swissmedic

Guidance document

Renewal and discontinuation of authorisation or change of status (main authorisation/export licence)

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List of contents

1 Terms, definitions, abbreviations

1.1 Abbreviations

FeeO-Swissmedic	Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 14 September 2018 (SR 812.214.5)
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act) (SR 812.21)
TPLO	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (SR 812.212.23)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (Therapeutic Products Ordinance) (SR 812.212.21)
KPTPO	Ordinance of 7 September 2018 of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Complementary and Phytotherapeutic Products (Complementary and Phytotherapeutic Products Ordinance) (SR 812.212.24)

2 Introduction

This guidance document describes the rules that apply to the renewal or discontinuation of authorisation, how these rules are to be handled and the associated rights and obligations incumbent on authorisation holders.

2.1 Legal framework

The rules that apply to the renewal or discontinuation of authorisation, how these rules are handled and the associated rights and obligations incumbent on authorisation holders are based on the following legal provisions:

TPA

- Art. 16 *Authorisation decision and duration of authorisation* (paras. 2 and 3)
- Art. 16a *Revocation and transfer of the authorisation* (paras. 4 and 5)
- Art. 16b *Renewal of authorisation* (paras. 1 and 2)
- Art. 16c *Review of authorisation*

TPO

- Art. 11 *Notification in case of no marketing and cessation of distribution* (paras. 2, 3 and 5)
- Art. 12 *Renewal of authorisation* (paras. 1 and 2)
- Art. 13 *Revocation and suspension* (para. 2)
- Art. 85 *Medicinal products approved under existing law*

TPLO

- Art. 21 *Time limitation and extension of authorisation* (para. 3)

3 Objective

Swissmedic uses this document first and foremost as a resource for applying the legal provisions on authorisation in auniform and equitable manner. The publication of the guidance document is

designed to make it clear to third parties what requirements must be fulfilled according to the practice of Swissmedic.

4 Scope

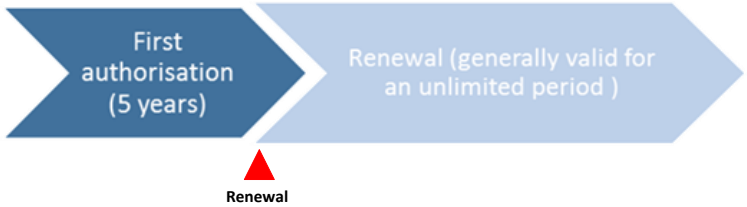
This guidance document applies to authorisation renewals, to notifications or applications to discontinue authorisation for a medicinal product, dosage strength or pack size, and to applications for changes of status between main authorisations and export licences for human and veterinary medicinal products authorised by the regular or notification procedure or holding temporary authorisation.

5 Description

5.1 Renewal of the authorisation

5.1.1 Duration of authorisation of medicinal products

Medicinal products are initially authorised for a period of five years (Art. 16 para. 2 TPA). Five years after first authorisation, a once-only application for extension of authorisation must be made. Renewal is subject to ongoing fulfilment of the conditions for authorisation. Once renewed, authorisation is



generally valid for an unlimited period (Art. 16b paras. 1 and 2 TPA).

If a medicinal product is granted temporary authorisation under Art. 9a TPA in response to an application to this effect or if ex officio time-limitation is necessary to protect health, the initial duration of authorisation may be less than five years (Art. 16 para. 2 TPA and Art. 16b para. 2 TPA). In such cases, authorisation is generally limited to two years.

Medicinal products processed under a notification procedure are deemed to be authorised for an unlimited period, i.e. it is not necessary to apply for renewal of authorisation (Art. 16 para. 3 TPA). This includes the following medicinal products:

- Co-marketing medicinal products authorised under Art. 34 TPLO
- Veterinary medicinal products authorised under Art. 39 TPLO
- Complementary medicinal products authorised under Art. 15 para. 1 let. a TPA (homeopathics, anthroposophics and medicinal products for gemmotherapy according to Art. 27 and 28 KPTPO and Asian medicinal products according to Art. 31 KPTPO).
- Medicinal products authorised under Art. 15 para. 1 let. b TPA (individual teas according to Art. 12 KPTPO, cough and throat sweets and pastilles according to Art. 13 KPTPO, and other medicinal products or groups of medicinal products for which authorisation under the simplified procedure seems excessive by virtue of their low risk potential).

