Veterinary Medicines Directorate

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Post Authorisation Assessments

Pathozone 250mg Intramammary Suspension for Cattle

•	22 January 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	29 March 2019	Minor changes to an approved test procedure of the finished product. Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Deletion of a non-significant specification parameter of the finished product. Replacement to a test procedure for the finished product. Replacement to a test procedure for the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the

		finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Deletion of a non-significant specification parameter of the finished product. Change in the specification limits of the finished product. Change in the specification limits of the finished product.
•	03 October 2018	Change in RMS from UK to BG.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	14 December 2017	Renewal – UK as RMS.
•	21 June 2017	Change in type of container for the finished product.
•	05 June 2015	Change to the QPPV contact details.
•	15 May 2014	Repeat Use procedure.
•	31 October 2013	Change to the QPPV contact details.
•	18 October 2013	Addition of a 10 syringe pack size.
•	31 July 2013	Change of MAH and Distributor to: Zoetis UK Ltd.