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Abstract

On the one hand, the Swiss healthcare system is based on a social health insurance system, according to which every resident in Switzerland is required to be assured with compulsory health insurance. It aims to ensure high-quality services at the most affordable price. On the other hand, regardless of whether a pharmaceutical product requires a prescription or not, it cannot be introduced to the market without authorisation from the competent authority, even if it is an over-the-counter product.

In general, therapeutic products are only reimbursed if they are listed on the so-called specialty list. To be listed thereon, a pharmaceutical product must be effective, appropriate and cost-effective, based on which the price for the therapeutic product in question is determined. Whether these three conditions are fulfilled is measured based on the marketing authorisation documentation, as well as from a foreign price comparison and a therapeutic cross-comparison carried out by public authorities.

Market introduction/overview

The Swiss compulsory insurance scheme

The healthcare system in Switzerland is based on a social health insurance system. The Federal Health Insurance Act (HIA), which contains the most fundamental regulations on its core component, the compulsory health insurance (Art. 3 *et seq*. HIA), and the optional daily allowance insurance (Art. 1a(1) HIA), outlines the basic principles of this social health insurance system. The Healthcare Benefits Ordinance (HBO) and the Health Insurance Ordinance (HIO) both contain additional provisions that further define the general provisions.

The federal government designated the implementation of social health insurance as a state task and monopolised it legally. However, rather than state authorities, health insurance companies carry out the actual implementation. These, however, function on public-law grounds because they are indirect state administration organs that are part of the state's task-fulfilment system. There are many different health insurers in Switzerland because there is no legal restriction on their numbers.

In Switzerland, social health insurance 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. In light of this, the following guidelines apply: (i) there is a national requirement to have health insurance (Art. 3(1) HIA) – the entire resident population of Switzerland is entitled to and required to participate in the solidarity community; (ii) insured persons are free to choose their health insurance and to switch between insurances (Arts 4(1) and 7(1) HIA) – health insurance companies are required to accept every insured person, regardless of health status, age or gender and thus cannot choose their insured persons; (iii) sick and healthy insured persons pay the same premium – gradation according to age is prohibited (except for children and young adults (Art. 61(3) HIA), as well as by gender and other indications pointing to an increased risk of illness; and (iv) a comprehensive statutory catalogue of benefits has been created, which is binding to health insurers – benefits under mandatory health insurance are therefore the same for all insured people. However, the economic capacity of each insured person is not considered by such a single premium. Therefore, there is a possibility that those who are less financially stable will not be able to afford their insurance premiums. However, the public authorities of the cantons may provide premium reductions as a preventative measure (Art. 65 *et seq*. HIA).

The insured's direct contribution to the costs of a medical treatment, monthly premium payments to his/her health insurance, and government subsidies all go toward funding mandatory health insurance. According to the guidelines of the Health Insurance Supervision Act (HISA), the Swiss Federal Office of Public Health (FOPH) also serves in this situation as the supervisory organisation for the health insurances. As a result, the FOPH must annually approve the tariffs for the compulsory health insurances (Art. 16 HISA). The amount of the monthly premiums that the insured must pay is not based on their level of income. The premiums, however, differ between insurers and between cantons and are also significantly influenced by the deductible applicable in each case.

The deductible that the insured chooses directly affects the premium amount. The deductible (also called "franchise") is a cost-sharing arrangement for Switzerland's compulsory health insurance. Each insured person is required to pay for his/her own medical expenses in addition to paying the health insurance's premiums. However, he/she has the option of choosing the deductible rate and is required to pay at least the first CHF 300 or a maximum of CHF 2,500 of the costs associated with receiving medical treatment each year; the remaining costs are covered by the health insurance. The higher the deductible, the lower the premium is. To ensure that every resident of Switzerland has access to affordable healthcare, insured individuals with low incomes, including children and young adults, frequently benefit from a reduction in premiums.

