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Switzerland

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Abstract

Every resident in Switzerland is mandatorily obliged to be covered by basic healthcare insurance which provides for a wide range of services. Persons with lower incomes are, in principle, granted reductions on the premiums payable for such basic healthcare insurance. Thus, every resident in Switzerland is granted access to affordable healthcare.

In general, therapeutic products are only reimbursed if they are listed on the so-called specialty list. In order to be listed thereon, a medicinal product must be admitted by the competent Swiss authority, and must satisfy the criteria of effectiveness, functionality and economic efficiency, based on which the maximum price for the therapeutic product in question is determined.

Market introduction/overview

Size and demographics

Switzerland has one of the world's most expensive healthcare systems. For example, in 2019, healthcare costs amounted in total to 82.08 billion Swiss francs (provisional result). Compared to the general domestic product, healthcare spending represented 11.3% in 2019 (provisional result). Every resident in Switzerland paid on average 798 Swiss francs per month (provisional result) for the healthcare system in 2019 (*cf.* https://www.bfs.admin; last visited on 21 May 2021). The corresponding numbers for 2020 are not yet available.

In 2020, there was a historical decline in both exports and imports from and to Switzerland due to the COVID-19 pandemic. The total value of goods and services exported from Switzerland amounted to 225 billion Swiss francs (provisional result), which corresponds to -7% compared to the previous year, whereas the value of imported goods and services amounted to 182 billion Swiss francs (provisional result), which corresponds to -11% compared to 2019. A new record surplus balance of 43 billion Swiss francs (provisional result) in favour of Switzerland resulted therefrom, compared to a positive balance of 36 billion Swiss francs in 2019. The most important part of Switzerland's exports were chemical and pharmaceutical products, which constituted 51.5% of the exports (116 billion Swiss francs). According to the Swiss Federal Customs Administration, exports of chemical and pharmaceutical products bucked the general downward trend registered by the other product groups (*cf*. Key figures 2020, available under the following link: https://www.ezv.admin.ch; last visited on 21 May 2021). Chemical and pharmaceutical products further constituted the second-largest group of imported products (51 billion Swiss francs respectively 28% of the imports). It must be noted that all numbers stated above are provisional results (*cf*. Key figures 2020, available under the following link: https://www.ezv.admin.ch; last visited on 21 May 2021).

According to the Association of research-based pharmaceutical companies in Switzerland ("**Interpharma**"), in 2019, reimbursable therapeutic products represented approximately 84.5% of the total pharmaceutical market (*cf*. Interpharma, Health Panorama 2020, p. 32).

In 2019, 47,500 people in Switzerland were employed by the pharma sector alone (*cf*. Interpharma, Health Panorama 2020, p. 71). Over 496,200 people in Switzerland (corresponding to approximately one in 12 of the working population) worked in the entire healthcare industry and the pharmaceutical sector in 2017 (*cf*. Interpharma, Healthcare Switzerland, 2019, p.38).

In Switzerland there is a very high density of hospitals which offer a wide range of medical services. In 2019, 281 hospitals and maternity units (38,057 beds) and 1,565 homes for elderly and care (92,838 residents per 31 December 2019) were registered in Switzerland (*cf*. https://www.admin.bfs.ch; last visited on 21 May 2021). The density of general practitioners is, however, relatively low compared to other countries.

Contrary to certain countries, such as the USA, most therapeutic products cannot be sold via supermarkets. Hence, pharmacies still remain the most important sales channel for medicines: 65% of all medicine packs (corresponding to approximately half of the sales in terms of value) were sold via pharmacies in 2020. In certain cantons, doctors are permitted to dispense medicines themselves. In terms of value, self-dispensing doctors and hospitals each account for approximately another quarter of sales of pharmaceuticals (*cf*. Interpharma, Health Panorama 2020, p. 30).

