Trends and Developments

Contributed by:
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Prager Dreifuss Ltd

Prager Dreifuss Ltd is a renowned Swiss law firm practising in every area of business law. The firm has 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 and companies in the medical device industry, as well as hospitals and physicians. Thanks to the attorneys' many years of experience in healthcare law and their excellent relationships with the regulatory authorities and the pharmaceutical and medical device industries, they are able to offer their clients tailor-made solutions of the highest quality.

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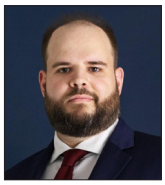

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The Current Legal and Political Situation in Switzerland

Since 2001, Switzerland has regulated medical devices in the same way as the EU. The former European Directives on classical medical devices ("MDD"), on active implantable medical devices ("AIMDD") and on in vitro diagnostic medical devices ("IVDD") were fully incorporated into Swiss law, and Switzerland was integrated into the European market surveillance system. As a result, there was a practically barrier-free market between the EU and Switzerland with regard to 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"), which impose stricter requirements on manufacturers, importers and distributors of medical devices and also on notified bodies that issue the certificates for medical devices of the higher-risk class. Both European regulations, which replaced the previous directives mentioned above, came into force in 2017. The MDR became fully applicable on 26 May 2021 and the IVDR on 26 May 2022. To ensure continuing equivalence with European law, 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 in Switzerland.

To ensure continued smooth market access between the EU and Switzerland, an update of the medical devices chapter of the Mutual Recognition Agreement ("MRA"), which regulates the mutual recognition of conformity assessments, was also necessary. The EU made the conclusion of this update conditional upon the conclusion of an institutional framework agreement with Switzerland ("InstA") which would have provided an overarching framework for relations between the EU and Switzerland which, currently, are governed by a plethora of separate agreements. On 26 May 2021, the Swiss Federal Council terminated the negotiations with the EU because of substantial differences on key aspects of the InstA. As of this date, Switzerland has been considered a "third country" by the EU with regard to medical devices. Although the Swiss Federal Council on 15 December 2015 passed a draft mandate for further negotiations with the EU in order to stabilise the bilateral relations, the MRA has to date not been updated, with the consequence that the EU continues to consider Switzerland a "third country".

The lack of an update of the MRA and the amended legal situation in Europe and Switzerland have had, in particular, the following impacts:

- Swiss high-risk medical devices must be certified by notified bodies established within the EU in order to be placed on the European market by Swiss manufacturers.
- Complicating matters even more, existing certificates issued under the previous MRA by notified bodies established in Switzerland are no longer recognised as valid in the EU.
- Swiss medical device companies have to mandate a European authorised representative based in the EU in order to export their products to the European market.
- Medical device companies from Europe that were previously able to distribute their medical devices on the Swiss market practically barrier-free in turn have to appoint a Swiss authorised representative based in Switzerland and have to fulfil other Swiss-specific requirements (eg, registration and labelling

obligations) in order to continue distributing their medical devices on the Swiss market.
- The changed legal situation has resulted in Swissmedic, the Swiss Agency for Therapeutic Products, no longer having access to the European database for medical devices ("EUDAMED") and to relevant European working groups.

Key Challenges for Switzerland

The Swiss medical device industry has emphasised the importance of updating the MRA as soon as possible, as it estimates annual administrative costs for complying with the "third country" requirements amount to around CHF120 million per year. The industry claims that the lack of an update could result in a reduced supply of medical devices in Switzerland and could also force Swiss medical device companies to relocate jobs abroad, which means that innovations are not or will not be taking place in Switzerland. This could harm Switzerland's global reputation as an attractive innovation and business location. Another challenge often mentioned by the Swiss medical device industry is that the revised European legislation, which has largely been incorporated into Swiss law, is too complicated, too bureaucratic and too expensive and will stint innovations. Other challenges facing the Swiss industry include the stricter Swiss data protection regulation, including the revised Swiss Data Protection Act, which came into force in the autumn of 2023, and new statutory obligations regarding sustainability.

