



## Post Authorisation Assessments

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### Chloromed 150 mg/g Oral Powder for Calves

Vm 05150/4001

27 February 2026	One-off alignment of the product information with version 9.0 of the QRD templates.
12 January 2024	Updated Ph. Eur. CEP from an already approved manufacturer. (GB & NI)
04 August 2021	Changes to a test procedure for the finished product. Increase in batch size (including batch size range*) of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form.
19 May 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
11 January 2017	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
01 November 2016	Submission of an updated Ph. Eur. certificate of suitability. Submission of an updated Ph. Eur. certificate of suitability.
16 December 2014	Renewal procedure – Ireland as RMS.
26 March 2014	Submission of three updated Ph. Eur. Certificates of Suitability for already approved manufacturers of the active substance.
31 January 2014	Changes to the test limits for the active substance.
03 May 2012	Tightening of finished product specification limits
03 May 2012	Replacement of an excipient with a comparable excipient.
15 December 2011	To change the withdrawal period from 35 days to 10 days.
12 August 2011	Grouped variation to submit a new certificate of suitability from an additional manufacturer.
12 August 2011	Grouped variation to submit an updated certificate of suitability from an already approved manufacturer.
05 August 2011	To make a change to the DDPS.
17 February 2010	To change the shelf-life of the veterinary medicinal product as packaged for sale from 1 year to 2 years.