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# Guidance document
# Transfer of marketing authorisation

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# 1 Terms, definitions, abbreviations

## 1.1 Abbreviations

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| 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) |
| TPLRO | Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22) |
| TPO | Ordinance of 21 September 2018 on Therapeutic Products (Therapeutic Products Ordinance) (SR 812.212.21) |

# 2 Introduction

This guidance document describes the requirements and preconditions (including the documentation to be submitted) for an application to transfer authorisations for human and veterinary medicinal products. Since this guidance document is aimed at administrative bodies, it does not directly specify the rights and obligations of private individuals.

## 2.1 Legal framework

Article 10 TPO and Article 11 and Annex 1 FeeO-Swissmedic.

# 3 Objective

Swissmedic uses this document first and foremost as a resource for applying the legal provisions on authorisation in a uniform 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

The guidance document is applicable in the Infrastructure, Medicinal Product Authorisation and Vigilance, and Medicinal Product Licences and Surveillance Divisionsto applications to transfer authorisations for medicinal products to a new marketing authorisation holder.

# 5 Description

## 5.1 Description of the process

The transfer of the authorisation comprises the transfer of all rights and obligations associated with the marketing of a medicinal product. The authorisation status of a medicinal product is not affected by the transfer to a new marketing authorisation holder.

### 5.1.1 Formal requirements

On the date the application to transfer the authorisation is submitted, the future authorisation holder must satisfy the authorisation conditions specified in Article 10 TPA (licence, registered office/branch in Switzerland).
If an application to transfer authorisation also includes medicinal products containing narcotics, the future authorisation holder must also already have the establishment licence for handing controlled substances required when the application to transfer the authorisation is submitted.

### 5.1.2 Application and documentation

The future marketing authorisation holder must submit to Swissmedic **at least three months** before the planned transfer date a written application requiring approval to transfer the authorisations from the previous (current) marketing authorisation holder to a new one (the applicant). (see application type *5328 OT Übertragung ZL*). If a transfer date with a shorter lead time is requested, this must be plausibly justified.

The application must contain:

a) A declaration of assignment bearing the legally valid signatures (as shown in the entry in the Commercial Register) of the previous marketing authorisation holder, stating the name of the medicinal products to be transferred, incl. planned transfer date;
b) The form *Transferring an authorisation* completed in full by the future marketing authorisation holder (the applicant).

Swissmedic may request further documentation as necessary.

### 5.1.3 Consequences of the transfer

With the transfer of authorisation, all obligations associated with the authorisation of a medicinal product are transferred in their entirety to the new authorisation holder. In particular, this means that the latter alone is authorised to release new batches for the market. This also applies to remaining stock of batches assumed from the “old” authorisation holder; these must be re-released after being incorporated into the stock of the “new” authorisation holder.
If batches that were manufactured under the responsibility of the former authorisation holder have to be released for the market, the new authorisation holder is responsible for this. The latter must ensure that it has all the information it needs to confirm that the batch was produced in accordance with Good Manufacturing Practice (GMP), that a valid manufacturer's batch certificate has been issued in accordance with Art. 5a TPA and that the batch meets the formal requirements for authorisation.

### 5.1.4 Exceptions, transitional arrangement

#### 5.1.4.1 Sale and assumption of batches already placed on the market

Unless there are particular grounds for doing so, batches already placed on the market by the former authorisation holder will not be recalled after the transfer of authorisation. This means that batches which are already on the market (at wholesale and retail level) may remain on the market unchanged until the end of their shelf life and be sold in the regular way.
If the former authorisation holder has a permit for wholesale trading in medicinal products, it may continue to sell those batches which it released for sale prior to the transfer of authorisation, provided

that it can meet in full all obligations under therapeutic products legislation that arise from this distribution (e.g. fulfilling the obligation to report in accordance with Article 59 TPA). An agreement may be concluded between the former and the new authorisation holder on the assumption of batches that were manufactured under the responsibility of the former authorisation holder (and possibly already released onto the market by them). Unless aspects relating to GMP/GDP are affected, such an agreement will come under private law.

#### 5.1.4.2 Changes to packaging, to Information for healthcare professionals and to Patient information

To avoid any interruption of distribution or the destruction of batches already manufactured, the new authorisation holder is entitled during a transitional period of up to one year to indicate the new authorisation holder by way of stickers affixed to the outer packaging and without making any other alterations to the existing packaging of the medicinal product or to other elements. Labelling of the folding boxes is mandatory for as long as the new authorisation holder uses the packaging materials of the former marketing authorisation holder. It should be noted that according to GMP, (already released) batches assumed from the former authorisation holder also have to be released by the RP of the new authorisation holder. As a result, the labelling specifications also apply to these batches. After one year at the latest, the authorisation holder may only release and place on the market batches in the packaging of the new authorisation holder. The new packaging is subject to the provisions and requirements of the TPO and the TPLRO.

### 5.1.5 Change to the name of the medicinal product

A change to the name of the medicinal product is not possible in connection with the application for transfer of the authorisation. For this, a separate application must be submitted to the Authorisation division of Swissmedic.

### 5.1.6 Modification of the logo or corporate design

Simultaneous modification of the logo or corporate design as part of an application to transfer the authorisation will be the responsibility of the authorisation holder. This means that it is not necessary to submit any documentation to Swissmedic for this purpose, provided the logo or corporate design has already been approved by Swissmedic at an earlier date.

If an application involving packaging is submitted at a later date, the accompanying letter must state that the authorisation holder is implementing/has implemented the changes autonomously.

If, however, the future logo and/or corporate design has not yet been approved by Swissmedic, a separate application must be made (see also the guidance documents *Packaging for human medicinal products* and *Packaging texts for veterinary medicinal products*) and this will attract a fee

If the transfer concerns the authorisation of a medicinal product that is still under review, the future logo and/or corporate design will be reviewed as part of the application for first authorisation.

### 5.1.7 Packaging and product information leaflets

The new marketing authorisation holder may only market the transferred medicinal product with packaging and package leaflets displaying the name of the new marketing authorisation holder. No modifications must be made to either the text or packaging design apart from the exceptions listed in sections 5.1.4 and 5.1.6.

### 5.1.8 Publication of the medicinal product information

The new authorisation holder is responsible for the correct publication of the information for healthcare professionals and patient information texts as of the time when the authorisation is transferred.

## 5.2 Fees

The fees stated in FeeO-Swissmedic apply.

## 5.3 Review

Swissmedic may verify the correct implementation of the measures in accordance with Art. 58 para. 2 TPA and instigate measures as appropriate in accordance with Art. 66 TPA. Art. 86 para. 1 letter a TPA also applies.

## Change history

| Version | Change | sig |
|---|---|---|
| 2.0 | Section 5.1.1 *Formal requirements* – new section<br>Section 5.1.2 to 5.1.4 – various clarifications<br>Section 5.1.6 Modification of the logo or corporate design – change to the procedure and harmonisation with the specifications according to the guidance document *Change name or domicile of the authorisation holder* | vy |
| 1.3 | New layout, no content adjustments to the previous version. | dei |
| 1.2 | Modification of the logo or corporate design | gf, mb |
| 1.1 | Formal adjustments to the header and footer<br>No content adjustments to the previous version. | dei |
| 1.0 | New rules regarding sale of batches already released and implementation of HMV4 | fua, stb |