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Switzerland: Trends & Developments

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Trends and Developments

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Introduction

In Switzerland, key legislative issues relating to the healthcare system are decided based on federal and cantonal referendums. This leads to a high level of acceptance. However, the Swiss healthcare system is not only characterised by the high quality of its medical services but also by a persistent rise in costs and a generally high expenditure level. In Europe, Switzerland spends both the highest proportion of GDP and the most financial resources per capita on healthcare, which is reflected in ever-increasing cost pressure and rising patient demands.

At the same time, Switzerland is one of the world's foremost innovators in biomedical research and life sciences technology. The chemical and pharmaceutical industry is Switzerland's largest export sector and contributes approximately 5% of the country's GDP. There are about 1,000 companies active in this industry, with Novartis and Roche (both headquartered in the life sciences hub of Basel) being among the largest in the world. Most products in the Swiss life sciences sector are exported to the EU, which is why the EU regulatory framework is highly relevant.

Given that Switzerland's largest trading partner is the EU, the Swiss legislator strives for a far-reaching harmonisation of Swiss and EU legislation. Consequently, developments in the Swiss life sciences sector often mirror EU regulatory developments. Thus, various EU regulations significantly inform Swiss legislation, even though Switzerland is not a member state of the EU.

Considering these aspects, the Swiss life sciences sector is currently undergoing significant changes. This overview discusses some recent initiatives in the sector.

Ongoing Revision of the Federal Therapeutic Products Act

The Federal Therapeutic Products Act (TPA), which contains the most basic regulations on the handling of medicinal products (ie, pharmaceuticals) and medical devices, entered into force in 2002 and is currently being revised. The revision draft was presented in December 2023 and the consultation period recently ended in March 2024. Once the results of the consultation period have been analysed, the Swiss legislator will tackle the drafting work. The main focuses of attention in the revision are the implementation of e-prescriptions and the improvement of patient medication safety, as well as drug safety

in paediatrics. These strategic thrusts serve to advance the digitalisation of the healthcare system – something that plays a central role in cutting healthcare costs, as well as meeting patient demands, and must be further strengthened.

A first priority for this revision is to establish a legal basis for the electronic issuance and digital transmission of prescriptions for medicinal products. The exclusively digital transmission of e-prescriptions aims to guarantee better legibility and thus contribute to increasing patient safety. Electronic prescriptions will prevent prescription forgeries and unauthorised duplicate prescriptions in the future. The framework conditions under which the e-prescription will be used are specified in the TPA. Nonetheless, patient autonomy and unrestricted pharmacy selection ought to be upheld.

Further, the revision will create a legal basis for a mandatory electronic medication plan and for the implementation of medication reconciliation when prescribing, dispensing or using medicinal products. The proposed law empowers patients to request a printed copy of their medication plan or receive it electronically. The objective is to improve medication safety, acceptability, and treatment compliance, in addition to fostering greater openness and information sharing among all treating healthcare providers.

Children's medication is another significant challenge. Few medications are specifically approved for use in children; however, dosages must be determined for each child based on age, weight, body size, and other pertinent considerations. The Swiss federal government has already issued a national directory with standardised dosage recommendations for the use of pharmaceuticals in paediatrics (Article 67a of the TPA). However, this does not include a calculator function for individual dosage calculations. To avoid calculation errors as far as possible and thus increase the safety of the use of medicines in children, the revision aims to make the use of electronic systems for calculating drug dosages mandatory.

Furthermore, reflecting the high pace in the development of advanced therapy medicinal products (ATMPs) and their importance in medical practice, ATMPs are also to be regulated more specifically in the TPA. In the EU, ATMPs are regulated in a separate regulation (Regulation (EC) No 2007/1394) and include gene therapy medicinal products, somatic cell therapy medicinal products, bioengineered tissue products, and combinations of ATMPs and medical devices. Not being a member state of the EU, Switzerland nonetheless seeks to mirror EU law as far as possible in the TPA to guarantee access to Swiss patients to novel, high-quality treatments and products. The EU and Swiss markets should become more competitive and compatible as a result, and an equivalent level of safety should be established.

