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Switzerland: Law & Practice

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SWITZERLAND

Law and Practice

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CONTENTS

1. LIFE SCIENCES REGULATORY FRAMEWORK

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

In Switzerland, pharmaceutical products are essentially governed by the following statutes:

- the Federal Act on Medicinal Products and Medical Devices (also the Therapeutic Products Act, TPA);
- the Federal Law on Narcotics and Psychotropic substances (BetmG);
- the Ordinance on Pharmaceutical Products (VAM);
- the Ordinance on Advertising of Pharmaceutical Products (AWV);
- the Products Licensing Ordinance (MPLO).

The regulation of medical devices is based primarily on the Therapeutic Products Act and the Medical Devices Ordinance (MedDO).

The Swiss Agency for Therapeutic Products (Swissmedic) is the Swiss authority for the licensing and monitoring of therapeutic products. Swissmedic grants the marketing authorisations for medicinal products and the establishment licences to companies that manufacture or distribute medicinal products. Swissmedic also controls the flow of narcotics and monitors the blood transfusion services. Pharmacovigilance and market monitoring are duties also attributed to Swissmedic, as is the surveillance of medical products on the Swiss market. Furthermore, Swissmedic monitors clinical trials of medical devices that are not yet authorised for the market. Swissmedic is a federal public law institution and is autonomous with respect to its organisation and management and has its own budget.

The Federal Office of Public Health (FOPH) is responsible for public health in the country. The FOPH is responsible for establishing reimbursement prices by the health care insurances for both pharmaceutical products and medical devices. As a federal office, the FOPH qualifies as the highest administrative unit of the Swiss federal administration and is part of the Federal Department of Home Affairs.

1.2 Challenging Decisions of Regulatory Bodies that Enforce Pharmaceuticals and Medical Devices Regulation

Decisions of Swissmedic or of the FOPH related to pharmaceutical products, medical devices, food and leisure products can be challenged in front of the Federal Administrative Court (FAC). There is no requirement that appellants be represented by legal counsel. Appeals may be filed due to violation of federal law, including the exceeding or abuse of discretionary powers, if there has been an incorrect or incomplete determination of the legally relevant facts of the case, or if the decision rendered is inadequate. The addressees of the decision of Swissmedic and the FOPH may legitimately appeal. Also, third parties that are affected by the decision may qualify for appeal, provided they have a legitimate interest granted to them by law.

Fees are charged for proceedings before the FAC. If the successful party is to be awarded compensation, this compensation may be imposed on the lower instance or on an unsuccessful respondent.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Swiss law essentially distinguishes between prescription-only and non-prescription (over-the-counter – OTC) pharmaceutical products. Pharmaceutical products available on prescription cannot be advertised to the public and can only be delivered by healthcare professionals, such as doctors and/or pharmacists. Certain medical devices are intended for use by healthcare professionals only.

2. CLINICAL TRIALS

2.1 Regulation of Clinical Trials

The Federal Act on Research Involving Human Beings (also known as the Human Research Act, HRA) and the Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance: ClinO) are the relevant regulations covering clinical trials. In addition, there is a new ordinance for clinical trials with medical devices (Ordinance on Clinical Trials with Medical Devices: ClinO-MD).

Clinical trials of therapeutic products require advance authorisation by the competent ethics committee. Exempted from mandatory authorisation are clinical trials involving (i) authorised pharmaceuticals administered in accordance with the approved conditions of use, and (ii) compliant medical devices applied in accordance with the intended use specified in the conformity assessment.

With regard to pharmaceuticals, Swissmedic verifies whether good manufacturing practices and product safety requirements are met. With regard to medical devices, Swissmedic verifies compliance with safety requirements as well as technical standards and examines whether product risks are duly considered, as well as whether the product data is in line with current scientific knowledge and correctly indicated in the protocol.

The competent ethics committee examines whether the safety and health of clinical trial subjects are sufficiently ensured. It also verifies whether the research project and the conduct thereof comply with ethical, legal and scientific requirements. The ethics committees are organised on a cantonal basis; responsibility lies with the ethics committee of the canton in whose territory the research is conducted.

To be granted authorisation, clinical trials must comply with the rules of good clinical practice laid down for pharmaceuticals in the ICH Guideline on Good Clinical Practice of 9 November 2016 and the WMA Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

The applicable rules on good clinical practice in clinical trials with medical devices were incorporated into Swiss legislation by way of reference to Article 72 and Annex XV Chapters I and III of REGULATION (EU) 2017/745 on medical devices (MDR) as well as in EN ISO 14155.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

In order to secure authorisation to undertake a clinical trial of a pharmaceutical or medical device, the investigator or the sponsor must submit an application to the responsible ethics committee. The competent ethics committee shall acknowledge receipt of the application as regards a pharmaceutical within seven days and notify the investigator or the sponsor of any formal deficiencies in the application documents. It shall then reach a decision within 30 days and inform Swissmedic of its decision (if an authorisation by Swissmedic is also necessary). In the case of multi-centre trials, the time limit to reach a decision after acknowledgement of receipt is extended to 45 days. The deadlines in the case of a medical device are ten days for the acknowledgment and deficiencies' notification and 40 days for its decision-rendering. In the case of multi-centre trials for medical devices, the deadline is at 40 days.

The submission of the application to Swissmedic is made by the sponsor. Swissmedic shall acknowledge receipt of the application for pharmaceuticals within seven days, notify the sponsor of any formal deficiencies and reach

a decision within a time-limit of 30 days from acknowledgement of receipt. For medical devices, the time-limits are ten days for the acknowledgment and deficiencies notification and 45 days for its decision-rendering. The time-limit for decision-rendering, however, may be extended, respectively, for another 30 days if the pharmaceutical, or for another 20 days if the medical device, is being applied to human beings for the first time or if it is being manufactured in a new process. For clinical trials involving gene therapy, genetically modified or pathogenic organisms, Swissmedic must seek opinions from the Swiss Expert Committee for Biosafety (SECB), the Federal Office for the Environment (FOEN) and the FOPH before granting the authorisation. For clinical trials involving ionising radiation, Swissmedic must, in the case of category C trials, seek an opinion from the FOPH before granting authorisation.

