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SWITZERLAND

Law and Practice

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1. Regulatory Framework

1.1 Legislation and Regulation

In Switzerland, pharmaceutical products are essentially governed by the following acts: the Federal Act on Medicinal Products and Medical Devices (TPA); the Federal Law on Narcotics and Psychotropic substances (BetmG); the Ordinance on Pharmaceutical Products (VAM); the Ordinance on Advertising of Pharmaceutical Products (AWV); and the Products Licensing Ordinance (MPLO).

The regulation of medical devices is based primarily on the Federal Act on Medicinal Products and Medical Devices (also the Law on Therapeutic Products, TPA) and the Medical Devices Ordinance (MepV).

Swissmedic is the Swiss authority for the licensing and monitoring of medically 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.

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 case insurances for both pharmaceutical products and medical devices.

1.2 Challenging Decisions of Regulatory Bodies

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 counsels. Appeals may be filed if there has been a 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 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 Federal Administrative Court. If the successful party is to be awarded compensation then this compensation may be imposed on the lower instance or on an unsuccessful respondent.

1.3 Different Categories

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

2. Clinical Trials

2.1 Regulation of Clinical Trials

The Federal Act on Research Involving Human Beings (also known as Human Research Act, HRA) and the Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance; ClinO) are the relevant regulations covering clinical trials.

Clinical trials of therapeutic products require advance authorisation by the competent ethics committee, upon which Swissmedic is notified and is required to state any objections within 30 days. 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 annexes VIII and X to the Directive 93/42/EEC, annexes 6 and 7 to the Directive 90/385/EEC, and Article

42 of the Guidelines on Medical Devices (MEDDEV 2.7/3) of December 2010, as well as in EN ISO 14155.

2.2 Procedure for Securing Authorisation

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 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 submission of the application to Swissmedic is made by the sponsor. Swissmedic shall acknowledge receipt of the application 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. This time-limit may, however, be extended for another 30 days if the pharmaceutical or medical device is applied to human beings for the first time or if it is 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 entities 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 Databases

The website www.kofam.ch is the FOPH's portal for human research in Switzerland and inter alia provides public access to the 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 ethical 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 trials, criteria for participation in the trial, the researched disease category and the health condition investigated, as well as an indication whether the trial includes rare diseases. Contact details for further questions and links (if any) to international primary registries, such as the World Health Organisation (WHO) primary registry, are also indicated.

The results of clinical trials are generally not publicly available. Members of 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.

2.4 Restriction for Using Online Tools

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

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 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 not identifiable anymore. Also, the purposes of processing and using personal data (eg, publication of that data) are limited to the ones specified in the information provided to the patients before starting the trial (ie, the ones 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 participant's initial prior written consent.

2.6 Further Requirements for the Creation of a Database

Any patient databases must fully comply with the data protection regulations under the HRA, as well as under the Federal Act on Data Protection (FADP). Storage of health-related personal data for research purposes must in particular take appropriate technical and organisational measures to prevent unauthorised use thereof, and 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

3.1 Assessment Process and Criteria

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, in vitro diagnostics, software and other goods or substances – that are intended to have or are presented as having a medical use and whose principal effect 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 physically affects the human body.

3.2 Granting a Marketing Authorisation

Marketing authorisations for pharmaceuticals are issued by Swissmedic and provide the authorisation-holder with the same rights for the products' marketing on the Swiss market. Certain homeopathic or anthroposophical products require only a notification to Swissmedic prior to marketing. Not-yet authorised pharmaceuticals for the treatment of life-threatening diseases may receive a temporary marketing authorisation, provided that a significant therapeutic benefit is expected from their administration and no comparable treatment options are available in Switzerland.

