

SMC - Medicinal products establishment licence

1. General

1.1 The issue at hand

To protect human and animal health, only safe and effective medicinal products should be placed on the market. For this reason, only companies that hold a [Swissmedic](#) establishment licence may import or export medicinal products.

1.2 Basis and information

- Therapeutic Products Act (TPA; [SR 812.21](#))
- Medicinal Products Licensing Ordinance (MPLO; [SR 812.212.1](#))

1.3 Reference in Tares

Tariff items that are relevant under therapeutic products law contain the note «Authorisation obligation: SMC-M EL».

1.4 Terminology

Medicinal products	Medicinal products are products of chemical or biological origin which are intended or claimed to have a medicinal effect on the human (human medicinal products) or animal (veterinary medicinal products) organism. In particular, they are intended to diagnose, prevent or treat diseases, injuries and disabilities.
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2. Information in the customs/goods declaration

Anyone importing or exporting medicinal products must provide an indication in the goods declaration regarding the regulation obligation and enter the establishment licence number.

Identification Regulation	Passar: <ul style="list-style-type: none">- Regulation 1 (yes)- Regulation code 510 «SMC - M Establishment licence»
	e-dec: <ul style="list-style-type: none">- Authorisation obligation «yes»- Authorising authority «SMC-M EL»- Authorisation type 2 General authorisation
Additional information	<ul style="list-style-type: none">- Authorisation number- Authorisation holder¹

Goods that would generally require a licence, but that can nevertheless be brought into the country without a licence due to an exemption from the requirement, must be declared accordingly:

Identification Regulation	Passar: <ul style="list-style-type: none">- Regulation 1 (yes)- Regulation code 510 «SMC - M Establishment licence»
Licence exemptions	<ul style="list-style-type: none">- Import/export of medicinal products by veterinarians and doctors in accordance with Article 20 paragraph 1 of the MPLO- Import of medicinal products by medical professionals in accordance with Article 49 of the MPLO- Import of medicinal products by individuals in accordance with Article 48 of the MPLO- Import of medicinal products by veterinarians in accordance with Articles 7 to 7d of the VMPO- Import/export of medicinal products for manufacture as defined in Article 4 paragraph 1 letter c of the TPA

¹ Only for declarations in the Passar system

	<ul style="list-style-type: none">- Import of medicinal products by international organisations in acc. with Art. 49a MPLO- Import of blood, blood products and immunological medicinal products by international organisations in acc. with Art. 49a MPLO
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