Switzerland is one of the world's leading players in the domain of biomedical research and technology. Given the high importance of the pharmaceutical market, the Swiss Federal Council has endeavoured to strengthen the international position of Switzerland with several initiatives, such as the "Masterplan for the promotion of biomedical research and technology" of 2013 (for further information, *cf*. https://www.bag.admin.ch and below section "Emerging trends"). Also, the costs of research and development are taken into account for the determination of the price of therapeutic products and a supplement for innovation may be granted (*cf*. below section, "What is the process of securing reimbursement for new pharmaceutical products and how are drug prices set?", in "Pharmaceutical pricing and reimbursement").

Healthcare system and access to care

The Swiss Federal Office of Public Health ("**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 pharmaceutical and medicinal products.

The Swiss Agency for Therapeutic Products ("**Swissmedic**") is the national authorisation and supervisory authority for therapeutic products. Swissmedic aims to ensure that only high-quality, safe and effective therapeutic products are made available in Switzerland.

The responsibility for the provision and funding of healthcare lies mainly with the 26 cantons of Switzerland, even if regulated on a federal level. Together with the compulsory health insurance, cantons also co-finance hospitals and nursing homes, which are mostly owned or controlled by the cantons and municipalities, and promote the prevention of disease. The responsibility for these tasks lies primarily with the cantonal and municipal departments of health (*cf*. also Interpharma, Swiss Healthcare and Pharmaceutical Market, 2017, p. 4).

Health insurance is regulated by the Swiss Federal Act on Health Insurance of 18 March 1994 ("**HIA**"; *Bundesgesetz über die Krankenversicherung, KVG*) and the Swiss Federal Act on the Supervision of Health Insurance of 26 September 2014 ("**SHIA**"; *Bundesgesetz betreffend die Aufsicht über die soziale Krankenversicherung, KVAG*) and various associated ordinances.

In principle, every person domiciled in Switzerland is mandatorily obliged to conclude basic health insurance within three months of moving to Switzerland or from the birth of a child (article 3 para. 1 HIA). Any such person may freely choose among insurers, which are authorised pursuant to the SHIA to offer basic health insurance (article 4 HIA). The SHIA defines insurers as legal entities organised pursuant to private or public law which do not pursue a profit-making purpose and offer basic health insurance. According to the FOPH, approximately 50 approved non-profit insurance providers currently offer basic mandatory insurance and optional daily allowance insurance.

The insurers offering compulsory health insurance must treat all insured persons equally. In particular, they are not permitted to decline a request for basic health insurance and must offer to all insured persons the same range of benefits. Insureds are free to change insurer by giving notice three months before the end of a calendar semester (article 7 para. 1 HIA).

The cantons are required to ensure compliance with compulsory insurance. If a person domiciled in Switzerland does not timely conclude a basic health insurance, the canton of its domicile must allocate such person to one of the insurers (article 6 HIA). Consequently, every resident in Switzerland has basic health insurance.

Compulsory health insurance reimburses the costs for the services of healthcare providers regarding diagnosis and treatment of diseases and their consequences (articles 25 para. 1 and 35 HIA). This includes all examinations and treatments carried out by doctors or physicians as well as chiropractors. Further services include, *inter alia*, laboratory analyses, therapeutic products, aids and equipment prescribed by medical doctors (article 25 para. 2 HIA). The aforementioned shows that the catalogue of services covered by compulsory health insurance is quite extensive (for further information, *cf.* "The compulsory health insurance system", a guide published by the FOPH, available under the following link: https://www.ezv.admin.ch; last visited on 21 May 2021).

In case of congenital diseases, basic health insurance pays the same costs as in the case of disease, if such costs are not covered by invalidity insurance (article 27 HIA). As regards accidents, the corresponding healthcare costs will be covered by basic health insurance, provided that no accident insurance is in place (articles 28 and 1a para. 2 lit. b HIA). Furthermore, healthcare costs related to maternity are also borne by health insurance (article 29 HIA).

In addition to compulsory basic health insurance, insurers may provide for supplementary health insurance. Such supplementary coverage may include additional services, such as, for example, homeopathy, and usually provides for more freedom with regard to the choice of doctor or hospital.

