Veterinary Medicines Directorate

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Post Authorisation Assessments

Clik 50 mg/ml Pour-on Suspension for Sheep

Vm 00879/3008

11 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.
01 December 2024	Reduction in the testing frequency of an analysis, from routine testing to skip or periodic testing (microbial testing of finished product).
27 April 2023	Introduction of a manufacturer of the active substance supported by an ASMF.
17 April 2023	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendations from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products: - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g., transitions are not yet agreed upon. One-off alignment of the product information with version 9.0* of the QRD templates.
23 March 2022	Change in type of container for the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Change in shape or dimensions of the container or closure (immediate packaging). Change in shape or dimensions of the container or closure (immediate packaging).
10 March 2022	Minor change in the manufacturing process of an immediate release oral solutions. Minor change in the manufacturing process of an immediate release oral solutions. Minor change in the manufacturing process of an immediate release oral solutions. Minor change in the manufacturing process of an immediate release oral solutions.
26 April 2021	Deletion of manufacturing site for manufacturer responsible for batch release.
03 February 2021	Replacement of a site where batch control/testing takes place.
29 December 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.
10 May 2019	Change in the address of a manufacturer supplier of active substance. Minor change in the manufacturing process of the active substance.
26 April 2019	Addition of a site where batch testing takes place.
07 February 2018	Change in RMS from UK to IE.
21 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
07 March 2017	Introduction of a new pharmacovigilance system.
07 February 2017	Tightening of specification limits of an active substance. Tightening of specification limits of an active substance. Addition of a new specification parameter for an active substance.
02 February 2017	Change in the specification parameters and limits of an excipient. Change in the specification parameters and limits of an excipient. Change in the specification parameters and limits of an excipient.
12 January 2017	Change in the name of a manufacturer for the finished product.
30 September 2016	Change in the name and address of the Marketing Authorisation Holder. Change of distributor details.
06 July 2016	Change in the name of an active substance manufacturer.
28 June 2016	Change in the name of the Marketing Authorisation Holder from Novartis Santé Animale to Elanco France in France only.
13 April 2016	Increase in batch size for the manufacturing of the finished product. Deletion of a non-significant in process control test. Replacement of the testing instructions of the finished product. Addition of a new testing site.
27 March 2014	Change to the QPPV contact details and updates to the DDPS that do not affect the pharmacovigilance system.
04 July 2013	Change of MAH address
11 April 2013	Changes to the Product Literature that do not affect the SPC
07 September 2012	Changes to the DDPS that do not impact on the pharmacovigilance system
17 June 2011	Change of manufacturer of the active substance Changes in the manufacturing process of the active substance Change in specification of the active substance Change in batch size of active substance
10 September 2010	Changes to an existing pharmacovigilance system as described in the DDPS
16 June 2010	Deletion of batch release site
12 March 2010	Change of manufacturer responsible for manufacture, filling, testing and batch release of the finished product
28 January 2010	Change of in process tests and limits Minor change in the manufacture of the finished product
12 January 2010	Change in batch size Change to in process tests
23 June 2008	Change to specification of starting materials used in the manufacture of the active substance
07 September 2007	Renewal

03 September 2007	Change of MAH address
18 April 2007	Replacement of a site of manufacture of the finished product Minor change in the manufacturing process of the active substance
27 February 2007	Addition of a site for batch release
14 March 2006	Addition of indication regarding blowfly strike
10 August 2005	Change of specification of the active substance
19 August 2004	Addition of 2 manufacturing sites of the active substance
20 March 2003	Change of batch size of the finished product
27 January 2003	Change of shelf life from 36 to 60 months
21 November 2002	Addition of duration of protection to product literature
21 February 2002	Mutual recognition procedure, UK as RMS
31 January 2002	Change of legal category
23 June 2001	Change in specification of the finished product