Veterinary Medicines Directorate

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Post Authorisation Assessments

Aurofac Granular 250 mg/g Premix for Medicated Feeding Stuff

Vm 42058/5186

01 November 2024	Change in the specification parameters and/or limits of an excipient.
22 June 2024	Extension of re-test period for an active substance.
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