Compulsory health insurance is funded by the monthly premiums payable by the insured, the deductible, the insured's contribution to the costs of a hospital stay and public subsidies.

The tariffs for mandatory basic health insurance must be approved annually by the supervising authority, which is the FOPH (articles 16 and 56 of the SHIA). The monthly premiums payable by the insured persons are not dependent on the income of such insured, but they vary between the cantons and between the insurers. The amount of the premium depends on the deductible chosen by the insured: the higher the deductible, the lower the premium. As regards insured persons with low revenues – children and young adults – they often benefit from a reduction in premiums, guaranteeing that every resident in Switzerland is given access to affordable healthcare.

Incidence and prevalence of disease

Since 1992, the Federal Statistical Office ("**FSO**") conducts a public consultation every five

years regarding the health status of the population, health determinants, diseases and their consequences, the healthcare system, including the number of doctor appointments, and health insurance (the so-called Swiss Health Status Consultation). The sixth consultation took place in 2017, the results of which may be seen online under the following link: https://www.bfs.admin.ch (last visited on 21 May 2021).

According to the FSO, 84.7% of the overall population assess their health as being good or very good: at the age of 75 and older, 67.1% still assess their health as being good or very good; 32.7% of the population declare having a chronic health problem; 75.7% are sufficiently physically active; 27% smoke; 4% have consumed cannabis during the 30 days preceding the public consultation; and 10.9% drink alcohol on a daily basis (*cf*. https://www.admin.bfs.ch; visited last on 21 May 2021).

Persons taking medication in the course of the week preceding the FSO consultation further increased from 46.3% in 2007, to 48.6% in 2012, and to 50.3% in 2017. This means that half of people aged 15 years and over take at least one medicinal product per week in Switzerland. Further, the number of persons using alternative medicine is increasing. In 2017, 28.9% used alternative medicine in the course of the 12 months preceding the FSO consultation, compared to 24.7% in 2007. Generally speaking, more female than male, and more elderly than young people, take medicinal products, and far more females than males use alternative medicine (*cf*. https://www.admin.bfs.ch; last visited on 21 May 2021).

The hospitalisation ratio per 1,000 residents was 118.3 in 2019, while infant mortality stood at 3.3‰, in 2019 (*cf*. FSO, Health – Pocket Statistics 2020, available under the link: https://www.bfs.admin.ch; last visited on 21 May 2021).

2.2 million people living in Switzerland are affected by a non-communicable disease (cancer, cardiovascular diseases, chronic respiratory diseases, diabetes and diseases of the musculoskeletal system). This corresponds to a quarter of the Swiss population. A growing number of people living in Switzerland is affected by dementia as life expectancy increases (*cf*. Interpharma, Health Panorama 2020, p. 8). The most common causes of death in Switzerland are cardiovascular diseases (approx. 30.7% of the deaths in 2018) and cancer (approx. 25.9% of the deaths in 2018; for more details, *cf*. FSO, Health – Pocket Statistics 2020, available under the link: https://www.bfs.admin.ch; last visited on 21 May 2021). According to the Swiss Cancer Report 2015 published by the FSO, cancer has become a chronic illness. In 2015, 317,000 people in Switzerland were living with a cancer diagnosis. This is twice as many as 25 years ago. Every year, approximately 17,000 people living in Switzerland die from the consequences of cancer. Pursuant to said report, it is expected that around 40% of the Swiss population will be diagnosed with cancer at any point in their lifetime. The main reason for this increase is due to the fact that the population is getting older. However, in comparison to the other European countries, Swiss incidence rates are still average for men and even low for women, except for melanoma, which have 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 among the highest in Europe (*cf*. for more details, Swiss Cancer Report 2015 of the FSO, available under the link: https://www.bfs.admin.ch; last visited on 21 May 2021).

Pharmaceutical pricing and reimbursement

Regulatory classification

Pharmaceutical products are regulated in the Swiss Federal Act on Medicinal Products and Medical Devices of 15 December 2000 ("**TPA**"; *Bundesgesetz über Arzneimittel und Medizinprodukte, HMG*) and several ordinances. 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.