If both the approvals of the ethics committee and of Swissmedic are required, the trial file may be submitted to the ethics committee and to Swissmedic simultaneously. The trial cannot start before the approvals of both authorities have been granted. Furthermore, significant changes to an authorised clinical trial have to be notified to and approved by the ethics committee and Swissmedic prior to their implementation.

2.3 Public Availability of the Conduct of a Clinical Trial

The website www.kofam.ch is the FOPH's portal for human research in Switzerland and provides public access to the Swiss National Clinical Trials Portal (SNCTP) clinical trials registry. The SNCTP portal displays trials submitted on the BASEC platform (ie, the platform used for submission of research projects to Swiss ethics committees) in real time as soon as approved by the ethics committee and released for publication by the researchers. The following are made publicly accessible: a brief description of the trial, the site(s) of the clinical trial, the criteria for participation in the trial, the researched disease category and the health condition investigated, as well as an indication of whether the trial includes rare diseases. Contact details for further questions and links (if any) to international primary registries, such as the World Health Organization (WHO) primary registry, are also indicated.

The results of clinical trials are generally not publicly available. Members of the FMH, the Swiss medical association are, however, bound by the ethical guidelines contained in the Declaration of Helsinki (2013). Consequently, members of the FMH are subject to a publication obligation, as the Declaration of Helsinki requests that results of research on humans be fully and correctly made public.

It should be further noted that Swiss law provides for the sponsor's mandatory obligation to record an authorised clinical trial either in a primary registry recognised by the WHO or in the registry of the US National Library of Medicine. Additionally, the data must be entered in the above-mentioned supplementary federal database SNCTP, using a Swiss national language. For medical devices, there is a duty to publish the trial's results in one of the above-mentioned international registries.

2.4 Restriction for Using Online Tools to Support Clinical Trials

Under Swiss law, there are no specific regulations or guidelines on the use of online tools (such as connected apps) to support clinical trials. Generally, the use of online and database tools may be limited by data protection considerations. Switzerland has not directly implemented the GDPR rules, but similar rules apply.

2.5 Use of Resulting Data from the Clinical Trials

Data from clinical trials are likely to be considered as sensitive personal data and are specifically protected. Prior informed consent by the data subjects is necessary for any collection and processing. In a clinical trial setting, data integrity and scientific integrity of patient data are also of the utmost importance.

Data protection requirements do not apply to anonymised, or at least pseudonymised, data to such an extent that the data subjects are no longer identifiable. Also, the purposes of processing and using personal data (eg, publication of that data) are limited to those specified in the information provided to the patients before starting the trial (ie, those that are covered by the patient's informed consent). In late 2018, the Swiss Ethics Committee laid down the further procedure regarding the applicability of the general data protection regulation (GDPR) to human research in Switzerland. In principle, it can be assumed that the principle of equivalence of Swiss law and the EU regulation applies and that patients in Switzerland do not need to be additionally and newly informed about the European data protection rights.

Transferring of non-anonymised sensitive personal data obtained during a clinical trial to a third party or an affiliate is permitted only with the subject's initial prior written consent.

2.6 Databases Containing Personal or Sensitive Data

Any patient databases must comply fully with the data protection regulations under the HRA as well as under the Federal Act on Data Protection (FADP). The storing of health-related personal data for research purposes requires in particular the taking of appropriate technical and organisational measures to prevent unauthorised use thereof, and must fulfil the operational and professional requirements. Since 2016, the Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks has complemented the Declaration of Helsinki.

3. MARKETING AUTHORISATIONS FOR PHARMACEUTICAL OR MEDICAL DEVICES

3.1 Product Classification: Pharmaceutical or Medical Devices

According to the TPA, a pharmaceutical is a product of chemical or biological origin, which is intended to have or is presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps. Also, blood products are by law considered medicinal products. In contrast thereto, medical devices are products – including instruments, apparatus, equipment, in vitro diagnostics, software, implants, reagents, materials and other goods or substances – that are intended to have or are presented as having a medical use and the principal effect of which is not obtained with a pharmaceutical. Thus, the distinctive criterion is the effect of the product on the human organism. Whereas a pharmaceutical has a pharmacologic, immunological, or metabolic effect on the organism, the medical device affects the human body physically.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biologic medicinal products have to pass the ordinary procedure for the granting of a marketing authorisation and need to fulfil the general requirements for the granting of a marketing authorisation. However, under specific circumstances, Swissmedic may grant certain easements on the documentation and proof requirements.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

The marketing authorisation (MA) is issued for the first time for a period of five years. Prior to the initial period's lapse (ie, one year to six months prior to its expiry), the MA-holder is required to file an application for a renewal. The renewal is usually issued for an unlimited period of time. The authorisation of medicinal products on the basis of a notification, ie, complementary medicines without indications and medicinal products with low risk, is valid for an unlimited period.

A "sunset clause" provides for a withdrawal of the marketing authorisation by Swissmedic if the authorisation-holder failed to place the pharmaceutical product on the market within three years from the grant of marketing authorisation or if the product is not marketed for three consecutive years. This three-year period starts only upon expiry of patent protection. In addition, pharmaceuticals authorised in connection with an emergency situation and pharmaceuticals for export only are not subject to the sunset clause.

Swissmedic has the right to withdraw, vary, or suspend a pharmaceutical's marketing authorisation after review, at any time, should the legal requirements for the marketing authorisation – ie, safety, quality, and efficacy – no longer be met.

Swissmedic does not have corresponding rights for medical devices, as it does not grant the respective marketing authorisations.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

Depending on the pharmaceutical product's characteristics and application field, the (i) ordinary, (ii) the simplified or the (iii) fast-track procedure applies for receiving marketing authorisation.

