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Switzerland: Trends & Developments

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Trends and Developments

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Third Country Status of Switzerland – Its Impact on the Medtech Industry

Third country status of Switzerland

Since 2001, Switzerland has regulated medical devices in the same way as the EU. The former EU Directives on classical medical devices (93/42/EEC), on active implantable medical devices (90/385/EEC) and on in vitro diagnostic medical devices (98/79/EC) were fully incorporated into Swiss law, and Switzerland was integrated in the EU market surveillance system and the EU internal market for medical devices. As a result, there was a practically barrier-free market between the EU and Switzerland with regard to medical devices.

Owing to various incidents and scandals in relation to medical devices, doubts were raised about the quality of the EU surveillance system put in place for medical devices. In order to improve the safety of medical devices, the EU passed the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR). Both regulations, which replaced the previous Directives mentioned above, entered into force in 2017. To ensure continuing equivalence with the EU, Switzerland adapted its national legislation for medical devices to the MDR and the IVDR. In particular, a new Medical Devices Ordinance (MedDO) and a new Ordinance on In Vitro Diagnostics (IvDO) were adopted.

To maintain the free trade of medical devices between the EU and Switzerland, an update of the mutual recognition of conformity assessments (MRA) was also necessary. However, the EU made the conclusion of the update of the MRA dependent on the conclusion of an institutional framework agreement with Switzerland (InstA), which had no direct relation to the regulation of medical devices. On 26 May 2021, the Swiss Federal Council terminated the negotiations with the EU because of substantial differences on key aspects of InstA. Since this date, the EU has considered Switzerland a "third country" with regard to medical devices.

As a result, Swiss medtech companies have to overcome higher hurdles to be permitted to continue selling their medical devices in the EU/EEA region. In parallel, there are increased requirements for medtech companies from EU/EEA states to introduce their medical devices on the Swiss market. This article provides an overview of the most relevant changes and consequences, and shows that the rift between the EU and Switzerland might open new opportunities for the medtech industry outside the EU/EEA states.

Impact on the medtech industry in Switzerland

Designation of an EU-REP and corresponding labelling requirement

Owing to Switzerland's "third country" status, the European Commission is of the opinion that Swiss manufacturers – as required for other non-EU manufacturers of medical devices – must mandate a competent EU representative (EU-REP) and label their medical devices with the relevant information about the EU-REP as of 26 May 2021 in order to continue selling their medical devices in EU/EEA states. The EU-REP acts as representative of the Swiss manufacturer vis-à-vis the European authorities and is jointly liable with the Swiss manufacturer for defective medical devices. The new obligation to appoint

an EU-REP and the corresponding labelling requirements give rise to considerable additional costs. According to industry estimates, the initial transition has cost the Swiss medtech industry CHF114 million with expected annual recurring costs of around CHF75 million.

Several legal experts are of the opinion that the European Commission has violated EU and WTO law and that the EU and its member states must recognise existing registrations of Swiss manufacturers and of Swiss authorised representatives in Switzerland. They are of the view that the European Commission may not require the appointment of an additional EU-REP. However, as long as this view is not confirmed by courts, Swiss manufacturers are forced to comply with these additional requirements. Alternatively, they risk that their medical devices will not be permitted to enter the EU/EEA market. Rather, they will already be intercepted and confiscated at customs.

Validity loss of SQS certificates

Another consequence affects the so-called "notified bodies" of Swiss manufacturers. A notified body is an organisation designated by an EU member state or by other countries under specific agreements to assess the conformity of medical devices before being placed on the market. These bodies are entitled to carry out tasks related to conformity assessment procedures set out in the applicable legislation. Since November 2017, such conformity assessment bodies have been able to apply for designation as notified bodies under the MDR and the IVDR. The European Commission publishes a list of such notified bodies.

The European Commission is of the opinion that, due to the "third country" status of Switzerland and the absence of an update to the MRA, the certificates issued by Swiss notified bodies – including certificates issued under the former EU Directives prior to the entry into force of the MDR and IVDR – are no longer valid in the EU. This has the effect that the only remaining notified body in Switzerland, the Swiss Association for Quality Management Systems (SQS), has lost a significant business sector. More serious consequences, however, arise for Swiss manufacturers that have certified their medical devices at the SQS. Since 26 May 2021, their SQS certificates are no longer valid and they are no longer able to place their medical devices verified with SQS certificates on the EU/EEA market, unless they get them recertified by a European notified body.