However, certainly the most important challenge of the Swiss healthcare and medical device industry is ensuring that the Swiss population has an ongoing and sufficient supply of safe and reliable medical devices. The aim of the revised European and Swiss medical device legislation was to increase the safety of medical devices by introducing stricter requirements. It was envisaged that, to a certain degree, medical devices that did not fulfil the increased safety requirements of the revised legislation would disappear from the market. At present, however, not only unsafe or poor-quality medical devices are disappearing from the European and Swiss markets, but also numerous safe, high-quality medical devices for the following reasons:

- Current Swiss and European legislation places stricter requirements on notified bodies than the previous law did. As a result, the number of notified bodies has decreased compared to previous years. This delays obtaining new certifications and re-certifications of medical devices from the remaining notified bodies.
- Some medical devices are no longer available on the Swiss and European markets because several medical device manufacturers have reduced their portfolios or even discontinued the production of certain medical devices as a result of the increased certification requirements compared to under the previous law.
- Another reason for supply shortages in Switzerland compared to the EU is that manufacturers from Europe who were previously able to distribute their medical devices in Switzerland almost barrier-free, are now – as mentioned above – obliged to appoint a Swiss authorised representative based in Switzerland and have to meet other Swiss-specific requirements in order to continue distributing their medical devices on the Swiss market, as a result of Switzerland's "third country" status. Several manufacturers are not willing to fulfil these additional and expensive requirements for the relatively small Swiss market and have therefore stopped supplying Switzerland.

The future will show whether there will be enough alternative medical devices available to replace those that have disappeared, and may yet disappear, from the Swiss market owing to the changed legislation. According to an article in the *Swiss Medical Journal* (*Schweizerische Ärztezeitung*), several hospitals in Switzerland are already struggling with medical device shortages. While in some cases medical devices can be replaced with alternatives if such alternatives are available, they often cannot be used immediately, as healthcare professionals generally require training or at least a certain period of familiarisation with a specific medical device. In some cases, it is simply not possible to replace specific medical devices without compromising the quality of medical treatments. In the above journal article, a physician mentioned the example of a jet tube which can be used to greatly reduce breathing movements for certain surgical techniques. If the tube is not available, a tumour has to be removed using a complex abdominal procedure, a technique that places unnecessary strain on the patient.

It is encouraging that the EU and Switzerland have recognised the problem of medical device shortages and have taken action, such as extending the validity of existing MDD certificates under certain conditions. This has at least decreased the risk of many medical devices disappearing from the market simply because they could not be recertified by a notified body in time. The next few months will show whether further corrective measures will be implemented in European and Swiss legislation to counteract existing and increasing supply shortages.

Trends and Developments in Switzerland and the EU

In Europe and Switzerland, various ideas are being discussed to minimise the negative impacts of the revised legislation and the present political impasse. For instance, the German Federal Medical Technology Association (*Bundesverband Medizintechnologie e. V.*, "BVMed") and the German Association of the Diagnostic Industry (*Verband der Diagnostica-Industrie*, "VDGH") have brought out a White Paper on how to develop the MDR and IVDR further, proposing various effective solutions and approaches. Among the presented approaches are, for example:

- extending the validity of legal certifications;
- introducing a fast-track process especially for so-called orphan devices or diagnostics for rare diseases;
- harmonising and centralising the notification and monitoring of notified bodies across Europe; and
- implementing measures to enhance the efficiency of conformity assessment procedures.

Another suggestion in the White Paper is that the EU should strengthen its international cooperation. In Switzerland, this proposal is not only being discussed, it is already in the process of being implemented.

As mentioned previously, Switzerland has always orientated and modelled its legislation in the medical device sector on the EU's position. This Swiss approach was reasonable because the EU has, until now, been Switzerland's most important trading partner. Moreover, the European regulatory system for medical devices was recognised worldwide as a highly respected and efficient system until the MDR and IVDR were introduced. Since Switzerland has largely adopted European medical device legislation into its national law, medical devices that have undergone a conformity assessment procedure outside the EU or that have not been

certified by a notified body recognised by the EU, do not benefit from free access to the Swiss market. For instance, to date, it is not possible for medical devices that have been certified in the USA or Australia to be placed on the Swiss market without an additional European conformity assessment, irrespective of the fact that these two countries may impose similarly high requirements on medical devices as the EU and Switzerland.

Owing to the rift between the EU and Switzerland, the question has arisen whether Switzerland should not only recognise European medical device certificates, but also medical device certifications from countries outside the EU. This idea is not completely new in the global context. Several states recognise medical device certifications from other 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"). The MDSAP allows a recognised auditing organisation to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the programme. Key participating regulators include the TGA of Australia, Brazil's *Agência Nacional de Vigilância Sanitária*, Health Canada, Japan's Ministry of Health, Labour and Welfare and the Japanese Pharmaceutical and Medical Devices Agency, and the US Food and Drug Administration ("FDA").