Pursuant to article 23 para. 1 of the TPA, therapeutic products are classified into categories according to whether (categories A and B) or not (category D) they are subject to prescription. Further, over-the-counter therapeutic products are classified into category E. More specifically, pursuant to articles 40 *et seqq*. of the Swiss Federal Ordinance on Medicinal Products of 21 September 2018 ("**OTP**"; *Verordnung über die Arzneimittel, VAM*), therapeutic products are classified as follows:

- single delivery prescription drugs (category A);
- prescription drugs that may be delivered several times with the same prescription (category B);
- non-prescription drugs that require previous consultation (category D); and
- non-prescription drugs that may be bought without further consultation (category E).

Previously, category C encompassed non-prescription drugs that required previous medical consultation. However, this category was abrogated at the end of 2018.

Irrespective of whether therapeutic products are subject to prescription or not and save for a few exceptions, they can only be brought to the market if authorised by Swissmedic. Any person applying for a marketing authorisation for a therapeutic product must have a registered address, registered office or a branch office in Switzerland. Swissmedic can impose restrictions and conditions to the marketing authorisation, such as the obligation to deliver further clinical-experimental data or other post-marketing obligations, the existence of which should be verified by due diligence.

The marketing authorisation is, in principle, valid for five years (article 16 para. 2 TPA). Swissmedic may at any time examine, adapt or revoke such marketing authorisation (article 16*c* TPA). On request, Swissmedic renews the authorisation if the requirements are still fulfilled (article 16*b* TPA). In principle, the renewed marketing authorisation is valid for an unlimited term. However, Swissmedic may put a time limit on it (article 16*b* TPA).

Who is/are the payer(s)?

In order to benefit from the reimbursement of therapeutic products by the compulsory health insurance, the respective products must be listed by the FOPH on the so-called specialty list (article 52 para. 1 lit. b HIA). The specialty list may be consulted online under the following link: https://www.spezialitätenliste.ch (last visited on 21 May 2021).

If a therapeutic product is more than 10% more expensive than a third of all therapeutic products listed on the specialty list with the same composition, the insured must pay 20% of the costs exceeding the deductible (article 38*a* of the Ordinance on the Benefits of the Mandatory Health Insurance of 29 September 1995 ["**OBHI**"]; *Verordnung des EDI über Leistungen in der obligatorischen Krankenpflegeversicherung, KLV*).

Furthermore, reimbursement may be obtained from invalidity insurance. Pursuant to article 13 para. 1 of the Federal Act on Invalidity Insurance of 19 June 1959 ("**IIA**"; *Bundesgesetz über die Invalidenversicherung, IVG*), insured persons are entitled up to the age of 20 to obtain the medical measures necessary to treat congenital diseases. Such medical measures include, *inter alia*, medical treatment and the dispensing of prescribed medicinal products (article 14 para. 1 IIA). The congenital diseases giving rise to such entitlement are listed in the Annex of the Ordinance on Congenital Diseases of 9 December 1985 ("**OCD**"; *Verordnung über Geburtsgebrechen, GgV*). In order to obtain funding from invalidity insurance, the insured person must file an application to the invalidity insurance.

Consequently, non-listed therapeutic products must be paid for by consumers themselves.

What is the process of securing reimbursement for new pharmaceutical product and how are drug prices set?

First of all, an application for a therapeutic product to be listed on the specialty list must be filed with the FOPH. In order to be listed thereon, a therapeutic product must be approved by Swissmedic and must satisfy the criteria of effectiveness, functionality and economic efficiency (article 65 para. 1 and 3 of the Ordinance on Health Insurance of 27 June 1995 ["**OHI**"]; *Verordnung über die Krankenversicherung, KVV*). Based on these criteria, the FOPH determines the maximum price for the therapeutic product in question. The approval process has been expedited and should not exceed 60 days from the date of the marketing authorisation (article 31*b* OBHI).

