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Switzerland: Trends & Developments

Markus Schott and Markus Wang
Bär & Karrer Ltd

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Trends and Developments

Contributed by:
Markus Schott and Markus Wang
Bär & Karrer Ltd see p.5

Healthcare Financing in the Spotlight

In Switzerland, the healthcare system is based on a compulsory health insurance provided by private health insurers, which operates on a non-profit-oriented basis and must be recognised by the Swiss Federal Department of Home Affairs (FDHA). In principle, the mandatory health insurance covers all inpatient and outpatient treatments. While outpatient treatments are fully covered by the insurance company after deduction of a contribution by the insured, the insurance covers only up to 45% of the inpatient treatment costs. The canton in which the respective insured lives must bear a minimum of 55% of such costs for inpatient treatment. The prices for treatment are determined based on tariffs, which are either agreed between the service-providers (hospitals, doctors' associations, etc) and the insurers, or which are set by the federal government. The insurers charge premiums from the insured. Insurance premiums differ from insurance company to insurance company but must generally be identical for all insureds from a certain canton. Young adults and children pay reduced premiums, and the cantons pay contributions to persons for whom the premiums constitute a considerable financial burden.

Due to the ageing society, advancements in medicine, and misaligned incentives, the costs for healthcare are constantly increasing. However, the current financing scheme in Switzerland has in principle remained unchanged since its inception in 1995. In order to reduce permanently the increase of healthcare costs, the federal government presented two sets of measures, in 2019 and 2020. The second set of measures introduced in 2020 is a counter-proposal to a popular initiative which requires that the costs of healthcare be strictly linked to the development of the Swiss economy and the average level of salaries in Switzerland.

A first set of measures was adopted by the federal parliament in June 2021. A few of the measures adopted entered into force in January 2022. These measures mainly concern the introduction of a national tariff organisation, which comprises the associations of healthcare professionals and the associations of insurers. This organisation is responsible for the further development and maintenance of the tariff structures for outpatient medical treatment. Moreover, sanctions were adopted that can be imposed on healthcare providers if they violate requirements laid down in the law or agreements concerning the efficiency and quality of the service provided or the provisions on invoicing. Additional measures will enter into force at a later stage. These measures concern the promotion of flat fees for outpatient treatments, data disclosure in the outpatient tariff system and the introduction of pilot projects for cost-development containment.

Some more measures to reduce healthcare costs suggested by the government are still under parliamentary discussion. These measures include, amongst others, a reference-price system for pharmaceuticals, according to which the Federal Office of Public Health shall determine how much the insurers have to pay for patent-expired pharmaceuticals and generics with the same ingredient (ie, the reference price). If a more expensive pharmaceutical is dispensed, the insured has to pay the difference to the reference price. The definition of certain cost targets on a national and cantonal level, as well as coercive measures if these targets are exceeded, as

one of the measures suggested by government, could be characterised as a change of one of the system's fundamental principles. So far, mandatory health insurance has basically been obliged to pay all costs for treatment, as long as that treatment met the requirements of effectiveness, adequacy and economic efficiency.

New Medical Device Regulations in Switzerland

Swiss medical device regulations basically correspond to the regulations in the European Union (EU) since 2001. The agreement between the Swiss Confederation and the European Community on mutual recognition in relation to conformity assessment (EU-MRA) has enabled mutual market access in both directions since 2002. In order to improve the quality and safety of medical devices and thereby increase patient safety, the EU has tightened its medical devices regulations. The new medical device regulation (EU-MDR) entered into force on 26 May 2017 and was fully implemented as of 26 May 2021. To maintain equivalence with the EU regulations and to maintain mutual market access to the European market, Switzerland had to adapt its regulations, too. The new revised medical devices legislation in Switzerland closely approximates to the new provisions in the EU. The new Ordinance on Medical Devices (MedDO) entered in force on 26 May 2021 and brings a clear tightening of the regulatory framework. The most important novelties are the following.

- Higher classification of certain medical devices, which entails additional regulatory obligations.
- Evidence of clinical evaluation of the products to confirm compliance with essential safety and performance requirements.
- An obligation of the manufacturer to implement a monitoring and quality management system appropriate for the risk class and nature of the device.
- An obligation of the manufacturer to prepare a safety report for each device in class IIa and higher.
- Manufacturers domiciled outside Switzerland must appoint an authorised representative in Switzerland. This obligation applies to manufacturers domiciled in an EU or EEA state as well as to manufacturers domiciled outside the EU or the EEA. For manufacturers within an EU or EEA state, a transactional period may apply regarding the appointment of a Swiss-authorised representative. The duration of the transitional period depends on the risk class of the device. The last period ends on 31 July 2022 for class I medical devices.
- An obligation to register with Swissmedic for the Swiss manufacturer, the authorised representative and the importer of medical devices.

