Ph. Eur. Certificates of Suitability.
•	18 September 2014	To extend the self-life of the finished product as packaged for sale, from 2 years to 3 years.
•	17 April 2014	Addition of an alternative site for batch testing of the finished product.
•	14 June 2013	Change of legal entity to Zoetis. Change in name of manufacturer and details of distributor. Change in QPPV contact details.
•	14 August 2012	Renewal
•	03 August 2012	Change in the name of the manufacturer of the finished product.
•	19 December 2011	Changes to the existing pharmacovigilane system already described in the Detailed Description of Pharmacovigilance System (DDPS).

•	10 August 2011	To change the Marketing Authorisation Holder and distributor from Alpharma Animal Health BVBA, to Pfizer Ltd.
•	15 June 2011	Changes to an existing pharmacovigilance system.
•	09 February 2011	To amend the withdrawal of laying birds as target species.
•	02 March 2010	To submit an updated Ph. Eur Certificate of Suitability for the active substance.
•	02 March 2010	To add an additional manufacturer of the active substance.
•	02 March 2010	To add an additional manufacturer of the active substance.
•	16 April 2008	To add three additional pack sizes of 4.8 kg, 6.4 kg and 8 kg.
•	12 Decmber 2007	Approval of mock-ups for 20 kg pack size