Veterinary Medicines Directorate

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Post Authorisation Assessments

Covexin 10 Suspension for Injection for Sheep and Cattle

Vm 42058/3020

•	14 November 2024	Changes to the manufacture of the active substance. Changes to identity testing of the active substance, Extension of the shelf life of antigens.
•	22 June 2024	Update to V9 of QRD template.
•	29 January 2021	Updates to the SPC and product information following a repeat-use procedure.
•	08 April 2020	Changes to a test procedure for the finished product.
•	14 November 2019	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.
•	23 October 2019	Repeat Use Application to add 1 new member state (HR)
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	12 June 2018	Change in RMS from UK to DE.
•	27 March 2018	Deletion of a test procedure for the active substance Submission of an updated Ph. Eur. TSE certificate of suitability for a reagent (used in manufacturing process of active) from an already approved manufacturer. Change in the manufacturing process of the active substance. Changes in the manufacturing process of the active substance. Changes in the manufacturing process of the active substance.
•	24 March 2017	Changes to a test procedure (including replacement or addition) for the active substance / intermediate.
•	28 December 2016	Deletion of non-significant in-process tests applied during the manufacture of the active substance. Change in the specification limits of the finished product.
•	08 December 2016	Change of MAH address in France, Czech Republic and Slovakia.
•	28 October 2015	Change in a minimum specification limit for a finished product component.
•	05 May 2015	Change in the QPPV contact details.
•	16 April 2015	Deletion of a non-significant in-process test.
•	09 April 2015	Renewal.
•	27 June 2014	Change to the potency test specifications for the finished product.

•	10 October 2013	Change in name and address of MAH
•	31 July 2013	Change in legal entity Change in distributor details
•	14 June 2013	Change of pack size (removal of 20ml vial presentation) Change of composition of the packaging
•	15 February 2013	Change of manufacturing site of manufacture of the finished product, batch release, control testing and secondary packaging
•	07 February 2013	Change in test procedure performed on the active substance
•	06 June 2012	Changes to an existing pharmacovigilance system as described in the DDPS
•	03 November 2011	Change of specification of an excipient
•	23 June 2011	Change of MAH address in Spain
•	08 April 2011	Change of MAH address in Poland
•	17 March 2011	Submission of a new Ph. Eur. Certificate of Suitability for an excipient Change in specification of an excipient to comply with Ph. Eur.
•	17 June 2010	Repeat use procedure
•	03 December 2009	Renewal
•	26 August 2009	Change of legal category from POM-V to POM-VPS
•	19 August 2009	Change of MAH
•	23 April 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	09 August 2007	Replacement of an in-process test performed on the finished product
•	11 December 2006	Change of address of MAH in Denmark only
•	16 November 2006	Change of test procedure performed on the finished product
•	18 May 2005	Mutual Recognition Procedure, UK as RMS
•	22 September 2003	Change of shelf life from 12 months to 30 months