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Post Authorisation Assessments

Tetra-Delta Intramammary Suspension

•	09 June 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	18 March 2021	Changes to the withdrawal period of the veterinary medicinal product from: Cattle (meat and offal): 7 days (milk): 108 hours to: Cattle (meat and offal): 4 days (milk): 108 hours.
•	06 November 2020	Change in the address of the marketing authorisation holder 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.
•	06 February 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of a Ph. Eur. certificate of suitability for an active substance.
•	15 July 2015	Submission of a new Ph. Eur. Certificate of Suitability.
•	29 November 2013	Transfer of the Marketing Authorisation Holder, including a change of Distributor.
•	30 September 2013	Submission of three updated Certificates of Suitability for three already approved active substance manufacturers.
•	10 May 2013	Variation to change a test procedure for the finished product.
•	06 July 2011	Renewal.
•	27 April 2011	Extension of the milk withdrawal period.
•	18 September 2009	Addition of an active substance manufacturer.
•	09 July 2008	Addition of a site responsible for batch release.
•	25 October 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.

•	16 August 2007	Variation to change the Marketing Authorisation Holder.
•	17 June 2005	Change of distributor.
•	29 August 2003	Addition of a distributor.
•	07 December 2001	Renewal.
•	07 December 2001	Variation to change the name of the Marketing Authorisation Holder.
•	18 November 1999	Variation to change the name and address of the Marketing Authorisation Holder.
•	11 June 1999	Harmonisation of the packaging with IE.
•	06 October 1998	Renewal.
•	04 June 1997	Variation concerning the manufacturer/assembler of dosage form.
•	14 May 19997	Change to the packaging details.