Due to the major changes in the medical device regulations in Switzerland and the EU and because it does not provide for automatic adaptation, the EU-MRA needs to be revised. In 2018, the EU had already made it clear that such an update is linked to the progress to be made regarding the signing of an institutional agreement (InstA) between the EU and Switzerland governing certain key questions of the relationship between the parties, such as the dynamic adaptation to new EU law. Since Switzerland unilaterally ended the negotiations on the InsTA in May 2021, it has not yet been possible to complete the updating of the EU-MRA. In order to mitigate the negative effects of the absence of an updated EU-MRA and to ensure that the Swiss people are sufficiently supplied with safe medical devices, the Swiss Federal Council approved supplementary provisions on the revised MedDO on 19 May 2021.

The lack of an updated EU-MRA affects the mutual market access and trading of medical devices, the co-ordinated market surveillance,

the sharing of information between authorities, and the mutual recognition of certificates of conformity. The latter was partly fixed by Switzerland unilaterally recognising conformity certificates issued by a notified body domiciled in an EU or EEA state. This rule allows for unilateral market access of medical devices certified in the EU according to the EU-MDR and thereby alleviates supply problems in Switzerland. The registration of economic operators with Swissmedic, the continuous reporting of serious incidents to Swissmedic and the obligation of manufacturers domiciled in the EU or EEA to establish an authorised representative are intended to enable Swissmedic to maintain its surveillance system, despite its exclusion from the monitoring network of the EU authorities.

Due to the lack of an updated EU-MRA, Swiss manufacturers who wish to export their products to the EU or EEA will, therefore, be required to appoint an authorised representative in the EU or EEA, as of 21 May 2026. Furthermore, conformity certificates issued by a notified body domiciled in Switzerland are no longer recognised within the EU and EEA. Medical devices of a Swiss manufacturer placed on the European market must be assessed by a notified body domiciled in the EU or EEA.

Organ Donation – Consent or Objection Solution?

In Switzerland, organs, tissues or cells may only be removed from a deceased person if valid consent has been given. If no such consent is known, organs, tissues or cells may only be removed with the consent of the closest relatives. The closest relatives have to take the presumed will of the deceased person into account (so-called extended consent solution).

In 2019, a popular initiative was submitted which aims to change this concept and introduce the objection solution in Switzerland, without taking into account the will of the relatives of the deceased. According to this so-called "strict objection solution", if no objection from the deceased person is registered or otherwise documented, the consent of the deceased person to donate its organs is presumed. The relatives do not have the right to object. The Federal Council has rejected the initiative, but has submitted a counterproposal which also protect the rights of the relatives of the deceased. Accordingly, relatives should continue to be involved in the decision-making process and have a right to object. The relatives can object to an organ removal if they know or suspect that the person concerned would have decided against it. The federal parliament adopted the Federal Council's proposal. Because a popular referendum was successfully submitted against the proposal, Swiss voters will vote on 15 May 2022 on the proposed amendments to the organ transplantation act. The popular initiative has been rescinded, subject to the condition that the government's counterproposal will be accepted in the popular vote of 15 May 2022.

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AUTHORS

Markus Schott co-heads the life science practice and focuses on regulation and litigation work. Markus has broad experience in all kinds of regulatory law matters, including governmental licences, authorisations, and supervision, pricing regimes, sanctions, and industry codes. He advises and represents pharmaceutical and medtech companies, laboratories, hospitals and other participants in the healthcare, cosmetics, food and beverage sectors, research institutions, and governmental agencies. He also drafts expert opinions and represents clients in court proceedings.

Markus Wang co-heads the life science practice and focuses on intellectual property (IP), pharma-licensing, research and development (R&D) as well as drug and medical devices marketing/distribution. His practice covers patent or licensing-related litigation and arbitration in the pharmaceutical, biotech and medical-device sector, drafting, negotiating and advising clients in respect to complex licence, R&D, drug distribution and similar industry-specific agreements. Furthermore, he regularly deals with regulatory questions concerning advertising and distributing drugs and represents clients vis-à-vis Swissmedic in related proceedings. He also serves on the board of start-ups in the life science industry.

Bär & Karrer Ltd

Brandschenkestrasse 90
8002 Zurich
Switzerland

Tel: +41 58 261 50 00
Email: zurich@baerkarrer.ch
Web: www.baerkarrer.ch

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