However, in addition to these fundamental principles of solidarity, the state aims to establish a successful system that ensures high-quality services at the most affordable prices. Costs ought to be restricted in addition to increasing solidarity. Thus, there are two different, mutually exclusive approaches in the Swiss healthcare system: more regulation on the one hand; and more competition on the other. The main emphasis in the health insurance sector is on competition. Numerous health insurers offer social health insurance and compete with one another. At the same time, however, the state intervenes in the market in a strong regulatory way by prohibiting risk-based premiums and defining the catalogue of medical services by law. With this risk equalisation, the legislator attempts to distribute the burden of risks.

Healthcare system and access to care

The FOPH is responsible for public health in Switzerland. In particular, the FOPH coordinates Switzerland's health policy and supervises the compulsory health insurance. Further, the FOPH is involved in decision-making with respect to pricing and reimbursement of medicinal products and medical devices. The latter are subject to regulation by the Federal Therapeutic Products Act (TPA) which contains the most basic regulations on the handling of medicinal products (i.e. pharmaceuticals) and medical devices. The TPA generically refers to medicinal products and medical devices as "therapeutic products". This also includes

over-the-counter medicinal products as well as supplements to medical devices. Due to the high export rate of such products to the European Union (EU), the Swiss legislator aims at a far-reaching conformity between Swiss and EU law.

Unless the cantonal authorities are responsible, the FOPH is the competent authority for all public health aspects by default. In the area of therapeutic products, however, neither the FOPH nor the cantonal health authorities, but the Swiss Agency for Therapeutic Products (Swissmedic), is the Swiss regulatory and supervisory authority for medicinal products, including over-the-counter products as well as medical devices (Arts 68, 69 and 82 TPA). Swissmedic is a federal agency governed by public law with its own legal personality. Swissmedic is legally and economically independent from the rest of the administration and is mainly financed by fees. Swissmedic has the competence to issue further regulations that supplement the legal requirements, in particular by means of guidelines, instructions and manuals.

The responsibility for the provision and funding of healthcare lies mainly with the 26 cantons of Switzerland, even if regulated on a federal level. Thus, the cantons are required to ensure compliance with compulsory insurance. For instance, if a resident in Switzerland fails to sign up for compulsory health insurance in a timely manner, the canton of his/her residence must assign the individual to one of the insurers (Art. 6 HIA). Consequently, every Swiss resident is covered by compulsory health insurance. Alongside compulsory health insurance, cantons also co-finance hospitals and elderly care facilities, which are primarily owned or controlled by cantons and municipalities. These responsibilities primarily fall under the jurisdiction of cantonal health departments.

Insurers may offer supplementary health insurance in addition to the mandatory compulsory health insurance. Such supplemental coverage may include additional services, such as homeopathy, and typically allows for greater flexibility in the choice of doctors or hospitals and is governed by private insurance law.

Statistics

Switzerland has one of the costliest healthcare systems in the world. In 2022, healthcare costs amounted to a total of CHF 91.759 billion and continued to rise, while healthcare costs for 2023 were forecast at CHF 93.952 billion, and the figure for 2024 is expected to rise to CHF 97.076 billion. Compared to the gross domestic product (GDP), healthcare spending represented 11.8% in 2024. Statistically, every one of the 9 million inhabitants in Switzerland paid on average CHF 871 per month for the healthcare system in 2022, while an average of CHF 880 was expected for 2023 and CHF 898 for 2024 (*cf.* https://www.bfs.admin.ch; last visited on 7 May 2025).

Switzerland is one of the world's foremost innovators in biomedical research and technology. The chemical and pharmaceutical industry is Switzerland's largest export sector and contributes approximately 5% of the GDP. There are approximately 1,000 companies involved in this industry, with *Novartis* and *Roche*, both headquartered in the life sciences hub Basel, being among the largest in the world.

According to the Swiss association of research-based pharmaceutical companies (Interpharma), medicinal products achieved in 2023 a volume of CHF 7.4 billion (+4.9% compared to 2022) while the average price of the individual medicinal products fell by 2.7% (*cf.* Interpharma, *Health Panorama 2024*, 23).

