EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE
Certification of Substances Department

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Certification of suitability to the Monographs of the European Pharmacopoeia

Stepwise process to get a CEP/having a change approved

1. Introduction

This document describes the process and steps to obtain a certificate of suitability (CEP) or to have a change approved, from the submission of the application to the communication of the decision for:

- New applications
- “Sister files”
- Revisions
- Renewals
- Notifications
- Transfers of holdership

The steps of the process are identical for all types of applications, but different timelines apply. The timelines for each step are given in the relevant Annexes (I to V) and are expressed either in working days (WD, excluding weekends, public holidays and EDQM closures) or in calendar days (CD) as indicated. The steps are:

- Submission
- Validation
- Assessment (or treatment)
- Communication of the decision

These steps may be repeated and are described in more detail in the next sections.

This document also clarifies the interactions between evaluation and Good Manufacturing Practice (GMP) inspection activities during the process.

2. New applications for CEPs including via the “sister files” procedure, applications for revisions and renewals

The same flow applies to new applications, sister files, applications for revisions and renewals. Relevant timelines for the applicant/CEP holder and for the EDQM are reflected in Annexes I (new applications), II (sister files) and III (revisions and renewals).

For some specific data packages (e.g. toxicological data), different timelines are applicable. These are described in Annex IV.

2.1. Submission

The applicant should make sure that the content of their CEP application complies with the EDQM requirements and submit it in electronic format as described in the EDQM’s “Guidance for electronic submissions for Certificates of Suitability (CEP) applications” [1].

2.2. Validation

The EDQM performs a validation of the submissions regardless of their stage in the flow (initial submission or at receipt of a response to a request for information). The validation includes the following elements:

- Format validation: the EDQM checks that the format is in accordance with the requirements for electronic CEP application submissions. If it is not, the application is blocked and the EDQM asks the applicant to solve format issues.
- Content validation: the EDQM checks that the application is suitable for assessment. If necessary, the EDQM requests complementary data and the application is blocked until data are received.

For new applications, the EDQM also checks that these are within the scope of the Certification procedure as defined in Resolution AP-CSP (07) 1. Any out-of-scope application is rejected at that stage.

Once the submission is successfully validated, the clock starts and the EDQM sends an acknowledgement of receipt mentioning the timelines for assessment. The timelines depend on:

- the type of application (new, revision etc);
- the stage in the flow (initial assessment, assessment of additional information).

After initial validation of an application, the fee has to be paid irrespective of the future outcome of the procedure.

2.3. Assessment

The application is assigned to assessors according to EDQM procedures and is assessed to check its compliance with the specific and general Ph. Eur. monographs concerned as well as the current regulatory requirements (EDQM, EMA and ICH guidelines).

2.4. Communication of the decision

When the assessment of the application is complete, the EDQM communicates the decision to the applicant.

2.4.1. The information provided is complete and satisfactory. For new applications and sister files, the certificate (CEP) is granted. For revisions and renewals, the certificate is revised with updated information, or the current certificate remains valid.

2.4.2. The information provided needs to be completed:

a) Major issues have been identified during the assessment: a *request for additional information* is sent to the applicant.
b) Minor issues have been identified during the assessment: a *request for clarification* is sent to the applicant.
c) An update of the documentation is needed for the procedure to be finalised without requiring an assessment: a *request for dossier update* is sent to the applicant.

This flow (submission, validation, assessment and communication of the decision) is repeated when the response to a request for additional information or clarification as mentioned above is submitted by the applicant.

To ensure efficient treatment of a CEP application, there are a maximum of 2 requests for information in a single procedure.

3. Notifications and transfers of holdership

The flow and timelines for notifications and transfers of holdership are described in Annex V.

3.1. Submission

CEP holders should make sure that their notifications or requests to transfer holdership comply with the EDQM requirements and should submit them according to the guidance given in the EDQM's "Guidance for electronic submissions for Certificates of Suitability (CEP) applications [1].

