Veterinary Medicines Directorate

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Post Authorisation Assessments

CLiK Extra 65 mg/ml Pour-On Suspension for Sheep

Vm 00879/3010

•	27 April 2023	Introduction of a manufacturer of the active substance supported by an ASMF.
•	14 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. One-off alignment of the product information with version 9.0* of the QRD templates.
•	08 March 2022	Change in shape or dimensions of the container or closure (immediate packaging). 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.
•	14 December 2021	Renewal – UK as CMS.
•	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.
•	23 October 2018	Increase in the shelf-life of the finished product as packaged for sale, from 30 months to 36 months.

•	05 July 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.
•	02 February 2017	Change in the specification parameters and limits of an excipient.
•	19 January 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. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	12 January 2017	Change in the name of a manufacturer of the finished product.