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Switzerland: Trends and Developments

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Trends and Developments

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Medical Devices in Switzerland: an Overview

Update on the MRA

Until 26 May 2021, commerce in and the trade of medical devices between the European Union (EU) and Switzerland was facilitated by the "Agreement between Switzerland and the EU on the mutual recognition of conformity assessments" (MRA). The MRA provides for the removal of technical barriers to the trade of industrial goods between Switzerland and the EU, applying to technical regulations in essential product sectors such as machinery, medical devices, electrical equipment, etc, that are consequently considered as harmonised. It further ensures that one conformity assessment in product sectors covered by the MRA is sufficient to access the Swiss market and the common market of the EU. Chapter 4 of the MRA concerns medical devices.

Over the last couple of years, the EU has updated the regulations on medical devices. With effect from 26 May 2021, the former Medical Device Directive (Council Directive 93/42/ECC) and Active Implantable Medical Devices Directive (Council Directive 90/385/EEC) were replaced by the Medical Device Directive (Regulation (EU) 2017/745 – EU-MDR); a year later, the In Vitro Diagnostics Directive (Directive 98/79/EC of the European Parliament and of the Council) was replaced by the In Vitro Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746 – EU-IVDR). As a consequence, Switzerland has aligned its legislation with these European provisions.

These changes would require an update of Chapter 4 of the MRA to ensure continued harmonisation between the EU and Switzerland of the technical regulations pertaining to medical devices. The European Commission, however, has so far rejected such an update due to institutional disputes between the EU and Switzerland. Since 26 May 2021 for medical devices, and since 26 May 2022 for in vitro diagnostic medical devices, the EU has classified Switzerland as a third-party country for the purposes of the medical device sector, meaning that previously existing trade facilitations are abandoned. For example, manufacturers are now obliged to mandate an authorised representative in the respective other country and label their medical devices with such information.

Not only did Switzerland anticipate major and costly consequences as a result of this suspended harmonisation between the EU and Switzerland in the medical device sector, but

it also expected an imminent supply shortage of medical devices. Following the institutional differences between the EU and Switzerland, the Swiss government (ie, the Federal Council) adopted mitigation measures to cushion these negative effects. The mitigation measures entered into force contemporaneously with the end of the harmonisation for medical devices on 26 May 2021. They comprise, inter alia, unilateral recognition of medical devices that have been certified in compliance with the EU-MDR for the purposes of access to the Swiss market.

The Federal Council has evaluated the consequences of such measures and concluded in June 2022 that the enacted mitigation measures have been successful to date. A renewed assessment of the current situation shall be carried out by the end of 2024.

The risk of a shortage of safe medical devices has also been of concern in the EU. For that reason, on 15 March 2023 it passed Regulation (EU) 2023/607, which prolonged the deadlines for manufacturers in certain circumstances to certify their products in line with the new requirements, and which also abandoned the "sell-off" deadline according to which products placed on the market before or during the transition periods that are still in the supply chain should have been withdrawn. Switzerland will transfer these changes made by the EU (together with the new EU requirements for products without an intended medical purpose) into Swiss law in autumn 2023.

Facilitated market access for non-EU products

So far, only medical devices that comply with the approval system of the EU or Switzerland, and as a result are marked "CE" or "MD", are permitted to be nationally distributed in Switzerland. In light of the difficult situation with the EU regarding varied institutional differences of opinion, there have been several political attempts to safeguard the supply of medical devices. With so-called political motion No 20.3211 by Council of States member Damian Müller, entitled "For more room for manoeuvre in the procurement of medical devices to supply the Swiss population" (the details in French, German and Italian are available at www.parlament.ch), the Federal Council was instructed by the Swiss parliament (the Federal Assembly) on 28 November 2022 to initiate legislation under which medical devices originating from non-European regulatory systems can also be accredited in Switzerland. Under the law, such motion mandates the Federal Council to submit a bill to the Federal Assembly or to take certain other actions.

