Veterinary Medicines Directorate

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Post Authorisation Assessments

Cevac Transmune Lyophilisate for Suspension for Injection with Solvent for Chickens

Vm 15052/4030

•	17 November 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF. (NI)
•	27 September 2022	Change of MAH address 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.
•	16 July 2021	Change in the fill volume of the finished product.
•	01 October 2020	Changes to the labelling and package leaflet.
•	12 May 2020	Update to Part II of the dossier.
•	07 February 2020	Change in shape or dimensions of the container or closure (immediate packaging). Change in the manufacturing process of the finished product. Reduction of the shelf life of the finished product as packaged for sale from 3 years to 30 months (solvent). Change to in-process tests or limits applied during the manufacture of the finished product. Change in the specification limits of the finished product.
•	07 February 2020	Change of the invented name of solvent.
•	28 January 2019	Change in RMS from UK to HU.
•	13 December 2018	Renewal - UK as RMS.
•	13 December 2018	Change in the number of units in a pack within the range of the currently approved pack sizes of the finished product. Change in shape or dimensions of the container or closure (immediate packaging).
•	05 April 2018	Change in the fill volume of the finished product.
•	23 March 2018	Change in the SPC, labelling or package leaflet due to new data.
•	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.
•	19 September 2017	Change in the name and/or address of the MAH in Spain only.
•	18 May 2017	Change of a test procedure for the finished product.
•	07 March 2016	Addition of SC Infomed Fluids SRL as manufacturing site

		for the saline solution solvent
•	07 March 2016	Minor changes to production at a new manufacturing site.
•	07 March 2016	Change to the specifications of the starting material Cyclodextrin in order to comply to Ph. Eur.
•	22 December 2015	Updating of the DDPS system.
•	06 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
•	03 July 2014	Change in test procedure for the finished product. Addition of an alternative solvent to the currently authorised solvent, used for reconstitution of the product.
•	08 May 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	11 October 2013	Changes to an existing pharmacovigilance system described in the DDPS.
•	17 September 2013	Repeat Use procedure – UK as RMS.
•	31 May 2013	Renewal.
•	17 January 2013	Addition of an alternative secondary packaging site.
•	05 July 2012	Addition of a presentation of a vial 4000 doses of freeze dried component (to reconstitute in 200 ml of solvent for in ovo use and 400 ml solvent for subcutaneous use).
•	05January 2012	To change the name and address of the MAH in Italy only.
•	11 October 2011	To change the address of the Marketing Authorisation Holder.
•	06 October 2011	Change in test procedure for the finished product.
•	16 March 2011	Approval of mock-up for authorised pack size (new pack size to UK)
•	05 October 2010	Extension to include an indication for one day old broiler chicks.
•	07 November 2008	To change the shelf life of the finished product.
•	14 February 2008	To change the shelf life of the finished product.