Swissmedic may review authorisation at any time, i.e. it can adapt it to altered circumstances or revoke it (Art. 16c TPA).

5.1.2 Applications for renewal of authorisation

Applications for renewal of authorisation should be submitted no earlier than one year and no later than six months before authorisation expires (Art. 12 para. 1 TPO). In justified cases, and particularly in the case of medicinal products that are subject to additional supervision, Swissmedic may demand a different timing for submission. This will be decided when the medicinal product in question is first authorised (Art. 12 para. 2 TPO).

It is the responsibility of the authorisation holder to submit applications on time. Swissmedic will not admit applications for renewal that are not submitted in accordance with the statutory timelines. If Swissmedic does not receive an application for renewal at least six months before the authorisation expires, the product will be deleted on the date its authorisation expires. However, authorisation holders have the option of applying for renewed authorisation for the medicinal product in question (see section 5.1.5 *Renewed authorisation*).

Authorisation holders must also apply for renewal for medicinal products that have been suspended. If suspension cannot be revoked before authorisation expires, the renewal application will not be reviewed and authorisation will expire.

5.1.2.1.1 Renewal of regular authorisation

Renewal of regular authorisation should be requested using the form *Renewal of authorisation* (for complementary and herbal medicinal products the form *Renewal of authorisation CHM* should be used). A covering letter is only required if it is necessary to draw Swissmedic's attention to particular circumstances. The medicinal product information and packaging texts do not need to be enclosed. Swissmedic may demand appropriate supplements to the application.

Authorisation renewals cannot be requested as a collective or multiple application.

Furthermore, applications for renewal of authorisation must not involve variations. Any variations must be requested or notified in a separation application (see guidance documents *Variations and extensions HMP / Variations VMP*). Applications for variations will be processed independently of the renewal procedure. The procedures in question do not have to be completed before unlimited authorisation can be issued.

For information on the formal requirements, please refer also to the guidance document *Formal requirements* in conjunction with the Directory *Overview of documents to be submitted*.

Swissmedic may require the submission of documentation and/or applications for variations as a prerequisite for renewal. In such cases, applicants will be notified in the preliminary decision. Failure to comply with this requirement by the stipulated date may result in applications for renewal being rejected, which will in turn result in authorisation expiring.

5.1.2.1.2 Renewal of authorisation issued under the notification procedure

Although authorisations issued under the notification procedure are not temporary (see section 6.1.1 *Duration of authorisation of medicinal products*), all relevant authorisations that were issued before

Art. 16 para. 3 TPA entered into force must, as part of a transitional arrangement, nevertheless be renewed at least once upon application (see section 5.1.6 *Transitional arrangement*).

For veterinary medicinal products authorised under the notification procedure, the form *Renewal of authorisation by notification procedure veterinary medicinal products* should be used for this purpose, while the form *Renewal of authorisation by notification procedure homeopathic and anthroposophic medicinal products* should be used for homeopathics, anthroposophics and medicinal products for gemmotherapy (individual notifications).

However, renewal of authorisation for co-marketing medicinal products authorised under the notification procedure and medicinal products according to Art. 15 para. 1 let. b TPA must be requested using the form *Renewal of authorisation*.

For information on the formal requirements, please refer also to the guidance document *Formal requirements* in conjunction with the *Overview of documents to be submitted*.

The basic company dossier (according to Art. 38 KPTPO), the master dossier (according to Art. 39 KPTPO) and the sample quality documentation for Asian medicinal products (according to Art. 40 KPTPO) do not have to be renewed.

The fee for renewed authorisation of homeopathics, anthroposophics and medicinal products for gemmotherapy authorised under the notification procedure and for medicinal products according to Art. 15 para. 1 let. b TPA is calculated on a time-spent basis (Art. 4 para. 2 FeeO-Swissmedic). The fee for renewed authorisation of veterinary medicinal products authorised under the notification procedure and of co-marketing medicinal products is the flat fee specified in FeeO-Swissmedic.

5.1.3 Applications for renewal of temporary authorisation

The requirements for extension of temporary authorisations can be found in the guidance documents *Temporary authorisation for human medicinal products HMV4* and *Temporary authorisation of veterinary medicinal products HMV4* respectively.