During all procedures, the applicant has to prove that the pharmaceutical in question is of high quality, safe, and effective. The documentation provided must comply with the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). In addition, the applicant must be the holder of a manufacturing, import, or wholesale licence and is required to have a registered address, office, or branch in Switzerland. However, the documentation to be submitted during a simplified procedure is more limited than in an ordinary procedure, as Swissmedic will take into consideration the reference product's files and only require additional documentation in so far as the applicant's pharmaceutical deviates from the reference product.

The fast-track procedure provides for shorter processing times, enabling receipt of the authorisation in approximately four months. In general, an ordinary authorisation procedure lasts for more than one year.

The ordinary procedure for obtaining the first marketing authorisation for pharmaceuticals follows the following steps; after the filing of the application, Swissmedic controls the dossier in respect of its compliance with formal (and, for electronic submissions, technical) aspects and its completeness. As a next step, the case managers and reviewers will evaluate the request and may draft a list of questions related to the content, which is forwarded to the applicant for reply. The answers are subsequently reviewed in terms of content and a preliminary decision is issued and communicated to the applicant. After an approving preliminary decision, the applicant submits revised product information and packaging element texts. Upon completion of necessary revisions and meeting of any additional

requirements communicated to the applicant, Swissmedic will issue its official decision and communicate it to the applicant.

Any variation of a marketing authorisation must be notified to Swissmedic and any substantial variation requires an additional marketing-authorisation procedure. Variations also trigger administrative fees. Their implementation deadlines depend on the variation type and can vary from 30 days up to one year.

A transfer of a marketing authorisation is permitted. The prospective MA-holder has to apply for the transfer with Swissmedic at least three months prior to the intended transfer and must meet all the requirements any marketing authorisation-holder has to meet.

The marketing of medical devices is not subject to the grant of prior authorisation by Swissmedic or any other public authority. Depending on their classification, medical devices have to undergo compliance assessment and certification. Additionally, the marketing of certain medical devices must be notified to Swissmedic prior to the start of marketing.

3.5 Access to Pharmaceutical and Medical Devices without Marketing Authorisations

There are limited circumstances under which pharmaceuticals not authorised by Swissmedic may be supplied to patients. Such limited circumstances include pharmaceuticals that:

- are supplied within clinical trials;
- cannot be standardised;
- are prepared according to a doctor's prescription or on a small industrial scale by a public pharmacy or a hospital pharmacy;
- are non-prescription pharmaceuticals prepared as required or on a small industrial scale by a public pharmacy, a hospital pharmacy, a drugstore or by another establishment holding a manufacturing licence;
- are proven to have no authorised or available alternative medicinal product;
- are pharmaceuticals imported by the patient in small quantities for their personal use.

Within patient-named programmes, pharmaceuticals with no marketing authorisation for Switzerland can be imported for an individual patient by healthcare professionals with a special Swissmedic permission.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Pharmacovigilance obligations, related to the detection, assessment, understanding and prevention of adverse effects, particularly long-term and short-term side effects, apply to all authorised pharmaceutical products.

Additional pharmacovigilance measures include the submission of yearly periodic safety update reports during the first five years of the marketing of a pharmaceutical with a new active ingredient. Swissmedic may impose additional conditions or obligations with its marketing authorisation grant. Such measures have to be adequate and proportionate and may include the further product evaluation (eg, in Phase IV clinical trials).

Although Switzerland does not issue marketing authorisations for medical devices, a company placing medical devices on the market has to introduce and maintain a pre- and post-market surveillance system for the collection and analysis of the experiences with the medical devices. Incidents involving medical devices that are classed as serious and occur in Switzerland must be reported to Swissmedic (materiovigilance/technovigilance). Problems with medical devices may require the manufacturer to recall devices or implement other safety measures.

Such safety measures and recalls are covered by the Field Safety Corrective Actions (FSCAs). Any manufacturer or distributor has to report a significant increase in the incident rate (reportable and non-reportable incidents) and any corrective actions to Swissmedic. Also, for medical devices in classes IIa, IIb, and III, the manufacturer needs regularly to provide a Periodic Safety Update Report to its notified body.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

Third parties cannot access any information, other than the fact that an application has been submitted, about pending applications for marketing authorisations of pharmaceuticals, as they are treated with total secrecy. The granting of a marketing authorisation, together with essential information about the pharmaceutical, is published in the monthly Swissmedic Journal. The detailed product information approved by Swissmedic is also available online (www.swissmedicinfo.ch). Moreover, Swissmedic publishes an assessment report (SwissPAR) for all pharmaceuticals with a new active pharmaceutical ingredient (API), as well as for transplant products, for which a decision to approve or reject authorisation has been issued. It also publishes a supplementary report for approved or rejected applications relating to additional indications for human medicinal products for which a SwissPAR has been published following the new authorisation. The SwissPAR includes the evaluation results of the application for a new authorisation or additional indication of a human medicinal product, but not the applicant's commercial or manufacturing secrets or personal data.

When it comes to medical devices, the compliance assessment and certification by Swiss conformity assessment bodies or European bodies (Notified Bodies) are not accessible for third parties during the assessment. When the conformity assessment procedure is completed, the manufacturer issues the declaration of conformity for the respective product attesting the compliance with the requirements with the applicable Swiss and EU requirements for medical devices and the standards and test methods used.

Based on the Swiss Federal Act on Freedom of Information in the Administration, any person has the right to inspect official documents and to obtain information about the content of those official documents. Limits to this right of access apply for documents of pending administrative proceedings, business secrets, or personal data.

3.8 Rules against Illegal Medicines and/or Medical Devices

Besides the measures against falsified or illegally distributed pharmaceuticals and medical devices available under intellectual property laws, the TPA provides for criminal sanctions (ie, fines or imprisonment) for the manufacturing, distribution, and import/export of pharmaceuticals without the necessary authorisation, as well as for the placing of non-compliant medical devices on the market.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

Swiss law provides for an application to the customs authorities to hold back shipments of pharmaceuticals and medical devices at the border or in a customs warehouse if an infringement of patent and trade-mark laws or unfair competition activities is suspected.

