Veterinary Medicines Directorate

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Post Authorisation Assessments

Amoxypen Injection 150 mg/ml, Suspension for Injection

Vm 01708/4339

•	13 July 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	27 May 2021	Deletion of a non-significant specification parameter of an excipient.
•	12 March 2021	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	27 January 2021	Reduction of the shelf life of the finished product as packaged for sale from 2 years to 12 months.
•	14 January 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	13 November 2018	Increase in batch size of the finished product.
•	08 March 2017	Change in the name of an excipient from Fractionated Coconut Oil to Propylene Glycol Dicaprylocaprate. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	23 January 2017	Change to a test procedure for the finished product.
•	01 November 2006	Change in legal category from POM to POM-V Changes to SPC and Product Literature to bring in line with new legislation
•	22 March 2006	Addition of site of sterilisation of the active substance to bring in line with the parent product
•	07 February 2006	Addition of a manufacturer of the active ingredient
•	29 November 2005	Renewal
•	20 April 2005	Change of distributor
•	03 July 2001	Change of distributor
•	15 May 2001	Renewal
•	02 June 2000	Change of MAH address
•	02 February 1999	Change in withdrawal period