3.2. Validation

The EDQM checks that the format complies with the requirements for electronic submissions for CEP applications. If it is not, the data package is blocked and the EDQM asks the company to solve format issues.

After format validation is completed the clock for treatment starts and the fee has to be paid irrespective of the future outcome of the procedure. The EDQM does not issue an acknowledgement of receipt for notifications or transfers of holdership.

3.3. Treatment

The EDQM checks the compliance of the data with the acceptance criteria for notifications or transfers of holdership, as described in the EDQM's "Guideline on requirements for revision/renewal of CEP" [3].

3.4. Communication of the decision

When the treatment of the request is complete, the EDQM communicates its decision to the CEP holder.

3.4.1. The notification or transfer of holdership is accepted. A revised certificate is granted, or the holder is informed that the certificate remains valid.

3.4.2. The notification or transfer of holdership is rejected and the EDQM informs the holder about the reasons for the rejection. It is not possible to submit additional information, and the associated fee is forfeit. Changes that have been rejected as notifications should normally be submitted again as a request for revision and the type of revision should be selected accordingly.

4. File closure for new applications and sister files – rejection of revisions

The EDQM has established strict procedures regarding the handling of CEP applications, including for revisions and renewals. When a request for information is sent by the EDQM to the applicant/holder, the deadline for providing a complete response is clearly indicated in the request and no extension is granted (timelines are described in Annexes I to IV). If the applicant or CEP holder fails to respond or to provide sufficient information, this results in the closure of the dossier (new dossiers and sister files) or in the rejection of the application (requests for revision). For renewals, the CEP expires when reaching the renewal due date.

In all cases the associated fee is forfeit and the applicant/CEP holder is informed.

5. Interactions between evaluation and GMP inspection activities of the CEP procedure

The EDQM inspection programme is an integral part of the Certification procedure.

Its purpose is to check compliance with both GMP and the CEP application (and any updates) at the manufacturing/distribution sites covered by CEPs.

Inspections of manufacturing sites are based on a risk assessment in accordance with EU guidelines, which include recommendations raised by the assessors during the evaluation of a CEP application or a request for revision. For the sites selected, an inspection may take place either before or after the CEP is granted. Actions are taken (suspension or withdrawal, closure of applications) on the CEPs and applications referring to the relevant site if the outcome of the inspection is negative, regardless of the stage in the assessment process [4].

