

Certification of Substances Division

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| Title: | Requirements for notifications to the EDQM |
| Reference Document: | PA/PH/CEP (10) 116 (EN) |

The revised “Guideline on Requirements for Revision/Renewal of Certificates of Suitability to the European Pharmacopoeia Monographs” (PA/PH/CEP (04) 2, 4R) has been applicable since 01 March 2010.

Since the new procedures for revisions were implemented, a significant number of notifications have been received and the EDQM has found a significant proportion to be incomplete. The deficiencies are generally of an administrative nature and, therefore, could be easily avoided.

The most common deficiencies noted are:

- Absence of supportive documentation as required by the EDQM Guideline, such as declarations, official documents, comparative tables or batch analysis data.
- Failure to demonstrate that all conditions for a notification are fulfilled.
- Incomplete application form (*e.g.* type of notifications not specified, implementation dates of the annual notifications not noted, omission of invoicing details, *etc.*).
- Incomplete list of changes and/or wrong codes specified for the changes.
- Absence of updated relevant section(s) or sub-section(s) of the dossier.

Applicants are therefore reminded that it is their responsibility to:

- Ensure that the application form is suitably completed.
- Make sure that the relevant conditions are met (if not applicable to a specific item, suitable justification should be provided).
- Provide complete supportive documentation, including updated sections of the CTD dossier affected by the changes (in accordance with our current requirements).

The procedure for treatment of notifications does not provide for the possibility of applicants sending additional information in cases of incomplete submissions.

Applicants should be aware that, in order to make the procedure efficient, from now on if the conditions for a notification are not met, or if the documentation submitted is incomplete, the notifications will be rejected and the relevant fee will be invoiced. Therefore, a new and appropriate data package will have to be submitted and the requisite fee paid.