



## Post Authorisation Assessments

### Deltamole 7.5 mg/ml Pour-on Suspension for Cattle

Vm 01708/4609

•	31 March 2023	Changes in the SPC, labelling or package leaflet intended to implement the outcome of a procedure. Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics. Changes to the SPC and / or product literature: - Corrections to layout.
•	07 March 2023	Deletion of a non - significant specification parameter for an excipient.
•	01 March 2023	Deletion of a test procedure for an excipient.
•	23 February 2023	Deletion of - a non-significant specification parameter in the specification parameters or limits of an excipient.
•	23 February 2023	Deletion of - (a) a test procedure for the active substance or a starting material or reagent or intermediate of the active substance, or (b) for the immediate packaging of the active substance for an excipient or the finished product or for the immediate packaging of the finished product
•	04 February 2022	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
•	18 March 2021	Minor change to an approved test procedure for an excipient.
•	12 March 2021	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	20 August 2020	Addition of a specification parameter with its corresponding test method of the finished product.
•	15 April 2020	Renewal – National.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	13 March 2018	Change in the name of a manufacturer used in the manufacture of the active substance.
•	17 January 2017	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	09 November 2016	Changes to an existing pharmacovigilance system as described in the DDPS.

•	06 September 2016	Change in the name of the supplier of a starting material used in the manufacture of the active substance. Addition of two manufacturers of an intermediate used in the manufacturing process of the active substance.
•	26 April 2016	Change in the specification limits of the finished product.
•	01 May 2015	Change in name of the manufacturer of the active substance.
•	31 March 2015	Change in the specification parameters of an excipient.