4. MANUFACTURING OF PHARMACEUTICAL AND MEDICAL DEVICES

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Manufacturing facilities for pharmaceuticals are subject to a mandatory establishment licence. Swissmedic grants such a licence upon compliance with the requirements set out in the Medicinal Products Licensing Ordinance and on the basis of a successful inspection. The establishment licence is limited to the specific field of activity of the manufacturing plant – ie, if a manufacturer produces only pharmaceutical ingredients, this will be specified in the authorisation. Other activities such as import, export, trade, etc, are not automatically covered by the establishment licence and require an additional authorisation. The establishment licence is valid for an unlimited period of time. However, Swissmedic performs periodic inspections to verify compliance with the requirements and can revoke granted licences if the requirements are no longer met.

Manufacturing plants of medical devices do not undergo an official Swiss authorisation or licensing procedure. For these devices, Switzerland has taken over the European Union's system of compliance assessment and certification. This can also include an inspection of the manufacturing plant.

5. DISTRIBUTION OF PHARMACEUTICAL AND MEDICAL DEVICES

5.1 Wholesale of Pharmaceutical and Medical Devices

Wholesale of pharmaceuticals is subject to a licence granted by Swissmedic. The applicant must comply with the requirements of the Medicinal Products Licensing Ordinance, such as having a quality-assurance system and a documentation system in place, as well as having appointed a responsible person (VP). Additional requirements apply to the release of ready-to-use pharmaceuticals to the market (authorisation for batch release). The authorisation process includes an inspection, during which it is verified that all prerequisites set out in the application form are complied with. The authorisation names the responsible person, the authorised activities (eg, wholesale authorisation with or without batch-release) and the operating site. The authorisation is valid for an unlimited period of time, subject to periodic reviews.

Currently, no authorisation is required for the wholesale of medical devices. However, each foreign manufacturer's products may only be placed on the Swiss market if the manufacturer has appointed an authorised representative domiciled in Switzerland. Also, since May 2021, certain registration duties with Swissmedic apply for both manufacturers and importers domiciled in Switzerland, as well as the authorised representative of a foreign manufacturer. Upon registration, they are granted a unique identification number, the so-called Swiss Single Registration Number (CHRN).

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are divided into the following supply categories:

- A – supply once with a prescription from a doctor or veterinarian;
- B – supply with a prescription from a doctor or veterinarian – pharmacists are also able to supply certain medicinal products of the supply category B to patients who do not have a prescription;
- D – supply on the advice of a specialist;

- E – supply in the absence of the advice of a specialist.

6. IMPORTATION AND EXPORTATION OF PHARMACEUTICALS AND MEDICAL DEVICES

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The relevant government entity in charge of applying and enforcing import regulations is the Federal Customs Administration and its regional offices; for medical devices and pharmaceuticals, Swissmedic is the market surveillance authority.

6.2 Importer of Record of Pharmaceutical and Medical Devices

The importer of pharmaceuticals must be a holder of an import licence, which licence is issued by Swissmedic after assessment of regulatory requirements. The applicant must comply with the requirements of the Medicinal Products Licensing Ordinance, such as having a quality assurance and a documentation system in place, as well as having appointed a responsible person (VP). Imports by a qualified healthcare professional are also permitted under restrictive conditions. Moreover, private persons, without any recording obligations, can import small doses of pharmaceuticals for private use only.

For the import of medical devices, the importer, who must be domiciled in Switzerland, needs to be registered with Swissmedic.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

As a rule, pharmaceuticals to be imported must have obtained a Swiss marketing authorisation, and medical devices must have obtained CE marking. Otherwise, imports may be blocked by the customs authorities, unless they have been prescribed by an HCP and are imported in small doses for private personal use.

6.4 Non-tariff Regulations and Restrictions Imposed upon Importation

Non-tariff restrictions are set forth in the Swiss customs tariff. The entries in the relevant Harmonised Tariff Schedule (HTS) line will determine which market surveillance authority is competent to examine and approve import. The product-related laws and implementing ordinances set out the restrictions in detail.

6.5 Trade Blocs and Free Trade Agreements

Switzerland is a member of the European Free Trade Association (EFTA) and is party to numerous free trade agreements, which provide for cross-border trade facilitation. Most important is the free trade agreement with the EU and the Agreement on Technical Barriers to Trade, which also deals with pharmaceuticals (market release) and mutual recognition of CE markings for medical devices. However, for political reasons in the context of Switzerland's relationship with the EU, the necessary updates of the relevant mutual recognition agreement for medical devices following the entry into force of the MDR are still pending. Hence, trade between Switzerland and the EU, in particular, for medical devices has become more burdensome since mid-2021.

7. PHARMACEUTICAL AND MEDICAL DEVICE PRICING AND REIMBURSEMENT

7.1 Price Control for Pharmaceuticals and Medical Devices

Prices for pharmaceutical products that are reimbursed under the compulsory health insurance are subject to price control by the FOPH. The compulsory health insurance covers, in general, only ready-to-use pharmaceuticals that are included in the FOPH's list of reimbursable pharmaceutical specialties (the Specialties List, SL). Additionally, pharmaceutical products that are manufactured in a pharmacy are only reimbursed if their active substances and ingredients are included in the list of active substances and other ingredients (the List of Medicines with Tariff, LMT).

The SL determines the ex-factory price and the public price, which is the maximum amount (including VAT) that must be reimbursed by health insurers under the compulsory health insurance. Wholesalers and retailers (pharmacies, hospitals and self-dispensing doctors) are free to allocate the margin between the ex-factory and the public price.

Prices for medical devices are not fixed by governmental authorities. However, the so-called List of Instruments and Tools (LIT) from the Federal Department of Home Affairs (FDHA) determines the maximum amounts (including VAT) which are reimbursed under the compulsory health insurance for certain types of medical devices that are directly applied by the patients themselves or by another layperson. In contrast to the SL, the LIT does not determine the maximum amount for a specific medical device of a certain brand, but only the maximum reimbursement amount for the same type of medical devices. Additionally, the LIT does not stipulate an ex-factory price.