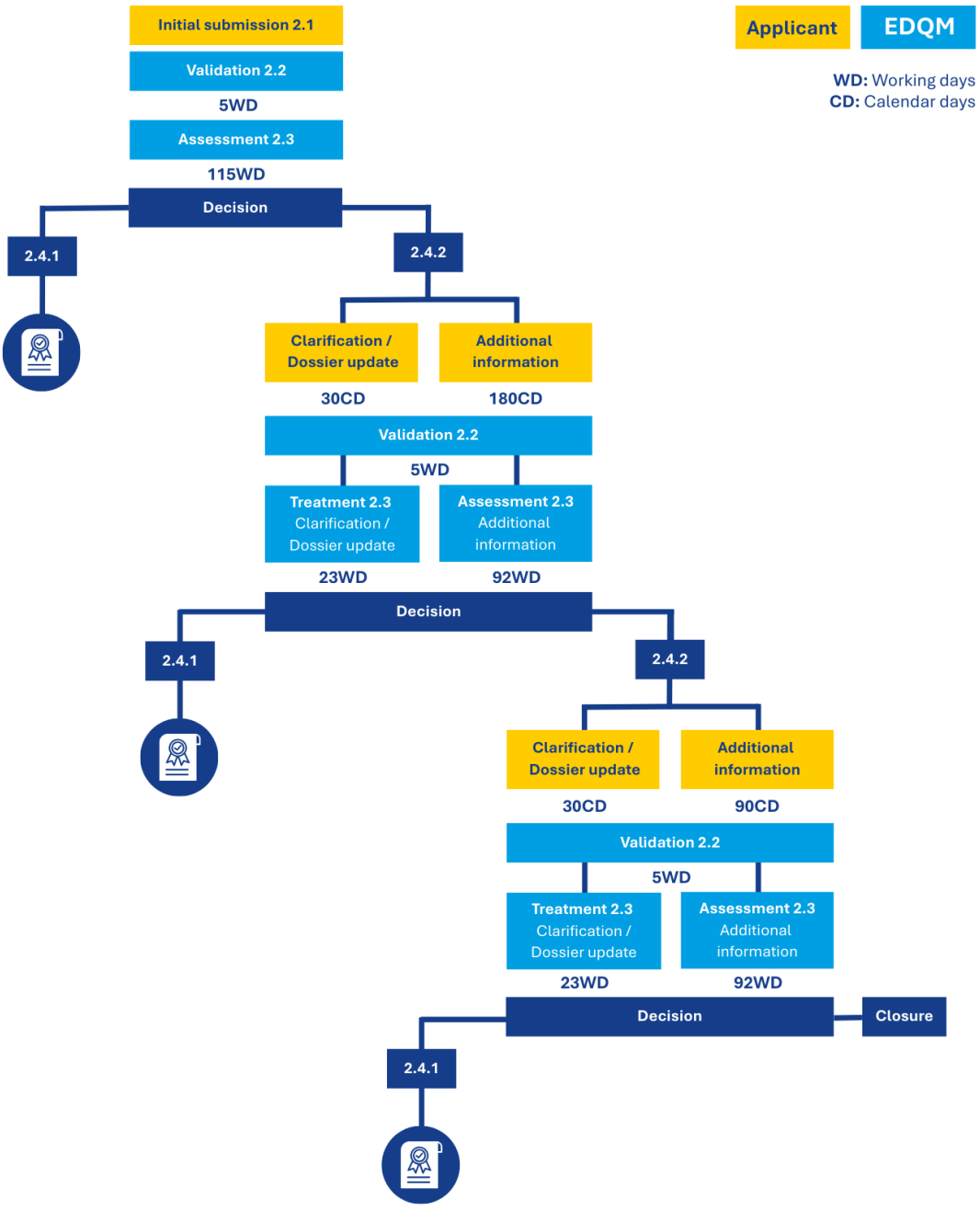
In the event that a new application (including via the "sister files" procedure) or a request for revision is intended to introduce a site for which a GMP non-compliance has been issued, the procedure will remain on hold pending completion of a pre-approval inspection confirming compliance with EU-GMP requirements. The timelines presented in annexes I to IV are not applicable.

Documents referenced:

[1] PA/PH/CEP (09) 108) Guidance for electronic submissions for Certificates of Suitability (CEP) applications
[2] Resolution AP CSP (07) 1 Certification of suitability to the Monographs of the European Pharmacopoeia
[3] PA/PH/CEP (04) 2 Guideline on Requirements on Revision/Renewal of Certificates of Suitability.
[4] PA/PH/CEP (08) 17 Suspension or cancellation of a Certificate of suitability

