VIEWS AND OPINIONS

SWISS MEDTECH

CHALLENGES FACING SWITZERLAND'S MEDICAL TECHNOLOGY INDUSTRY FOLLOWING THE 2021 CHANGES TO MEDICAL DEVICE LEGISLATION

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In order to improve the safety of medical devices, the European Union and Switzerland made significant changes to their respective medical device legislation, which went into effect on 26 May 2021. The same day, Switzerland lost its privileged access to the European market. These legislative and political changes have impacted not only medical device manufacturers but also patients. This article discusses the challenges to the supply of medical devices in Switzerland and outlines what is needed to overcome them.

INTRODUCTION OF THE MDR AND THE REVISED MEDDO

The Medical Device Regulation (**MDR**) is the legislation setting out the requirements that manufacturers must meet in order to sell medical devices in the European Union (**EU**). The MDR aims to further increase the safety of medical devices on the EU market. It has applied since 26 May 2021 and has had a major impact on all economic actors, including manufacturers, importers, distributors, and, last but not least, patients. Manufacturers selling devices in Switzerland must also adhere to the Swiss Medical Devices Ordinance (**MedDO**), which has been completely revised to comply with the EU's MDR.

SWITZERLAND'S THIRD COUNTRY STATUS

Switzerland was well aware that it would become a third country to the EU and lose its privileged market access if its mutual recognition agreement (**MRA**) with the EU was not updated prior to 26 May 2021. As an update became increasingly unlikely given the political climate between Switzerland and the EU, Swiss Medtech advised Swiss manufacturers and distributors as early as 2019 to prepare for third country status. A manufacturer from a third country must establish an authorised representative in the EU (**EC REP**), and in return the MedDO requires a Swiss authorised representative (**CH REP**) for all foreign manufacturers, which leads to additional administrative costs of around 2% of sales.

On the same day the MDR came into effect, the Federal Council broke off negotiations on the institutional agreement between Switzerland and the EU (**InstA**). Within the hour, the EU Commission sent out a notice to stakeholders declaring all Swiss certificates invalid and requesting an EC REP immediately and without a transition period. This pinprick mainly affected the 54 Swiss manufacturers who held Swiss certificates, i.e. CE certificates issued by the Swiss Association for Quality and Management Systems (**SQS**), the Swiss notified body. Their medical devices were declared non-compliant for export to the EU, which is traditionally their most important trading partner and accounts for around 30% of their turnover. To regain conformity, these manufacturers must have their products recertified by a European notified body – a process that takes at least two years. Fortunately, Germany, the largest EU market, validated the Swiss certificates in January 2022, but the rest of the EU has not followed suit.

THREE CHALLENGES FOR THE SUPPLY OF MEDICAL DEVICES

Today, with the hurdles established by the MedDO, a quarter of the foreign manufacturers that used to export their medical devices to Switzerland (1,200 out of 5,000 companies) have decided not to establish a CH REP and thus to stop trading. As a result, 15% of imported medical devices (60,000 of 400,000 products) are no longer available to Swiss patients. It is now up to importers and health professionals to urgently search for adequate replacements for the missing products.

The next two challenges are already emerging. According to a survey by MedTech Europe, the transition to the MDR will lead to a global portfolio reduction in CE-marked products by another 15%.[1] Even more alarming is that innovation is leaving Europe. The results of the survey show that a paradigm shift is currently taking place. Half of the European manufacturers no longer give priority to the EU market for the initial approval of their new products. Instead, they have decided to apply for initial approval outside of Europe, for example at the US Food and Drug Administration (**FDA**). Especially in the case of forward-looking digital technologies, such as artificial intelligence and software as a medical device, the regulatory approach at the FDA is more advanced than in the European approval process. A novel medical device is first approved by the FDA and used by doctors in those parts of the world where FDA products are accepted. This leads to the paradoxical situation in which an innovation developed by a Swiss company with the help of Swiss doctors only becomes available to Swiss patients three to five years later than in other parts of the world where FDA approval is accepted.

THE FUTURE OF SWISS REGULATION

In order to overcome the current supply challenge, Switzerland needs a stable relationship with the EU, a resolution of the outstanding institutional issues, and finally an update of the MRA between Switzerland and the EU. To overcome the emerging second and third supply challenges, Switzerland needs more room to manoeuvre by accepting medical devices from non-European regulatory systems with comparable quality and safety standards. Such a step would not only significantly increase the attractiveness and innovative power of Swiss medical technology companies but also serve patients because they could immediately benefit from the most modern medical technologies.

REFERENCES

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