swissmedic

Guidance document

Import of a human medicinal product according to Art. 14 para. 2 and 3 TPA (parallel import)

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1 Definitions, abbreviations

1.1 Definitions

Parallel imported medicinal product
Any medicinal product that is imported from a country with comparable medicinal product control and has been authorised by Swissmedic in response to an application under Article 14 para. 2 and 3 TPA is termed a parallel imported medicinal product.

Original medicinal product
The medicinal product already authorised in Switzerland is termed the original medicinal product.

Country of export
The country of export is the country with comparable medicinal product control in which the national authorisation for the parallel imported medicinal product was issued.

Foreign source of supply
The foreign source of supply refers to manufacturers (domiciled in the country of export) or wholesalers (domiciled in the country of export or in a country with comparable medicinal product control) that supply the importer with batches of the parallel imported medicinal product.

Importer (additional placer on the market)
Swiss-domiciled company that is responsible for importing the parallel imported medicinal product into Switzerland. The importer is the marketing authorisation holder for the parallel imported medicinal product.

Repackaging company
Company that is responsible for repackaging the parallel imported medicinal product.

1.2 Abbreviations

Para.	Paragraph
TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22)
Art.	Article
IHP	Swiss Information for healthcare professionals
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
GTIN	Global Trade Item Number
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
OMCL	Official Medicines Control Laboratory
PE	Swiss packaging elements
PI	Swiss Patient information
SR	Classified Compilation of Federal Legislation (Fedlex)

TPO	Ordinance of 21 September 2018 on Therapeutic Products (Therapeutic Products Ordinance, TPO, SR 812.212.21)
TPLO	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Authorisation of Therapeutic Products by the Notification Procedure (SR 812.212.23)
WL	*Wegleitung* = guidance document

2 Introduction and objective

Parallel imported human medicinal products can be authorised under the simplified procedure. This guidance document describes the documentation requirements for submitting and obtaining authorisation of parallel imported human medicinal products: It is intended primarily for administrative bodies. Swissmedic uses the guidance document as a resource for applying the legal provisions in a uniform and equitable manner. For applicants, the document is intended to elucidate the specific requirements that must be fulfilled to ensure that applications for the authorisation of and variations to parallel imported human medicinal products under Art. 14 para. 2 and 3 TPA are processed as quickly and efficiently as possible.

3 Scope

This guidance document applies to applications for authorisation of parallel imported human medicinal products within the Medicinal Product Authorisation and Vigilance Sector of Swissmedic.

4 Legal framework

The procedure for simplified authorisation of parallel imported medicinal products is based, in particular, on the following legislative texts:

TPA
Art. 14 para. 2 and 3
Art. 67
TPO
Art. 26 - 29
TPLRO
Art. 12 - 17
TPLO
Art. 28 - 31

5 General requirements and assessment principles

5.1 General principles

Parallel imported human medicinal products can only be authorised if they are imported from a country with comparable medicinal product control (see *List of countries with comparable medicinal product control*).

A parallel imported human medicinal product must satisfy the same requirements as the original medicinal product that is already authorised in Switzerland, particularly as regards its labelling and medicinal product information in accordance with Section 4 TPLRO and Art. 26 ff. TPO.

The importer must satisfy the same safety and quality requirements with respect to the parallel imported medicinal product as the marketing authorisation holder with respect to the original medicinal product.

5.2 Formal requirements

The formal requirements are based on the guidance document *Formal requirements* and the associated *Overview of documents to be submitted.*

5.3 Requirements for applications

The requirements for applications are set out in Art. 29 TPLO.
A separate application must be submitted for each country of export in which the medicinal product is authorised. As a result, a separate authorisation number is assigned for each export country, which ensures traceability in the event of defects.
In particular, the applicant must fulfil the requirements in terms of official licences and GMP/GDP certificates in accordance with the guidance document *GMP compliance by foreign manufacturers*.
In addition, applicants must submit two sample packages per dosage strength.

5.4 Requirements relating to medicinal product information

Information for healthcare professionals (IHP) and Patient information (PI) for the parallel imported medicinal product must be identical to those for the original medicinal product; differences and additional mandatory information (sample texts) are listed in Section 8, Annex.

If variations are made to the original medicinal product that also affect the parallel imported medicinal product, the variations in question should be applied to the parallel imported medicinal product.
If not all pharmaceutical forms, dosage strengths or pack sizes are being imported or if the imported pack size is not one that is authorised for the original medicinal product in Switzerland, a note must be added indicating the medicinal product pack size that is being imported.

