Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Cephaguard DC 150mg Intramammary Ointment

Vm: 05653/3017

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| • | 18 April 2024 | Minor changes to the test procedure for assay and determination of impurities in the finished product. |
| • | 02 November 2023 | Update to the latest version of the EU QRD template. |
| • | 12 June 2023 | Change in the name of a manufacturer of the finished product. (NI) |
| • | 15 December 2022 | Change in the name of a manufacturer of the finished product. (GB) |
| • | 18 March 2022 | Deletion of manufacturing site for finished product. |
| • | 10 December 2021 | Addition of a manufacturer responsible for batch release including batch control/testing.<br>Minor change in the manufacturing process of an immediate release solid oral dosage form.<br>Change in storage conditions of the finished product.<br>Addition of a manufacturing site of the finished product. |
| • | 10 December 2021 | Changes in the SPC, labelling or package leaflet following the outcome of a PSUR.<br>Updates made to the SPC and QRD texts to align with the current QRD Template. |
| • | 08 April 2021 | Extension of a re-test period of the active substance. |
| • | 06 April 2020 | Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 11 June 2018 | Update of the test procedure to comply with the updated general Ph. Eur monograph.<br>Deletion of a non-significant specification parameter of the finished product. |
| • | 31 March 2013 | Addition of a manufacturer of the active substance |
| • | 27 July 2012 | Minor change in manufacturing process of the finished product |
| • | 18 July 2012 | Additional batch size added |
| • | 13 July 2012 | Change to part of the packaging not in contact with the finished product formulation |
| • | 15 March 2012 | Minor change in the manufacture of the active substance |
| • | 10 November 2011 | Addition of a site of secondary assembly |
| • | 26 April 2011 | Deletion of a manufacturer of the active substance<br>Change in test method performed on the active substance<br>Update of the Active Substance Master File (ASMF) |
| • | 26 January 2011 | Approval of previously unseen mock ups |
| • | 24 August 2010 | Addition of pack sizes:<br>Box of 6 sachets of 4 applicators and 24 cleaning towels<br>Box of 30 sachets of 4 applicators and 120 cleaning |

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| | | towels |
| • | 15 April 2010 | Change of name of product in the RMS and all CMS's except UK and IE. |
| • | 08 January 2010 | Addition of a manufacturing site of the dosage form |
| • | 21 December 2009 | Renewal |
| • | 29 October 2008 | Change of MAH |
| • | 12 August 2008 | Change to batch release arrangements<br>Addition of a site of secondary assembly |
| • | 12 May 2008 | Repeat use procedure |
| • | 20 December 2006 | Change of milk withdrawal period from 49 days to 35 days |
| • | 03 November 2005 | Change of distributor |
| • | 21 September 2005 | Addition of a manufacturer of the active substance |