Veterinary Medicines Directorate

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Post Authorisation Assessments

Perlium Amoxival 100 mg/g Premix for Medicated Feeding Stuff for Pigs

Vm 15052/5044

•	23 August 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	21 June 2023	Deleting manufacturer site of finished product. Deleting manufacturer site of finished product.
•	26 May 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Minor change in the manufacturing process. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	17 January 2023	Addition of a manufacturer responsible for batch release including batch control or testing of a non-sterile finished product. Addition of a primary packaging site of a non-sterile finished product. Addition of a secondary packaging site of a finished product.
•	October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire HP10 0HH, United Kingdom.
•	15 December 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	15 April 2020	Addition to a test procedure for an excipient. Addition to a test procedure for the finished product.
•	17 March 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 May 2019	Replacement of a site where batch control/testing takes place.
•	22 August 2018	Replacement of a manufacturer responsible for batch release of the finished product.
•	05 June 2018	Deletion of a non-significant specification parameter of the immediate packaging of the finished product.
•	15 March 2018	Change in RMS from UK to NL.
•	13 March 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 January 2018	Change in the specification limits of an excipient.

		Change in the specification limits of the finished product.
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	08 September 2016	Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of the manufacturer of the finished product.
•	06 September 2016	Change in the name an address of the MAH in Italy only.
•	29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	16 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd.
•	15 September 2015	Change in distributor and assessment of mock-ups
•	14 May 2015	Renewal – UK as CMS.
•	20 March 2015	Submission of an updated and a new Ph. Eur. Certificate of Suitability.

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