Veterinary Medicines Directorate

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Post Authorisation Assessments

Denagard 10% w/w Premix for Medicated Feeding Stuff for Pigs, Chickens, Turkeys and Rabbits

•	19 January 2022	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor change in the manufacturing process of the finished product. Change to comply with Ph. Eur. Addition of a site where batch control/testing takes place. Replacement to a test procedure for an excipient. Addition of a manufacturing site of the finished product.
•	24 November 2021	Changes to a test procedure (replacement) for the active substance. Changes to a test procedure (replacement) for the active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	17 August 2021	Change in the specification parameters of the active substance, and of the finished product. Change in the specification parameters of the active substance, and of the finished product.
•	26 March 2021	Change in the address of the marketing authorisation holder from: Elanco Europe Ltd. Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to: Elanco Europe Ltd. Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	03 March 2021	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	14 August 2020	Tightening of specification limits of the finished product Addition of a new specification parameter to the specification with its corresponding test method of the finished product
•	06 July 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Introduction of a re-test period of the active substance.
•	05 May 2020	Minor change in the manufacturing process of the finished product. Decrease in batch size range of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product. Addition of a manufacturing site of the finished product.

•	05 May 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Replacement of a manufacturer responsible for batch release including batch control/testing. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Replacement of a primary packaging site of the finished product. Changes to a test procedure for the finished product. Decrease in batch size range of the finished product. Change in the specification parameters and/or limits of the finished product. Replacement of an excipient with a comparable excipient. Changes in the composition (excipients) of the finished product. Replacement of a manufacturing site of the finished product.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	31 January 2018	Minor changes to an approved test procedure of the finished product.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	10 August 2016	Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release
•	16 March 2016	Change in distributor details Change in legal entity
•	11 June 2015	Minor changes in the manufacturing process.
•	09 October 2014	Minor changes to the control monograph of the excipient, to comply with Ph. Eur.
•	06 March 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved active substance manufacturer.
•	28 February 2014	Changes to an existing pharmacovigilance system.
•	31 January 2014	Renewal.
•	06 August 2013	Changes to comply with the update to the Ph. Eur monograph for an excipient.
•	27 September 2012	Changes to the pharmacovigilance system as described in the DDPS.
•	12 June 2012	Submission of a new/updated certificate of suitability.
•	15 June 2011	To add additional species: chickens (broiler, replacement pullet, layer/breeder), turkeys (poult grower and breeder), and rabbit. To add indications for pigs.
•	05 April 2011	To add an additional site for the release of the finished product.