CHAMBERS

Global Practice Guides

Life Sciences

Switzerland – Law and Practice

Contributed by

Pestalozzi

2018

CHAMBERS® AND PARTNERS

SWITZERLAND

The 'Law & Practice' sections provide easily accessible information on navigating the legal system when conducting business in the jurisdiction. Leading lawyers explain local law and practice at key transactional stages and for crucial aspects of doing business.

Law and Practice

Contributed by Pestalozzi

CONTENTS

Pestalozzi's Life Sciences practice group offers high-quality legal and regulatory advice for domestic and international companies specialising in life science technologies. The areas we cover range from biotechnology, pharmaceuticals, diagnostics and personalised medicine to nutraceuticals, cosmetics, food processing, biochemical and medical devices, as well as other regulated products and services. In addition, we support organisations and institutions committed to research and development, the processing of digital data, technology transfer, commercialisation and distribution. Lawyers offer a comprehensive range of services covering the following fields: regulatory legal advice in connection with establishment licences, marketing authorisations, industry-specific permits, import and export, compliance and vigilance, corporate/M&A, legal advice on the structuring of activities, contractual arrangements for supply chain and distribution, transactions, merger and acquisition of structures, financial services support for the funding of business operations, research and distribution activities, intellectual property advice on the protection of know-how, techniques, inventions, related licensing and research and development agreements, including advertising and data protection, product security and defence product liability, particularly for medical devices, pharmaceuticals, clinical trials and in respect of recalls and litigation and arbitration: legal support for national and international disputes.

Authors

Lorenza Ferrari Hofer is head of the IP & TMT practice group, and co-head of the life sciences group. Her practice covers regulatory legal advice in connection with establishment licences, marketing authorisations, industry-specific permits, import and export, compliance and vigilance, intellectual property advice on the protection of know-how, techniques, inventions, related licensing, distribution and research and development agreements, including advertising and data protection and product liability. She regularly publishes in industry publications.

Christian Roos co-heads the life sciences group. His practice covers corporate/M&A, legal advice on the structuring of activities, contractual arrangements for supply chain and distribution, transactions, merger and acquisition of structures and regulatory legal advice in connection with establishment licences, marketing authorisations, industry-specific permits, import and export, compliance and vigilance.

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 (also Law on Therapeutic Products, 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 TPA and the medical devices Ordinance (MepV).

1.2 Regulatory Bodies

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. Phamacovigilance and market monitoring are duties also attributed to Swissmedic for both pharmaceuticals and medical products.

The Federal Office of Public Health (FOPH) is responsible for public health in Switzerland. The FOPH is responsible for establishing the reimbursement prices by the healthcare insurances for both pharmaceutical products and medical devices.

1.3 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). 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 address-

ees of the decision of Swissmedic and FOPH are legitimate to appeal. Also third parties that are affected by the decision in their legitimate interests may qualify for appeal.

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.

1.4 Borderlines Between Pharmaceuticals and Other Life Sciences Products

Both pharmaceutical products and medical devices are defined as products that have an effect or impact on the human or animal organism, either directly or through their use. Medicinal products are products of chemical or biological origin whose medicinal effect is particularly in the diagnosis, prevention or treatment of diseases, injuries and handicaps. Medical devices are instruments, apparatus, in vitro diagnostics, software and other goods or substances which are intended to have or are presented as having a medical use.

Cosmetics, nutritional products, food supplements, novel foods, etc, are products that are intended to develop and maintain the human body and which are not marketed as therapeutic products as they do not have an effect or impact on the human organism.

The Delimitation Expert Working Group of Swissmedic is responsible for clarifying delimitation issues relating to the areas of human and veterinary medicines and medical devices. The Federal Food Safety and Veterinary Office (FSVO) is responsible for delimitations in respect of foodstuffs, consumer items and cosmetics.

1.5 Functional Foods and Nutraceuticals

With validity as of 2017, specific regulations were enacted for different categories of functional foods, such as the Ordinance on food supplements, the Ordinance on vitamins and other stuffs in food, the Ordinance on foodstuff for persons with dietary needs, and the Ordinance on flavours.

1.6 Intermediate Categories

Besides the categories mentioned above, there are no further intermediate categories.

1.7 Different Categories

Swiss law essentially distinguishes between prescription and non-prescription (OTC) pharmaceutical products and medical devices. Pharmaceutical products and medical devices upon 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) apply to both clinical trials of pharmaceuticals and of medical devices.

Clinical trials of therapeutic products require advance authorisation by Swissmedic and 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 the 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 to clinical trials with medical devices, incorporated into Swiss law by reference, are found in annexes VIII and X to the Directive 93/42/EEC, in annexes VI and VII to the Directive 90/385/EEC, in Article 42 of the Guidelines on Medical Devices (MEDDEV 2.7/3) of December 2010 as well as in norm 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 multicentre 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. Also Swissmedic shall acknowledge receipt of the application within seven days and notify the sponsor of any formal deficiencies as well as 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 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 approval of both entities has 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. Publicly accessible are a brief description of the trial, the locations, 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. Details of contact 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 by law generally not publicly available. Members of the Swiss medical association (FMH) are, however, according to their professional regulations, bound by the ethical guidelines contained in the Declaration of Helsinki of 2013. Consequently, members of the FMH are subject to a publication obligation, as the Declaration of Helsinki requests that results of research on humans are 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.