5.1.4 Option not to renew authorisation

Authorisation holders may opt not to renew authorisation. If they choose to do so, they should notify Swissmedic accordingly at the earliest one year before expiry of the authorisation using the form *Renewal of authorisation*, the form *Renewal of authorisation by notification procedure veterinary medicinal products* or the form *Renewal of authorisation by notification procedure homeopathic and anthroposophic medicinal products*. In such cases, authorisation automatically expires on the last day of validity. Swissmedic makes no charge for processing such notifications.

If authorisation of a medicinal product expires, any pending administrative proceedings (concerning applications for variations, for example) will be dismissed. Applicants will be invoiced for the flat fee or time-spent costs of the procedure in question.

If a medicinal product is authorised permanently, the medicinal product can no longer expire using the above-mentioned form *Renewal of the authorisation*. In this case, an application for discontinuation must be submitted to end the authorisation of a medicinal product.

5.1.5 Applications for renewed authorisation

Authorisation holders who miss the deadline for applying for renewed authorisation can still do so provided the authorisation for the medicinal product in question has not expired. In addition, a cover letter confirming that the documentation, including all additions approved since, is identical to that of the authorised medicinal product for which the renewed authorisation application is being submitted and complies with the requirements of therapeutic legislation must be submitted. No other documents from Module 1 or scientific documentation (Modules 2 to 5) are required (see also the guidance document *Formal requirements* in conjunction with the Directory *Overview of documents to be submitted*).

If the authorisation is renewed, the medicinal product's existing name and authorisation number (incl. packaging code) will be continued.

Any variations must be applied for separately and cannot be submitted until new authorisation has been granted. However, variation applications can only be submitted if the authorisation status of the medicinal product is “authorised”, i.e. either before expiry of the authorisation or following completion of the application for renewed authorisation.

Homeopathics, anthroposophics and medicinal products for gemmotherapy authorised under the notification procedure have to be re-notified using the HOMANT reporting platform. If authorisation is renewed, the medicinal products may continue to use their existing names. However, they will be assigned new authorisation numbers.

An interruption in the marketable status of the medicinal product in question cannot always be prevented by applying for renewed authorisation. Uninterrupted marketability will only be possible if Swissmedic has sufficient time to review the above-mentioned documents.

The fee for processing applications is calculated on a time-spent basis (Art. 4, para. 2 FeeO-Swissmedic).

5.1.6 Transitional rules

All medicinal product authorisations issued before Art. 16b TPA entered into force must be renewed at least once upon application (Art. 85 TPO). The same applies to medicinal products authorised under a notification procedure (co-marketing medicinal products, veterinary medicinal products according to Art. 39 TPLO, complementary medicinal products according to Art. 15 para. 1 let. a TPA and medicinal products according to Art. 15 para. 1 let. b TPA).

5.2 Discontinuation of authorisation

5.2.1 Notifying discontinuation of authorisation for a medicinal product

Authorisation holders are required to notify Swissmedic when distribution of a medicinal product is definitively terminated. Notification must be given at least:

- three months in advance for all medicinal products intended solely for paediatric use for which the authorisation holder has obtained protection under Article 11*b* paragraph 3 and 4 TPA or under Article 140*n* or 140*t* of the Patents Act of 25 June 1954 (PatA).
- two months in advance for all other medicinal products,

unless distribution is being terminated or temporarily discontinued in response to circumstances that the authorisation holder could not have reasonably foreseen (Art. 11 para. 2 and 3 TPO).

Notification of discontinuation can be combined with an application for a revocation order effective from a particular date (delayed revocation). A maximum delay of one year can be requested in such cases, but not longer than the date on which regular authorisation ends. Delayed revocation is only available for medicinal products with a main authorisation. Furthermore, there must be no public health reasons to prevent delayed revocation. Veterinary medicinal products for livestock reared for food production are subject in particular to food safety requirements (Art. 9 para. 3 TPO).

Notifications of discontinuation, including applications for delayed revocation where applicable, cannot be submitted as part of a collective or multiple application. The notification/submission should be submitted with a covering letter setting out the reasons for the discontinuation. If the medicinal product is described in a grouped product information text, a separate variation application (C.I.7.a, type IB for human medicinal products, or B.3.v. Variation without assessment for veterinary medicinal products) requesting modification of the product information texts for the remaining medicinal product(s) must be submitted at the same time (see forms "*Variations and extensions HMP*" / *"Variations VMP*").

