



**Certification of Substances Division**



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**Certification of suitability to Monographs of the European Pharmacopoeia  
欧洲药典适应性证书**

**Procedures for management of revisions/renewals of certificates of  
suitability to the European Pharmacopoeia monographs  
CEP证书修订/更新管理程序**

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## **PROCEDURES FOR MANAGEMENT OF REVISIONS/RENEWALS OF CERTIFICATES OF SUITABILITY TO THE EUROPEAN PHARMACOPOEIA MONOGRAPHS CEP证书修订/更新管理程序**

### **Introduction: 引言**

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.

本文应与EDQM “欧洲药典适应性证书修订/更新要求指南(PA/PH/CEP (04) 2修订版” 一同使用。该指南规定了修订条件和申报文件要求。

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

CEP证书修订管理程序规定如下。

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

程序允许在一个修订申请中同时申报多个变更。该变更视为对原申报文件的变动。

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.

修订申请初评后可以会签发缺陷。若未能充分答复补充所需资料，修订申请将予以驳回。

### **1. Implementation 执行**

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

2008年7月1日后起收到的修订/更新申请都将按此新程序受理。

## **2. How to apply for a request for revision/renewal** 如何提交修订/更新请求

### **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.

### 申请表

修订/更新申请表应和修订申请一起提交。可从EDQM网站上下载Word或pdf格式表格。

### **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”.

### 申报文件资料

修订/更新资料要求见“欧洲药典适应性证书修订/更新要求指南”。

Consequential changes should be identified and the relation between the changes should be described.

必须具体说明变动内容，以及各项变动之间的联系。

**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.**

多数情况下，必须申报变动前后对照清单。可以表格形式列出，分别罗列出已批准文件和拟变更的对照内容，将变动之处用阴影表示。

### **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.

### 收费和时间表

收费和时间表取决于修订的类别。第4点列出了具体时间表。收费标准在申请表有规定。费用必须在EDQM验收文件、收到发票后再予以支付。

### 3. Procedures 程序

#### 3.1. Notifications 通知

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.

EDQM在收文件2周内认定是否属于通知类变更（多项通知：4周）。之后会向持有人签发一封变更有效确认函，如有必要，会签发更新后的CEP证书。

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.

如果收到的通知文件不完整，将不再发函索取补充资料，而直接驳回变更申请，同时向持有人签发驳回信。这意味着申请人必须重新申报完整资料，并支付有关费用。

An application for multiple simultaneous notifications is possible under conditions:

- maximum 3 changes
- fee and deadlines are increased

可以一次同时申请多个通知类的变动，但必须符合以下条件：

- 变动上限是3个
- 收费增加，受理周期延长

#### 3.2. Minor revisions 微小变更

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

**T0** (收到申请5日内)：向申请人签发收件确认函。

**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).

**T 30天**（多项微小变更：T60天）：两种情况：批准申请；或要求补充更多资料（计时停止）。

**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.

**如果计时停止:** 申请人必须在30天内提交补充资料。如不按时申报补充资料, 变更申请将被拒绝

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

**新T0:** CEP证书秘书处收到申请人答复后5天内。

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.

**新T30天:** 批准; 或者, 如果申请人答复不当, 签发拒绝函。如果拒绝变更申请, 申请人必须重新申报正确的资料, 并支付相关费用。

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

可以一次同时申请多个微小类或多个微小+通知类变动, 但必须符合以下条件:

- 多个微小变更(上限是3个)或者
- 综合变更(3个以上变更, 详见3.6规定)
- 收费增加, 受理周期延长

**\*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.

**\*批准:** 根据“欧洲药典适应性证书修订/更新要求指南”规定, 如果微小变更不是R3a类, 并且该变更不影响CEP证书的具体内容时, 向持有人签发批准函。

In the other cases, the certificate is revised.

其他情况下, 将修订CEP证书。

### 3.3. Major revisions

#### 重大变更

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

**T0** (收到5日内): 向申请人签发收件确认函。

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

**T 90天:** 批准申请; 或要求补充更多资料 (计时停止)。

**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.

**如果计时停止:** 申请人必须在30天之内进行答复。如不按时答复, 更新申请将被拒绝。

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

**新T0:** CEP证书秘书处收到申请人答复5日内。

**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.

**新T30天 (TSE证书: 90天):** 批准; 或者, 如果申请人答复不当, 签发拒绝函。如果变更申请遭到拒绝, 申请人必须重新申报正确的资料, 并支付相关费用。

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

申请得到批准后, 将签发修订后的CEP证书。

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)

可以一次同时申请多个变动, 即: 一个重大+微小/通知类, 但必须符合以下条件:

- 重大变更 (上限是3个, 不影响收费标准和受理周期) 或
- 综合变更 (变更超过3个, 详见3.6)

### 3.4. Renewal 更新

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.

