SWISS MEDTECH

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Position Paper

Motion 20.3211 (Damian Müller) «For more room for manoeuvre in the procurement of medical devices for the care of the Swiss population».

What's the issue?

A land the size of Switzerland is not able to independently produce the approximately 500,000 medical products required by its population. Like many other countries it must rely on the import of devices. Currently, only products complying with European medical device regulations bearing the CE (Conformité Européenne) mark are permitted in Switzerland.

On 28 November 2022, Parliament passed Motion 20.3211 titled: «For more room for manoeuvre in the procurement of medical devices for the care of the Swiss population», submitted by Damian Müller, member of the Council of States. The Federal Council is thereby instructed to adapt national law so that, in addition to medical devices with the CE mark, Switzerland also recognises those from non-European regulatory systems with comparably strict requirements – in particular medical devices approved for use in the USA by the U.S. Food & Drug Administration (FDA).

Our Position

Swiss Medtech expects the Federal Council to implement Parliament's mandate **swiftly** and **pragmatically**. It is the only way to guarantee a sustainable and sufficient supply of safe medical products for the Swiss population. This is currently not the case. Switzerland's dependence on medical devices which comply with European medical device regulations has become a risk for patients. It is therefore urgent that Switzerland create more room for manoeuvre – by implementing the motion and ensuring the import of sufficient high-quality medical devices to supply its own population.

The Medical Device Regulation (MDR) has led to European legislation which is overly bureaucratic and inhibits innovation. The result is a weakening of Europe's competitiveness as a business location. Swiss Medtech expects the Federal Council to use the mandate from Parliament as an opportunity to promote progressive regulations and strengthen Switzerland's position as a location for research, innovation, and business. This must, however, be accomplished without abandoning the MDR, as the European Union remains the most important trading partner for the Swiss medtech industry.

Supporting Arguments

Expand the room for manoeuvre for the procurement of medical devices

Switzerland is obliged to import around half (in terms of value) of its medical devices from abroad to meet the medical needs of its population. To date, only medical devices complying with European medical device regulations (bearing the CE mark) may be imported. This dependence endangers the security of supply in Switzerland, as the European Medical Device Regulation (MDR) which came into force in 2017, is fraught with problems. Its aim of improving patient safety threatens to miss its mark: tried-and-tested medical devices are disappearing from the market, as the time-consuming and

expensive re-certification process is not commercially viable. In Europe, manufacturers are reducing their product range by an average of 15% and shortages of medical products are becoming increasingly apparent.

Diversify, to increase independence

Selective changes to the MDR – like those introduced by the EU in March 2023 – are not sufficient to correct the fundamental weaknesses of this regulation. The MDR's negative effect on the availability, quality, and innovation of medical devices is obvious. Relying solely on the MDR system is irresponsible in view of these multi-layered problems. In this context, Switzerland must free itself from this dependence by also recognising medical devices validated by a well-established and secure procedure, such as that of the federal Food and Drug Administration (FDA) in the USA.

Ensure rapid patient access to innovative medical devices

The USA has overtaken Europe for the initial approval of medical devices. More and more businesses – already over 50% of companies across Europe[1] – are prioritising FDA approval over CE certification. Reasons include the bureaucracy associated with the MDR, as well as the FDA's advanced position regarding cutting-edge digital technologies such as «artificial intelligence» and «software as a medical device». In recent years, the FDA has taken significant regulatory steps to keep up with technological advancements. This has been achieved without compromising patient safety. Innovations approved first in the USA are (at best) delayed for years before they reach Europe. Already today, innovative medical products developed and manufactured in Switzerland are first being approved in the USA. This unsustainable situation discriminates against patients in Switzerland.

Strengthen Switzerland as a medtech business location

MDR weakens the competitiveness of Europe as a location for research, innovation, and business. It diverts human and financial resources that would otherwise be available to further innovation. SMEs and start-ups often cannot afford to gain market access in Europe and the USA at the same time. The result is a decrease in innovation under the MDR. The parliamentary mandate is an opportunity to implement progressive regulations which strengthen Switzerland as a medtech location. This will positively impact the entire Swiss value chain; from R&D, to production and marketing. Domestically, the sector includes approximately 1,400 companies (over 90% small and medium-sized enterprises, SMEs) which employ over 67,500 individuals. Swiss medical technology is one of the most innovative in the world. It is in the interest of the entire Swiss population to preserve this leading position.

[1] Interstates and Autobahns, Global Medtech Innovation and Regulation in the Digital Age, Boston Consulting Group (BCG) and UCLA Biodesign, (May 2022)