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Life Sciences

Stricter rules for MedTech companies: The Revised Medical Devices Ordinance

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Key Take-aways

1.
To strengthen product safety, a new and stricter regulation for medical devices applies in Switzerland and the EU since 26 May 2021.

2.
Manufacturers, importers and distributors must adhere to additional regulatory requirements.

3.
As the Mutual Recognition Agreement with the EU (MRA) could not be adjusted in due time, the Federal Council issued additional provisions at short notice to mitigate related negative effects.

1 Revision of the Swiss Medical Devices Ordinance

On 26 May 2021, the **revised Medical Devices Ordinance** ("**revMedDO**") entered into force in Switzerland after several years of revision.

The revMedDO regulates the requirements for the placing on the market and the distribution of medical devices. **Medical devices** are therapeutic products whose principal effect is not obtained with a medicinal product (i.e. a product of chemical or biological origin). They include **instruments, apparatuses, devices, software, implants and other goods or substances** that, according to their intended purpose, act in or on the human body. Examples of applications for medical devices are thermometers, bandage materials, syringes, blood glucose meters as well as health apps with a medical purpose.

The previous medical devices regulation necessarily **presupposed a medical purpose** for the qualification as a medical device. Such medical purpose could, for example, lie in the diagnosis or treatment of diseases, injuries and disabilities, the investigation or modification of the human anatomy, in vitro diagnostics or the field of contraception.

The revMedDO defines various additional **product groups** that are newly subjected to the Swiss medical devices regulation even though they **do not include a medical purpose**. The majority of these are products whose use in or on the body is associated with certain safety or health concerns, because they either have an effect on the body or require a surgical procedure. By way of example, (corrected or colored) contact lenses, fillers for wrinkle treatments, fat removal devices and certain hair and skin removal devices must comply with the requirements of the new medical devices regulation. In addition, products that are specifically intended for the cleaning, disinfection or sterilization of medical devices also qualify as medical devices themselves under the new regulation.

2 Background: New EU Medical Devices Regulation (MDR)

Although it already came into force in May 2017, the new EU Medical Devices Regulation 2017/745 ("**MDR**") simultaneously began to apply as the entry into force of the Swiss revMedDO.

The MDR, which replaces the previous EU Medical Devices Directive, essentially aims to increase the **effectiveness and safety of medical devices**. This relates to several incidents involving defective medical devices in the past. As before, medical devices – in contrast to medicinal products – are not subject to an official marketing authorization or admission as such. The principle of self-regulation remains applicable. However, the MDR sets higher requirements for the safety and the conformity assessment of medical devices before they can be placed on the market, as well as on the expected post-market surveillance.

The movement of goods in the sector of medical devices, both from Switzerland to the EU and vice versa, is significant. In order to secure the **free movement of goods** within Europe for the future, **Switzerland has largely adapted its regulatory provisions to the rules in the MDR**. This is in the interest of both, Swiss manufacturers of medical devices that export to the EU, as well as foreign manufacturers distributing their medical devices in Switzerland. Last but not least, the free movement of goods also serves to secure the supply of the Swiss healthcare system with medical devices from other European countries.

Against this background, the **Mutual Recognition Agreement** ("**MRA**") between Switzerland and the EU, which has been in force since 2002, is of great importance. It reduces impediments in the market access by removing technical trade barriers. In order to reflect the fundamental regulatory changes in the EU's and Swiss medical devices regulations, the MRA needs to be updated. However, this process has come to halt due to the parallel ongoing negotiations on the **Institutional Framework Agreement** between Switzerland and the EU. As the adjustment of the MRA could not be completed in time for the revMedDO to enter into force, the Federal Council passed an amending enactment to the fully revised revMedDO at short notice on 19 May 2021. The envisaged amendments also entered into force on 26 May 2021 and were intended to mitigate the impending negative effects of the lacking update of the MRA. Without the facilitation of the MRA, manufacturers from the EU, for example, have to appoint an authorized representative in Switzerland under the revMedDO since 26 May 2021, and label the products with such information. The revMedDO now provides for transitional periods to give the affected parties more time to do so.

3 Most Important Novelties

3.1 Higher Classification and New Conformity Assessment

Depending on the risk associated with a particular medical device, the duration of its contact with humans, and its invasiveness, the new regulation reclassifies medical devices under classes I to III. This results in a **higher classification of certain medical devices**. For example, software and apps with a medical purpose, which previously were listed as class I, will now regularly – at least – qualify into class IIa under the new law. As a further example, nanomaterials that are often contained in dental fillings and prostheses will likewise be classified higher in future.

