Veterinary Medicines Directorate

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Post Authorisation Assessments

Canaural Ear Drops, Suspension for Dogs and Cats

Vm 24883/4004

•	18 July 2023	Change in dimension of the finished product container.
•	24 June 2022	Addition of a manufacturer of the active substance or addition of a site of manufacture. Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	29 March 2022	Addition to a test procedure for the finished product.
•	09 September 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	04 August 2021	Changes to a test procedure (including addition) for the active substance. Addition to a test procedure for the finished product.
•	23 June 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	05 May 2020	Changes to a test procedure for the active substance. Changes to a test procedure for the finished product.
•	16 March 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 July 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	06 March 2019	Deletion of manufacturing site for an active substance.
•	12 February 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	04 October 2017	Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer.
•	26 July 2017	Change in the specification limits of the finished product
•	02 November 2016	Submission of an updated certificate of suitability.
•	15 January 2016	To change the manufacturing process of the finished product.
•	14 May 2015	Submission of a new Ph. Eur. Certificate of Suitability.
•	14 May 2015	Change to the style of packaging.
•	15 January 2015	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance.
•	28 November 2014	Submission of a new Ph. Eur. Certificate of Suitability.
•	20 August 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer and deletion of a manufacturing site of an active substance.

•	03 October 2012	Addition of a safety warning.
•	19 April 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	10 April 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	28 March 2012	Change in test procedure performed on the finished product and change in test procedure performed on an active substance.
•	20 February 2012	Addition of a manufacturer of secondary packaging.
•	20 July 2011	Submission of an updated Ph. Eur. Certificate of suitability for an active substance from an already approved manufacturer.
•	15 June 2011	Replacement of a site of bulk manufacturing.
•	25 May 2011	Replacement of a site of primary packaging.
•	16 February 2011	Change of distributor.
•	27 January 2011	Minor change to test procedure performed on the finished product. Change to batch release arrangements of the finished product and addition of a manufacturer of the dosage form and assembly.
•	07 July 2010	Change in tests performed on an active substance.
•	09 December 2009	Minor change to manufacturing process of an active substance.
•	04 August 2009	Change of manufacturer of the immediate packaging and change of packaging dimensions.
•	01 July 2009	Removal of 7.5ml pack size.
•	03 June 2009	Submission of updated Ph. Eur. Certificates of Suitability for an active substance from an already approved manufacturer.
•	02 April 2009	Change of MAH name from VetXX A/S to Dechra Veterinary Products A/S.
•	20 January 2009	Changes to bring the SPC and Product Literature in line with new legislation and change of legal category from POM to POM-V.
•	11 September 2008	Corrections to the SPC and Product Literature.
•	15 July 2008	Change of specification of the finished product.
•	03 July 2008	Change in re-test period of an active substance.
•	26 June 2008	Change of distributor.
•	05 June 2008	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	04 June 2008	Change in re-test period for active substance.
•	15 May 2008	Change of name of a manufacturing site of an active substance. Submission of a new Ph. Eur. Certificate of Suitability for an active substance from a new manufacturer.
•	22 September 2007	Submission of updated Ph. Eur. Certificates of Suitability from an already approved manufacturer of the active substance.
•	30 October 2006	Renewal.

•	24 August 2006	Corrections to the Product Literature.
•	01 August 2005	Change of MA holder from Leo Laboratories Ltd to VetXX A/S.
•	24 June 2005	Change of distributor.
•	14 January 2005	Changes to the Product Literature.
•	09 April 2003	Renewal.
•	31 July 2002	Addition of a manufacturer of an active substance.
•	24 June 2002	Change of manufacturers of active substances.
•	01 November 2000	Addition of a contraindication.
•	05 June 2000	Change of manufacturing process of the active substance.
•	12 August 1999	Addition of 1x7.5ml and 1x15ml pack sizes.
•	27 May 1998	Change of manufacturer of the active substance.
•	10 December 1997	Changes to specification of the finished product.
•	29 April 1997	Changes to product literature.