The Federal Council had initially recommended rejecting this motion, for the following reasons:

- existing legislation in the EU and Switzerland already allows the granting of exemptions, including managing supply shortages of vital medical devices if it is in the interest of public health or for the safety of patients;
- the marketing of medical devices is regulated heterogeneously throughout the world (eg, Europe and the USA would be very different), so the unilateral recognition of certificates from foreign regulatory systems other than the EU should be examined carefully; and
- identical technical regulations between Switzerland and the EU in the area of medical devices should be ensured.

The competent authority is currently examining how this motion can be implemented against the background of the challenges mentioned by the Federal Council. If a motion is still pending in two years' time, the Federal Council will be obliged

to report annually to the Federal Assembly on what has been done in relation thereto and on how the government intends to fulfil the mandate. Consequently, an update on the implementation process of the motion may be expected by the end of 2024 at the latest.

Qualification issues of medical device software

Mobile health applications (apps) have become popular, and lifestyle apps, such as fitness or wellbeing apps, have emerged rapidly, as well as apps for medical purposes. The legal framework for such apps depends largely on their qualification as a medical device.

Apps applied for medical purposes are qualified as medical devices and have to abide by the healthcare regulations. In contrast, apps aiming only to improve a person's lifestyle do not qualify as medical devices. The qualification of health apps (and software in general) as medical devices has been a frequent question in legal practice.

Pursuant to Article 3 of the Medical Device Ordinance (MedDO), a product is a medical device if the manufacturer intends it to have one or more of the following specific medical purposes (abbreviated definition):

- the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- the diagnosis, monitoring, treatment or alleviation of, or compensation for, injuries or disabilities;
- the investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; or
- the provision of information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

The term "medical devices" would also include devices for the control or support of conception (including software).

The Federal Administrative Court (FAC C-669/2016 of 17 September 2018, E. 5.3) summarised that software is considered a medical device if it:

- serves a medical purpose as specified by the legislator (see above);
- creates or modifies medical information, in particular through calculation processes or the quantification or comparison of recorded data with certain references (whereas purely administrative processing of health-related information does not suffice to qualify software as a medical device); and
- provides information about a specific patient.

Thus, the qualification of a medical device largely depends on its intended medical purposes. The intended purpose always follows from a holistic view and is subject to an objective/subjective test. This means that the qualification is objectively based on its intended use by the manufacturer as well as on subjective elements such as the device's presentation (eg, instructions for use, promotional materials like the website or app store information, or the information displayed in the user interface). Disclaimers (eg, "this software is not a medical device") are not conclusive for the effective qualification of the product.

In order to differentiate between non-regulated lifestyle apps and apps that are regulated as a medical device, it is therefore important to assess whether the app processes health data

for the pure purpose of administering or visualisation, or whether it serves the purpose of evaluating a person. A technical examination of the app may give further indications as to its qualification; if the entry of personal data by the user is required as an input to receive an output from the app that is a specific assessment or recommendation for action, the app is likely to qualify as a medical device.

Generally, it should be noted that software can fall into the medical device category as an accessory to, or component of, a medical device, even if it does not qualify as a medical device on a standalone basis. For standalone software, Swissmedic publishes an information sheet that gives relevant guidance (retrievable at www.swissmedic.ch).

Classification of medical device software

Once software is qualified as a medical device, it has to be classified– like every medical device – and for that reason, taking into account its purpose, the medical device will be assigned a specific risk class. The classification determines the possible conformity assessment procedures, which are required to prove the product's conformity with legislative requirements before it can be placed on the market. The classification also stipulates the obligation, or lack thereof, of the involvement of what is called a designated body, which corresponds to the EU term "notified body". The designated body is only involved in the conformity assessment procedures; however, authorisation from Swissmedic is not required for medical devices. The classification further affects the manufacturer's obligations. Swissmedic has issued an information sheet on the roles and obligations of Swiss economic operators under MedDO, which is available at www.swissmedic.ch.