Several legal experts consider this view of the European Commission to be unlawful and are of the opinion that EU member states must continue to permit sales of all medical devices with a valid certificate issued by a Swiss notified body prior to 26 May 2021 and may not require an EU certificate as a condition for import. A few Swiss manufacturers with SQS certificates have therefore filed a claim with the competent EU court. This is currently still pending.

Germany, which is an important export country for the Swiss medtech industry, has also objected to the view of the European Commission and decided that SQS certificates notified under the former EU Directives will continue to be valid in Germany until the deadlines set out in the MDR expire. Swiss manufacturers may therefore continue to sell their medical devices with SQS certificates in Germany, but not in other EU/EEA states. However, the European Commission announced that it considers this arrangement between Switzerland and Germany to contradict EU law. Therefore, it seems that the last word in this matter has not yet been spoken.

Refused EUDAMED access

EUDAMED is the IT system established by the MDR and the IVDR aimed at improving transpar-

ency and co-ordination of information regarding medical devices available on the EU market. It is structured around six interconnected modules and a public website. However, presently only three modules are available ("Actors registration", "UDI/Devices Registration" and "Notified Bodies and Certificates"). The remaining modules ("Clinical Investigation & Performance Studies", "Vigilance and Post-Market Surveillance" and "Market Surveillance") are still under development and will only be released when the entire EUDAMED is fully functional.

Owing to Switzerland's "third country" status, the European Commission has refused Swissmedic, the Swiss medical enforcement authority, access to EUDAMED. Switzerland is thus denied participation in this key element of the MDR and IVDR structure, which is intended, in particular, to enhance joint market surveillance. This decision by the European Commission is also considered unlawful by several legal experts. They are of the opinion that the EU and its member state authorities must grant Swiss authorities access to EUDAMED.

At present, the denial of access to EUDAMED is still of limited consequence to Switzerland with regard to market surveillance, as the relevant module is not yet accessible. Moreover, Switzerland is still a member of the Medicrime Convention, which was concluded by member states of the Council of Europe and other states. This convention provides for a comprehensive exchange of information and joint co-operation between its member states regarding the fight against counterfeiting of medicinal products and medical devices and similar offences that threaten public health.

Consequences

Irrespective of the question of whether the action of the European Commission is lawful or not, the Swiss medtech industry has lost its previously barrier-free access to the EU/EEA market. This loss is undoubtedly serious. However, since the EU already made it clear at the end of 2018 that it would neither conclude new bilateral agreements with Switzerland nor update existing ones without the conclusion of InstA, the majority of Swiss medtech companies had already prepared for the prospect of a "third country" scenario at an early stage in order to continue exporting their medical devices to EU/EEA markets.

Nevertheless, the Swiss medtech industry is concerned about the possible loss of its international appeal owing to its "third country" status. Switzerland risks losing its competitive edge compared to EU countries owing to the perceived bureaucracy associated with its "third country" status. Naturally, the objective of the Swiss medtech industry is to continually strengthen its international attractiveness. With an export share of over 70%, a portion of 16.4% of Switzerland's positive trade balance, more than 63,000 employees in the sector and the most patents per inhabitant across Europe, the medtech industry is of great economic importance in Switzerland.

Impact on the medtech industry of EU/EEA states

Maintaining Market Access

Despite Switzerland's "third country" status, Swiss medical device legislation still largely adopts the rules of the MDR and the IVDR. Switzerland continues to recognise the European Conformity Markings as well as the certificates issued by notified bodies based in EU/EEA states, even though the EU reciprocally no longer recognises the certificates of the only existing Swiss notified body (SQS). Medtech companies from EU/EEA countries are therefore still permitted to distribute their medical devices certified in the EU in Switzerland. Since 26 May 2021, however, they no longer benefit from the almost barrier-free market access to Switzerland, but

rather have to meet more stringent requirements, as the following sections will illustrate.

Designation of an CH-REP and corresponding labelling requirements

As a result of the non-updated MRA, Switzerland requires that manufacturers from EU/EEA countries mandate a Swiss authorised representative (CH-REP) – whose rights and obligations are comparable to those of an EU-REP – and label their medical devices with the relevant information about the CH-REP within certain legal transitional periods, in order to continue placing their medical devices in Switzerland. These additional requirements are associated with considerable costs. It is therefore expected that many manufacturers from EU/EEA states will not be willing to take on this additional effort for the relatively small Swiss market.