Homeopathics, anthroposophics and medicinal products for gemmotherapy authorised under the notification procedure are excepted from this rule. In such cases, the notification of discontinuation can include one or more individual notifications. When applying for delayed revocation, applicants must apply for the same delay for all medicinal products within their application. The fee for processing such applications is calculated on a time-spent basis (Art. 4, para. 2 FeeO-Swissmedic).

For information on the formal requirements, please refer to the guidance document *Formal requirements* in conjunction with the Directory *Overview of documents to be submitted*.

All administrative proceedings that are still pending when the notification of discontinuation is made (e.g. concerning applications for variations, for example) will be dismissed or, if they are still relevant to an application for delay revocation, completed. Applicants will be invoiced for the flat fee or time-spent costs of the procedure in question.

Definitive termination of distribution will always result in revocation of authorisation (Art. 13 para. 2 TPO).

The procedures for temporary discontinuation of distribution, resumption of distribution and delayed placing on the market after first-time authorisation are described in the guidance document *No marketing / interruption of distribution*.

5.2.2 Applying for discontinuation of authorisation for a dosage strength

A dosage strength may only be discontinued if the recommended dosage can still be fulfilled using the remaining dosage strengths. If not, a corresponding variation application must be submitted for the medicinal product.

For human medicinal products, discontinuation of the authorisation of a dosage strength is a minor type IB variation that must be notified in advance (*VA IB deletion of dosage strength C.I.7 b*) whereas for veterinary medicinal products it is a variation without assessment (*Discontinuation of a dosage strength B.3.v*). The formal requirements that the submission must meet and the specifications for

processing applications are based on the guidance documents *Variations and extensions HMP / Variations VMP*.

An application for discontinuation of the authorisation of a dosage strength cannot be submitted for a specific date in the future (deferred implementation).

5.2.3 Applying for authorisation for a pack size

A pack size may only be discontinued if the recommended dosage and duration of treatment can still be appropriately fulfilled using the remaining pack sizes. If not, a corresponding variation application must be submitted for the medicinal product.
For human medicinal products, discontinuation of the authorisation of a pack size is a minor type IA variation that can be notified after the event (*VA IA deletion of pack size A.103*) whereas for veterinary medicinal products it is a variation without assessment (*Discontinuation of a pack size B.3.r*). The formal requirements that the submission must meet and the specifications for processing applications are based on the guidance documents *Variations and extensions HMP / Variations VMP*.

5.3 Status change from main authorisation to export licence and vice versa

For human medicinal products, applications for a status change from main authorisation to export licence and vice versa are a minor type IB variation that must be notified in advance (*AE IB ZL Haupt-ZL → Export-ZL A.104* bzw. *AE IB ZL Export-ZL → Haupt-ZL A.105*) whereas for veterinary medicinal products they are a variation with assessment (time limit “Reduced”) (*ZL Haupt-ZL → Export-ZL E.101* bzw. *ZL Export-ZL → Haupt-ZL E.102)*. The formal requirements that the submission must meet and the specifications for processing applications are based on the guidance documents *Variations and extensions HMP / Variations VMP*. An application for a status change between main authorisation and export licence cannot be submitted for a specific date in the future (deferred implementation).

5.3.1 Conversion of a main authorisation to an export licence

A medicinal product that holds an export licence may not be distributed in Switzerland or the Principality of Liechtenstein.
Export licences do not contain any approved product information texts (e.g. packaging texts or Patient information) apart from the basic medicinal product information. Furthermore, Swissmedic does not approve pack sizes in these cases.
It is the responsibility of the authorisation holder to keep the dossier of medicinal products with export licences constantly up to date. Authorisation holders have a particular obligation to ensure that the basic product information reflects the current state of science and technology (Art. 28 TPO).
Corresponding variation applications must be submitted in accordance with the guidance documents *Variations and extensions HMP / Variations VMP*.

5.3.2 Conversion of an export licence to a main authorisation

When converting an export licence into a main authorisation, it is necessary to request pack sizes and submit all medicinal product information (Information for healthcare professionals, Patient information, package leaflets for veterinary medicinal products and/or packaging texts) for approval.