In 2021, Damian Müller, a member of the Swiss Council of States, submitted Motion 20.3211 titled "For more room for manoeuvre in the procurement of medical devices for the supply of the Swiss population". Motion 20.3211 pursues the approach described above by requesting that the Swiss Federal Council adapt Swiss legislation in such a way that medical devices from non-European regulatory systems with requirements regarding medical devices which are similarly strict to the Swiss requirements, in particular medical devices approved by the FDA, could also be introduced to the Swiss market. The motion emphasises that it is not currently guaranteed that the Swiss population could be supplied with sufficient medical devices in the future and that it is, therefore, irresponsible to rely exclusively on European certification to satisfy national demand.

On 28 November 2022, the Swiss parliament passed Motion 20.3211. The Swiss Federal Council was thereby instructed to adapt national law accordingly. However, the Swiss Federal Council has not yet presented a draft for the legislative amendment. It would certainly be valuable, and speed up the process, if the Swiss Federal Council would consult Australia or other countries which have already implemented such a regulatory system to recognise medical device certifications from different regulatory systems in their national laws. A dialogue between Switzerland and these countries could clarify to what extent the respective legislations on medical devices are similar and to what extent they differ. It is not currently known whether such an international dialogue has been initiated by the Swiss Federal Council, nor how far legislative work has already progressed.

The Swiss medical device industry is urging the Swiss Federal Council to implement Motion 20.3211 quickly and efficiently, taking into account the following key principles in particular:

- Medical devices that are legally authorised in the USA for the US population should not,

under any circumstances, require a second approval procedure in Switzerland.
- National laws should only be adapted where absolutely necessary.
- The legislative amendment should be limited solely to implementation of the motion and should be clear and comprehensible for all stakeholders.
- The concept should also be applied to other non-European systems, not only to the USA. It should be ensured that, in addition to medical devices with FDA approval, medical devices from other non-European regulatory systems may be recognised in Switzerland in the future.

The implementation of Motion 20.3211 into Swiss law will increase Switzerland's independence from the EU and minimise the negative effects related to the MDR and IVDR, especially the shortage problem described above. It will also strengthen Switzerland's attractiveness as a business and innovation location. Moreover, the implementation of Motion 20.3211 will ensure rapid access by Swiss patients to innovative medical devices from the USA. Today, innovations approved first in the USA are (at best) delayed by years before they reach Europe and Switzerland. This is problematic, especially since an increasing number of medical device manufacturers across Europe and Switzerland are prioritising FDA authorisation for their medical devices over European certification, because of the bureaucracy associated with the MDR and IVDR.

Chances and Opportunities for the USA and Other Countries

The implementation of Motion 20.3211 will further strengthen the already strong trade relations between Switzerland and the USA. Switzerland's decision to open up its medical device market to US certificates will considerably facilitate trade between both countries. Moreover, other countries with comparable regulatory systems for medical devices to that of Switzerland will profit from simplified market access to Switzerland in the future. At the moment, however, it is unclear to which countries – beside the USA – this will apply.

Swissmedic has compiled a list of countries with human medicinal product controls comparable to those in Switzerland. It is conceivable that, upon closer evaluation, countries mentioned on this list will also be considered as comparable to Switzerland in terms of their medical device systems. Beside the EU/EFTA states and the USA, this list includes Australia, Japan, Canada, New Zealand, Singapore and the UK.

If a closer comparison of the medical device regulatory systems of these countries and that of Switzerland reveals that the systems of these countries are comparably strict, not only with regard to the control of human medicinal products, but also with regard to the control of medical devices, it might be possible that medical devices from these countries will also be recognised in Switzerland and could be distributed practically barrier-free on the Swiss market in the future. Manufacturers of medical devices from these countries should follow legislative developments in Switzerland closely, as it is currently unclear how the Federal Council will implement Motion 20.3211 with regard to specific aspects, for example, regarding registration, market surveillance, etc. Familiarising themselves with Swiss law appears essential if these manufacturers wish to benefit early from the future opening of the Swiss medical device market.

Conclusion

The past few years have been a time of significant change and adaptation for the Swiss medical device industry. Despite the changed legal and political environment, Switzerland's medical device sector has proved to be extremely resilient and innovative. The industry has used the political challenges with the EU to its advantage and is now taking the first step to reducing its dependence on the EU and to offering the USA, as well as other countries with comparable regulatory systems, simplified access to the Swiss market in the future.

With this expanded and international focus, the Swiss medical device industry will not only preserve its leading position as one of the most innovative in the world but could even strengthen it. This interesting development will result in new or reinforced trade relations between Switzerland and other countries outside the EU. Not only Switzerland, but also those countries, will benefit from this enhanced access to the Swiss medical device sector, which is characterised by its high level of precision, quality and reliability, as well as its close proximity to leading Swiss universities and research institutes.