Pharmaceutical pricing and reimbursement

Regulatory classification

Pharmaceutical products are regulated in the TPA and in several related ordinances such as the Medicinal Products Ordinance (MPO). The purpose of the TPA is to protect human and animal health and to guarantee that only high-quality, safe and effective therapeutic products are brought to the market. In general, medicinal products are divided into prescription and non-prescription categories (Art. 23(1) TPA).

Specifically, medicinal products are classified as follows (Art. 40 *et seq*. MPO): (i) single-delivery prescription medicinal products (category A); (ii) prescription medicinal products that can be delivered multiple times with the same prescription (category B); (iii) non-prescription medicinal products that require a prior consultation (category D); and (iv) non-prescription medicinal products that can be purchased without further consultation, i.e. over-the-counter medicinal products (category E). Previously, category C included over-the-counter medicinal products that required prior medical consultation. This category was nonetheless eliminated at the end of 2018.

Regardless of whether a medicinal product requires a prescription, it cannot be introduced to the market without Swissmedic's authorisation. Any undertaking applying for a marketing authorisation for a medicinal product is required to have a registered address, registered office or branch office in Switzerland. Swissmedic may impose restrictions and conditions on the marketing authorisation, such as the obligation to provide additional clinical-experimental data or other post-marketing obligations, the existence of which must be confirmed through due diligence. The marketing authorisation is granted initially for a period of five years (Art. 16(2) TPA). Swissmedic may examine, modify or revoke this marketing authorisation at any time (Art. 16c TPA). After the initial five years, the authorisation is renewed if the marketing requirements continue to be met. Typically, it is then valid indefinitely (Art. 16b TPA). Swissmedic may, however, impose a time limit under certain circumstances (Art. 16b TPA).

Contrary to certain nations, most medicinal products cannot be sold in supermarkets. Therefore, pharmacies continue to be the most significant sales channel for these products; 67% of all medicinal products (representing roughly half of the sales in terms of value) are sold through pharmacies. In certain cantons, doctors are permitted to dispense medicinal products. These self-dispensing doctors and hospitals account for an additional 26.3% of medicinal product sales in terms of value (*cf*. Interpharma, *Health Panorama 2024*, 29).

Who are the payers?

In the outpatient sector, particularly when a patient visits a doctor in his/her practice, the patient is responsible for the costs of treatment and any medicinal products prescribed, regardless of the existence of an insurance relationship. In this case, however, the patient is entitled to reimbursement from the health insurance, except for the part that he/she must pay himself/herself based on the deductible chosen (so-called "*system of tiers garant*", Art. 42(1) HIA). In the inpatient sector, however, particularly when a patient is treated in a hospital, the health insurance must pay for the treatment and any prescribed medicinal products (so-called "*system of tiers payant*", Art. 42(2) HIA).

The main reason for the separation into two separate systems is that, on the one hand, patients shall be incentivised to utilise medical care only when necessary. On the other hand, medical treatment in hospitals, which is significantly more expensive than medical treatment in doctors' practices, should be accessible to all individuals through social health insurance if they require it.

What is the process for securing reimbursement for a new pharmaceutical product?

The Swiss economic order is based on the principle of economic freedom. However, in the healthcare system, particularly in areas covered by compulsory health insurance, the range of services and pricing is left to the competition coordination system only to a very limited extent. State control typically has precedence in this context. Thus, the HIA intervenes in both the process of reimbursement of medicinal products as well as in their pricing by designating the reimbursable medicinal products and by stipulating their prices or maximum remuneration amounts.

In general, compulsory health insurance covers the costs of medically prescribed medicinal products and medical devices, regardless of whether they are new or have been on the market for a long time (Art. 25(2)(h) HIA). This includes all examinations and treatments performed by doctors, chiropractors and/

or pharmacists, as well as laboratory analyses, therapeutic products, aids and equipment prescribed by doctors (Art. 25(2) HIA). Consequently, the list of services covered by compulsory health insurance is quite extensive.