For information on the issuing of new packaging codes due to the conversion of an export licence into a main authorisation, see the guidance documents *Variations and extensions HMP section* 9.3 / *Variations VMP section 9.3*.

5.4 Particular requirements applicable to basic products and co-marketing medicinal products

5.4.1 Discontinuation/status change from main authorisation to export licence and vice versa for basic products of co-marketing medicinal products

If the medicinal product for which authorisation is not being renewed, distribution is being definitively terminated, authorisation of dosage strengths or pack sizes is being discontinued or whose status is being changed from main authorisation to export licence or vice versa is the basic product for a co-marketing medicinal product, the holder of authorisation for the medicinal product in question must submit confirmation that the holder of authorisation for the co-marketing medicinal product has been appropriately informed.
The holder of authorisation for the co-marketing medicinal product must ensure that the requirements applicable to co-marketing medicinal products in accordance with Art. 34 to 38 TPLO are fulfilled at all times (see also guidance document *Authorisation of co-marketing medicinal product*).

5.4.2 Discontinuation/status change from main authorisation to export licence and vice versa for co-marketing medicinal products

If the medicinal product for which authorisation is not being renewed, distribution is being definitively terminated, authorisation of dosage strengths or pack sizes is being discontinued or whose status is being changed from main authorisation to export licence or vice versa is a co-marketing medicinal product, the holder of authorisation for the medicinal product in question must ensure that the requirements applicable to co-marketing medicinal products in accordance with Art. 34 to 38 TPLO are fulfilled at all times (see also guidance document *Authorisation of co-marketing medicinal product*).

5.5 Processing time

The time required to process notifications or applications for renewal, discontinuation and status change from main authorisation to export licence and vice versa are based on the guidance document *Time limits for authorisation applications*.

5.6 Fees

The fees for processing notifications or applications for renewal, discontinuation and status change from main authorisation to export licence and vice versa are charged in accordance with FeeO-Swissmedic.

5.7 Publication

Renewal, renewed authorisation, discontinuation and expiry of authorisation of a medicinal product, discontinuation of a dosage strength or pack size and status change from main authorisation to export

licence and vice versa will be published in the Swissmedic Journal in the month following the official decision.
If discontinuation, expiry or conversion of a main authorisation to an export licence concern a medicinal product intended solely for paediatric use and for which the authorisation holder has obtained protection under Article 11*b* paragraph 3 and 4 TPA or Article *n* or 140*t* of the Patents Act of 25 June 1954 (PatA), Swissmedic will also publicly announce that the scientific documentation on which authorisation is based will be made available to third parties free of charge so that they can obtain their own authorisation. Swissmedic publishes this additional information on the Internet list for document protection (Art. 16a para. 5 TPA and Art. 11 para. 5 TPO; see also guidance document *Document protection*).

Change history

Version	Change	sig
5.0	Change to the documentation to be submitted for renewed authorisation. "Editorial change: Deletion of “HMV4” suffix, “Other valid documents” section and deletions in Scope section	lm, mag
4.1	New layout, no content adjustments to the previous version.	dei
4.0	Section 6.1.3 Applications for renewal of temporary authorisation: deletion of content, addition of cross-reference to guidance documents Temporary authorisation for human medicinal products HMV4 or Temporary authorisation for veterinary medicinal products HMV4. Section 6.1.4 Option not to renew authorisation: Clarification of the process when waiving temporary authorisations, clarification of the timing for submission of waiving renewal of the authorisation	lm, stb
3.0	Adaptation of guidance document due to new structure of VMP variations (early revision of VMP regulations)	fg, ps
2.4	Clarification in section 6.1.5. Submission of variation applications for renewed authorisation.	lm
2.3	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
2.2	Explanation: Section 6.2.2. An application for discontinuation of a dosage strength cannot be submitted for deferred implementation. Section 6.3.2. Conversion of an export licence into a main authorisation, issuing of new packaging codes	lm, vy
2.1	Adaptation of the formal requirements for the renewed authorisation.	ze, wph
2.0	Explanation chapter 7 Status change from main authorisation to export licence and vice versa.	ze
1.0	Implementation of TPO4	ze