ANNEX I

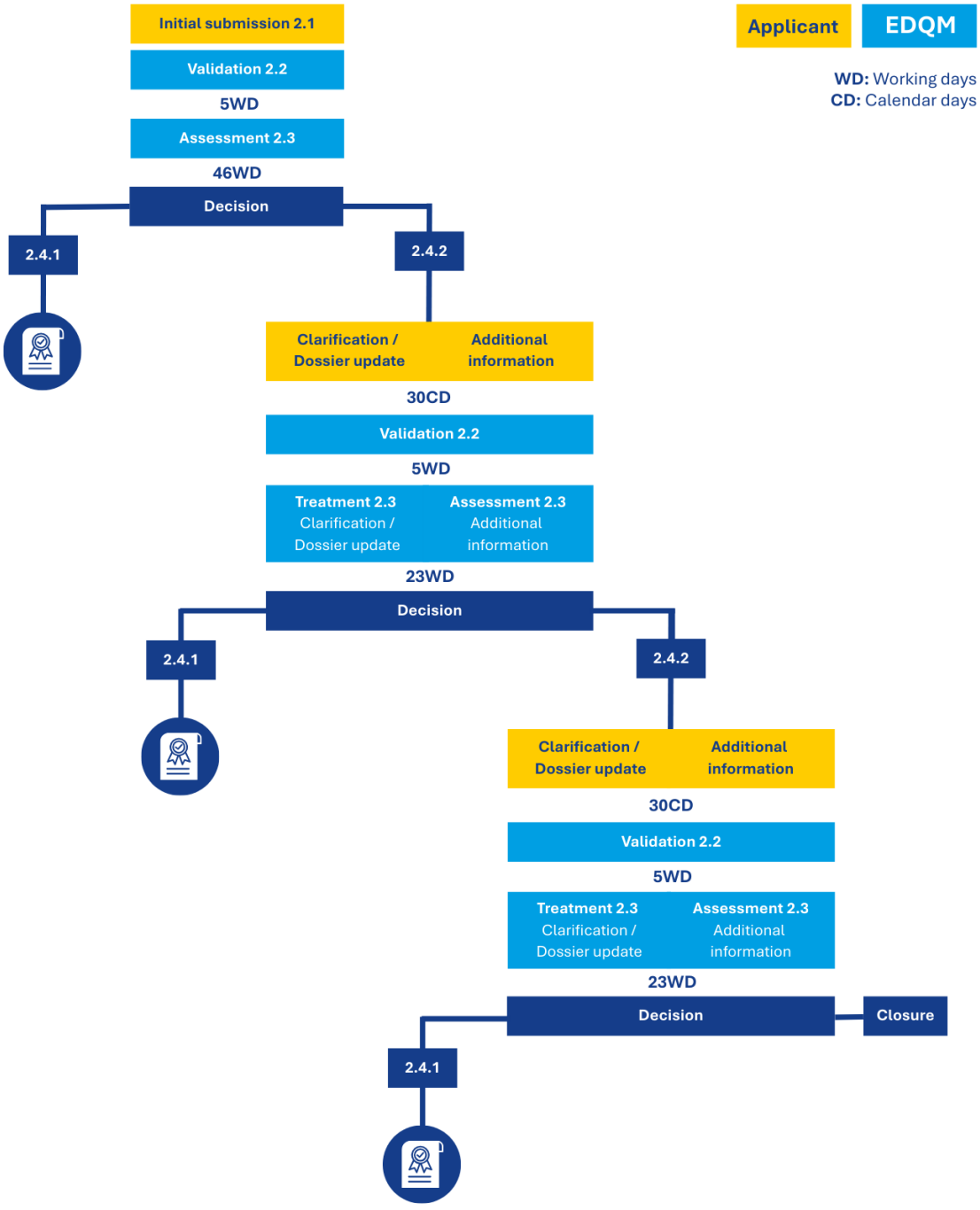
Flow and timelines for new CEP applications



Failure to respond within the timelines or to provide sufficient information will result in the closure of the application (section 4).

