

Switzerland Will Open Its Market for U.S. Food & Drug Administration (FDA) - Regulated Medical Devices

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Since the Mutual Recognition Agreement between the European Union (EU) and Switzerland was put into force in July 2002, Switzerland has adhered to the New Legislative Framework approach (NLF). This framework, developed by the EU, aims to improve the internal market for goods and strengthen the conditions for placing a wide range of products on the EU market. This includes the conformity assessment of medical devices to meet high safety and health protection requirements for products before being traded and placed on the European Single Market. Today, Switzerland only accepts medical devices for national supply that comply with and have been certified under the [European Medical Devices Regulation \(EU\) 2017/745 \(MDR\)](#), i.e., medical devices that are EU CE marked.¹

However, the revised MDR that entered into application on May 26, 2021, requires all medical devices -existing and new products - to be (re)certified under the new regulation. Due to challenges in the implementation of the new MDR, in particular due to the lack of sufficient notified bodies (i.e., private institutions authorized to assess the conformity of medical devices with the MDR), and a substantial increase in technical and administrative requirements, manufacturers of medical devices have started to drastically reduce their product portfolios. This has negatively affected Switzerland's supply of medical devices. This impact has been even more severe because Swiss law requires foreign manufacturers of medical devices to fulfill requirements even beyond the revised MDR, such as the requirement to designate an (additional) Swiss-Authorized Representative (CH-REP, i.e., natural or legal person in Switzerland who receives and accepts a written mandate from a manufacturer located in another country, to act on the manufacturer's behalf in relation to specified tasks in accordance with the Swiss regulation). It is expected that when the transitional period of the MDR ends in 2024 at the latest, the cumulative effect of these additional requirements could severely jeopardize the supply of medical devices in the Swiss market, and thus jeopardize the treatment of Swiss patients.

Due to the new regulatory hurdles medical device manufacturers have to overcome as a result of the MDR, many Swiss startups and small and midsize enterprises are increasingly turning to the FDA for the initial approval of their devices. This development would lead to innovative Swiss products being made available outside of Switzerland but not to Swiss patients.

Given this background and concerns about the supply of medical devices in the Swiss market, on November 28, 2022, the Swiss parliament took the decision (based on a [motion by Councilor of](#)

[States Damian Müller's motion \(20.3211\)](#)) to instruct the Swiss Federal Council to adapt the respective Swiss national laws to allow medical devices regulated by the FDA to be placed on the Swiss market in parallel with devices with an EU CE mark.

Swiss Medtech, the trade association of the Swiss medical devices industry, supported the motion and now [calls for a quick and pragmatic implementation](#) in favor of patient care.

Examples such as Australia and Israel show that efficient procedures to recognize FDA marketing authorizations in parallel with EU CE-marked medical devices have proven successful and can be achieved in a straightforward manner (for background, please see the [memorandum published on the Swiss Medtech website](#)).

With regard to the duration of implementing adjustments to the Swiss medical devices regulation, it must be decided whether a revision can only be carried out at the level of a federal ordinance issued by the Swiss Federal Council or whether the [Swiss Therapeutic Products Act](#) would also have to be amended for this purpose. In any case, implementation should take place by 2024 in order to counter the expected gaps in supply.

The scope of the recognition and whether it will extend to all FDA medical device approvals, clearances, and authorizations - has not been clarified. Manufacturers with FDA-regulated medical devices are well advised to closely monitor the developments in the Swiss legislative processes to be prepared to supply the Swiss market with their products in a timely manner.

¹ There is also a Swiss-specific mark certifying conformity, but it is of no real relevance for the industry.

CONTACTS

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