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Post Authorisation Assessments

Hipragumboro G97 Vm 17533/4002

• 21 October 2021	Deletion of a specification parameter of the finished product.
• 15 July 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
• 16 May 2018	Change in RMS from UK to FR.
• 16 March 2018	Repeat use MRP to add 3 new member states
• 04 February 2016	Change in the name of the local UK representative.
• 20 May 2011	Addition of two presentations – one vial of 1000 doses and one vial of 5000 doses
• 17 November 2010	Change of distributor
• 20 January 2010	Changes to comply with Ph. Eur.
• 14 January 2009	Renewal
07 September 200	7 Change of shelf life of the finished product from 12 months to 24 months
• 25 July 2007	Change of distributor
• 18 January 2005	Repeat Use
• 26 November 2003	3 Mutual Recognition procedure, UK as RMS