The date of revision of the text corresponds to that of the original medicinal product.

5.5 Packaging element requirements

5.5.1 Primary packaging

The primary packaging is not assessed and is accepted in the version used in the country of export. Information on primary packaging that patients in Switzerland will not understand must be explained in the *Other information* or *What else needs to be observed?* sections of the IHP or PI.

5.5.2 Secondary packaging

The labelling and medicinal product information requirements in Art. 26–29 TPO or Art. 12–17 TPLRO must be satisfied. This also extends to any mobile technologies that are used.
Swiss secondary packaging (folding carton) can be produced for parallel imported medicinal products. There is also the option of placing the foreign version of parallel imported medicinal products on the market with a non-removable label setting out the Swiss requirements in two official languages.
In addition to the excipient composition statement, the disclaimer “Composition as per foreign package leaflet” should be placed below the declaration on the packaging elements (PE) or label.

Swiss secondary packaging (folding carton)

The information on the folding carton must be identical with that on the carton of the original medicinal product.

In addition, the importer of the parallel imported medicinal product, the product’s authorisation number and packaging code and information on the holder of authorisation for the original medicinal product and the authorisation number of the original medicinal product must be stated. It must be possible to clearly distinguish the details of the holder of authorisation for the original medicinal product from those of the importer.

Illustrative example:
Authorisation holder (original): XY Pharma (Switzerland) Ltd, City
Authorisation no. 11111
Authorisation holder (importer): ABC Import Ltd, Location
Authorisation no. 66666 001

The packaging of the parallel imported product must carry the GTIN code of the country of export.

Label on the folding carton of the parallel imported medicinal product

All the information required by Annex 1, 1a or 1b TPLRO must be visible on the packaging in two official languages and be identical to that on the original medicinal product, including the medicinal product name.
Where the foreign packaging does not include all the information required in Switzerland, the missing information must be printed on the label.
The Swiss package leaflet must be affixed to the parallel imported package by suitable means (e.g. banding).

5.6 Deviations from the original medicinal product

5.6.1 Medicinal product name

The name of the medicinal product in the foreign country is generally the same as that of the original medicinal product.

If the parallel imported medicinal product has a different name from the original medicinal product, Swissmedic will assess that name in accordance with Art. 9 para. 4 TPO (see guidance document *Medicinal product names*). If Swissmedic approves the diverging name, the difference must be explained in the *Other information* or *What else needs to be observed?* sections of the IHP or PI.

5.6.2 Pack size

Where pack sizes are different, the differences must not create safety implications, i.e. the imported pack size must not conflict with the recommended dosage for the original medicinal product. Diverging pack sizes must be listed in the medicinal product texts (IHP and PI).

5.6.3 Other deviations

The following deviations are regarded as having particular safety implications and will not be accepted:

- Diverging pharmaceutical form
- Deviations in excipient quality (except printing ink components)
- Differences in medicinal product colour (e.g. blue rather than yellow tablets)
- Deviations in active substance quantity
- Original medicinal product has a score line that is essential for dosage, but parallel imported medicinal product does not.
- Different primary containers for injectables/infusions

The following deviation in particular is non-critical:

- Differences in printing ink components. However, such differences must be listed in the medicinal product texts (IHP and PI).

6 Requirements after authorisation

6.1 Vigilance

The holder of authorisation for the parallel imported medicinal product is subject to the vigilance reporting obligation set out in Art. 61 ff TPO.

6.2 Variations

In the event of a variation, the holder of authorisation for the parallel imported medicinal product must submit a *Variations and extensions* form.

- Any variation in the medicinal product information (IHP and/or PI) or PE of the original medicinal product cannot be implemented for the parallel imported human medicinal product until Swissmedic has approved the variation for the original medicinal product. The variation should be notified after the fact for the parallel imported medicinal product. This should be done using a type C.I.2 IA_{IN} application and the modified medicinal product information texts (IHP, PI and PE) should be submitted.
- The marketing authorisation holder must submit a type IB A.z variation application for changes in source of supply and/or repackaging company.

6.3 Revocation of original medicinal product's authorisation

Revocation or suspension of the original medicinal product's authorisation also results in revocation or suspension of the parallel imported human medicinal product's authorisation.

