Guidance document on the application for an establishment licence for medicinal products or TP/GT/GMO

1 Objective and scope

Companies that intend to manufacture and/or distribute medicinal products or TP/GT/GMO (transplant products/gene therapy products/genetically modified organisms) must obtain an establishment licence from Swissmedic. This guidance document serves as a guide to the submission of the relevant application forms and provides additional information on the requirements that must be met by these companies.

Separate forms should be submitted for the handling of narcotics (controlled substances); see www.swissmedic.ch under *Human medicines* > *Special categories* > *Authorised narcotics* > *Forms and Checklists.*

2 Useful links

www.swissmedic.ch under *Human medicines* > *Licensing* > *Authorisations:*
- *Forms*: Application forms
- *Authorisation holder:* Lists of authorisation holders with details of the scope of the licence
- *Inspectorates*: I-SMI.TI.17e “Responsible Person: Requirements” and other technical interpretations on issues relating to GMP/GDP

www.ema.europa.eu > *Search Document:* “compilation of community procedures on inspections and exchange of information”. From page 144 this document provides interpretations on the manufacturing activities stated in the application forms.

3 General information

3.1 Reference numbers and correspondence language

When the receipt of your licence application is confirmed you will be informed of your application number. Please cite this number in all future correspondence relating to the application.
The licence number can be found in the header of the existing establishment licence. When an establishment licence is issued for the first time, “does not yet exist” should be checked since the number is only assigned during the licensing procedure.

The licence is issued in the correspondence language (i.e. in the official language used in the submitted application).

3.2 Fees

The review of an application is subject to a fee even if the application is withdrawn during the course of the procedure or the application is rejected. If submitted applications are incomplete, the additional time incurred as a result may be invoiced separately. The fees are charged in accordance with the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic, SR 812.214.5).

3.3 Conditions to be met by the company

- The company must be entered in the commercial register if its annual sales exceed CHF 100’000.-.

- The company must operate a quality assurance system that ensures the GMP-compliant manufacture and/or the GDP-compliant distribution of medicinal products.
  - GMP Guide: http://www.picscheme.org > *Publications* > *GMP Guide*
  - GDP Guidelines: https://eur-lex.europa.eu > *Guidelines on Good Distribution Practice of medicinal products for human use*
- The company must nominate a Responsible Person. The requirements pertaining to the Responsible Person can be found in the Medicinal Products Licensing Ordinance (MPLO, SR 812.212.1). For further explanations see I-SMI.TI.17e "Responsible Person: Requirements".

4 Submission of application

4.1 Procedure for initial issue

- The completed application, together with the official forms, should be sent by post to Swissmedic (submission via the Swissmedic Portal is not yet possible).
- On receipt of the application, Swissmedic sends an inspection order to the corresponding regional inspectorate.
- The competent inspectorate performs an inspection. If deviations are noted during the inspection, these will have to be rectified within a reasonable period and, based on the outcome, the inspectorate will ask Swissmedic to issue or reject the licence.
- Time frame: From the application submission to the initial issue of an establishment licence can be expected to take from 6 to 18 months.
- Fees: see 3.2.
- Inspection interval: Depending on the type of activity, the company will be inspected every 2 to 4 years.

4.2 Documentation to be supplied

4.2.1 Basic form

The basic form must be submitted with every application and signed by an authorised signatory. Authorised signatories are usually those individuals entered in the commercial register who are entitled to sign individually or jointly. If the basic form is missing, the application will be returned.

4.2.2 Supplementary sheets

A) Supplementary sheet: Medicinal products or TP/GT/GMO

A supplementary sheet with all activities should be completed for each affected site. The supplementary sheet should be signed by the Responsible Persons/s or, in the event of a change, by the person newly proposed for this function.

In the event of a **discontinuation** the basic form will suffice.

Manufacture: Contrary to the procedure adopted up to now, the packing activities (Codes 1.5.1.N and 1.5.2) and quality control (Code 1.6.N) must be applied for with the new forms, even if the manufacture of the corresponding pharmaceutical form (Codes 1.1.N, 1.2.N, 1.3.N and 1.4.N) is the subject of the application.

Issuing manufacturing orders for medicinal products or TP/GT/GMO as the ordering party: Companies with a licence to trade abroad that have issued manufacturing orders in accordance with the existing law must, after 01.01.2019, apply for an extension to the licence for wholesale trading in medicinal products (Code S.4.6).

B) Supplementary sheet: Change of name or domicile

If the authorisation holder (for authorised medicinal products) changes its domicile or company name, the supplementary sheet “Change of name or domicile” should also be submitted. The permitted period for processing this application (type IA_{IN} A.1) only starts when the application for a change to the establishment licence has been approved.

Note for **contract manufacturers and contract laboratories**: If the applicant is contracted to manufacture or carry out analyses, it must inform its clients in the event of the following changes:

- Change of name
- Change of address (even if just one site is affected)
- Discontinuation of activities (reduced scope of the licence)
- Discontinuation or loss (suspension, revocation) of the establishment licence

C) Supplementary sheet: RP Multiple mandates

If the RP has other mandates at other companies or has applied to Swissmedic for such mandates, the supplementary sheet RP Multiple mandates should be completed and enclosed with the application.