Medical devices shall be divided into classes I, IIa, IIb and III, and in vitro diagnostic medical devices into classes A, B, C and D, both taking into account the intended purpose of the device and its inherent risks. According to the respective classification, the device must then comply with the provisions of Annex VIII to EU-MDR or Annex VIII to the EU-IVDR. Rule 11 of Annex VIII to the EU-MDR provides the following classes for software (abbreviated definition):

- class IIa is for software intended to provide information that is used to take decisions with diagnosis or therapeutic purposes (unless such decision has an impact that may cause death or an irreversible deterioration of a person's state of health, or the serious deterioration of a person's state of health or a surgical intervention, in which cases it is classified as class III or IIb, respectively), or intended to monitor physiological processes (unless the monitoring of vital physiological parameters could result in immediate danger to the patient, in which case it is classified as class IIb); and
- class I is for all other software.

In class I, a self-declaration of the manufacturer is sufficient, while software of higher classes requires the involvement of a designated body. In general, most health apps that qualify as medical devices should fall into class IIa.

Even though the European guideline MDCG 2019-11 "Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR" is not directly applicable in Switzerland, European interpretative aids will usually be taken into consideration by Swiss courts and authorities, because Swiss and European legal concepts are

converging in the field of medical device regulations.

Further matters pertaining to software classification often relate to software consisting of modules and updates, mainly due to the lack of related legal provisions and precedent. According to MDCG 2019-11, only modules and software updates that are subject to the medical device regulations must undergo a conformity assessment. However, that may include modules interacting or having interfaces with non-medical devices, provided there is a functional or technical impact on the intended purpose of a medical device software. Similarly, software changes or updates may require a new conformity assessment, or merely a supplement to the conformity certificate, which is the case if any changes made are relevant for the safety and performance. Relevant changes have to be notified to the designated body in advance if it is involved in the conformity assessment procedure. Thus, software updates should be well planned ahead, both within the company and with the designated body.

Labelling and product information of medical device software

Product information consisting of a label and instructions for use must be provided with a medical device. The term "label" means the written, printed or graphic information appearing either on the medical device itself or on the packaging of each unit or on the packaging of multiple medical devices.

As to medical device software, the Swiss authorities have so far accepted that the product information is provided electronically (eg, in the system information). It should be noted that the product information must be displayed in all three of the official languages of Switzerland. Furthermore, the manufacturer and its authorised representative (if applicable) must be displayed on the label. The importer may be indicated on the label or on a document accompanying the product.

Any conformity marking on medical device software, affixed as a "CE" or "MD" mark in order to give proof of conformity, must be displayed in an easily readable, pure text format at the start of the program or in another section accessible to the user (eg, in the system information).

Remuneration of medical device software within the framework of compulsory health insurance

It is conceivable that medical device software that can legally be placed on the market in Switzerland will be reimbursed by the compulsory health insurance in Switzerland. Medical device software may only be reimbursed if its main function itself serves a medical purpose. In contrast, medical device software supporting the activities of healthcare professionals (eg, reading and analysing data or controlling a device) is regularly excluded from separate reimbursement.

The Federal Office of Public Health, the competent Swiss authority, has recently issued a Fact Sheet on the "Reimbursement for Digital Health Applications under the OKP" (available in French, German and Italian at www.bag.admin.ch), in which the general principles for reimbursement are explained.

Legislation update: genetic tests for self-testing

On 1 December 2022, the revised Federal Law on Genetic Testing in Humans (GTHA) came into effect. This law regulates the conditions under which genetic and prenatal examination may be performed in the medical field and outside

thereof, in employment, insurance and liability cases and for the creation of DNA profiles for the purpose of clarifying parentage or identifying persons.