Prices for pharmaceuticals and medical devices that are not reimbursed by the compulsory health insurance are not controlled. Manufacturers, wholesalers, and retailers are free to set their prices.

The requirements for listing pharmaceuticals and medical devices are primarily embodied in the Health Care Ordinance (KVV) and the Health Care Benefits Ordinance (KLV).

The authorisation-holder must submit an application to the FOPH to have a pharmaceutical product included in the SL. In the ordinary admission procedure, the FOPH decides after consultation with the Federal Drugs Commission (EAK). A simplified procedure without consultation of the FPC, which lasts only around seven weeks, is applied to certain pharmaceutical products (such as generics, co-marketing products or new galenic forms or package sizes of already listed products).

Pharmaceuticals are only included in the SL if they already have a marketing authorisation by Swissmedic and if they are effective, useful, and economically efficient. The FOPH reviews every three years whether the listed products still fulfil these requirements. In addition, a review takes place when the patent protection expires and in the case that Swissmedic authorises another indication.

There is no equivalent listing procedure as for medical products. However, every person may request an addition, change, or delisting of a certain position of the LIT to the FDHA, which decides upon consultation of the Federal Commission for Analyses, Instruments and Tools (FCAIT). The types of medical devices included in the LIT must also meet the requirements of effectiveness, usefulness, and economic efficiency. A position of the LIT is only reviewed upon request and no regular review applies.

7.2 Price Levels of Pharmaceutical or Medical Devices

The price level of the same products in foreign countries is considered by the FOPH when determining the reimbursement price of the pharmaceuticals for Switzerland. The price comparison abroad (APV) is carried out according to the recommendations of the Swiss Federal Drugs Commission (EAK). The price comparison with foreign countries takes into account countries that are economically comparable with Switzerland in the pharmaceutical sector. Currently, Denmark, Germany, The Netherlands, the United Kingdom, Austria, France, Sweden, Belgium, and Finland are included as reference countries.

7.3 Pharmaceuticals and Medical Devices: Reimbursement from Public Funds

Health insurers are, under the compulsory health insurance, obliged to reimburse pharmaceuticals that are listed in the SL or ALT and prescribed by a physician. The reimbursement of listed products may be restricted to certain medical indications, specified quantities, or durations.

The costs of pharmaceuticals which are not listed in the SL, or which are listed but used outside the approved indications (off-label use) or specific quantities (off-limitation use), are not reimbursed under the compulsory health insurance. In individual cases, these costs are reimbursed if one of the following conditions is met:

- if there are no effective and authorised therapeutic alternatives to treat an illness that may be fatal or cause serious chronic harm and the pharmaceutical in question is expected to have a substantial beneficial effect; or
- if the pharmaceutical is an indispensable precondition for another treatment which must be reimbursed under the compulsory health insurance.

The health insurer has to consult its independent medical adviser and decide within approximately two weeks whether the conditions for reimbursement are met. The health insurer reviews thereby whether the costs are within a reasonable therapeutic benefit. It will then decide in consultation with the authorisation-holder of the pharmaceutical on the reimbursable price, which may not exceed the price specified in the SL (if listed).

Medical devices applied by the patient himself or herself are reimbursed under the compulsory health insurance if they correspond with a certain type of medical devices defined in the LIT, are prescribed by a physician and are dispensed by an authorised provider. The reimbursement of listed medical devices may be restricted to certain medical indications, specified quantities, or durations. The reimbursement under the compulsory health insurance of medical devices that are applied or implanted by healthcare professionals (irrespective of whether they are listed in the LIT) is stipulated in tariff agreements between healthcare professionals and health insurers.

If the costs of pharmaceutical products or medical devices are not reimbursed by the compulsory health insurance, they might be covered by an additional voluntary health insurance.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The FOPH systematically and regularly re-evaluates medical services and products that are reimbursed under the compulsory health insurance.

Before a pharmaceutical is included in the SL, a safety, efficacy and quality assessment must take place. Moreover, the FOPH determines where the prescription of the pharmaceutical is economical. In its decision, the FOPH also considers the prices in foreign countries. Phar-

maceuticals that no longer meet the economic criteria are removed from the SL by the FOPH.

Three years after admission to the SL, each pharmaceutical is subject to a new price review by the FOPH. Besides a therapeutic cross-comparison, a price comparison with the prices in foreign countries, indication extensions and patent expiry are also considered for the establishment of the price.

Since 2015, the FOPH has also conducted Health Technology Assessments (HTA), a programme which is currently being expanded. The programme focuses not only on pharmaceuticals, but also on medical technologies, with the aim of removing potentially obsolete technologies paid under compulsory health insurance from the catalogue of benefits or limiting insurers' liability to pay them (disinvestment).

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

In general, physicians are free to prescribe any authorised pharmaceutical without regard to its price, provided there is a medical indication for it. However, if the physician prescribes a pharmaceutical which is not included in the SL, or which is listed but used outside the approved medical indications (off-label use) or specific quantities (off-limitation use), he or she must inform the patient that the costs might not be reimbursed under the compulsory health insurance.

Physicians are not obliged to prescribe cheaper generics instead of the original product. However, if the SL contains different pharmaceutical products with the same active substance, the cost share that a patient has to bear under the compulsory health insurance may be different. Normally, a patient has to bear a cost share for pharmaceuticals of 10% of the costs in excess of the annual deductible amount. For original, co-marketing or even generic products that are more than 10% more expensive than the average ex-factory price of the cheapest one third of the comparable pharmaceuticals listed in the SL, a higher cost share of 20% applies. Physicians must inform the patient accordingly.

Pharmacists have the right, but are not obliged, to substitute a prescribed original pharmaceutical with a generic unless the physician expressly requests prescription of the original. In the case of substitution, the pharmacist must inform the physician. In certain cantons of Switzerland, physicians are allowed to dispense pharmaceutical products directly to their patients (ie, self-dispensation).

