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Questions and answers on the use of Product Lifecycle Management (PLCM) document

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Q&A on the use of Product Lifecycle Management (PLCM) document

1. What is a PLCM document?

The PLCM document is one of the lifecycle management tools foreseen by the revised Variation Regulation (Article 6a Additional regulatory tools), and the revised Annex of the Variations Guidelines (chapter Q.I.e & Q.II.g Additional Regulatory Tools).

The PLCM document is a tool which facilitates global harmonisation of post-approval CMC changes. While it is not considered necessary for effective lifecycle management of EU-authorised medicinal products, it is recognised that having a globally harmonised tool to facilitate lifecycle management activities can be beneficial for applicants.

Guidance on the scientific and technical content of a PLCM document can be found in the ICH Q12 guideline on Lifecycle Management (chapter 5).

2. When and how should a PLCM document be submitted?

Use of a PLCM document is optional in the EU. Submission of a PLCM document should be made via a Type II variation procedure. It is recommended to discuss the planned variation with the Agency prior to submission.

If in the future it may be possible to include a PLCM document as part of an initial MAA submission, this Q&A will be updated accordingly.

3. Where should a PLCM document be located in the dossier?

When a PLCM document is submitted (via a Type II variation procedure) in an EU marketing authorisation dossier, it should be located in CTD Module 3.2.R (regional section).

A future location for the PLCM document within the quality dossier will be defined as part of the ongoing revision of the ICH M4Q(R2) guideline on the Common Technical Document for the registration of pharmaceuticals for human use (Quality). Until this revised guideline becomes applicable, EU MA Holders should use Module 3.2.R when submitting a PLCM document.

4. What should be in the content of a PLCM document?

The PLCM document can refer to any part of the quality dossier, up to and including the full quality dossier. In practice, it is expected that the PLCM will be used for specific manufacturing process step(s) or analytical procedure(s), and that it will apply to specific manufacturing and/or testing site(s). It should be clearly stated in the variation submission if the PLCM document is intended to refer to the full quality dossier or to specific and clearly delineated parts (e.g. manufacturing steps, analytical procedures). The use of PLCM document is possible whether a minimal/traditional approach or enhanced approach to pharmaceutical development in line with ICH Q8-Q11 has been followed.

Applicants should refer to the ICH Q12 guideline on Lifecycle Management for further guidance on the content of PLCM. While the term ‘established conditions’ mentioned in the ICH Q12 guideline is not specifically defined in the legal framework of the EU, in the context of the EU Variations Regulation and Guidelines, it is considered to mean the legally binding elements of the dossier necessary to assure product quality, throughout the lifecycle of the medicinal product. Any changes to these elements

trigger submission of a variation, in line with the Annex of the EU Variations Guidelines, whether or not addressed in the PLCM. For example, these elements would include material attributes, quality attributes, process parameters or analytical procedure parameters, with their proposed limits and ranges, but would not include development and validation data.

5. How should future variation types be described?

The PLCM document may or may not include reference to the variation types applicable to future changes.

Future variation submissions must follow the appropriate classification as defined in the Annex of the current EU Variations Guidelines, regardless of the variation type listed in the PLCM. There should be a clear statement in the PLCM document that the types of future variation submissions will follow the appropriate classification as defined in the Annex of the current EU Variations Guidelines. In case of doubt, the Variation Guidelines take precedent over the content of the PLCM.

To facilitate global harmonisation, ICH Q12 terminology may be used in the PLCM document when referring to variation types, provided a clear definition of the meaning is stated with respect to EU variation types, i.e. 'prior approval' = Type II, 'notification moderate' = Type IB, 'notification low' = Type IA / IA_{IN}.

6. How should variations be submitted when a PLCM document is registered?

The PLCM document may or may not include reference to the variation types applicable to future changes.

Variations impacting elements defined in a PLCM, should be submitted under the relevant change code and scope as foreseen in the Annex to the Variations Guidelines (i.e. chapters E, Q.I, Q.II, Q.III, Q.IV, Q.V, M).

Until further guidance is provided, the variation code(s) and scope(s) defined in chapters Q.I.e.7 and Q.II.g.7 should not be used.

7. What are the GMP requirements to support the use of a PLCM document?

A prerequisite for the use of a PLCM document as a lifecycle management tool is that the manufacturing and/or testing sites in scope are shown to be GMP compliant, and that the site's Pharmaceutical Quality System (PQS) is effective in relation to change management.

Applicants should contact the Agency and Supervisory Authority for the manufacturing and/or testing sites prior to submission of a variation containing a PLCM document.

References:

- EU Variations Regulation (EC) No 1234/2008 (as amended)
- EU Variations Guidelines (C/2025/5045)
- ICH Q12 guideline on Lifecycle Management (EMA/CHMP/ICH/804273/2017)