ANNEX II

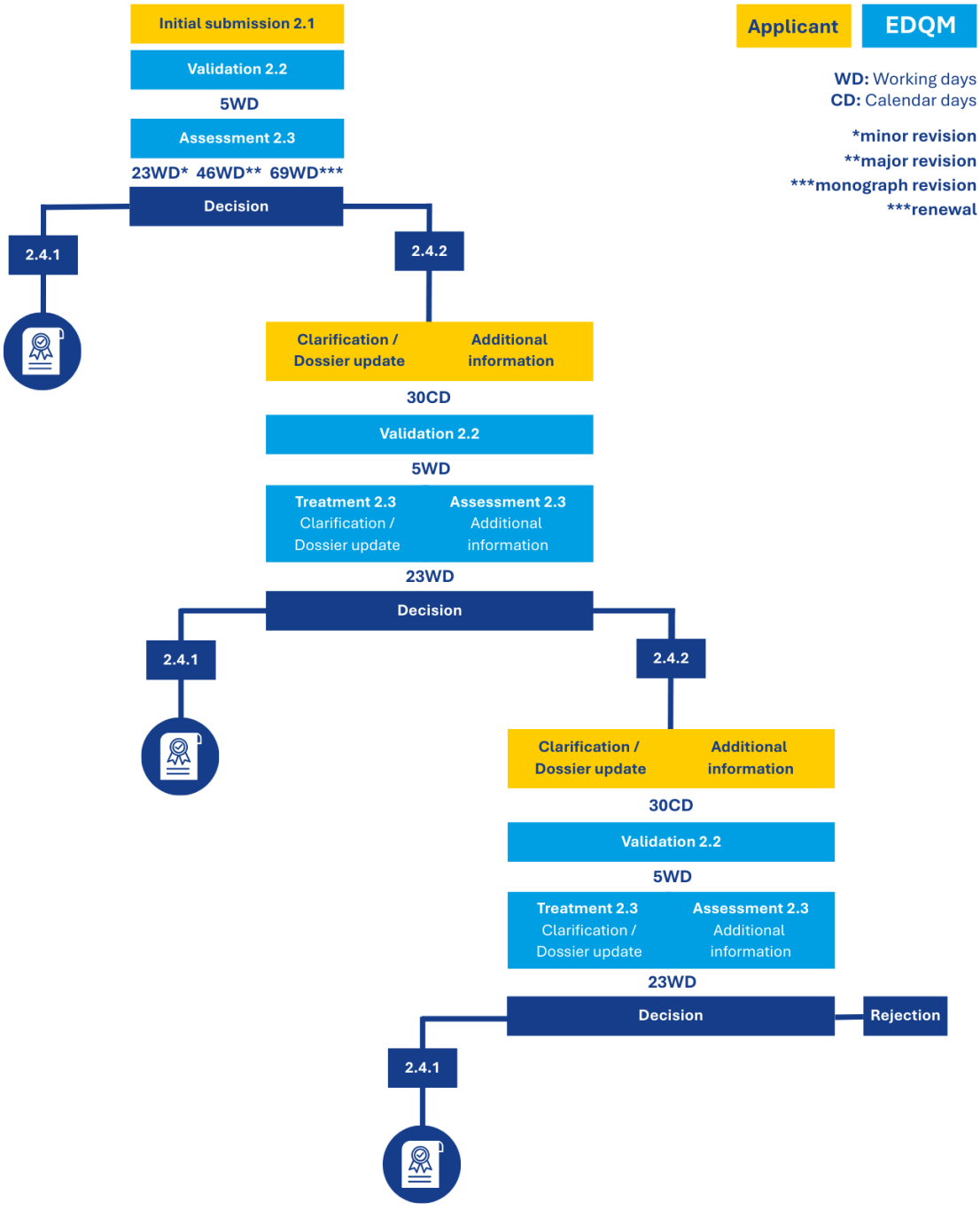
Flow and timelines for sister files applications



⚠ Failure to respond within the timelines or to provide sufficient information will result in the closure of the application (section 4).

ANNEX III

Flow and timelines for revisions and renewal applications



⚠ Failure to respond within the timelines or to provide sufficient information will result in the rejection of the request (section 4).

ANNEX IV

For some specific data packages (e.g. toxicological data, sterility, TSE) different timelines are applicable as described in the table below.

Type of data package	**EDQM timelines for the assessment of original application**	**Applicant timeline to reply to the first request for additional information**	**EDQM timelines for the assessment of first reply**	**Applicant timeline to reply to the second request for information**	**EDQM timelines for the assessment of second reply**
Toxicological	See Annexes I, II & III	See Annexes I, II & III	46 WD	30 CD	46 WD
Sterile	See Annexes I, II & III	See Annexes I, II & III	69 WD (additional information) 23 WD (clarification or update)	See Annexes I, II & III	69 WD (additional information) 23 WD (clarification or update)
TSE	See Annexes I, II & III	See Annexes I, II & III	46 WD	See Annexes I, II & III	46 WD

WD: Working days:

CD: Calendar days

ANNEX V

Flow and timelines for notification and transfer of holdership