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Certification of suitability of Monographs of the European Pharmacopoeia

New procedures for management of revisions/renewals of certificates

(Revision of the Annex XI to Resolution AP-CSP (93) 5 as amended)

Strasbourg

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

(Revision of Annex XI of Resolution AP-CSP (99) 4:

Certification of suitability to the monographs of the European Pharmacopoeia)

Introduction:

Following the implementation of European Regulations on variations (EC) 1084/2003 and (EC) 1085/2003 which came into force on 1 October 2003, the procedures for the management of revisions of certificates of suitability are going to be revised accordingly. The main changes are a new classification of different types of revisions as well as changes to the evaluation timetables.

Annex XI to Resolution AP-CSP (99) 4 has been revised and replaced by a new guideline on “Requirements on Revisions/Renewals of Certificates” (see document PA/PH/CEP (04) 2). This guideline describes the conditions to be fulfilled as well as documentation to be submitted for each request for revision.

The procedures to be applied are described below. The new system allows the submission of several changes in a same request for revision, with a limit of 3 changes. In addition, applicants should be aware that the submitted documentation shall be fully in accordance with the requirements of the procedure, since for reasons of efficacy the number of assessments per request will be limited and therefore requests which are deemed deficient will be rejected.

1. Implementation

All requests for revision/renewal received from **1 September 2004** will be treated according to this new 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 our website in Word or Acrobat 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” (see document PA/PH/CEP (04) 2).

3. Procedures

3.1. Notifications

The determination of validity of a notification is completed within 2 weeks after receipt of a request. Then either an acknowledgement of a valid notification is sent 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 applicant. 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 (see Table in Section 4).

3.2. Minor changes

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

T 30 days: either the request is approved and a revised certificate is granted, 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: response from the applicant received at the Certification Secretariat.

New T 30 days: Approval (a revised certificate is granted), 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.

An application for multiple simultaneous minor changes, or minor + notifications is possible under conditions:

- maximum 3 changes
- fee and deadline are extended (see Table in Section 4).

3.3. Major changes

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 and a revised certificate is granted, 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: response from the applicant received at the Certification Secretariat.

New T30 days (except TSE certificates: 90 days): Approval (a revised certificate is sent), 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.

An application for multiple simultaneous changes, i.e. one major + minor/notifications is possible under conditions:

- maximum 3 changes, which includes only 1 major change
- fee is increased (see Table in Section 4).

3.4. Quinquennial renewal

The holder of the certificate should apply for the renewal of their certificate about **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 approval and a renewed certificate is sent, 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: response from the applicant 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 changes in the application is possible at the time of renewal, with no conditions.

3.5. Monographs revisions

When a revised monograph is published, 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: At receipt of the data, start of evaluation (no letter from EDQM)

T120 days: sending of an acknowledgement of valid data, or a revised certificate if necessary, 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: response from the applicant received at the Certification Secretariat.

New T30 days: Approval or new request for information.

4. Fee and timetables:

Type of revision	Fee (Euros)	Timetable
Simple Notification	500	2 weeks
Multiple notifications	1000	30 days
Simple Minor change	1000	30 days
Multiple minor changes / minor changes+notifications	1500	60 days
Simple major change	1500	90 days
Major change + minor changes / notifications	1500	90 days
Quinquennial renewal	1500	120 days
Monograph revision	0	120 days

More information:

For any question concerning the new procedures for revisions/renewals: please contact us at ceprevision@pheur.org