Veterinary Medicines Directorate
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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Locatim, Oral Solution for Neonatal Calves Less Than 12 hours of Age

Vm 57846/5000

•	10 May 2023	Change of MAH holder from Biokema Anstalt, Pflugstrasse 12, 9490 Vaduz, Fürstentum, Liechtenstein to Biokema Europe, Centre des Affaires des Lilas, 77 Avenue des Lilas, 64000 Pau, France. Change to the batch release site from Biokema Anstalt, Fuerstentum Lichtenstein to Biokema Europe, France.
•	25 April 2023	To update the extraneous agents risk assessment based on updated Ph. Eur. monograph 5.2.5 and remove extraneous agents testing from the finished product tests.
•	12 July 2022	Minor change to an approved test procedure for the finished product.
•	10 January 2022	Replacement of a test procedure for the finished product.
•	10 December 2021	Change in the composition (excipients) of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product Deletion of a non-significant in-process test applied during the manufacture of the finished product Deletion of a non-significant in-process test applied during the manufacture of the finished product Minor change in the manufacturing process of the active substance Change to in-process tests or limits applied during the manufacture of the finished product Change to in-process tests or limits applied during the manufacture of the finished product Change to in-process tests or limits applied during the manufacture of the finished product
•	29 September 2021	Change in the number of units (e.g. tablets) in a pack outside the range of the currently approved pack sizes of the finished product
•	17 September 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	30 July 2021	Change in the specification limits of an excipient. Change of specification of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State

		Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State Changes related to the specification parameters of the excipients.
•	28 May 2021	Change to quality control testing of the finished product. Change to quality control testing of the finished product.