

(NEW 22/03/24) How to use a CEP?



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Answer:

The EMA has published a Q&A document that describes how to use a CEP in the context of a Marketing Authorisation Application (MAA) or a Marketing Authorisation Variation (MAV) and provides a compilation of the data to be submitted in a MAA or in certain MAVs that refer to a CEP. See EMA website, QWP Questions and Answers (Q&A): how to use a CEP in the context of a Marketing Authorisation Application (MAA) or a Marketing Authorisation Variation (MAV), EMA/CHMP/CVMP/QWP/5/2024.