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20 Jahre 2002 - 2022

Medicinal products and procedures authorised in foreign countries for complementary and herbal medicines (Art. 13 TPA)

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Medicinal products and procedures authorised in foreign countries under Art. 13 TPA

Purpose and scope

Consideration of the results of foreign authorisation procedures is intended to assist in processing authorisations of medicinal products in Switzerland in such a way that medicinal products already authorised in foreign countries are made available to patients in Switzerland as rapidly as possible, and also to ensure the targeted, risk-assessed use of Swissmedic's resources (Art. 1 para. 2 letter c and Art. 1 para. 3 letter a TPA).

What procedures are possible in application of Art. 13 TPA, with a focus on complementary and herbal medicines?

- **New authorisation applications for medicinal products with known active substances**
- **New authorisation applications for medicinal products containing new active substances and additional indications for these***
- **Applications for minor variations (types IA/IA$_{IN}$ and IB)***
- **Applications for major variations (type II)***
- **Applications for extensions***
- New authorisation applications for biosimilars that have already been authorised by the *European Commission* or the US FDA
- New authorisation applications for medicinal products that are not eligible for simplified authorisation under Art.12 para. 5 TPLO*
- New authorisation applications for temporary authorisation under Art. 9A TPA

See applicable preconditions -> Guidance document "Authorisation of human medicinal products under Art. 13 TPA HMV4"

Conditions for submission under Art. 13 TPA

Countries with comparable control systems for medicinal products

Land	Anmerkung
Australien	Vereinbarung zum Informationsaustausch *ICH Beobachter*
EWR-Mitgliedstaaten (EU und EFTA-Länder)	*ICH Mitglied*
Grossbritannien	
Japan	*ICH Mitglied*
Kanada	Vereinbarung zum Informationsaustausch *ICH Mitglied*
Neuseeland	Vereinbarung zum Informationsaustausch *Orientiert sich an ICH Standards*
Singapur	Vereinbarung zum Informationsaustausch *ICH Mitglied*
USA	Vereinbarung zum Informationsaustausch *ICH Mitglied*

Can be found on: swissmedic.ch

Reference authority / procedure

(e.g. centralised vs decentralised procedure)

(new authorisation application vs variation application or indication extension)

Submission under Art. 13 TPA

- **Comparability of foreign and Swiss documentation**

  Note: Module 1 of the reference authority and the Swiss country-specific Module 1 must be submitted.
- **Full and final Assessment Report (AR)**
  (no older than 5 years)
- **Review decision(s) of the reference authority**
- **Variations and/or additions after the decision by the foreign authority must be submitted.**
- **Information regarding safety signals**

Submission under Art. 13 TPA

- **GLP / GMP / GCP**
- **Risk Management Plan in accordance with ICH E2E**

  (for NAS and indication extensions for these, as well as for biosimilars)
- **Drug Master File (DMF / ASMF)**
- **Medicinal product information (information for healthcare professionals and patient information)**

  (Swiss requirements must be taken into account (TPLRO))

*List not exhaustive. Please note the Guidance document *Authorisation human medicinal product under Art. 13 TPA HMV4* and the table *Overview of documents to be submitted HMV4*

Differences permitted compared to the medicinal product authorised by the reference authority

- batch release
- quality control(s)
- secondary packaging or secondary packer
- pack size (if this does not conflict with the use of the product)
- name of the medicinal product authorised in the foreign country

Important
Please note that Swissmedic reserves the right to carry out its own full or partial review in the event of safety concerns or if the documentation is incomplete.

Legal framework

The procedure for taking into account the results of assessments carried out during the course of foreign authorisation procedures is derived in particular from the following legal bases (provisions of laws and ordinances):

Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (TPA):

- Art. 13 Medicinal products and procedures authorised in foreign countries

  Ordinance of 21 September 2018 concerning Medicinal Products (TPO):

- Section 2: Medicinal products and procedures authorised in foreign countries (Art. 13 TPA):

  Art. 16-20 SR **812.21** SR **812.212.21**

Further information

- Guidance document *Authorisation human medicinal product under Art. 13 TPA HMV4*
- Directory *List of all countries with comparable control of human medicinal products HMV4*
- Table *Overview of documents to be submitted HMV4*
- Art. 13 TPA SR **812.21**
- FAQ: *Questions and answers Art. 13 TPA* (Swissmedic website)