证书持有人至少应在**证书到期前6个月**提出更新申请。由于评估文件需要时间，如不能事先对证书进行有效的更新，可能会在证书到期和再次更新之间存在时间差。

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

**T0** (收文5日内): 向申请人签发收件确认函。

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

**T120天**: 批准; 或要求补充更多资料 (计时停止)。

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

**如果计时停止**: 则要求申请人在30天之内进行答复。

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

**新T0**: CEP证书秘书处收到申请人答复后5日内。

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

**新T30天 (TSE证书: 90天)**: 批准 (签发更新后的CEP证书); 或要求补充新资料。

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

更新时，可以同时包括微小变更或通知类变更。但不得包括重大变更。

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

批准更新申请后，将签发更新后的CEP证书。



### 3.5. Monographs revisions

#### 药典修订

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.

如果欧洲药典增补版收录了修订后的药典个论，证书秘书处会致函持有人，要求持有人更新其申报文件。

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

持有人必须在90天之内申报资料。

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

**T0:** 收到资料5日内开始计时，EDQM不再签发收文确认信。

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

**T90天:** 或者批准，或者签发补充资料函（计时停止）

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

若计时停止：申请人必须在30天之内进行答复。

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

**新T0:** 证书秘书处收到申请人答复后5日之内

**New T30 days:** Approval or new request for information.

**新T30天:** 批准或再次要求补充资料。

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

资料批准后，签发批准函，或必要时，签发修订后的CEP证书。

### 3.6. Consolidated revision

#### 综合变更

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

综合变更：同一个申请中包括3个以上的所有变更。

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

**T0（收文后5日内）：** 向申请人签发收文函。

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

**T120天：** 批准申请\*，或要求补充资料（计时停止）。

**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.

**如果计时停止：** 申请人必须在30日内进行答复。若未按时答复，将会拒绝变更申请。

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

**新T0：** 证书秘书处收到申请人答复5日内。

**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.

**新T30天（TSE证书：90天）：** 批准\*，或：答复不完整，驳回申请。若驳回申请，申请人必须重新申报完整、正确的资料，并支付相关费用。

#### \*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.

#### \*批准:

根据“欧洲药典适应性证书修订/更新要求指南”如果综合变更包括所有重大变更或R3a类微小变更，或者变更会影响CEP证书内容，将签发修订后的CEP证书。

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.

如果综合变更只有R3a类变更，或通知类变更，又不影响CEP证书内容，则只向证书持有

人签发批准函。

### 3.7 Transfer of holdership

#### 持有人转让

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.

收到申请后2周内，将完成对CEP证书持有人转让进行认定，并签发修订后的证书。

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.

如果收到的申请内容不完整，将直接驳回，而不再要求补充资料，并向持有人签发拒绝函。这意味着申请人必须重新申报完整、正确的资料，并支付相关费用。

### 4. Fee and timetables: 收费标准和受理周期

The fee for the kinds of revisions are available in the application form, and published on the EDQM website [www.edqm.eu](http://www.edqm.eu)

收费标准按类别在修订申请表格中有具体说明，并在EDQM网站[www.edqm.eu](http://www.edqm.eu) 上公示。

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
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Type of revision 修订类别	EDQM Timetable (original assessment) EDQM受理周期 (首次评审)	EDQM Timetable (answer to deficiency letter) EDQM受理周期 (缺陷信答复评审)
Simple notification 答复通知	2 weeks 2 周	n/a
Multiple notifications (up to 3) 多项通知 (上限3个)	4 weeks 4 周	n/a
Simple minor revision (1 minor change) 简单微小变更 (1个微小变更)	30 days 30 天	30 days 30 天
Multiple minor revision (up to 3 minor changes+notifications) 多项微小变更 (上限3个微小+通知)	60 days 60天	30 days 30 天
Major revision (may include introduction of minor changes/notifications, up to 3 in total) 重大变更 (可以包括微小/通知, 但总计不得超过3个)	90 days 90 天	30 days (TSE: 90 days) 30天 (TSE: 90天)
Consolidated revision (more than 3 changes, of any kind) 综合变更 (3个以上所有变更)	120 days 120 天	30 days (TSE: 90 days) 30天 (TSE: 90天)
Renewal 更新	120 days 120 天	30 days (TSE: 90 days) 30天 (TSE: 90天)
Monograph revision 药典修订	90 days 90 天	30 days 30 天
Transfer of holdership 持有人转让	2 weeks 2 周	n/a