8. DIGITAL HEALTHCARE

8.1 Rules for Medical Apps

Depending on their purpose, medical apps may be considered as medical devices. This applies to all medical apps serving to diagnose, prevent or treat illnesses, injuries or disabilities. Medical devices in the field of fitness or nutrition counselling do not qualify as medical devices in so far as they do not have therapeutic purposes. Also, apps providing for medical information only, such as medical dictionaries, are not considered as medical devices. All medical apps considered as medical devices have to comply with the general prerequisites for medical devices.

8.2 Rules for Telemedicine

There are currently no specific and separate rules for telemedicine in Switzerland. The general provisions applicable to the services offered by physicians apply also to telemedicine. Provided that the physician can comply with his or her duties of care, he or she may provide medical attention through a mobile device. Many compulsory health insurances offer telemedicine, in an effort to reduce the insurance fees. If subscribed, a patient having a medical issue must first contact

the insurance's telemedicine department, which then decides whether the patient should see a physician in his or her office.

8.3 Promoting and/or Advertising on an Online Platform

The general rules applicable to:

- the promotion of medicines and medical devices;
- the promotion of healthcare professionals; and
- advertisement via online channels,

are to be complied with, as there are currently no special Swiss rules in place for the promotion and/or advertising of medicines and medical devices through online portals, company webpages and social networks.

8.4 Electronic Prescriptions

Rules on electronic prescription are part of the regulation on the electronic patient record. Thus, in accordance with those rules, electronic prescription is allowed.

8.5 Online Sales of Medicines and Medical Devices

In principle, online sales of medicines, in the sense of mail-order trade, are prohibited. Under very restricted circumstances, however, mail-order trade may be permitted; any such permitted online sale requires at least a doctor's prescription for the medicine, irrespective of the status of the medicine as a prescription-only product. Hence, a prescription is also necessary for medicines that in general would not require a prescription (ie, OTC products) when bought in a regular dispensing pharmacy.

Online sales of medical devices are only permitted where:

- the relevant medical device is classified as a product for the public (ie, a medical device that is intended either for direct dispensing to the public or for direct use by the public); and
- the manufacturer has designated the product suitable for self-service dispensing.

8.6 Electronic Health Records

The Federal Law on the Electronic Patient Record provides the legal framework for the set-up of and access to electronic health records, as well as the certification for providers of electronic patient records.

Data on health-related issues are statutorily defined as sensitive personal data, to which stricter rules apply. These stricter rules require the data controller to inform the person concerned about the collection of sensitive personal data, disclosure of sensitive data to third parties only with justification, as well as specific notification and registration obligations with the Federal Data Protection and Information Commissioner (FDPIC).

General provisions of the Swiss Data Protection Act (DPA) have to be complied with; for example, data subjects must be informed transparently about the data processing in the cloud and implementation of the necessary security and organisational measures is required. Swiss law qualifies the transfer and processing of personal data in the cloud as data processing outsourcing, which requires a written data-processing agreement between the data controller and the cloud-provider.

It is permitted to transfer and store a patient's sensitive data in cloud platforms. However, the more confidential or sensitive the data is, the more cautious the FDPIC recommends one

should be with the use of cloud computing, in particular with regard to a cloud storage system with servers located abroad. Therefore, security measures and their control should be all the more stringent and comprehensive. The Swiss Medical Association (FMH) does recommend that doctors do not store medical information in clouds located abroad.

9. PATENTS RELATING TO PHARMACEUTICALS AND MEDICAL DEVICES

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The Federal Act on Patents for Inventions (PatA) sets forth the requirements for the granting of patents for new inventions applicable in the industry. Pharmaceutical active substances and technical processes integrated in medical devices can be patented. Not patentable are naturally occurring gene sequences, as well as processing for human cloning or for modifying the germline genetic identity of human beings. Also excluded from patentability are methods for treatment by surgery or therapy and diagnostic methods.

9.2 Second and Subsequent Medical Uses

Any pharmaceutical substance or composition that forms part of the current state-of-the-art is deemed to be new, provided it is intended solely for such use (first medical use) and can be patented. Subsequent medical uses of known pharmaceutical substances can also be patented.

The following medical uses are considered to be patentable through Swiss national patents:

- new therapeutic application (in general);
- the treatment of a new indication;
- a new therapeutic application based on the group of subjects to be treated;
- a new therapeutic application based on a different mode of administration;
- a new therapeutic application based on a dosage regimen; and
- a new therapeutic application based on a different technical effect (Swiss-type claims – ie, claims directed to the use of a substance for the manufacture of the pharmaceutical products for a therapeutic indication).

European patents with protection in Switzerland can protect purpose-limited – ie, new use of X for the manufacture of a medicament for the treatment of Y – and Swiss-type claim formats. Patent protection is not available for method of treatment claims, either through Swiss national patents or European patents.

The manufacturing and/or the marketing of the pharmaceutical product with label instructions which describe the patented use can result in an infringement of a second or subsequent granted patent. A patent is not considered directly to infringe a Swiss-type or a purpose-limited product claim (private-use exemption). Also, use of a non-patented substance in the research related to a patented second medical use is exempt from infringement (research and experimental-use exemption). A physician prescribing, or a pharmacist dispensing a product, for the patented use is not directly infringing a second medical-use patent claim (medical-practice exemption). Accordingly, the manufacturing and or the marketing of a pharmaceutical product with label instructions that do not describe the patented use does not result in a contributory patent infringement (ie, cross-label use).

9.3 Patent Term Extension for Pharmaceuticals

Supplementary protection certificates (SPCs), extending the term of protection for medicinal

and plant protection products, are available. The SPC is valid as from the expiry of the maximum term of the patent for a period corresponding to the time between the application date and the date of first approval for marketing the product in Switzerland. It is valid for a maximum of five years. Requirements for an SPC grant are: (i) a valid granted patent and a valid marketing authorisation for the Swiss market, (ii) the filing of a SPC request within six months of the delivery of the patent or of the marketing authorisation grant. Special rules have been introduced for paediatric extensions.

