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Post Authorisation Assessments

•	February 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
•	20 December 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
•	26 July 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Minor change in the manufacturing process.
•	21 January 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.