Considering the fact that manufacturers from EU/EEA countries did not need a CH-REP to place their medical devices on the Swiss market until 26 May 2021, the question seems justified as to why this should now be necessary. In view of potential supply shortages, Swiss industry associations have already called on the Swiss Federal Council in March 2021 to ensure that no unnecessary import barriers are created by Swiss legislation. However, as noted above, their intervention was without success.

Obligation to register medical devices and economic operators

Until the MRA is updated, Swissmedic is unable to register economic operators domiciled in Switzerland via EUDAMED. To mitigate the consequences of this loss and to continue to ensure market surveillance in Switzerland, manufacturers, authorised representatives and importers domiciled in Switzerland are required to register once with Swissmedic to market their medical devices in Switzerland. Economic operators have to register within three months of placing their first medical device on the Swiss market. At present, the registration obligation only applies to economic operators domiciled in Switzerland. A precise date by which registration must take place for all medical devices and economic operators has not yet been announced. This additional registration requirement, which results from Switzerland's "third country" status, also constitutes an import hurdle for foreign medtech companies in distributing their medical devices in Switzerland.

Consequences

Owing to Switzerland's "third country" status, manufacturers from EU/EEA countries that had previously profited from barrier-free market access to Switzerland must overcome increased hurdles in order to sell their medical devices in Switzerland. It is expected that many EU/EEA manufacturers will be reluctant to comply with these additional measures solely to access the relatively small Swiss market. The Swiss healthcare sector is therefore concerned that there will not be enough medical devices available to supply the Swiss population in the future. Forecasts suggest that around one out of eight medical devices will, in future, no longer be available in Switzerland.

This worry is justified because Switzerland could face supply shortages regardless of its "third country" status. This is because the EU/EEA countries are also concerned about supply shortages as a result of the different legal situation related to the MDR and the IVDR. The MDR and the IVDR, for example, require stricter review processes for notified bodies. As a result, there are currently far fewer notified bodies than under the previous regime. This will most likely lead to delays in certification of medical devices. Another reason for possible supply shortages in the EU and Switzerland is that the MDR and the IVDR provide for various upgrades in the classification of medical devices, which means that medical

devices have to meet higher requirements and therefore could either come onto the market with some delay or be prevented from being placed on the market, because certain manufacturers might reduce their product portfolio as a result of the higher classifications.

Impact on the medtech industry outside EU/EFTA states

No direct market access

Medical devices thathave not been certified by a notified body recognised by the EU do not have free access to the Swiss market. In principle, it is therefore not possible for medical devices that have been certified in the USA or Australia, for example, to be placed on the Swiss market without an additional European conformity assessment, regardless of the possibility that these countries impose comparable or even higher safety requirements on medical devices.

Switzerland's "third country" status does not affect this regulatory system. However, owing to the rift between the EU and Switzerland, the question arises as to whether Switzerland should also recognise certifications from countries outside the EU/EEA. This idea is not totally new in the global context. There are different states that recognise certifications from different regulatory systems. For example, the Australian authority, the Therapeutic Goods Administration (TGA), not only accepts European certifications, but also accepts certificates from the USA, Canada and Japan, as well as certificates issued under the Medical Device Single Audit Program (MDSAP).

Political Intervention

Swiss politicians have recognised that, in view of the imminent supply shortages of medical devices, Switzerland should not only continue its negotiations with the EU but should also consider options for action outside the EU. A motion submitted in 2020 by the Council of States member Damian Müller pursues this approach. With this motion, the Swiss Federal Council was requested to adapt the Swiss legislation in such a way that medical devices from non-European regulatory systems could also be placed on the Swiss market. This motion emphasised that it is not guaranteed that the Swiss population will be supplied with sufficient medical devices in the future and that it is therefore irresponsible to rely exclusively on EU certification to satisfy national demand.

The Swiss Federal Council commented on this motion on 2 September 2020, at the time still expecting that the MRA between the EU and Switzerland would be updated. It stated that recognition of certificates from regulatory systems outside the EU had to be assessed with care.

In May 2020, National Council member Albert Rösti submitted a similar motion. He also requested that Switzerland should recognise certificates of non-European notified bodies, in particular, the certificates of the United States Food and Drug Administration (FDA). He emphasised that his motion had become even more urgent as Switzerland had been classified as a "third country" by the EU.

At present, it is uncertain whether these two motions, which have already overcome several political hurdles, will be implemented by the government. In order to limit supply shortages and to strengthen the attractiveness of Switzerland as a target market, the adoption of these motions would be beneficial. This would not only be advantageous to Switzerland, but would also provide new opportunities to medtech companies outside the EU/EEA territory, which might profit from easier market access to Switzerland in the future.

