



Certification of Substances Division



HB/CB

PUBLIC DOCUMENT

(Level 1)

English/French

PA/PH/Exp. CEP/T (04) 18, 1R

June 2008

Certification of suitability to Monographs of the European Pharmacopoeia

Procedures for management of revisions/renewals of certificates of suitability to the European Pharmacopoeia monographs

Strasbourg

Address: 7 allée Kastner CS 30026 - F 67081 Strasbourg
Telephone: 33 (0) 3 88 41 30 30 - E-mail: cep@edqm.eu - Fax: 33 (0) 3 88 41 27 71
Internet : <http://www.edqm.eu>

PROCEDURES FOR MANAGEMENT OF REVISIONS/RENEWALS OF CERTIFICATES OF SUITABILITY TO THE EUROPEAN PHARMACOPOEIA MONOGRAPHS

Introduction:

This document should be read in conjunction with the EDQM “Guideline on Requirements on Revisions/Renewals of Certificates of Suitability to the European Pharmacopoeia monographs” (PA/PH/CEP (04) 2, as amended), which describes the conditions to be fulfilled as well as the documentation to be submitted for each request for revision.

The procedures for the management of revisions of certificates of suitability (CEPs) are described below.

The system allows the submission of several changes in the same request for revision. Consequential changes are considered as part of the original variation.

Following the initial assessment of the request for revision, a deficiency letter may be sent. Should the response not sufficiently address the request for information, the application for revision will be rejected.

1. Implementation

All requests for revision/renewal received from **1st July 2008** will be treated according to this updated policy.

2. How to apply for a request for revision/renewal

Application form:

A specific application form for revisions/renewals is to be submitted together with each request for revision. It can be downloaded from the EDQM website in Word or pdf format.

Documentation to be submitted:

The documentation to be submitted for each request for revision/renewal is described in the “Guideline on Requirements on Revisions/Renewals of Certificates of Suitability”
Consequential changes should be identified and the relation between the changes should be described.

In most cases, a comparison with the previously submitted dossier is required. This should be made in a tabular format, where the approved and proposed parts of the dossier are compared, and the changes highlighted.

Fee and timetables:

The fee and timetables depend on the kind of revision. Timetables are described in Section 4. Fee are described in the application form. They have to be paid after validation of the request by EDQM and receipt of an invoice.

3. Procedures

3.1. Notifications

The determination of validity of a notification is completed within 2 weeks after receipt of a request (4 weeks for a multiple notification). Then either an acknowledgement of a valid notification is sent to the holder or a revised certificate is granted if necessary.

If the notification dossier is incomplete at receipt, the request is rejected without asking for any additional information, and a letter of rejection is sent to the holder. This means that the applicant will have to resubmit the appropriate package of data and pay the relevant fee.

An application for multiple simultaneous notifications is possible under conditions:

- maximum 3 changes
- fee and deadlines are increased

3.2. Minor revisions

T0 (within 5 days after receipt of the request): a letter of acknowledgement of receipt is sent to the applicant.

T 30 days (T 60 days for multiple minor revision): either the request is approved*, or a letter of request for additional information is sent (clock-stop).

If clock-stop: the applicant is requested to submit a reply within 30 days. Failure to submit a reply in time will lead to the rejection of the request for revision.

New T0: within 5 days after the response from the applicant is received at the Certification Secretariat.

New T 30 days: Approval*, or letter of rejection of the request if the answer is deemed deficient. If the application is rejected, the applicant will have to resubmit the appropriate package of data and pay the relevant fee.

It is possible to apply for several simultaneous minor changes, or minor changes + notifications, in the following conditions:

- multiple minor revision (maximum 3 changes) or
- consolidated revision (more than 3 changes, see 3.6)
- fee and deadlines are extended

*Approval: If the minor revision is not a type R3a according to the “Guideline on Requirements on Revisions/Renewals of Certificates of Suitability”, and when the content of the certificate of suitability is not affected by the change, a letter of approval is sent to the holder.

In the other cases, the certificate is revised.

3.3. Major revisions

T0 (within 5 days after receipt): a letter of acknowledgement of receipt is sent to the applicant.

T 90 days: either the request is approved, or a letter of request for additional information is sent (clock-stop).

If clock-stop: the applicant is requested to submit a reply within 30 days. Failure to submit a reply in time will lead to the rejection of the request for revision.

