



## Post Authorisation Assessments

### Cephaguard DC 150mg Intramammary Ointment Vm 05653/3017

29 July 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
20 March 2025	Substantial changes in the updated version of the ASMF.
16 January 2025	Change in the address of a manufacturer (FC France SAS).
20 November 2024	Deletion of an obsolete specification parameter for the active substance.
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. Minor change in the manufacturing process of an immediate release solid oral dosage form. Change in storage conditions of the finished product. 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. 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. 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

	Change in test method performed on the active substance Update of the Active Substance Master File (ASMF)
26 January 2011	Approval of previously unseen mock ups
24 August 2010	Addition of pack sizes: Box of 6 sachets of 4 applicators and 24 cleaning towels Box of 30 sachets of 4 applicators and 120 cleaning 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 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