To:
Swiss importers

Bern, 25.04.2025

Swissmedic will be conducting targeted inspections of Swiss importers in 2025

Dear Sir/Madam,

You are registered with Swissmedic as a Swiss importer of medical devices. By this you play a central role in the supply and verification of these devices.

The **obligations of an importer** include, among other things:

- a verification of formal product conformity before placing devices on the Swiss market, including the requirements set out in the transitional provisions[1];
- compliance with the required storage and transport conditions of the products;
- cooperation with and provision of information to the authorities and economic operators in the event of complaints, incidents, and field safety corrective actions including recalls.

A focus campaign carried out in 2023 to verify compliance with importer obligations revealed that full compliance with these obligations poses a challenge for many importers[2]. In the interest of patient and user safety, it is important that importers are aware of their responsibilities. It is their responsibility to know and comply with the requirements for medical devices. As the competent authority, Swissmedic is committed to ensuring compliance with the requirements for safe and effective medical devices on the Swiss market by means of regular inspections.

This year, Swissmedic will be conducting another focus campaign aimed at verifying importers' compliance with their obligations.

- **How will Swissmedic conduct the review?**

  As part of a focus campaign, a certain number of Swiss importers will be selected through a random sample. The review will be conducted on-site at the selected importers in the form of an inspection, following written prior notice.

- **Do you need to provide Swissmedic with feedback on this information letter?**

  No. If you have been selected by Swissmedic as part of the random sample in this year's focus campaign, you will be notified by a separate letter.

- **Where can you find more information?**

  Swissmedic's information sheet for authorised representatives, importers and distributors[3] provides detailed information on the obligations of importers.

[1] Transitional provisions in the final provisions from Art. 100 of the Medical Device Ordinance (ODim, SR 812.213) as well as from art. 81 of the Ordinance on In Vitro Diagnostic Medical Devices (IvDO; SR 812.219)
[2] www.swissmedic.ch >Medical devices > Market surveillance > Focus campaigns > Swissmedic reviews Swiss importers
[3] www.swissmedic.ch >Medical devices > Market access > Obligations for authorised representatives, importers and distributors

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products
Swissmedic | Hallerstrasse 7 | 3012 Bern | Schweiz | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

Information on the procedure required for formal verification of legacy devices within the framework of the transitional provisions can be found here: Request to review legacy devices[4]
Swissmedic also relies on European practices when interpreting the applicable provisions. Further information can be found in the relevant guidelines of the European Commission[5].

Help ensure safe medical devices and fulfil your obligations as an importer of medical devices within the scope of your responsibility and due diligence.
Regardless of the current focus campaign, Swissmedic may conduct additional inspections of importers at any time [6].

This information letter is being sent to all importers registered with Swissmedic and is published on our website[7].

Kind regards,

Swissmedic, Swiss Agency for Therapeutic Products
Division Medical Device Surveillance (MDS)
Hallerstrasse 7
3012 Bern
Switzerland
medical.devices@swissmedic.ch
www.swissmedic.ch

[4] www.swissmedic.ch >Medical devices > Obligations for authorised representatives, importers and distributors
[5] health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en > Authorised representatives, importers and distributors
[6] Chapter 9 ODim, Chapter 8 IvDO
[7] www.swissmedic.ch > Medical devices > News