The higher classification of medical devices entails additional regulatory obligations. One important obligation is that a conformity assessment body (so-called *notified body*) has to be involved for conformity assessments of medical devices of class IIa or higher. In such case, it is not sufficient for the manufacturer to confirm in a conformity declaration that its devices meet the regulatory requirements. Rather, these medical devices must undergo a **new conformity assessment** under the new, stricter rules within certain transitional periods. This is currently causing a bottleneck at the few notified bodies, which may lead to delays.

It should be noted, that certificates issued by notified bodies designated under EU law with their registered office in an EU or EEA state and which were automatically recognized under the old law will also be treated in the same way as certificates issued by Swiss bodies until the MRA is updated. This

is the case if it can be credibly demonstrated that the applied conformity assessment procedures meet the Swiss requirements and that they were issued by a body that is sufficiently qualified from Switzerland's point of view.

Clear tightening of the regulatory framework for MedTech companies.

3.2 Evidence of Clinical Evaluation

The new regulation now explicitly requires evidence of **clinical evaluation** to confirm compliance with essential safety and performance prerequisites. Clinical evaluation involves establishing a systematic and planned process for the continuous collection and analysis of clinical data on the safety and performance of the device. Accordingly, clinical evaluation must be continuously updated over the life cycle of a medical device. For implantable and class III medical devices, it is generally required, in addition, to perform clinical investigations.

3.3 Extended Post-Market Surveillance and Duty to Ensure Traceability

Manufacturers and distributors shall monitor their medical devices also **after they have placed them on the market** (so-called *post-market surveillance*). Additional requirements now apply also in this respect. In the event of serious **incidents relevant to the safety of the device** the competent authorities must be **informed** immediately upon becoming aware of them (so-called *vigilance*).
Manufacturers must implement a **monitoring and quality management system** appropriate for the risk class and nature of the device. Manufacturers of devices in class IIa and higher must prepare a separate **safety report** for each device. Inter alia, this report summarizes the results and conclusions of the post-market surveillance data gathered and describes preventive and corrective actions taken. The safety report must be amended regularly and submitted to the notified bodies involved in the conformity assessment procedure.

Manufacturers who are not domiciled in Switzerland must now appoint an **authorized representative for Switzerland**. The authorized representative is responsible for formal and safety-related matters in connection with the placing of the product on the market. In Switzerland, the authorized representative is the primary contact person for Swissmedic and must ensure, for example, that the authorities have access to the technical documentation and the declaration of conformity. If the manufacturer is from an EU or EEA state or has appointed an authorized representative domiciled in such a state, the following transitional periods apply to the appointment of a Swiss authorized representative:

— for class III products, implantable class IIb products and active implantable medical products: until 31 December 2021;
— for non-implantable class IIb products and class IIa products, such as medical device software in particular: until 31 March 2022;
— for Class I products: until 31 July 2022.

Since the authorized person is subject to considerable regulatory obligations and liability risks, a detailed contractual arrangement between the manufacturer and the authorized representative is essential.

For all downstream operators in the manufacturer's distribution chain (authorized representatives, importers, distributors), various **cooperation and documentation duties** are foreseen in the new regulation. These duties inter alia intend to ensure the traceability of the medical devices distributed. In case of safety concerns and adverse events, this allows for rapid identification and contacting of affected persons.

Manufacturers or their authorized representatives, as well as importers, must **register with Swissmedic** within three months of first placing medical devices on the market and regularly update the registered data. Market participants who have already placed devices on the market before 26 May 2021 in compliance with the requirements of the MDR must register by 26 November 2021. The Swiss authorities will not have access to the central European database for medical devices implementing the MDR (EUDAMED) for the time being, with the exception of publicly available data.

4 Outlook

The revised provisions of the Medical Devices Ordinance mean a **clear tightening of the regulatory framework** for MedTech companies. In the future, the medical devices regulation will apply to many products that previously were not considered medical devices. Manufacturers of devices now classified higher under the new regulation (such as software and apps) will have to meet stricter safety and documentation requirements.

For medical device manufacturers and distributors operating across all of Europe, it will be of central importance whether the MRA between Switzerland and the EU can still be updated and adjusted soon. Unfortunately, this does not seem likely at the moment. This could mean that the mutual facilitations of market access for medical devices that have been valid between Switzerland and the EU so far will definitely be lost in the future.

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