New T0: within 5 days after the response from the applicant is received at the Certification Secretariat.

New T30 days (except TSE certificates: 90 days): Approval, or letter of rejection of the request if the answer is deemed deficient. If the application is rejected, the applicant will have to resubmit the appropriate package of data and pay the relevant fee.

When the request is approved, a revised certificate is granted.

It is possible to apply for multiple simultaneous changes, including one major + minor/notifications, in the following conditions:

- major revision (maximum 3 changes, no impact on fee and deadlines) or
- consolidated revision (more than 3 changes, see 3.6)

3.4. Renewal

The holder of the certificate should apply for the renewal of their certificate at least **6 months prior to expiry date**. Considering the time taken for the assessment of the dossier, failure to submit a request for renewal sufficiently in advance could lead to a gap between the expiry date of the certificate and its renewal.

T0 (within 5 days after receipt): a letter of acknowledgement of receipt is sent to the applicant.

T 120 days: either the request is approved, or a letter of request for additional information is sent (clock-stop).

If clock-stop: the applicant is requested to submit a reply within 30 days.

New T0: within 5 days after the response from the applicant is received at the Certification Secretariat.

New T30 days (except TSE certificates: 90 days): Approval (a renewed certificate is sent) or new request for information.

Introduction of minor changes or notifications in the application is possible at the time of renewal. Introduction of major changes is not accepted.

When the request is approved, a renewed certificate is granted.

3.5. Monographs revisions

When a revised monograph is published in a supplement or a new edition of the European Pharmacopoeia, a letter is sent by the Certification Secretariat to the relevant holders of certificates to ask them to update their dossier.

The holder is requested to submit the data within 90 days.

T0: within 5 days of receipt of the data, the clock starts, with no letter of acknowledgement of receipt from EDQM.

T90 days: either approval, or a letter of request for additional information (clock-stop).

If clock-stop: the applicant is requested to submit a reply within 30 days.

New T0: within 5 days after the response from the applicant is received at the Certification Secretariat.

New T30 days: Approval or new request for information.

When the data are approved, either a letter of approval is sent or a revised certificate is granted if necessary.

3.6. Consolidated revision

A consolidated revision includes more than 3 changes of any kind in the same request.

T0 (within 5 days after receipt): a letter of acknowledgement of receipt is sent to the applicant.

T 120 days: either the request is approved*, or a letter of request for additional information is sent (clock-stop).

If clock-stop: the applicant is requested to submit a reply within 30 days. Failure to submit a reply in time will lead to the rejection of the request for revision.

New T0: within 5 days after the response from the applicant is received at the Certification Secretariat.

New T30 days (except TSE certificates: 90 days): Approval*, or letter of rejection of the request if the answer is deemed deficient. If the application is rejected, the applicant will have to resubmit the appropriate package of data and pay the relevant fee.

***Approval:**

If the consolidated revision includes any major change or minor change coded R3a as described in the “Guideline on Requirements on Revisions/Renewals of Certificates of Suitability”, or if the content of the CEP is affected by the changes, a revised certificate is granted.

If only minor changes other than R3a, or notifications are made, and when the content of the CEP is not affected by the changes, a letter of approval is sent to the holder.

3.7 Transfer of holdership

The determination of validity of a transfer of holdership is completed within 2 weeks after receipt of a request, and a revised certificate is granted.

If the request is incomplete at receipt, it is rejected without asking for any additional information and a letter of rejection is sent to the holder. This means that the applicant will have to resubmit the appropriate package of data and pay the relevant fee.

4. Fee and timetables:

The fee for the kinds of revisions are available in the application form, and published on the EDQM website www.edqm.eu

Type of revision	EDQM Timetable (original assessment)	EDQM Timetable (answer to deficiency letter)
Simple notification	2 weeks	n/a
Multiple notifications (up to 3)	4 weeks	n/a
Simple minor revision (1 minor change)	30 days	30 days
Multiple minor revision (up to 3 minor changes+notifications)	60 days	30 days
Major revision (may include introduction of minor changes/notifications, up to 3 in total)	90 days	30 days (TSE: 90 days)
Consolidated revision (more than 3 changes, of any kind)	120 days	30 days (TSE: 90 days)
Renewal	120 days	30 days (TSE: 90 days)
Monograph revision	90 days	30 days
Transfer of holdership	2 weeks	n/a