How is the reimbursement amount set? What methodology is used?

The so-called list principle determines the cost-coverage scope. According to the list principle, a medical service, a medicinal product and/or a medical device is only reimbursed by health insurance if and to the extent that it appears on specific lists. The FOPH issues these lists for medicinal products, medical products and medical analyses (Art. 52 HIA). The authority is advised by expert committees. The lists not only specify in detail the services and products covered by compulsory health insurance, but also determine their prices (Art. 52(3) HIA).

For pharmaceutical products, the so-called speciality list is relevant; this list, compiled by the FOPH, contains the prices of pharmaceutical products and ready-to-use medications. This list must also contain the lower-priced generics that are interchangeable with the original preparations (Art. 52(1)(b) HIA). However, the Federal Council, i.e. the Swiss government, has defined exceptions to this list principle in accordance with the practice of the Federal Supreme Court (Art. 71a HIO); such an exception exists, for example, in the case of off-label use (Art. 71a(1) HIO). In addition, there are also exceptions for cases in which medicinal products not included in the speciality list are used, the so-called "off-list use" (Art. 71b HIO).

In addition, reimbursement may be obtained through state disability insurance programmes governed by the Federal Disability Insurance Act (DIA). Thus, insured individuals have the right to receive the necessary medical treatment for congenital diseases until the age of 20 (Art. 13(1) DIA). These medical measures include medical treatment and the distribution of prescribed medicinal products (Art. 14(1) DIA). To obtain those benefits from invalidity insurance, however, the insured must apply to the invalidity insurance.

How are drug prices set? What is the relationship between pricing and reimbursement?

As mentioned above, the speciality list is of particular importance for medicinal products. This list contains the pharmaceutical specialities and prepared medicinal products and their prices and is therefore a "list of medicinal products" (Art. 52(1)(b) HIA). The speciality list also includes the lower-priced generics that are interchangeable with the original preparations. The manufacturer of a medicinal product applies to the FOPH for the inclusion of its medicinal product on the speciality list (Art. 69(1) HIO). All medicinal products that are included in the speciality list must be reimbursed by the health insurers. The Swiss Federal Supreme Court has ruled that health insurance companies have no right of appeal regarding the inclusion of medicinal products in the speciality list (FSC 127 V 80).

Services and medicinal products that are to be included on a list and thus covered by mandatory health insurance must be effective, appropriate and cost-effective (Art. 32(1) HIA). The effectiveness, appropriateness and economic efficiency of all medicinal products and services are evaluated periodically (Art. 32(2) HIA).

Effectiveness must be demonstrated through scientific methods. To evaluate the effectiveness and appropriateness of a medicinal product, the FOPH relies on the documentation that Swissmedic used to grant marketing authorisation (Art. 9 *et seq.* TPA). The FOPH may, nonetheless, request additional documentation. A medicinal product is considered cost-effective if it provides the desired therapeutic effect at the lowest possible cost.

Cost-effectiveness is assessed on the basis of a twofold comparison (Art. 65b(2) HIO): (i) a comparison with the price in reference countries (foreign price comparison); and (ii) a comparison with similar medicinal products (therapeutic cross-comparison). The foreign price comparison compares the ex-factory price of a

medicinal product with the ex-factory prices of the same product (i.e. original preparations with the same active substance and the same pharmaceutical form) in countries defined by the authorities (Art. 65b(3) HIO and Art. 34a(2) HBO). Reference countries are Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Sweden and the United Kingdom (Art. 34a(1) HBO). The therapeutic cross-comparison examines the efficacy and the costs of the medicinal product in relation to other medicinal products used for the treatment of the same disease.