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. The simplified procedure is applicable to pharmaceuticals with known active ingredients (generics), pharmaceuticals for complementary medicine, orphan drugs, and certain parallel imports from countries with equivalent authorisation systems. The applicant may request a fast-track procedure for pharmaceuticals with a high therapeutic value against severe, disabling, or life-threatening diseases without authorised satisfactory treatment opportunities. This fast-track procedure is an expedited ordinary procedure. All other pharmaceuticals receive the marketing authorisation by means of the ordinary procedure. In particular, biologic pharmaceuticals, such as biosimilars, have to be approved by means of the ordinary procedure.

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 insofar 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 marketing authorisation fees depend on the applicable authorisation procedure as well as on the product's characteristics.

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 new medical devices must be notified to Swissmedic prior to marketing.

The marketing authorisation's initial term of validity is five years. Upon submission of renewal applications, including supporting information six months before its expiry, the marketing authorisation for pharmaceutical products is usually renewed for an unlimited period of time.

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 respective marketing authorisations.

3.3 Period of Validity

The marketing authorisation is issued for the first time for a period of five years. The renewal is then 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, shall be valid for an unlimited period.

3.4 Procedure for Obtaining a Marketing Authorisation

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

3.5 Access to Unauthorised Products

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 own 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 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.

3.7 Third-Party Access to Pending Applications

Third parties cannot access any information 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 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 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 such 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 of fines or imprisonment for the manufacturing, distribution, and import/export of pharmaceuticals without the necessary authorisation, as well as for the placing of medical devices not compliant with the legal requirements on the market.

3.9 Border Measures

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 they suspect an infringement of patent and trade-mark laws or unfair competition activities.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Manufacturing Plants

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 Ordinance on Establishment Licences 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 only produces 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 a maximum period of five years and can be renewed upon request.

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 are subject to an authorisation (establishment licence) granted by Swissmedic. The applicant must comply with the requirements of the Ordinance on Establishment Licences, such as having a quality assurance 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 a maximum of five years and is renewable.

To dispense and import medical devices, no authorisation is required. Dispensing points and importers must comply with the relevant TPA's provisions (including product surveillance) and are subject to a duty of care. Furthermore, the person first

placing certain medical devices (eg, class I medical devices, in vitro diagnostic medical devices and systems) on the Swiss or foreign market and whose place of business is in Switzerland must notify Swissmedic.

5.2 Different Classifications

Pharmaceuticals are divided up 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 now 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 advice of a specialist.

6. Import and Export of Pharmaceuticals and Medical Devices

6.1 Governing Law and 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

The importer must be a holder of an import licence (as part of an establishment licence), which licence is issued by Swissmedic after assessment of regulatory requirements. The applicant must comply with the requirements of the Ordinance on Establishment Licences, 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 record obligations, can import small doses of pharmaceuticals for private use only.

6.3 Prior Authorisations

As a rule, pharmaceuticals to be imported must have obtained a Marketing Authorisation in Switzerland, 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 use.

6.4 Non-tariff Regulations and Restrictions

Non-tariff restrictions are set forth in the Swiss customs tariff. The entries in the relevant 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 Provisions on Trade/Regulatory Facilitation

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.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control

Prices for pharmaceutical products which are reimbursed under the compulsory health insurance are subject to control by the FOPH. The compulsory health insurance covers, in general, only ready-to-use pharmaceuticals which are included in the FOPH's list of reimbursable pharmaceutical specialties (the Specialties List, SL). Additionally, pharmaceutical products which 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 which 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 of the Federal Pharmaceutical Commission (FPC). 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 Comparison

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 Drug Commission (EAK). The price comparison with foreign countries takes into account countries that are economically comparable with Switzerland in the pharmaceutical sector. Until May 2015, the average price of the countries Germany, Denmark, Holland, England, France and Austria was decisive. Since June 2015, the prices of Belgium, Finland and Sweden are also included.

7.3 Reimbursement from Public Funds

Health insurers are, under the compulsory health insurance, obliged to reimburse pharmaceuticals which are listed in the SL or ALT and prescribed by a physician. The reimbursement of listed products may be restricted to certain medical indications or 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, such 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 or 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 or not 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 Analysis

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

Before a pharmaceutical is included in the SL, a safety, efficacy and quality assessment takes 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. Pharmaceuticals 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.