In order to assess the effectiveness of a therapeutic product, the FOPH relies in principle on the same documents which were used by the applicant for the approval of Swissmedic. However, the FOPH may demand that further documents are submitted (article 32 OBHI). As regards the criteria of functionality, the FOPH examines the impact and composition of the therapeutic product in question by taking into account clinical-pharmacological and galenic considerations, possible side effects and the risk of misuse (article 33 OBHI). Finally, a therapeutic product is deemed economically efficient if the indicated therapeutic effect is reached most cost-efficiently (article 65*b* OHI).

The FOPH bases the evaluation of a therapeutic product's economic efficiency on two aspects: on the one hand, on a comparison with the prices in foreign reference countries – which are Austria, Belgium, Denmark, Finland, France, Germany, Great Britain, Netherlands and Sweden (so-called *Auslandpreisvergleich*); and on the other hand, on an assessment with respect to other therapeutic products (so-called *therapeutischer Quervergleich*). As regards the comparison with other therapeutic products, the FOPH examines the efficiency and costs of the therapeutic product in question compared with other drugs used for the treatment of the same disease (article 65*b* OHI and articles 34*a et seqq.* OBHI).

The costs for research and development are taken into account for the examination of the economic effectiveness of a product, unless the original therapeutic product in question is a successor product that brings no therapeutic progress. Further, a so-called innovation supplement is granted for a maximum of 15 years for therapeutic products providing a significant therapeutic progress (article 65*b* paras 6 and 7 OHI).

The therapeutic products on the specialty list are re-examined every three years, as well as after the expiration of the patents in question. As a result of this re-examination, the FOPH may order a reduction of the price for the therapeutic product in question (article 65*d* and 65*e* OHI).

Policy issues that affect pricing and reimbursement

Population growth (growth in size of elderly population/growth in populations with chronic diseases)

Life expectancy in Switzerland is among the highest in the world. A newborn in 2019 is expected to reach the age of 81.7 (men) or 85.4 (women) (*cf.* https://www.bfs.admin.ch; last visited on 21 May 2021). According to a study conducted by the FSO, it is to be expected that the Swiss population will significantly and rapidly grow older. In particular, between 2020 and 2035, the baby boomer generation will reach retirement age (*cf.* Media Release of the FSO of 22 June 2015). Given that among the population over 80 years, 15.0% lived in retirement homes per 31 December 2019 and 29.2% needed care at home, and that the total costs of retirement homes alone amounted to 10.550 million Swiss francs in 2019 (*cf.*

FSO, Health – Pocket Statistics 2020, available under the link: https://www.bfs.admin.ch; last visited on 21 May 2021), the costs for healthcare will most presumably further rise.

As already discussed herein above, the most common causes of death in Switzerland are cardiovascular diseases and cancer (*cf.* above, "Incidence and prevalence of disease", in "Market introduction/overview"). Since the costs of certain therapeutic products for the treatment of cancer are very high, a further increase of healthcare costs is to be expected in this respect too.

The extremely high costs for the healthcare system and, in particular, the financing of these costs are currently a controversial political topic in Switzerland (*cf.* also above, "Size, demographics" in "Market introduction/overview"). Also, costs and benefits of very expensive treatments, in particular when carried out with regard to old persons, are debated increasingly vehemently.

Prohibition of benefits and kick-back

The Swiss legislation regarding integrity and transparency has recently been revised. The previous provision with respect thereto (article 33 TPA) has been abolished and replaced by two new provisions (article 55 TPA and article 56 TPA), which entered into force on 1 January 2020. Further, the HIA has been amended. The details are set forth in the new Ordinance on Transparency and Integrity of ("**OTI**"; *Verordnung über die Integrität und Transparenz im Heilmittelbereich, VITH*), which also entered into force on 1 January 2020.