The results from the foreign price comparison (average price of the reference countries) and the therapeutic cross-comparison (average price of similar medicinal products) are each weighted half (Art. 65b(5) HIO) when determining the price of a medicinal product. In addition, research and development costs are considered when determining the cost-effectiveness of an originator product, unless the originator product is a successor product that does not bring any therapeutic progress compared to the originator product previously included on the speciality list (Art. 65b(6) HIO). If the medicinal product brings significant therapeutic progress, an innovation supplement is considered for a maximum of 15 years within the context of therapeutic cross-comparison (Art. 65b(7) HIO). In order to promote the sale of generic medicinal products, patients who wish to use an original medicinal product instead of a generic medicinal product must pay 20% of the original medicinal product's price (Art. 38a(1) HBO).

Medicinal products on the specialty list are re-evaluated every three years and after the expiration of the relevant patents. As a result of this re-examination, the FOPH may order a price reduction for the medicinal product (Art. 65d and 65e HIO).

Issues that affect pricing

The Swiss legislation regarding integrity and transparency regarding therapeutic products has recently been revised. The new provisions (Arts 55 and 56 TPA) entered into force on 1 January 2020. The specific regulations are stipulated in the new Transparency and Integrity Ordinance (TIO), which went into effect on the same day. Since then, it has been illegal for prescribers, dispensers, users or purchasers of prescription-only medicinal products, as well as their employers, to solicit, be promised or accept any improper benefit for themselves or for the benefit of a third party (Art. 55(1) TPA). By contrast, it is prohibited to offer, promise or grant an improper benefit to such a person or organisation for their benefit or the benefit of a third party. The law contains a list of contributions that are not considered improper benefits (Art. 55(2) TPA): (i) material benefits of modest value (maximum of CHF 300 per medical professional and year) that are relevant to the medical or pharmaceutical practice; (ii) subject to certain criteria, support for research, education and training; (iii) compensation for equivalent services in return, in particular those provided in connection with orders and deliveries of therapeutic products; and (iv) price discounts or refunds granted on medical purchases, provided they have no influence on the choice of treatment.

Compared to the previous regulation regarding benefits and kickbacks, the personal scope of application has been expanded to include purchasers of medicinal products, such as members of medicines' commissions in hospitals or elderly care institutions, as well as purchasers of medicinal products for practitioner networks. In contrast, the material scope has been narrowed from all therapeutic products to prescription-only medicinal products. However, considering the latest revision of medical device regulations, the integrity provision will be extended to benefits related to the prescription, supply and use of medical devices. This will require a partial revision of the TIO, which is expected to begin in the course of 2025.

In addition, in the interest of transparency, all price discounts and rebates granted on purchases of medicinal products must be indicated on receipts and invoices and in the accounts of both the selling and purchasing persons and organisations and must be reported to the FOPH upon request (Art. 56(1) TPA). This requirement does not apply to low-risk remedies, such as over-the-counter therapeutic products

(category E). Finally, service providers (e.g. doctors, hospitals, pharmacists) are obliged to pass on price discounts and reimbursements granted to them to patients or insurers (Art. 56 HIA).

Previously, pharmaceutical companies would sponsor events and congresses for practitioners. The increasingly stringent regulations have resulted in a substantial reduction of such sponsorship. It is expected that the above-mentioned new regulations will encourage this trend.

Policy issues that affect pricing and reimbursement

Population growth

Life expectancy in Switzerland is among the highest in the world. According to a study conducted by the Swiss Federal Statistical Office (FSO), the Swiss population is expected to age significantly and rapidly, especially between 2020 and 2035, when the baby boomer generation will reach retirement age. Given that 13.5% of the population over 80 years old resided in retirement homes as of 31 December 2023, that 39% required care at home, and that the total costs of elderly care homes alone amounted to CHF 11.1 billion in 2023 (*cf.* https://www.bfs.admin.ch; last visited on 7 May 2025), it is evident that healthcare costs will almost certainly continue to rise.