SPCs can be challenged by a third party. As of June 2018, the Swiss Supreme Court has aligned its jurisprudence with the EU courts and now applies the so-called disclosure test, according to which an assessment must also be made of whether the product itself is disclosed in the claims of the basic patent.

9.4 Pharmaceutical or Medical Device Patent Infringement

Liability under civil and criminal law applies to:

- any person who uses a patented invention unlawfully (imitation is also deemed to constitute use);
- any person who refuses to notify the authority concerned of the origin and quantity of products in his or her possession which are unlawfully manufactured or placed on the market, and to name the recipients and disclose the extent of any distribution to commercial and industrial customers; and
- any person who removes the patent mark from products or their packaging without authorisation from the proprietor of the patent or the licensee.

Applications for marketing authorisation of pharmaceuticals and for SL listing, as well as the filing of samples in such proceedings, are not considered to result in patent infringements.

Any person who is threatened with a patent infringement may demand an injunction or that the unlawful situation be remedied by interim civil actions. In this respect, the harm must be imminent – ie, the infringement cannot be remedied within ordinary proceedings. The applicant has to show credibly that:

- his or her patent rights have been violated or a violation is anticipated; and
- the violation threatens to cause harm to the applicant that is not easily reparable.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Research and experimental-use exceptions are recognised under Swiss patent law and apply to both pharmaceuticals and medical devices. These exceptions cover all experiments carried out in view of a request for a marketing authorisation for pharmaceuticals, such as pre-clinical and clinical testing, production, import and storage of samples and validation batches for the purpose of registration (the Bolar exception), except stockpiling.

Compulsory licences are available if they are in the public interest and in the event that a patentee declines to grant a licence without plausible reasons. A licence of right can be obtained for semi-conductors, research tools, for diagnostic tools and for the export of pharmaceutical products. The proprietor of the patent has the right to appropriate remuneration.

9.6 Proceedings for Patent Infringement

Civil action against the infringement of patent rights includes (i) actions for injunction or remedy and (ii) actions for damages. These actions are available to the patent-holder and the exclu-

sive licensees. Actions for injunction or remedy can also be requested as preliminary measures. The Federal Patent Court rules on civil law disputes concerning patents (patent validity as well as patent infringement) in first instance and the Federal Supreme Court as second instance. Civil actions that have a factual connection to patents, in particular concerning the contractual rights to patents (ownership and licensing) or their assignment, can also be filed with the sole cantonal civil instances. Penal proceedings need to be filed with the competent cantonal penal authorities.

Within patent-infringement proceedings, the defendant may plead the nullity of the patent as a defence or as a counterclaim. The court may then allow him or her an appropriate time limit within which to file a nullity action. Within interim measures' proceedings, the court will examine the patent with regard to novelty and inventive step as a preliminary question and then decide about the infringement claim.

9.7 Procedures Available to a Generic Entrant

A generic entrant with a proven interest can claim the nullity or partial nullity of a patent. Declaratory action is not a requirement for generic products to enter the Swiss market; in principle, a market authorisation and even a listing in the SL can be requested and validly granted to pharmaceuticals before the expiry of the patent/SPC protecting original products, as these authorisation procedures do not result in a patent infringement.

10. IP OTHER THAN PATENTS

10.1 Counterfeit Pharmaceuticals and Medical Devices

Swiss legislation on counterfeiting directly applies to pharmaceuticals and medical devices, such as the Patent Act (PA) regarding the counterfeiting of patents, under the Trademark Protection Act (TmPA) regarding the counterfeiting of trade marks, as well as under the Swiss Federal Act against Unfair Competition (AUC), which prohibits the false and misleading declaration of goods. Furthermore, the Swiss Criminal Code (SCC) sanctions the counterfeiting of goods in general.

The most effective means of combating counterfeiting are the strict approval procedures and the criminal sanctions for the distribution of non-authorised medicinal products under the TPA. The holding back of shipments by custom authorities at the border or in a customs warehouse is also very effective. Switzerland also agreed to implement the Medicrime Convention of the Council of Europe, aiming at the prevention of counterfeiting medical products.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Trade marks for pharmaceuticals and medical devices are subject to the general restrictions as set out in the TmPA. Excluded from trade-mark protection are:

- signs that are in the public domain;
- shapes that constitute the nature of the goods themselves, or shapes of goods or their packaging that are technically necessary;
- misleading signs;
- signs contrary to public policy, morality or applicable law; or

- signs that are identical or similar to an earlier trade mark and intended for the same or for similar goods or services, such that a likelihood of confusion results.

Consequently, the names of globally recognised pharmaceutical substances or ingredients (INNs) are deemed to be public property and may not enjoy Swiss trade-mark protection.

The principle of international exhaustion applies and parallel imports of pharmaceuticals or medical devices into Switzerland cannot be restricted based on the TmPA. It should be noted that the parallel import of pharmaceuticals protected by patents, and for which prices are fixed by the regulatory authorities on the SL, can be blocked, based on the PA.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The Design Act protects the design of products or parts of products, including the trade dress and design of pharmaceuticals and medical devices or their packaging.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

If a medicinal product is submitted with one or more known active substances, the corresponding documentation on new indications, modes of administration, dosage forms or dosages, or on its application to a new target animal species, shall be protected for a period of three years.

For a new indication, this period of protection shall be set by Swissmedic, on request, at ten years if it is expected to bring a significant clinical benefit in comparison with existing therapies and if it is backed up by extensive clinical trials. For paediatric use in accordance with the paediatric investigation plan, a ten-year protection is also available, provided that no document protection exists for another medicinal product authorised with the same active substance for the same specific paediatric use. Finally, in the case of an important orphan medicinal product, the document protection shall be granted upon request for a period of 15 years.

For biosimilars, document protection is in general not granted.

