# SMC - Medicinal products authorization import individual batches

## 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, an individual import authorisation from Swissmedic is required to import blood, blood products and immunological 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 IIB».

### 1.4 Terminology

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| Blood | Human blood (including in the form of stored blood) |
| Blood products | Products extracted from human blood by physical, chemical or biological means (e.g. cell preparations, plasma, coagulation preparations, albumin and immunoglobulins) |
| Immunological medicinal products | Medicinal products used to create active or passive immunity or help diagnose immunity status (e.g. vaccines, toxins and sera) |

## 2. Information in the customs/goods declaration

Anyone importing blood, blood products or immunological medicinal products must provide an indication in the goods declaration regarding the restriction obligation and enter not only the Swissmedic establishment licence number, but also the corresponding individual import batches.

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| **Identification**<br>Regulation | Passar:<br>- Regulation 1 (yes)<br>- Regulation code 512 «SMC – M Import individual batches»<br>- In addition to regulation code 510 «SMC - M Establishment licence» |
| | e-dec:<br>- Permit obligation «yes»<br>- Authorising authority «SMC-M IIB» |
| **Additional information** | - Authorisation number<br>- Authorisation holder<br>- Quantity to be depreciated<br>- Quantity to be depreciated unit |

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:

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| **Identification**<br>Regulation | Passar:<br>- Regulation 1 (yes)<br>- Regulation code 512 «SMC - M Import individual batches» |
| **Licence exemptions** | - Import of blood and blood products in accordance with Article 44 paragraph 2 letter b. number 1 of the MPLO<br>- Import of blood and blood products in accordance with Article 44 paragraph 2 letter b. number 2 of the MPLO |

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| | - Import of blood and blood products in accordance with Article 44 paragraph 2 letter b. number 3 of the MPLO |