swissmedic

Information sheet

Individual import licence for immunological medicinal products, blood or blood products

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List of contents

1 Objective

This information sheet explains those cases where an application is required to import immunological medicinal products, blood or blood products which are authorised or exempt from authorisation in Switzerland.

Note:
This information sheet summarises the legal requirements arising from the Therapeutic Products Act (TPA) and the Medicinal Products Licensing Ordinance (MPLO). For greater clarity, the description of certain situations has been simplified. The original text of the Act and the Ordinance applies in all cases.

2 Scope

This information sheet is valid:

- for anyone wishing to import immunological medicinal products, blood or blood products which are authorised or exempt from authorisation in Switzerland.
- for customs authorities

3 Other valid documents

Document ID
BW301_30_001d_FO_Einfuhr_immunologischen_Arzneimitteln_Blut_und_Blutprodukten
The list of currently authorised vaccines and blood products can be downloaded under point 5. “Vaccines, blood products and other immunological products” on the Swissmedic website.

4 Need for an application for an individual import

- As a rule, an application for an individual import licence in accordance with Article 44 of the Medicinal Products Licensing Ordinance is required for any consignment of immunological medicinal products which are authorised or exempt from authorisation in Switzerland, if these are:
  - for use in humans and animals, or
  - blood and blood products for use in humans.
- This also applies if the products are to be imported into Switzerland for the purpose of re-export.

- Even the storage of corresponding products in a customs warehouse counts as an import.

5 Exceptions

An individual import application in accordance with Art. 44 of the Medicinal Products Licensing Ordinance is not required for:

a) allergens
b) blood and blood products that are authorised or exempt from authorisation if these medicinal products:
   1st are submitted in medical emergencies or for autologous transfusion;
   2nd are not intended for use in humans; or
   3rd have an official batch release from one of the control authorities belonging to the Official Control Authority Batch Release Network (OCABR Network)
c) immunological medicinal products that are authorised or exempt from authorisation, provided an official batch release from one of the control authorities belonging to the OCABR Network has been issued for the batch to be imported

Examples of exceptions	Remarks:
Import of immunological medicinal products, blood or blood products which are authorised or exempt from authorisation, and which have an official batch release issued by a control authority within the Official Control Authority Batch Release (OCABR) network.	The batch release document must be presented to customs upon importation.
Import of ready-to-use medicinal products which are not authorised in Switzerland	These are imported in accordance with Article 49 of the Medicinal Products Licensing Ordinance (MPLO)
Allergens (immunological medicinal products for diagnosing immunity status)	e.g.: tuberculin tests
Blood and blood products imported in medical emergency situations.	Ideally Swissmedic should be notified.
Import of immunological medicinal products, blood and blood products which are authorised or exempt from authorisation and which are not intended for use in humans and animals.	e.g. as test reagents, laboratory samples or samples for laboratory diagnostics
Recombinant / genetically engineered stable blood products	e.g. erythropoietin, factor VIII.

6 Application

- The import applications must be submitted by the importer using form BW301_30_001d – “Einfuhr von immunologischen Arzneimitteln oder von Blut und Blutprodukten”.
- An application must be submitted for each consignment to be imported.
- The application form must be signed.
- Under authorisation number, the number of the:
  - authorisation or
  - temporary licence or
  - clinical trial

  must be entered.

7 Applicant's entitlement to import

- The applicant must be in possession of a valid establishment licence for the import of immunological medicinal products or blood and blood products (labile and stable). A corresponding individual import licence is also required to import intermediate products.
- Individuals and healthcare professionals who are legally entitled to import small quantities of medicinal products do not require a general establishment licence for import.
- This also applies if the goods are being imported for notified clinical trials.

8 Cancellation by customs

When the goods are imported, customs completes the cancellation note in part C of the form. Part cancellations are generally not permitted. Customs returns the cancelled licences to Swissmedic.

9 Contact address

The application must be submitted to (by e-mail or by post):

E-Mail: inspectorates@swissmedic.ch

Swissmedic
Inspectorates and Licences
Section Certificates and Licences
Hallerstrasse 7
3012 Berne

Phone: +41 58 462 04 55

Change history

Version	Change	sig
6.1	New layout, no content adjustments to the previous version	tsj
6.0	Revision due to transfer of immunological veterinary medicinal products to Swissmedic	seb, hul
5.0	Extension of the table of contents (new contact address)	seb
4.0	Change to points 4 and 5	seb
3.0	Complete reworking due to revision of MPLO/Medicrime	seb
2.0	Content change	bep
01	New QM-Ident: BW301_30_001d_MB Old QM-Ident: BW301_00_002d_MB	feh
01	Transfer from QM inspectorates (former QM-Ident: I-304.AA.01-A04e) to QM-Swissmedic.	gme, bep