Increased importance of exemptions

Without a change in legislation, there is no way that medical devices which have been certified

outside of the EU/EEA countries can be imported into Switzerland. This is only possible by means of an exceptional authorisation by Swissmedic.

Article 22 paragraph 1 MedDO provides for such an exemption. According to this provision, Swissmedic may, upon reasoned application, grant an exemption for the distribution of a specific medical device even if it has not undergone the relevant conformity assessment procedure if its use is in the interest of public health or patient safety. An exemption according to Article 22 paragraph 1 MedDO may be granted, for example, for medical devices that have been certified by a notified body outside the EU/EEA territory.

Another exemption is established in Article 23 paragraph 1 of the COVID-19 Ordinance 3. According to this provision, Swissmedic may authorise the placing on the market and use of medical devices that have not undergone the relevant conformity assessment procedure, provided their use for preventing and combating COVID-19 in Switzerland is in the interests of public health. This exemption is only expected to be available until the end 2022, unless the COVID-19 Ordinance 3 is extended again.

Owing to the predicted supply shortages, it is expected that these exemptions will gain more importance in practice and that Swissmedic will increasingly issue such exemptions for medical devices with non-European certifications and relax its hitherto restrictive practice. This might open up opportunities for foreign manufacturers who have certified their medical devices outside the EU.

Consequences

The rift between Switzerland and the EU/EEA and the "third country" status of Switzerland have, in principle, no direct impact on medtech companies outside the EU/EEA. They still do not have free market access to Switzerland unless they get their medical devices certified by a notified body within the EU/EEA territory. However, owing to the strained relationship with the EU, Switzerland may be forced to examine alternative supply options outside the EU/EEA countries. The political impasse between the EU and Switzerland might therefore become an opportunity for the medtech industry in non-European countries with comparable or even higher safety standards to introduce medical devices into the attractive Swiss market. Switzerland has one of the best healthcare systems worldwide and spends over EUR8,300 per capita on healthcare per annum. The majority of European countries spend less than half of that amount. The Swiss market therefore offers considerable economic potential despite its relatively small size.

Summary

After Switzerland's designation as a "third country" by the EU, the Swiss medtech industry is faced with two existential challenges. On the one hand, it must ensure the sustainable supply of medical devices to the Swiss population. On the other hand, it must maintain the competitiveness and innovative strength of Switzerland in the global medical market.

Both challenges could be overcome if the EU and Switzerland were to agree on an update of the MRA. At present, however, the positions of the EU and Switzerland seem increasingly irreconcilable. Therefore, it is presently uncertain how the relationship between the EU and Switzerland will develop. What is clear, however, is that the EU is by far Switzerland's most important trading partner. One in every three jobs in the Swiss medtech industry depends on orders from the EU. Therefore, it is crucial, not only for the Swiss medtech industry but also for other fields of industry, that Switzerland puts its relations with the EU back on a solid foundation.

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A parallel way to tackle the challenges facing the Swiss medtech industry would be for Switzerland to extend its focus to countries outside the EU/EEA with comparable regulatory systems in the medical device sector. In the short term, this can be done by granting more exemptions for medical devices with non-European certificates. In the longer term, a change in the Swiss legislation might come into force, whereby non-European certificates would also be recognised in Switzerland. The current challenges might therefore offer new opportunities for the medtech companies from non-European countries (eg, from Canada, Australia, Singapore and the USA), which might benefit from easier access to the affluent and attractive Swiss market in the future.

Despite the expected easing of access requirements, importing medical devices into the lucrative Swiss market is still heavily regulated. Should any questions arise as to business opportunities, do not hesitate to contact the Health and Medical Law team at Prager Dreifuss.

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Prager Dreifuss Ltd is a renowned Swiss law firm practising in every area of business law. The firm is a team of 40 attorneys located in offices in Zurich, Bern and Brussels. Its Health and Medical Law team consists of three lawyers who advise and represent public and private institutions as well as individuals in the healthcare sector. The firm's clients include pharmaceutical companies, companies in the medical device industry as well as hospitals and physicians. Thanks to many years of experience in healthcare law and excellent relationships with the regulatory authorities and the pharmaceutical and medical device industry, the firm can offer our clients tailor-made solutions of the highest quality. Recent work includes a legal opinion for Swiss Medtech, the association of Swiss medical technology, regarding the question of when a medical device is considered to be "placed on the market" in Switzerland.

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