



## Post Authorisation Assessments

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### Duphacycline 10% w/v Solution for Injection

•	30 July 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.
•	05 January 2016	Submission of a new Ph. Eur. certificate of suitability.
•	28 December 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	09 February 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	02 December 2009	Addition of a manufacturing site of assembly
•	14 January 2009	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation