Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Ectofly 12.5 mg/ml Pour-on Solution for Sheep

Vm 50146/4017

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| 22 July 2026 | Downscaling down up to 10-fold change in batch size (including batch size ranges) of the finished product.<br>Replacement of a manufacturing site responsible for batch release and batch control of the finished product.<br>Replacement of a secondary packaging site of the finished product. |
| 22 July 2026 | Replacement of a primary packaging site of the finished product. |
| 22 July 2026 | Replacement of a manufacturing site for part or all of the manufacturing process of the finished product. |
| 10 October 2025 | One-off alignment of the product information with version 3 and version 9.1 of the QRD template. |
| 17 November 2023 | Deletion of an in-process control applied during the manufacture of the finished product. (NI) |
| 17 November 2023 | Deletion of an in-process control applied during the manufacture of the finished product. (GB) |
| 17 November 2023 | Change to the in-process controls applied during the manufacture of the finished product. (NI) |
| 17 November 2023 | Change to the in-process controls applied during the manufacture of the finished product. (GB) |
| 06 July 2023 | Tightening of specification limits of the immediate packaging of the finished product. |
| 06 July 2023 | Change to importer, batch control arrangements and quality testing for a finished product. |
| 23 December 2022 | Replacement of a quality testing site. |
| 21 December 2022 | Change in the specification parameters or limits of the immediate packaging of the finished product:– tightening of specification limits.<br>Change in the specification parameters or limits of the immediate packaging of the finished product:– tightening of specification limits.<br>Change in the specification parameters or limits of the immediate packaging of the finished product:– tightening of specification limits. |
| 26 January 2021 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| 20 September 2019 | Change in the name (only) of quality control testing site.<br>Change in the name and address of a manufacturer of the finished product, also responsible for batch release.<br>Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. |

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| 19 October 2018 | Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland. |
| 09 October 2018 | Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product.<br>Deletion of a non-significant specification parameter of the immediate packaging of the finished product. |
| 06 July 2018 | Change in RMS from UK to FR. |
| 29 December 2017 | Minor changes to an approved test procedure of the finished product.<br>Deletion of a non-significant specification parameter of the finished product. |
| 25 October 2017 | Change in the number of units (e.g. tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes of the finished product. |
| 02 May 2017 | Changes to the labelling and package leaflet |
| 27 July 2016 | Renewal – UK as RMS |
| 22 March 2016 | Change in the dimensions of the immediate packaging container.<br>Addition of a new specification parameter for the immediate packaging of the finished product. |
| 19 June 2015 | Changes to the specification parameters of an excipient. |
| 05 June 2015 | Changes to the withdrawal period. |
| 10 April 2014 | Change in test procedure for the finished product.<br>Change in specification parameters of an excipient. |
| 28 June 2013 | Change in method for identification and quantification of the active substance. |
| 07 May 2013 | To change the manufacturing process of the finished product and to increase the batch size of the finished product. |