

Certification of Substances Division

NV/CB

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Certification of suitability to Monographs of the European Pharmacopoeia

New procedure for the assessment of “sister files”

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Scope:

There are cases when a manufacturer has been granted a CEP for a substance and where they apply for a second CEP for the same substance to cover an alternative process, generally because the existing one cannot cover the new process/conditions. Any differences compared to the approved CEP from a content point of view could be considered as revisions. These applications will be called sister files.

Since the original dossier has already been approved, it is proposed to treat sister dossiers with a fast track procedure and focus the evaluation on the variations compared to the approved CEP dossier.

This is applicable typically in case of changes of solvents used in the final purifications steps or processes carried out in two sites belonging to the same company, if the company wants to have both situations covered by CEPs.

Sterile and TSE applications are outside the scope of this procedure.

Conditions and documentation:

Conditions:

- The original application should already have been approved by EDQM and the CEP granted
- The manufacturer should be the same for both applications
- Differences described in the new dossier compared to the already granted CEP can be classified and hence treated as a revision.

The final decision on whether the fast track procedure can be applied to a specific application will be made by EDQM at receipt.

Documentation and information to be provided by the applicant:

- a complete new application according to the current procedures
- reference to the already approved dossier and explanation of differences
- a comparative table of the affected dossier sections for both the approved and the new application
- a subtitle for the CEP of the sister application, in order to differentiate both CEPs

Timetables and fee:

The deadline for the treatment of the dossier will be 3 months after validation of the receipt of the dossier. The fee will be 3000 Euros as for a “New application”.

If additional information is needed after the first assessment, the company will have to submit the requested documentation within 1 month, which will be assessed within 1 month by EDQM.

If undeclared differences compared to the original application are detected during assessment, the fast track procedure will be stopped and the dossier will go through the standard rules for new applications.

Life-cycle:

Once the CEP of the sister dossier is granted, as 2 CEPs will exist for the same substance/manufacture, both dossiers must be updated individually after any significant change that may alter the quality, safety or efficacy of the substance covered by the CEPs. Any changes have to be submitted as a revision as described in the relevant EDQM Guidelines. Changes likely to affect both CEPs have to be submitted in parallel for each dossier. Changes which affect only one CEP should be submitted for the concerned application only.

To get more information about this new procedure or to ask questions about the applicability of fast-track to specific cases, please post your questions through the Helpdesk on the EDQM website: www.edqm.eu