Finally, the last area of revision is also due to developments in the EU aimed at avoiding trade barriers, preventing the emergence of antibiotic resistance, and guaranteeing market access to cutting-edge veterinary medicine therapies. The EU has revised and modernised its regulation in the area of veterinary medicinal products (Regulation (EU) No 2019/6), which entered into force on 28 January 2022. Thus, amendments to Swiss law are required to preserve the safety of the country's veterinary medicine supply as well as the ability to export animals and animal products to the EU. Amendments include modifications concerning antimicrobial active substances and – in this context – resistance-reducing measures, as well as modifying the duration of

the authorisation for veterinary medicinal products. In addition, market access to novel and innovative therapies in veterinary medicine is to be guaranteed.

Switzerland Remains an Attractive Location for Headquarters and Research

Switzerland continues to attract life sciences companies, as evidenced by inbound establishment of their business presence in Switzerland. By the end of 2022, 20% of European life sciences companies had their headquarters in Switzerland, according to a study by EY. Key factors in their location selection include Switzerland's central location, modern infrastructure, business-friendly environment and highly skilled labour force, according to this study.

An additional noteworthy advancement was recently realised by the federal authorisation and supervisory authority for pharmaceutical and medical products (Swissmedic), with the establishment of the Swissmedic Innovation Office, whose innovative framework intends to expedite the delivery of novel pharmaceuticals. As Swissmedic is responsible for the licensing, authorisation and monitoring of pharmaceutical and medical products in Switzerland, the Swissmedic Innovation Office aims to close the gap to the innovators so that small companies and start-ups can be supported from the outset.

Developments in Digital Health

Telemedicine solutions enjoy an extensive presence and are widely recognised in Switzerland. Many companies are active in this sector and provide telemedicine solutions, telemedical consultations, and remote monitoring of vital parameters. Hence, an important part of Swiss population has already been exposed to telemedicine. By way of example, the largest medical telemedicine centre in Europe is operated by the Swiss digital health company Medgate in Basel, providing health insurance providers with the opportunity to serve as their policyholders' family physicians and/or gatekeepers. It is to be expected that the spreading of telemedicine services will continue and that telemedicine companies operating in Switzerland will aim for European expansion in the medium term.

To promote the use of electronic patient records (EPRs), the Federal Electronic Patient Record Act (EPRA) came into force in April 2017. The purpose of the law is to ensure that, in the future, all patient records are maintained exclusively in digital format and that all essential health documents (eg, nursing and hospital reports, examination results, and x-rays) are centrally stored and securely shareable among healthcare professionals. The EPRA and its implementing ordinances regulate the framework conditions for the introduction and dissemination of electronic patient records in Switzerland. Therefore, all hospitals are required to join a state-certified parent organisation that provides EPRs to private individuals.

However, the use of an EPR is voluntary for physicians (so far) and the general public. Consequently, implementation is currently advancing only incrementally – although there is great public interest and extensive media coverage. Therefore, to help EPRs reach a breakthrough, the EPRA is currently undergoing a revision with the aim of mandating all healthcare providers to use EPRs.

Increasing Costs of the Swiss Healthcare System

The healthcare system in Switzerland is based on a social health insurance system – according to which, every Swiss resident is required to be insured with a compulsory health insurance

provider. This system is designed to guarantee high-quality care at the lowest possible cost while also fostering greater solidarity between those who are ill and those who are healthy. However, this also means that all Swiss citizens are equally affected by cost increases in the Swiss healthcare system in the form of higher insurance premiums.

Insurance premiums have been rising continuously for the past 15 years or more. For 2024, health insurance premiums rose by an average of 8.7% compared with the previous year, even though inflation is low compared to other European countries. Thus, in recent years, these ongoing cost and premium hikes have become a significant challenge.

