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 has to 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 2016, healthcare costs amounted in total to 80.7 billion Swiss francs (an increase of 3.8% compared to 2015), of which approximately 13.2 billion was paid for healthcare goods, including therapeutic products in hospitals. Compared to the general domestic product (GDP), healthcare spending represented 12.2% in 2016 (an increase from 11.9% in 2015). Every resident in Switzerland paid on average 803 Swiss francs per month for the healthcare system in 2016 (*cf.* www.bfs.admin; last visited on 5 April 2019). The corresponding numbers for 2017 and 2018 are not yet available.

In 2018, the total value of goods and services exported from Switzerland amounted to 304 billion Swiss francs (provisional result), whereas the value of imported goods and services amounted to 273 billion Swiss francs (provisional result). A positive balance of 31 billion Swiss francs (provisional result) in favour of Switzerland resulted therefrom. The most important part of Switzerland's exports were chemical and pharmaceutical products, which constituted 34.3% of the exports (104 billion Swiss francs). Chemical and pharmaceutical products further constituted the second-largest group of imported products (18.4% of the imports, respectively 50 billion Swiss francs). It has to be noted that all numbers stated above are provisional results (*cf.* Key figures 2018, available under the following link: www.ezv.admin.ch; last visited on 5 April 2019).

According to the Association of research-based pharmaceutical companies in Switzerland (Interpharma), in 2017, reimbursable therapeutic products represented more than 84% (compared to 83% in 2016) of the total pharmaceutical market. This corresponds to 67% of all packs of therapeutic products sold in 2017 in Switzerland. Most of these reimbursable

therapeutic products' packs were prescription-only products. (*cf*. Interpharma, Pharmaceutical Market Switzerland, 2018, p.40).

Over 435,000 people in Switzerland worked in the healthcare industry and the pharmaceutical sector. This corresponds to approximately one in twelve of the working population (*cf*. Interpharma, Swiss Healthcare and Pharmaceutical Market, 2018, p.18).

In Switzerland there is a very high density of hospitals which offer a wide range of medical services. In 2017, 281 hospitals and maternity units (38,157 beds) and 1,561 homes for elderly and care (99,242 places) were registered in Switzerland (*cf*. www.admin.bfs.ch; last visited on 5 April 2019). The density of general practitioners is, however, relatively low compared to other countries. For a million inhabitants in Switzerland there are only 1,143 general practitioners. The same applies with respect to pharmacies, whose density is comparatively low, as in certain cantons doctors are allowed to dispense medicines themselves (*cf*. Interpharma, Swiss Healthcare and Pharmaceutical Market, 2018, p.18). Contrary to certain countries, such as the USA, most therapeutic products cannot be sold via supermarkets.

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*. 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 60 approved non-profit insurance providers currently offer basic mandatory insurance and optional loss of earnings insurance.

The insurers offering compulsory health insurances must treat all insured persons equally. In particular, they are not allowed 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 has to 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.

In case of congenital diseases, basic health insurance pays the same costs as in case of disease, if such costs are not covered by invalidity insurance (art. 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 have to 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 every five years a public consultation 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: www.bfs.admin.ch (last visited on 5 April 2019).

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.* www.admin.bfs.ch; visited last on 5 April 2019).

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.* www.admin.bfs.ch; last visited on 5 April 2019).

The hospitalisation ratio per 1,000 residents was 119.3.0, while infant mortality stood at 3.5‰, in 2017. The most common causes of death in Switzerland are cardiovascular diseases (approx. 32% of the deaths in 2016) and cancer (approx. 26% of the deaths in 2016). 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: www.bfs.admin.ch; last visited on 5 April 2019).

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 as per 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 16c TPA). On request, Swissmedic renews the authorisation if the requirements are still fulfilled (article 16b TPA). In principle, the renewed marketing authorisation is valid for an unlimited term. However, Swissmedic may put a time limit on it (article 16b 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: www.spezialitätenliste.ch (last visited on 5 April 2019).

If a therapeutic product is more than 20% more expensive than a third of all therapeutic products listed on the specialty list with the same composition, the insured has to pay 20% of the costs exceeding the deductible (article 38a 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 has to file an application to the invalidity insurance.

Consequently, non-listed therapeutic products have to 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 has to 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 recently been expedited and should not exceed 60 days from the date of marketing authorisation (article 31b 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, composition and possible side effects of the therapeutic product in question (article 33 OBHI). Finally, a therapeutic product is deemed economically efficient if the indicated therapeutic effect is reached most cost-efficiently (article 65b 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 Germany, Denmark, Great Britain, Netherlands, France, Austria, Belgium, Finland 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 65b OHI and articles 34a 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 65b para. 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 65d and 65e 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 2017 is expected to reach the age of 81.4 (men) or 85.4 (women). 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, 15.7% lived in retirement homes per 31 December 2017 and 28.1% needed care at home, and that the total costs of retirement homes alone amounted to 10.128 billion Swiss francs in 2017 (*cf.* www.bfs.admin.ch; last visited on 5 April 2019), 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 highly 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

Pursuant to article 33 TPA, it is prohibited to grant, offer or promise material benefits to persons who prescribe or dispense medicinal products, or to the organisations which employ them. Further, it is prohibited for persons who prescribe or dispense medicinal products as well as for the organisations which employ them, to solicit or accept material benefits. However, material benefits of modest value, which are related to medical or pharmaceutical practice, as well as commercially and economically justified discounts on the price, are permitted.

In the context of the current revision of the TPA (*cf*. below section "Emerging trends"), it is planned to further increase transparency and integrity with respect to therapeutic products (*cf*. below section "Emerging trends") by clarifying the legal provisions regarding pecuniary benefits and strengthening the implementation of these provisions.

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 entering into force of the new ordinance 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 are currently under revision. The revision aims at improving the population's access to therapeutic products and the conditions for biomedical research and industry. The Federal Council transferred the dispatch on the revision of the TPA to the Parliament on 7 November 2012, which accepted the core elements of the Federal Council's draft, amended part of it, and adopted the revised TPA on 18 March 2016.

Certain provisions have already entered into force on 1 January 2018. With regard to the remaining implementing provisions, a consultation process was conducted in 2017. Thereupon, most of the revised provisions of the TPA and the corresponding ordinances entered into force on 1 January 2019. However, as a result of the consultation process, the implementing provisions relating to integrity, transparency and the obligation to pass on discounts needed to be amended: the new ordinance on transparency and integrity in the context of therapeutic products will enter into force on 1 January 2020.

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.

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