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Life Sciences 2025

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Switzerland: Trends & Developments

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SWITZERLAND

Trends and Developments

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Initiatives and Challenges Impacting the Development of the Swiss Life Sciences Sector

In Switzerland, key legislation at federal level relating to the healthcare system is subject to federal referendums. This leads to a high level of acceptance in the population. In substance, 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 constantly increasing cost pressure and rising patient demands.

Regarding innovation, Switzerland is one of the world's foremost innovators in biomedical research and life sciences technology. The chemical and pharmaceuticals industry is Switzerland's largest export sector and contributes approximately 5% to 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 top ten global pharma companies. 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 highlights 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 ended in March 2024. Once the results of the consultation process 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 digitisation 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 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 aim to 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.

The revision also aims to 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 Swiss patients access 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 prod-

ucts. In addition, market access to novel and innovative therapies in veterinary medicine is to be guaranteed.

Other current legislative revisions

Effective 1 January 2025, the principle of voluntary blood donation has been codified (Article 33a of the TPA). It forbids any remuneration or advantages associated with blood donations, aligning with the principle of voluntary donation for organs, tissues and cells already established in the Federal Constitution. In addition, a prohibition on discrimination has been established to guarantee that individuals cannot be barred from donating blood due to their sexual orientation (Article 36(2bis) of the TPA).

Furthermore, the amendment to the Federal Ordinance on Research Involving Human Beings (the *"Human Research Ordinance"*, or HRO) came into force in November 2024. It is aimed at enhancing the protection of research participants and improving research conditions, especially via digitisation. Consent may now be provided electronically (new Article 8c of the HRO) and further amendments have been made, inter alia, to meet data protection and data security requirements (Article 4(1)(d) of the HRO). Finally, researchers are to engage pertinent demographic groups – such as women and the elderly – more extensively.

Another significant legislative revision that came to an end recently is the uniform financing of inpatient and outpatient medical services regulated by the Federal Health Insurance Act (HIA), which was approved by referendum on 24 November 2024. Thus, starting in 2028, outpatient and inpatient acute services will be uniformly financed, with care services to follow four years thereafter. To date, 55% of inpatient expenses have been jointly financed by the cantons (ie, the taxpayers) and 45% by health insurance funds (ie, the premium payers).

Conversely, outpatient expenses have been entirely covered (ie, 100%) by health insurance funds – something that has led to misplaced incentives. An unnecessarily large number of inpatient treatments have been carried out, even though outpatient treatments would have been often medically more appropriate and less expensive. Hence, both methods of treatment will in future be financed according to a uniform distribution mechanism.

Implementation of the Care Initiative

As in other Western countries, the population of elderly citizens in Switzerland is rising. The population of persons aged 100 and above has increased from 61 in 1970 to 2,086 in 2023, according to a survey recently published by the Swiss Federal Statistical Office. The demographic ageing of society is concurrently escalating the demand for nursing personnel. As the population of elderly persons rises, the prevalence of diseases such as cancer, diabetes, and cardiovascular conditions – as well as increasing multimorbidity – is expected to increase in the forthcoming years. This exacerbates the current shortage of qualified care staff in the healthcare sector.

In November 2021, 61% of Swiss voters approved an initiative to improve working conditions for care staff (the *"Care Initiative"*) and hence mitigate the shortage of care staff. As a result of this initiative, legislative measures will be implemented to:

- enhance the training of care staff at the tertiary level;
- enhance the granting of care degrees by higher technical colleges (*Höhere Fachschu-*

len, or HFs) and universities of applied sciences (*Fachhochschules*, or FHs); and
- authorise care staff to directly bill specific medical services to social insurance funds, thereby eliminating the need for a doctor's prescription.

Additional measures are currently under consideration.

In addition, a national monitoring programme for care staff has been introduced that aims to systematically assess the impact of measures implemented based on the Care Initiative over an extended duration. This aims to provide to the federal government, cantons, and employers with a specific management instrument that determines the conditions within the various care sectors and to monitor in detail the consequences of the measures. The data recorded includes the number of vacancies, completed training courses, attrition rate, care staff count, and patient-perceived quality of care.

Continued development of digitisation of Swiss healthcare system

Telemedicine solutions thrive 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, numerous providers of telemedicine services offer health insurance companies the opportunity to serve as their policyholders' family doctors and/or medical 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.