The requirement that Swiss patients personally finance a significant amount of healthcare expenses is an entrenched component of the system – universal healthcare coverage is compulsory for all Swiss citizens. The premiums for such health insurance coverage vary considerably between providers. However, in the event of illness or accident, compulsory health insurance does only reimburse healthcare costs incurred in excess of a contractually defined "deductible" of up to CHF2,500 per annum. As a result, costs below such deductible are not insured but fully borne by the patients themselves. In the aggregate, patients directly fund a quarter of the Swiss healthcare system themselves. In 2021, healthcare costs in Switzerland amounted to a total of CHF86.34 billion. Compared to the GDP, healthcare spending represented 11.8% in 2021. Statistically, every one of the 8.7 million inhabitants in Switzerland paid on average CHF827 per month for the healthcare system in 2021. These costs are expected to rise further, placing an increasing financial burden on insured persons. Accordingly, it does not come as a surprise that numerous political and legislative proposals for the reform of the healthcare system are presently under consideration.

Increase in the Number of Multimorbid and Chronically Ill Patients

Life expectancy in Switzerland has almost doubled in the past 100 years. Thus, the Swiss healthcare system – as in other European countries – is confronted with the downside of longevity. The demand for medical treatments and the prevalence of age-related diseases both increase in sync with the higher life expectancy.

Currently, 2.2 million Swiss citizens (ie, approximately 25% of the population) are afflicted with a non-communicable disease, including conditions such as cancer, cardiovascular disease, chronic respiratory disease, diabetes, and musculoskeletal disease. Furthermore, dementia is affecting an increasing number of Swiss citizens.

The Swiss Cancer Report 2021, which was published by the Swiss Federal Statistical Office (FSO), indicates that the increasing number of older people has led to rising numbers of cancer patients. This report projects that approximately 45% of the Swiss population will receive a cancer diagnosis at some stage in their lives, with 39% of women and 51% of men falling within this proportion. In contrast, Swiss incidence rates for both men and women are relatively low when compared internationally – with the exception of melanoma, which has a high incidence rate despite having extremely low mortality rates. Switzerland exhibits a five-year survival rate that falls within the upper middle echelon for all types of cancer (FSO, Swiss Cancer Report 2021). Consequently, the costs of necessary medical treatments, which are covered by compulsory health insurance, contribute to the increase in

costs of the Swiss healthcare system and thus also fuel the political debate on how to counteract the increase in healthcare costs.

Relationship With the EU

As the EU is Switzerland's largest trading partner, Switzerland and the EU entered into a Mutual Recognition Agreement (MRA) in relation to conformity assessment. The MRA is designed to remove technical barriers to the trade of industrial goods between the parties and applies, inter alia, to Good Manufacturing Practices (GMP) inspections of medicinal products and to the certification of batches. Consequently, in the case of medicinal products, each party recognises the results of inspections conducted by the competent authorities of the other party at the premises of manufacturers, as well as the production authorisations provided by the competent authorities of the other party. In addition, foreign authorities are permitted – under certain conditions and after notifying Swissmedic – to audit Swiss companies active in the life sciences sector.

The MRA also applies, inter alia, to medical devices. Conformity assessments of medical devices authorised in the territory of a party are therefore, in principle, also acknowledged within the jurisdiction of the other party. In view of the recent changes to the EU regulatory framework on medical devices, it is necessary to revise the MRA's provisions on medical devices to guarantee mutual recognition of certificates of conformity, facilitation of reciprocal market access, co-ordinated market surveillance, and information sharing between authorities. However, the EC ties such an update to further progress in the stalled political negotiations with Switzerland, which were interrupted between May 2021 and March 2024.

As a result of this impasse, the EU currently treats Switzerland as a third country in terms of medical devices, requiring Swiss companies to incur higher administrative efforts to place medical products on the EU market. To counteract these negative impacts, in May 2021 the Swiss Federal Council amended the legal framework regarding medical devices to provide unrestricted access to EU-certified medical devices and to establish long transitional periods, therefore reducing supply issues in Switzerland. With the negotiations between Switzerland and the EU having resumed in March 2024, the current standstill looks set to be overcome in the foreseeable future.

Conclusion

Switzerland's life sciences sector has faced significant challenges in recent years due to developments in the EU, cost increases, regulatory amendments, and policy changes. The trends and developments discussed in this overview will continue to have a strong influence on the future development of the Swiss life sciences sector.

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