Veterinary Medicines Directorate

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Post Authorisation Assessments

Scabigard
Vm 42058/4213

•	22 June 2022	Transfer of the legal entity of the MAH from MSD Animal Health Limited, UK to Zoetis UK Limited, UK and removal of Intervet Ireland Ltd as a named distributor. Replacement of the current manufacturer responsible for batch release; change from MSD Animal Health UK Limited to Zoetis Belgium SA, Belgium.
•	26 May 2022	Change in the pharmacovigilance system master file.
•	04 May 2022	Change in the invented name of the medicinal product, from Scabivax Forte to Scabigard.
•	19 May 2021	Change in name of manufacturer of the finished product, also responsible for batch release. Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	08 April 2021	Changes to the labelling and/or package leaflet intended to implement the outcome of a procedure concerning PSUR.
•	24 February 2021	Change in the specification parameters of the active substance. Submission of a Ph. Eur certificate of suitability. Change(s) in the manufacturing process of the active substance.
•	02 February 2021	Deletion of a supplier of packaging components or devices.
•	26 November 2019	Change in the specification parameters of the finished product. Addition of a new in-process test and limit applied during the manufacture of the active substance.
•	01 February 2019	Change in container closure system of the finished product.
•	11 October 2018	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product
•	10 September 2018	Replacement of a site where batch control/testing takes place.
•	09 May 2018	Change in source of an excipient.
•	23 January 2014	Change of importer from outside the EU and retesting site.
•	11 December 2013	Introduction of parameters as the standard manufacturing procedure.
•	28 June 2013	Change in the name of the manufacturer of the active substance, site for blending filling, labelling and

		packaging, and QC testing site.
•	20 December 2011	Change of MAH from Schering-Plough Ltd to Intervet UK Ltd, change in the manufacturer for batch release, addition of a distributor in Northern Ireland, and increase in font size and reduction of text on the packaging.
•	11 November 2009	Addition of a new supplier of a starting material.
•	11 September 2008	Renewal.
•	18 June 2008	Changes to the SPC and product literature to bring them into line with new legislation.
•	18 June 2008	Change of legal category from POM to POM-V.
•	22 February 2008	Change in the name/address of the manufacturer of the finished product.
•	23 January 2008	Change in storage conditions for the antigen.
•	23 January 2008	Change in storage conditions of the bulk vaccine.
•	25 May 2006	Changes to the test methods for the finished product.
•	20 October 2004	Change of shelf-life of finished product.
•	13 August 2004	Change of shelf-life of finished product.
•	12 March 2004	Change to storage instructions.