

## **Post Authorisation Assessments**

## Paraclav Intramammary Suspension for Lactating Cows

• 18	8 November 2021	Change in the name of the manufacturer of the finished product.
• 29	9 July 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
• 27	7 November 2020	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
• 21	1 January 2020	Change in control of excipient in the finished product. Change in control of the active substance.
• 22	2 August 2019	Addition of the distributor to the QRD.
• 21	1 June 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
• 21	1 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
• 11	1 June 2019	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 2 years.
• 01	1 March 2019	Change in RMS from UK to DE.