Under the previous law, it was prohibited to supply genetic in vitro diagnostics – defined as ready-to-use products for the detection of hereditary characteristics – to laypersons. Under the revised law, genetic in vitro diagnostics are renamed "genetic tests for self-testing" and are, as such, legal. However, any supply to laypersons is confined to genetic testing outside the medical field, pursuant to Article 31, paragraph 2 of the GTHA. Such genetic testing outside the medical fields within this sense is outlined as testing that is not performed for:

- medical purposes;
- the clarification of characteristics requiring special protection (physiological characteristics, knowledge of which can influence lifestyle; personal characteristics such as character, behaviour, intelligence, preferences or talents; or ethnic or other characteristics related to origin); nor
- the creation of a DNA profile.

Accordingly, the scope of supplying genetic tests for self-testing directly to the consumer may be rather limited. It should, however, be noted that genetic tests in other areas are not prohibited, although they do necessitate the supervision of an authorised person. In particular, so-called "lifestyle gentests" and tests for purposes of genealogical research may only be initiated by a specialist, and the sampling must be taken in their presence.

The revised GTHA provides for business opportunities in the field of genetic self-testing, but providers of genetic tests intended for self-testing should be aware of the dispensing (and further) restrictions under the GTHA.

Legislation update: data privacy

Switzerland is not a member state of the EU. In Switzerland, the Federal Data Protection Act (FDPA) applies; Regulation (EU) 2016/679 (the General Data Protection Regulation or GDPR) may also apply in specific contexts only. The FDPA has been completely revised recently, with the revised version entering into force on 1 September 2023. The revised FDPA builds on the existing Swiss data protection regime, but provides for increased transparency requirements and liability risks. The following topics of the revised FDPA are of particular importance to medical devices.

- In contrast to the GDPR, data processing is generally permitted under the FDPA, with some exceptions requiring justification. The processing of sensitive personal data is one of the exceptions that warrants a justification to avoid a breach of privacy rights of the person concerned. Sensitive personal data means, inter alia, all data relating to health as well as genetic data or biometric data that uniquely identifies a person. Evidently, personal health data falls within this definition. A justification under the law may be the informed voluntary and explicit consent of the concerned person, an overriding private or public interest, or any law.
- Personal data may be disclosed abroad if the Federal Council has decided that the legislation of the state concerned, or an international body, guarantees an adequate level of protection. Otherwise, an adequate level of protection must be guaranteed by other means. Typically, contractual guarantees are used, such as the EU standard contractual clauses, but with some Swiss adaptations.

On 20 July 2023, the European Commission adopted its adequacy decision for the EU–US Data Privacy Framework. It ruled for the purpose of Article 45 of the GDPR that the United States ensures an adequate level of protection for personal data transferred from the EU to organisations in the United States that are included in the "Data Privacy Framework List" maintained and made publicly available by the US Department of Commerce (Article 1 of the Commission implementing decision of 10 July 2023, C(2023) 4745). However, the EU–US Data Privacy Framework does not apply to Switzerland. Therefore, Switzerland is currently in well-advanced discussions with the United States on an equivalent data privacy framework. Until such is finally agreed and recognised, companies are obliged to continue with the current guarantees to ensure an adequate level of protection.

- Under the revised Swiss Data Protection Ordinance, log files for certain processing operations (such as changes and the person making changes) must be kept where such operations relate to the large-scale automated processing of health data. Logs must be retained separately from the productive system for one year at least, and cannot be used for any purpose other than ensuring security and data protection compliance.
- The revised FDPA provides for criminal fines of up to CHF250,000 (for instance, penalising the wilful violation of obligations to provide information when collecting personal data or the wilful violation of certain duties of care).

The currently existing Swiss data privacy regime has been recognised by the European Commission as an adequate protection of personal data under EU regulations, thereby allowing data transfers from the EU to Switzerland. A new decision on the adequacy of the revised FDPA will be needed, which is still pending at the time of writing.

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