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Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
1.1	**11.02.2019**	**Corrections of point 4.1 Applications and documentation**	**seb**
1.0	**01.01.2019**	**Implementation of HMV4 and amendments based on the revision of the MPLO/Medicrime**	**seb**

1 Introduction and purpose

This guidance document describes the requirements and preconditions (including those applicable to documents to be submitted) to be satisfied by applications for changes to establishment licences resulting from changes to the name or domicile of the authorisation holder. Swissmedic uses this guidance document first and foremost as a resource for applying the legal provisions in a uniform and equitable manner. For applicants, the document is intended to make clear the specific requirements that must be fulfilled so that corresponding applications can be processed by Swissmedic as quickly and efficiently as possible.

2 Scope

This guidance document applies to the Licensing and Authorisation divisions of Swissmedic and is valid in the following circumstances:

- Change to the name of the authorisation holder:
  Changes to the legal status or company form of authorisation holders also count as a change of name;
- Change to the domicile of the authorisation holder:
  Any changes to postal addresses, such as street name, house or building number, P.O. box, post code, town or city, etc. count as a change to the authorisation holder's domicile (place of residence, registered office or branch).

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3 Legal framework

Art. 10 para. 1 let. b TPA, Art. 21 to 24 TPO, Art. 22a to 22c and Annex 7 TPLRO and FeeO-Swissmedic.

4 Description of the process

The application process for changes to the name or domicile of authorisation holders is described in more detail below.

4.1 Applications and documentation

The basis for changes to the name and/or domicile of authorisation holders is an application for a change to an establishment licence resulting from changes to the company's name or domicile. For this purpose, submit the following set of filled out documents:

- I-301.AA.05-A02 Application for an establishment licence - Medicinal products
- I-301.AA.05-A03 Application for an establishment licence - Additional sheet to the medicinal products (one form must be submitted per site)
- I-301.AA.05-A04 Application for an establishment licence - Additional sheet change of name and domicile medicinal products

Applications for a change to an establishment licence generate the fee-based regulatory change applications A.1: Change in the name and/or domicile of an authorisation holder (type IA_{IN}); including new licence certificates. You can download the authorisation documents yourself from the eGov portal. Authorisation documents will only be sent to the applicant if specifically requested, and dispatch is subject to a fee. Such a request must be expressly stated in the cover letter. The period allowed for processing the above-mentioned application (type IA_{IN} A.1) only starts when the application for a change to the establishment licence has been approved.

4.2 Packaging elements and product information leaflets

On receipt of the official decision approving the change to the establishment licence in the form of the changed name or domicile, all affected medicinal products placed on the market by the authorisation holder must be supplied with packaging elements and product information leaflets bearing the new name or domicile. No additional modifications must be made to either the text or packaging design apart from the exceptions listed in sections 4.3 and 4.5.

4.3 Exceptions, transitional arrangement

For a time-limited transitional period not to exceed one year from the approval of the variation application A.1: "Change in the name and/or address of the marketing authorisation holder" (type IA_{IN}), an adhesive label displaying the new address of the authorisation holder (company and registered office as given in the Commercial Register) may be applied to the outer packaging of products. Information for healthcare professionals and Patient information do not have to be adapted during the transitional period. If the company makes use of the transitional arrangement, it is the company's responsibility to produce an adhesive label and to comply with the transitional period (a maximum of one year).

4.4 Changes to the names of medicinal products

The names of medicinal products may not be changed as part of an application for a change to an establishment licence. Names must be changed by submitting a separate application, which will attract a fee, to the Authorisation division of Swissmedic (A.2 b): Changes to the names of medicinal products, type IB).

4.5 Modification of logos or corporate design

Any simultaneous modifications to logos or corporate design will be the responsibility of the authorisation holder. This means that it is not necessary to submit any documentation to Swissmedic

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for this purpose, provided the logo or corporate design has already been approved by Swissmedic at an earlier date.

If an application involving the packaging elements 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 or corporate design has not already been approved by Swissmedic, a separate application must be made to the Authorisations division of Swissmedic and this will attract a fee.

4.6 Responsibility

From the time changes to names or domiciles are approved, it is the authorisation holder's responsibility to ensure correct publication of Information for healthcare professionals and Patient information.

4.7 Note on changes to the name or address of marketing authorisation holders

In the case of medicinal products (A.1, type IA_{IN}), authorisation holders must not implement changes to names and/or domicile until the new establishment licence has been issued in accordance with Art. 10, para. 1 let. b TPO or until Swissmedic has modified the licence.

5 Fees

The fees specified in the Ordinance of 14 September 2018 on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic, SR 812.214.5) apply.

6 Review

Swissmedic can verify correct implementation of measures in accordance with Art. 58, para. 2 TPO and may initiate measures in accordance with Art. 66 TPO if appropriate.

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