11. COVID-19 AND LIFE SCIENCES

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

In the constantly evolving legal environment around COVID-19, the Ordinance 3 on Measures to Combat the Coronavirus (COVID-19 Ordinance 3) currently includes provisions for the commercialisation or distribution of pharmaceuticals and medical devices aimed at handling the pandemic in Switzerland. The COVID-19 Ordinance 3 establishes (i) notification duties relating to stocks of essential medical goods, their procurement, allocation and distribution, and (ii) simplifications in the marketing-authorisation procedure for and the import of medicinal products used in the treatment of COVID-19 patients.

See also **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices**.

11.2 Special Measures Relating to Clinical Trials

With regard to ongoing clinical trials, Swissethics and Swissmedic issued a joint guidance notice regarding the management of clinical trials with medicinal drug products in Switzerland during the COVID-19 pandemic, setting forth the special measures and procedures applicable during the pandemic. This included certain easements on the collection of the ICF in writing.

Also, an addendum to the patient's information and informed consent form was published, setting the base for telephonic visits (instead of site visits) and home delivery of the investigational drug, subject to agreement of the investigator and the drug's suitability for use at home. Such direct delivery is subject to certain restrictions: (i) only during the COVID-19 pandemic; (ii) made from the trial site to the patient, ensuring that no personal data is submitted to the sponsor for the drug delivery to the patient.

Submissions regarding COVID-19-related clinical trials were handled with priority.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

For pharmaceuticals as such, no emergency approval regimes were newly introduced. However, certain products used in the treatment of COVID-19 patients may already be marketed in the period after submission of the MA request, pending Swissmedic's decision on authorisation. In addition, the "rolling submission" procedure is available during the pandemic, allowing applicants to collect and compile the data required for the authorisation of the medicinal product continually and to make it available to Swissmedic as soon as possible (in contrast to filing a complete dossier in the initial submission). Issues and questions were addressed with the applicants on an ongoing basis. As regards import measures, see **11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19**.

For medical devices, Swissmedic, under certain circumstances, may authorise the placing on the market and use of medical devices that have not undergone a conformity assessment procedure in accordance with the regular requirements if such products are urgently needed to combat the pandemic.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

So far, no simplification with regard to obtaining required certifications were implemented due to COVID-19. However, Swissmedic defines on a risk-based approach whether routine inspections can be conducted in different formats (eg, by means of remote assessments) or are postponed.

Swissmedic also informed that the GMP certificates it issued and based on a routine GMP inspection in 2017 or 2018 (which do not have an expiry date) remain fully valid until the end of 2021 (or until the next routine inspection), provided the scope of activities described in the certificates corresponds to the currently valid establishment licence. Recently, Swissmedic informed that it was able to carry out all planned routine inspections in Switzerland and that the usual inspection intervals were maintained. Consequently, Swissmedic found that there is no longer any need generally to extend the validity dates on its GMP certificates.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Switzerland introduced certain flexibilities as regards the import of pharmaceuticals due to the COVID-19 pandemic. In essence, these measures included:

- import rights for hospital pharmacies of certain non-authorised pharmaceuticals in Switzerland that are based on a defined list of APIs necessary for the treatment of COVID-19 patients;
- Swissmedic is granted the right to approve the import of essentially identical medicinal products as a short-term solution for any temporary non-availability of medicinal products;
- COVID-19 vaccines may be already imported and stored in Switzerland before the respec-

tive MA is granted. For medical devices, see **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices**.

11.6 Drivers for Digital Health Innovation Due to COVID-19

In order to facilitate digital healthcare and ensure compliance with the distancing requirements, healthcare professionals (HCPs) could profit from a broader spectrum of remote services (by telephone or video call) that could be invoiced via the compulsory health insurance during the first wave. For psychiatric services, similar measures were again introduced during the second wave of the pandemic. So far, such measures have not been introduced to the standards applicable in non-pandemic times.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

So far, the Swiss government has not announced any intention to make use of compulsory licensing means for COVID-19-related treatment or vaccines. Under the current legal framework, third parties with a legitimate interest may, under certain circumstances, initiate actions for the grant of compulsory licences against appropriate remuneration at court if the public interest so requires. In any case, the action may only be initiated if the applicant was unsuccessful in obtaining a contractual licence on appropriate market terms within a reasonable period.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

There are no specific liability exemptions introduced in existing or new provisions regarding COVID-19 vaccines or treatments. The usual liability rules applying to medicinal products and vaccines also apply to COVID-19 vaccination and treatment.

This means in essence that (i) the vaccine manufacturer may be liable for vaccination damages based on product liability, and (ii) the vaccination centre may be liable, based on (medical) contractual liability or state liability. Finally, and on a subsidiary basis, the federal government may be liable to pay compensation for vaccination damages for vaccinations recommended or ordered by the authorities.

11.9 Requisition or Conversion of Manufacturing Sites

No measures as regards the requisition or conversion of manufacturing sites due to COVID-19 were used or introduced.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

The system of public procurement of pharmaceuticals and medical devices has been supplemented in so far as the army's pharmacy has been granted some extended rights to support and procure essential medical goods. In addition, an increase of urgent procurements of pharmaceuticals and medical devices by way of direct awards may be expected.

Pestalozzi is a multicultural Swiss business law firm focusing on high-end work for domestic and international clients since 1911. Pestalozzi lawyers are strong and empathic personalities, known for their truly independent approach to advising and representing their clients. The firm guides and supports its clients in their strategic business decisions, anticipates their future challenges and helps them solve their critical issues. Fully integrated, Pestalozzi encounters no internal limits in shaping the most competent and efficient teams for the clients' needs. With over 100 professionals in Zurich and Geneva, the firm is at home in Switzerland's two main commercial hubs – and has developed a wealth of experience in its key industries of banking, life sciences, commodity trading and insurance. While being locally embedded, Pestalozzi has also developed sought-after expertise in dealing with multi-jurisdictional transactions and disputes.

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