Pursuant to article 55 TPA, it is prohibited for persons who prescribe, dispense, use or purchase for this purpose prescription-only medicinal products as well as for the organisations that employ them, to solicit, be promised or accept any undue advantage for themselves or for the benefit of a third party. Further, it is prohibited to offer, promise or grant an undue advantage to any such person or organisation for their benefit or for the benefit of a third party. Article 55 para. 2 TPA contains a list of contributions, which are not regarded as undue advantages. Those are (i) material benefits of modest value (300 Swiss francs per medical professional and year at maximum), which are of relevance for 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 for 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 kick-backs, the personal scope of application has been extended (for example, purchasers of medicinal products, such as members of medicines' commissions in hospitals, homes for elderly or nursing homes and purchasers of medicinal products for practitioners' networks are now covered). In contrast, the material scope of application has been reduced from all medicinal products to prescription-only medicines. However, with regard to the current medical device revision, 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 VITH, which is expected to enter into force in 2025 at the earliest.

In addition, for the purpose of transparency, according to article 56 TPA, all price discounts and rebates granted on purchases of medicinal products must be shown on the receipts and invoices and in the accounts of both the selling and the purchasing persons and organisations and must be reported and disclosed to the FOPH upon request. This obligation does not apply to remedies with a low risk potential, such as over-the-counter therapeutic products (category E) or classical medical devices of class I according to annex IX of the EU Directive 93/42/EEC on Medicinal Devices (e.g. plasters, thermometers or walking aids) available in the retail trade (article 10 OTI).

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

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

Emerging trends

As part of the master plan of the Confederation for strengthening biomedical research and technology, the TPA and the corresponding ordinances were revised. The revision aimed at improving the population's access to therapeutic products and the conditions for biomedical research and industry. Certain provisions entered into force on 1 January 2018, the remaining revision of the TPA and the corresponding ordinances entered into force on 1 January 2019 and 1 January 2020, respectively.

Further, Switzerland has adapted its legislation in view of the developments regarding medical devices and *in vitro* diagnostics in the EU. The new regulations regarding medical devices were originally scheduled to come into force on 26 May 2020. However, in connection with the COVID-19 pandemic, implementation of the Medical Devices Regulation ("**MDR**") in the EU was deferred by one year. As Switzerland wishes to achieve equivalence with the EU legislation, the entry into force of the revised Swiss medical device legislation were also deferred by one year, to 26 May 2021. With the coming into force of the new provisions, the transition of the EU regulations regarding medical devices into Swiss law has been completed. In a final step, *in vitro* diagnostic medical devices shall be regulated in a separate ordinance on *in vitro* diagnostics.

In parallel to the above-mentioned legislative projects regarding medical devices and *in vitro* diagnostics, the Agreement between the EU and Switzerland on mutual recognition in relation to conformity assessment ("**MRA**"), which aims at overcoming technical barriers to the trade of numerous industrial goods (including medical devices), shall be updated, to maintain facilitated reciprocal market access between Switzerland and the EU and to ensure joint implementation of the regulations. However, the EU Commission has made the update of the MRA conditional upon progress being made on the Institutional Agreement between the EU and Switzerland. As the negotiations on the Institutional Agreement have been closed end of May 2021 without success, the Federal Council has adopted supplementary provisions regarding the new medical device legislation, which also entered into force on 26 May 2021, in order to mitigate the negative consequences of the lack of an update of the MRA. The revision of the legislation will however be continued based on equivalent EU provisions, so that the MRA could still be updated within the next one to two years.

Successful market access

In our opinion, the following factors are key to successfully entering the Swiss national market:

- in-depth knowledge of the healthcare legislation in Switzerland;
- taking into account that for certain questions the cantons are competent and not the federal authorities;
- considering that most therapeutic products cannot simply be sold via supermarkets;
- rigorous documentation of the process from research to marketing;
- requests for authorisation in a timely manner and within the time limits; and
- high efficiency and quality.

Acknowledgment

The authors would like to thank Melanie Müller for her invaluable contribution to this chapter. Melanie Müller is an associate at the firm's Basel office. She is a member of the IP and IT team as well as the Life Sciences and Health Law team. She advises national and international companies as well as individuals on the full range of intellectual property matters, focusing primarily on trademarks, copyright and licensing.

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