Veterinary Medicines Directorate

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Post Authorisation Assessments

Milbemax 12.5 mg/125 mg Tablets for Dogs

Vm 00879/3026

04 March 2025	Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible.
30 January 2025	Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance.
19 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
23 August 2024	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
30 July 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
30 July 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
04 May 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
14 October 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
11 August 2021	Change in shape or dimensions of the container or closure (immediate packaging).
17 June 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Changes in primary materials specifications. Changes in primary materials specifications. Change of the primary packaging not in contact with the finished product, that does not affect the product information. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product.

11 February 2021	Addition of a new specification parameter with its corresponding test method of a reagent used in the manufacturing process of the active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
16 September 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
29 May 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
29 January 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
04 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur.
27 September 2018	Change in the SPC, Labelling or Package Leaflet of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR.
14 August 2017	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance Changes to a test procedure (including replacement or addition) for the active substance Introduction of a new site of manufacture Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
21 June 2017	Change in batch size (including batch size ranges) of active substance used in the manufacturing process of the active substance Change in the specification parameters or limits of an active substance
07 March 2017	Introduction of a new pharmacovigilance system.
15 August 2016	Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release.
06 July 2016	Change in the name of the Marketing Authorisation Holder from Novartis Santé Animale to Elanco France in France and Poland only.
06 July 2016	Change in the name and address of the Marketing Authorisation Holder in Spain and Italy only.
16 March 2016	Change in distributor details Change in legal entity

09 April 2015	Changes in the specification parameters and limits of the finished product.
18 February 2015	Change in the packaging material of the bulk product. Change in holding time of the bulk product. Change in the test method of an in-process-control.
28 August 2014	Approval of mock-ups.
30 April 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
27 March 2014	Submission of updated Ph. Eur. Certificates of Suitability.
07 February 2014	Change in MAH address.
18 July 2013	Change in address of manufacturer/supplier of reagent used in the manufacture of the active substance. Change in the manufacturing process of the active substance. Change of in process limits applied during manufacture of the active substance. Change to in process tests applied during the manufacture of the active substance. Change in specification limits of a reagent involved in the manufacture of the active substance. Minor amendments to part 2 of the dossier. Inclusion of restricted part of ASMF in part 2 of the dossier.
05 July 2013	To change the address of the MAH in Denmark, Finland, Norway and Sweden and corrections to the address of the MAH in Cyprus.
25 June 2013	Addition of new therapeutic indications.
28 March 2013	To change the address of the marketing authorisation holder (MAH) in France only.
12 November 2012	Changes to the DDPS that do not impact on the operation of the pharmacovigilance system. Addition of a primary packaging site and a secondary packaging site.
18 April 2011	Submission of 2 new or updated Ph. Eur. Certificates of Suitability.
6 August 2008	Changes to an existing pharmacovigilance system.
29 February 2008	Renewal.
29 February 2008	Deletion of a manufacturing site.
5 November 2007	Change in the name/address of the active substance manufacturer.
3 October 2007	Change in the name and /or address of the Marketing Authorisation Holder.
15 January 2007	Changes to the SPC.
28 March 2006	Addition of a new therapeutic indication.
06 February 2006	Addition of new therapeutic indications.
26 May 2005	Repeat use procedure.
08 November 2004	Change to the name of a supplier of an active substance.
08 April 2004	Addition of a new pack size.