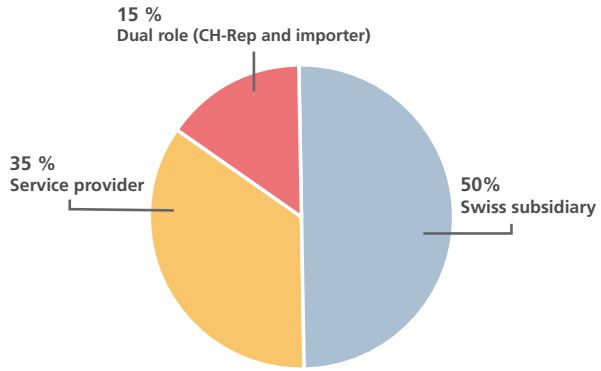
swissmedic

Medical devices
Swissmedic inspects Swiss authorised representatives (CH-REP)

Foreign manufacturers of medical devices who want to place devices on the market in Switzerland are required to mandate a Swiss authorised representative (CH-REP). The CH-REP represents the manufacturer in dealings with Swissmedic, cantonal authorities and patients, and is jointly and severally liable with the manufacturer for the devices.

Due to Switzerland's exclusion from the European market surveillance system for medical devices, the role of Swiss authorised representatives is of central importance. In dealings with the authorities, they are responsible for providing data and documentation on the safety and performance of the devices and undertaking comprehensive vigilance duties on behalf of the manufacturers.



Swissmedic carried out systematic, focused inspections of Swiss authorised representatives in the first half of 2022 to check their implementation of the provisions in the market.

Between March and May 2022, Swissmedic inspected a randomly generated sample of 20 Swiss authorised representatives registered with Swissmedic throughout Switzerland. Information, including about their operating models, was recorded to obtain a general overview of the market situation.

The inspections took place in the three official Swiss languages and English.

In this focus campaign, Swissmedic reviewed whether the contractual agreements with the foreign manufacturers, the expertise and the arrangements of the authorised representatives met the requirements stipulated in the Medical Devices Ordinance (Art. 51, 52 and 66 para. 2bis MedDO).

In most cases, the authorised representatives demonstrated a good understanding of the new regulation and satisfactory implementation of the legal requirements. All inspections took place in a constructive and open working atmosphere.

No deviations were found for six of the 20 authorised representatives inspected. The non-conformities found for 14 authorised representatives concerned in particular

- the scope and content of the contracts with the foreign manufacturers, and
- responsibility for reporting serious incidents to Swissmedic.

The authorised representatives were given the opportunity to remedy the deviations found, in particular in the form of adjustments to contracts. Swissmedic is monitoring the corrective actions and will order measures if the deviations are not remedied.

The Swiss authorised representative is a mainstay of the Swiss medical devices regulatory system for foreign manufacturers. It is vital for both patients and the authorities that, for each device placed on the market in Switzerland, the authorised representative is stated on the device itself or in its accompanying documents.

Importers of medical devices are obligated to verify that foreign manufacturers have appointed an authorised representative and that they are stated on the device or in its accompanying documents. Under its statutory market surveillance mandate, Swissmedic will continue to check in the years ahead that these elements, which are essential for market surveillance separate from the European system, are implemented.

You can find more information at the following link:
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