

Is it possible to submit changes during the dossier assessment phase?



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Answer:

No, changes that are not a direct result of a request for additional information from the EDQM are not accepted and must be submitted as a revision after the end of the CEP procedure.

However, changes or additions **strictly** in response to a request for additional information from the EDQM may be accepted. Amendments resulting from the revision of a monograph, updates to stability data in support of a re-test period or a longer re-test period and administrative notifications (such as changes in the company name) may also be accepted.

Changes submitted during the assessment phase may not be sufficiently documented, potentially leading to the identification of new deficiencies in the dossier, which would delay granting of the CEP and, ultimately, a risk of the application being rejected.