Veterinary Medicines Directorate

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Post Authorisation Assessments

Engemycin 10% DD Solution for Injection

Vm 01708/4623

•	18 May 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
•	23 January 2024	Addition of a test procedure for the finished product.
•	16 August 2023	Deletion of a manufacturing site of the finished product.
•	31 July 2023	Change in immediate packaging of the finished product.
•	10 August 2022	Change in excipient specification to comply with the Ph.Eur.
•	23 December 2021	Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release where batch control/testing takes place. Addition of a manufacturing site of the finished product. Addition of secondary packaging site of the finished product.
•	13 July 2021	Change in distributor details. From various addresses to Same as MAH, Alternative distributor in Northern Ireland, Intervet Ireland Limited, Magna Drive, Magna Business Park, Citywest Road, Dublin 24.
•	11 January 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 November 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	17 July 2020	Change of MAH from Intervet International BV represented by: Intervet UK Ltd. Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	23 June 2020	Deletion of manufacturing site for an active substance
•	24 May 2016	Deletion of a manufacturing sites (for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier). Submission of a new or updated Ph. Eur. certificate of suitability
•	20 August 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance
•	16 February 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance

•	09 February 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance
•	30 December 2008	Updates to section 4.11 of the SPC
•	12 September 2007	Change of batch size
•	03 April 2007	Addition of a manufacturer of an active substance
•	09 November 2006	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	02 May 2006	Renewal
•	23 June 2005	Change of distributor
•	21 April 2005	Renewal Change of withdrawal period for: Meat from Pigs from 8 days to 14 days Meat from Cattle – from 8 days to 35 days (24 hour dosing regimen) / from 10 days to 21 days (prolonged dosing regimen)
•	28 January 2005	Change of withdrawal period for: Milk from Sheep – not for use in sheep producing milk for human consumption Milk from Cattle – from 48 hours (24hour dosing regimen)/72 hours (prolonged action dosing regimen) to 6 days for all dosing regimens Meat from Sheep – from 8 days to 14 days
•	23 April 2003	Addition of a manufacturing site for batch release
•	22 August 2001	Change of distributor
•	02 June 2000	Change of address of the MAH Update of licence particulars
•	28 August 1998	Deletion of a target species
•	27 October 1997	Change of type of sterile container