A further digitisation of the Swiss healthcare system is to be carried out with the programme *"DigiSanté"*, which was launched on 1 January 2025. The programme consists of approximately 50 distinct projects, all designed to advance digital transformation in the healthcare sector. These projects encompass legislative initiatives, software development, and the establishment of nationally co-ordinated guidelines for standardisation. Given that data constitutes a central element of digital transformation, standardised data structures and content shall be implemented to ensure that systems work together smoothly (ie, are interoperable) and that information only needs to be recorded once (the *"once-only principle"*). DigiSanté aims to establish specific regulations for data access and utilisation by various stakeholders, alongside the digitisation and co-ordination of governmental services and the provision of centralised services, including registers, interfaces, and identifiers.

Such measures will be implemented not only when providing medical services but also in their billing procedures. Thus, envisaged amendments to the HIA that are currently undergoing the consultation process aim to uphold the once-only principle in matters of social insurance law as well. Service providers of inpatient hospital care shall in the future be obliged to centrally transmit certain data to a platform managed by the Swiss Federal Statistical Office. As the one-only principle has not been consistently applied so far, hospitals frequently need to submit identical data multiple times to various authorities. By establishing the once-only principle in the future, the revision aims to eliminate redundant surveys, to organise data flows more transparently, and to enhance and access potential applications of the data.

Electronic patient records

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. To implement this, all hospitals are required to join a state-certified parent organisation that provides EPRs to private individuals.

However, the use of an EPR is currently voluntary both for physicians and the general public. Consequently, implementation is advancing only incrementally – although there is great public interest and extensive media coverage. According to the Swiss Federal Office of Public Health, only 72,000 EPRs have been opened until August 2024. Therefore, to further promote EPRs, the EPRA is currently undergoing a revision with the aim of mandating all healthcare providers to use EPRs. Thus, it is envisaged that all Swiss residents subject to compulsory health or military insurance will automatically get an EPR. However, individuals may contest the issuance of an individual EPR (opt-out). The implementation date of the revision remains undetermined.

Organ donation

Digitisation also affects organ donation. In a referendum held on 15 May 2022, voters approved an amendment to the Transplantation Act introducing an opt-out system. As soon as the law comes into effect, it will in principle be possible to remove organs, tissues and cells from persons after their death, provided that they did not object to this during their lifetime (nevertheless, numerous exceptions will persist).

Digitisation plays an important role, as an electronic register will be established to document objections or consents to organ donation. The electronic identity (*"e-ID"*) will ensure the reliable and accurate identification of each registered individual. However, the implementation of such identification method – and thus the register – is contingent upon the enactment of the Federal Act on Electronic Identity, which is currently scheduled for 2026.

Increasing costs of 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. For 2025, health insurance premiums rose by an average of 6% compared to 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 economic challenge and political topic. In addition to the above-mentioned uniform financing of outpatient and inpatient treatments in an effort to reduce disincentives, the federal government addresses this issue through a cost-containment programme, whereby various stakeholders of the healthcare system convene biannually to collaboratively formulate specific cost-containment strategies. During an initial meeting in November 2024, stakeholders con-

curred on the objective of achieving annual savings of approximately CHF300 million starting in 2026, which corresponds to 1% of health insurance premiums.

Additionally, by 2026, the TARMED tariff framework for outpatient medical services – instituted in 2004 and serving as the principal basis for invoicing outpatient medical services – will be replaced by a new TARDOC single-service tariff framework and a flat-rate tariff structure.

Relationship with EU

As already mentioned, the EU is Switzerland's largest trading partner. Thus, 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 recognising the production authorisations provided by the competent authorities of the other party. In addition, foreign authorities are permitted – under certain conditions and after notifying the Swiss Authority for Therapeutic Products (*"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 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 (still) 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 and the substantive negotiations being concluded in December 2024, a political breakthrough seems possible – albeit still subject to the uncertainty of a legislative referendum. The achieved agreement focuses on health security, including full access of Switzerland to the EU's health security mechanisms, the European Centre for Disease Prevention and Control (ECDC) and the crisis preparedness area in the EU's multi-year programme (currently *"EU4Health"*). Thus, it remains an open question whether the compromise will also unblock the impasse regarding the MRA on medical devices.

Outlook

Switzerland's life sciences sector has faced significant challenges in recent years due to technological progress, 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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