As a result of the exorbitant price of certain cancer-treating medicinal products, it is reasonable to anticipate a further rise in healthcare expenses. Also, age increases the prevalence of non-communicable diseases and multiple illnesses. Ten per cent of the 50-year-old population is afflicted, while over 40% of the 75-year-old population is affected. In the future, the problem of non-communicable diseases will become even more severe due to the rising average age and the increasing number of elderly people (*cf.* https://www.bag.admin.ch; last visited on 7 May 2025).

Cost pressure due to non-communicable diseases

As in other European countries, the highly developed Swiss healthcare system faces an increase in the number of multimorbid and chronically ill patients due to increasing life expectancy. Increasing life spans increase the prevalence of age-related diseases and the demand for medical treatments. Additionally, the prevalence of chronic diseases will increase.

The number of people living in Switzerland affected by a non-communicable disease (cancer, cardiovascular diseases, chronic respiratory diseases, diabetes and diseases of the musculoskeletal system) currently stands at 2.3 million. This corresponds to a quarter of the Swiss population. Furthermore, a growing number of people living in Switzerland are affected by dementia. The most common causes of death in Switzerland are cardiovascular diseases and malignant tumours (*cf.* FSO, *Health – Pocket Statistics 2025*, available at: https://www.bfs.admin.ch; last visited on 7 May 2025). According to the *Swiss Cancer Report 2015*, published by the FSO, cancer has become a chronic illness. However, a comparison of multiple years shows a certain stabilisation in the number of new cancer cases according to the latest *Swiss Cancer Report 2021*, while mortality for most types of cancer is on the decline. In 2021, an estimate of 226,850 people in Switzerland were living with a cancer that was diagnosed less than 10 years ago. Every year, approximately 45,000 people living in Switzerland develop cancer and 17,000 die from the consequences of cancer. Pursuant to the *Swiss Cancer Report 2021*, it is expected that around 45% of the Swiss population (51% for men and 39% for women) will be diagnosed with cancer at one point in their lifetime. However, in international comparison, Swiss incidence rates are low for men as well as for women, except for melanoma, which has a high incidence rate in Switzerland (nevertheless, mortality rates for melanoma are very low). As regards survival rates across all types of cancer, Switzerland's five-year survival rates are in the upper middle range (*cf.* FSO, *Swiss Cancer Report 2021*, available at: https://www.bfs.admin.ch; last visited on 7 May 2025).

Thus, the extremely high costs of the healthcare system and the financing of these costs are currently a contentious political issue in Switzerland.

Emerging trends

In addition to the trends mentioned above, the evolution of Swiss health policy in conjunction with the EU is of particular significance. Since 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 GMP inspections of medicinal products and 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 (Chap. 15 of Annex 1 MRA). In addition, foreign authorities are permitted, under certain conditions and after notifying Swissmedic, to audit Swiss companies active in the life sciences sector (Art. 64a TPA).

The MRA also applies, *inter alia*, to medical devices. Accordingly, conformity assessments of medical devices authorised in the territory of a party are, in principle, also acknowledged within the jurisdiction of the other party (Chap. 4 of Annex 1 MRA). 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, coordinated market surveillance and information sharing between authorities. However, the European Commission ties such an update to further progress in the stalled political negotiations with Switzerland, that 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 make higher administrative efforts to place medical products on the EU market. To counteract these negative impacts, the Swiss Federal Council amended in May 2021 and May 2022 the Swiss medical devices legislation 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 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.

Successful market access

In our opinion, the following factors are crucial for successfully entering the Swiss national market: (i) in-depth knowledge of the healthcare legislation in Switzerland, its players and institutions; (ii) the recognition that for certain questions, the cantons and not the federal authorities are competent, and the incorporation of this reality into the business strategy; (iii) the recognition that most therapeutic products cannot be sold via supermarkets; (iv) rigorous documentation of the research-to-marketing process; (v) the timely and punctual submission of all required documentation; and (vi) all products must meet high standards of efficiency and quality.

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