7 Fees

The fee for applications to parallel import human medicinal products under Art. 14 para. 2 and 3 TPA is charged in accordance with FeeO-Swissmedic.

8 Annex

8.1 Prescribed wording and explanations for Information for healthcare professionals

Examples:

Medicinal product name	Product ABC, film-coated tablets Medicinal product imported under Art. 14 para. 2 and 3 Therapeutic Products Act (“parallel import”) of Product ABC, film-coated tablets (auth. no. 11111) of marketing authorisation holder XY Pharma (Switzerland) Ltd, City.
Composition Active substances: Excipients: *(In addition to the excipient composition statement, the disclaimer “Composition as per foreign package leaflet” should be placed below the declaration on the packaging elements (PE) or label.)*	 AS1, AS2 EX1, EX2 Composition as stated in the foreign package leaflet.
Pharmaceutical form and active substance quantity per unit	Film-coated tablets x mg AS1, y mg AS2 per film-coated tablet
Other information	*Identical text as for original medicinal product + statement of known deviations from original medicinal product*
Authorisation number *(Shown here: Example for a medicinal product imported from various countries)*	Authorisation number (original) 11111 (Swissmedic). Authorisation number (importer) 99999 (0.5 mg, 1 mg and 5 mg) (Swissmedic) (Austria) 88888 (1 mg) (Swissmedic) (France) 77777 (1 mg) (Swissmedic) (Belgium) 66666 (0.5 mg, 1 mg and 5 mg) (Swissmedic) (Poland)
Packs *(Shown here: Example for a medicinal product imported from various countries)*	Available for auth. no. 99999 Capsules 0.5 mg 50. (A) Capsules 1 mg 50. (A) Capsules 5 mg 50. (A) Available for auth. no. 88888 and 77777 Capsules 1 mg 50. (A) Available for auth. no. 66666 Capsules 0.5 mg 60. (A) Capsules 1 mg 60. (A) Capsules 5 mg 60. (A)
Marketing authorisation holder	Marketing authorisation holder (original) XY Pharma (Switzerland) Ltd, City; Authorisation holder (importer)

	ABC Import Ltd, Location
Date of revision of the text	*(The date of revision of the text is that of the original medicinal product)*

8.2 Prescribed wording and explanations for Patient information

Examples:

Medicinal product name	Product ABC, film-coated tablet Medicinal product imported under Art. 14 para. 2 and 3 Therapeutic Products Act (“parallel import”) of Product ABC, film-coated tablet (auth. no. 11111) of marketing authorisation holder XY Pharma (Switzerland) Ltd, City.
What else needs to be observed?	*Insert identical text as for original medicinal product + known deviations from original medicinal product here*
What *Product ABC* contains	One film-coated tablet contains x mg of active substance AS1, y mg of active substance AS2 and excipients EX1, EX2.
(In addition to the excipient composition statement, the disclaimer “Composition as per foreign package leaflet” should be placed below the declaration on the packaging elements (PE) or label.)	The composition of the excipients is as stated in the foreign package leaflet.
Authorisation number *(Example for a medicinal product imported from various countries)*	Authorisation number (original) 11111 (Swissmedic). Authorisation number (importer) 99999 (0.5 mg, 1 mg and 5 mg) (Swissmedic) (Austria) 88888 (1 mg) (Swissmedic) (France) 77777 (1 mg) (Swissmedic) (Belgium) 66666 (0.5 mg, 1 mg and 5 mg) (Swissmedic) (Poland)
Where can you get Product ABC? What packs are available? *(Example for a medicinal product imported from various countries)*	In pharmacies on presentation of a medical prescription that is intended for single use only. Packs: Available for auth. no. 99999 Capsules 0.5 mg 50. Capsules 1 mg 50. Capsules 5 mg 50. Available for auth. no. 88888 and 77777 Capsules 1 mg 50. Available for auth. no. 66666 Capsules 0.5 mg 60. Capsules 1 mg 60. Capsules 5 mg 60.
Marketing authorisation holder	Marketing authorisation holder (original) XY Pharma (Switzerland) Ltd, City. Authorisation holder (importer)

This package leaflet was last revised by the medicines agency (Swissmedic) in (month/year).	ABC Import Ltd, Location. *(The date of revision of the text is that of the original medicinal product.)*

Change history

Version	Description	sig
1.0	First version	ski, zsa, vit, nma, cho, tay, hv, vy