Veterinary Medicines Directorate

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Post Authorisation Assessments

Tuberculin PPD Kit

Vm 36410/4000

•	05 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	24 November 2022	This variation is to add an additional manufacturer for two growth media that are used in the production of the active substance of Bovine and Avian Tuberculin PPDs.
•	17 June 2022	Change in the name and address of a manufacturer of the finished product. Change in the name and address of a manufacturer of the active substance.
•	09 March 2022	Change in the source of an excipient used in the manufacture of the finished product. Addition of a manufacturer for a reagent involved in the manufacturing process of the active substance.
•	05 October 2021	Repeat Use application to add 1 new member state.
•	23 July 2021	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 March 2021	Repeat Use application to add 1 new member state
•	11 June 2020	Changes to a test procedure (including replacement) for the active substance. Change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier. Change in the manufacturer of the active. Addition of a site where batch/control testing including a biological method takes place.
•	28 October 2019	Change of a test procedure for the finished product.
•	18 April 2019	Changes (Safety/Efficacy) to Veterinary Medicinal Products
•	21 March 2019	Change in RMS from UK to NL.
•	12 December 2018	Change in source of an excipient or reagent. Change to in-process tests or limits applied during the manufacture of the finished product. Replacement of a secondary packaging site of the finished product. Changes to a test procedure for an excipient. Replacement of a site where batch control/testing takes place. Addition of a manufacturing site of the finished product.

•	05 April 2018	Change in the specification parameters of the finished product. Correction of the quantitative composition of 3 components. Correction of fill volume units. Change in unit in the header of the tables for blending. Corrections and inclusion of holding times of intermediate product. To update name of supplier. Changes in the manufacturing process of the active substance.
•	14 June 2017	Increase in the shelf-life of the finished product, from 3 years to 4 years
•	16 August 2016	Replacement of the current Seed Lot Systems for M. bovis and M. avium with a new Seed Lot System for each Mycobacterium. Change in the manufacturing process of the active substance. Change in the manufacturing process of the active substance.
•	13 April 2016	Increase in shelf life for Avian Tuberculin PPD 2500, 20-doses presentation from 3 years to 4 years.
•	17 November 2015	Increase in the shelf-life of the finished product as packaged for sale.
•	07 May 2015	Renewal – UK as RMS.
•	17 July 2014	Deletion of non-significant in-process controls. Addition of a secondary supplier for a component used in the manufacturing process of the active substance.
•	17 April 2014	Extension of shelf life from 24 to 30 months for the Bovine Tuberculin PPD component, addition of a supplier of the packaging components and change of name of the manufacturer of packaging components.
•	8 November 2013	Change in specification parameters and test procedures for the finished product.
•	26 April 2013	Variation to extend the shelf life of the two components of the Tuberculin PPD kit for the 50 dose presentation from 18 months to 2 years.
•	02 November 2012	Variation to extend the shelf-life of the two components of Tuberculin PPD for the 50-dose presentation: from 12 to 18 months.
•	22 March 2012	Text changes to SPC and package leaflet.
•	24 January 2012	Changes in the manufacturing process of the active substance.
•	12 January 2012	Changes to an existing pharmacovigilance system as described in the DDPS.
•	12 January 2012	Changes to an existing pharmacovigilance system as described in the DDPS.
•	7 December 2010	Addition of pack size of the finished product and amendment of transport temperature to +2°C – 37°C for a period of no longer than 14 days.