

# 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 «Permit 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 restriction obligation and enter the establishment licence number.

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

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:

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