7.5 Prescriptions and Dispensing

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. But, 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 which 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 insofar 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 first has to 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:

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

are to be complied with, as there are currently no special Swiss rules in place in this regard.

8.4 Electronic Prescriptions

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

8.5 Online Sales

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 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 the 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 and access to electronic health records as well as the certification for providers of electronic patient records.

Data on health-related issues is 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 FDPIC.

General provisions of the 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 FDPIC recommends being more cautious with the use of cloud computing the more confidential or sensitive the data is, 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. Licensing

9.1 Customary Deal Structures

In Switzerland, co-development and cross-licence agreements are customary to develop and manufacture complex technology products. There are several life sciences hubs and exchanges between industry and research are intensive.

9.2 Dispute Resolution Provisions

In respect of the resolution of disputes, Swiss life sciences stakeholders rely on state courts and civil proceedings. Dedicated judges are available for disputes related to intellectual property rights and unfair competition. Generally, no mediation proceedings are agreed by the parties and such proceedings are not mandatorily provided by civil procedure rules. Arbitration proceedings are the preferred dispute resolution tool for larger companies.

9.3 Diligence Obligations Provisions

To define a party's diligence within a licence and development agreement, best efforts and good faith are generally considered to be customary for life science contractual partners. Agreement on milestones and achievement of specific timelines and tasks are usually agreed.

9.4 Change of Control

Licensees' and licensors' interests are usually protected by change of control clauses in licence agreements.

9.5 Termination

In the case of termination of a licence and development agreement, each contractual party retains its background rights and know-how. Each party usually retains the right to use and further develop jointly created clinical data and intellectually property rights. It is common to see jointly owned patents, also between research institutes, such as universities, and the industry.

10. Patents

10.1 Applicable Laws

The Federal Act on Patents for Inventions (PatA) rules 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.

10.2 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:

- a 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 patient 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 which do not describe the patented use does not result in a contributory patent infringement (ie, cross-label use).

10.3 Patent Term Extension

Supplementary protection certificates (SPCs), extending the term of protection for medicinal and plant protection products, is 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 as of the delivery of the patent or of the marketing authorisation grant.

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

10.4 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.

10.5 Defences to Patent Infringement

Research and experimental use exceptions are recognised under Swiss patent law and apply to both pharmaceuticals and medical devices. This exception covers all experiments done 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 in the public interest 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.

10.6 Bringing Proceedings

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 exclusive 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.

10.7 Available Procedures

A generic entrant with 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.

11. IP Other Than Patents

11.1 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 AUC which prohibits the false and misleading declaration of goods. Furthermore, the 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 recently agreed to implement the Medicrime Convention of the Council of Europe, aiming at the prevention of counterfeiting medical products.

11.2 Restrictions on Trade Marks

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 TmPA. It should be noted that the parallel import of pharmaceuticals protected by patents and which prices are fixed by the regulatory authorities on the SL can be blocked, based on the PA.

11.3 IP Protection for Trade Dress or Design

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.

11.4 Data Exclusivity

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.

Pestalozzi is a multicultural Swiss business law firm, established in 1911, which focuses on high-end work for domestic and international clients. Pestalozzi lawyers are strong and empathic personalities who can be singled out for their truly independent approach to the representation of their clients' interests, offering guidance and support in their strategic business decisions, anticipating their future challenges and helping them solve critical issues. Being fully integrated, Pestalozzi encounters no internal limits in shaping the most adequate and efficient teams for the clients' needs. The firm has over 100 professionals in Zurich and Geneva, who have a wealth of experience in the key industries of banking, life sciences, commodity trading and insurance. Pestalozzi also has significant expertise in dealing with multi-jurisdictional transactions and disputes.

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