2.5 Public or Sensitive Data

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

Data protection requirements do not apply to anonymised, or at least pseudonymised, data to the extent that the data subjects are not identifiable anymore. Also, the purposes of processing and using personal data (eg, publication of the same) are limited to those specified in the information provided to the patients before starting the trial (ie, the ones that are covered by the patient's informed consent).

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 prior written consent.

2.6 Further Requirements

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

3. Marketing Authorities

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 and 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 Types of Marketing Authorisations

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. Hitherto unauthorised 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, (i) the ordinary, (ii) the simplified or (iii) the fast-track procedure applies for receiving marketing authorisation. The simplified procedure is applicable to, inter alia, 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 a 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 the simplified procedure is more limited than in an ordinary procedure, as Swissmedic will take into consideration the reference product's files and will 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 roughly four months. In general, an ordinary authorisation procedure lasts for more than one year. Also, 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.

3.3 Period of Validity

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 can be renewed for an additional five years each 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 the 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.

Also, 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.

3.4 Procedure for Obtaining a Marketing Authorisation

The ordinary procedure for obtaining the first marketing authorisation for pharmaceuticals generally follows the following steps:

- After filing of the application, Swissmedic controls the dossier in respect of its compliance with formal (for electronic submissions, including technical) aspects and its completeness.
- Next, the case managers and reviewers will evaluate the request and draft a list of questions related to the content, which is forwarded to the applicant for reply.

- The answers are reviewed in terms of content and a preliminary decision is issued and communicated to the applicant.
- With the exception of the product information's text, the applicant does not have any further opportunities to clarify questions of content after issuance of the preliminary decision.
- 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 type of variation and can range 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:

- supply within clinical trials;
- certain pharmaceuticals manufactured by a (hospital) pharmacy for its own patients;
- patient's import of pharmaceuticals in small quantities for their own use;
- import of pharmaceuticals from countries with equivalent marketing-authorisation systems for an individual patient by healthcare professionals, provided there is (temporarily) no treatment alternative available in Switzerland;
- import of pharmaceuticals 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 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 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 post-market surveillance system for the collection and analysis of the experiences with the medical devices.

Distributors of pharmaceutical products and of medical devices must provide a notification system for adverse events or reactions.

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 complete 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). The refusal of a marketing-authorisation grant is not published.

As medical devices are subject to compliance assessment and certification by private entities, these data are also not accessible for third parties during the assessment. Once the medical device is certified, the product information will be published. A refusal of certification will not be published either.

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; these limits include access for documents of pending administrative proceedings, business secrets, or personal data.

3.8 Specific Rules for Online Platforms and/or Medical Apps

Online platforms offering or promoting therapeutic products have to differentiate as regards the access of lay persons to healthcare professionals if they offer information addressed to healthcare professionals.

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 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.

3.9 Existing 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 – eg, 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.

3.10 Available 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 for unfair competition activities.

4. Pricing and Reimbursement

4.1 Controlling Prices

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 specialities (Specialities List, SL). Additionally, pharmaceutical products which are compounded in a pharmacy are only reimbursed if their active substances and ingredients are included in the list of active substances and other ingredients (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 can freely determine the resale prices to the retailers (pharmacies, hospitals and self-dispensing doctors).

Prices for medical devices are not fixed by governmental authorities. However, the so-called List of Instruments and Tools (LIT) by 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 lay person. 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.

4.2 Regulations and Specific Procedures

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 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 have already 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 event that Swissmedic authorises another indication.

There is no equivalent listing procedure for specific medical devices as for pharmaceuticals. 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.

4.3 Initial Price Negotiation

In its application for listing, the authorisation-holder of a pharmaceutical must elaborate the fulfilment of the listing requirements (effectiveness, usefulness and economic efficiency) and indicate the intended ex-factory price. The economic efficiency is assessed by a combined, equally weighted (i) foreign price and (ii) therapeutic cross-comparison. The foreign price comparison compares the intended price with the ex-factory prices of the same product in several reference countries (Germany, Denmark, UK, Netherlands, France, Austria, Belgium, Finland and Sweden). The therapeutic cross-comparison compares the intended price with the ex-factory prices of already Swiss-listed pharmaceuticals with

the same indication or a similar mechanism of action. If the pharmaceutical constitutes a remarkable therapeutic advantage, an innovation premium is granted within the therapeutic cross-comparison for a period of a maximum of 15 years.

The economic efficiency of generics is only assessed by a comparison with the relevant original product. The ex-factory price of generics must be between 20% and 70% lower than the price of the listed original product, depending on the sales volume of the original and its co-marketing products three years before the end of the patent protection.

The same mechanism applies when the prices of already listed pharmaceuticals are reviewed. If the current price is found to be too high, the FOPH orders a reduction. The FOPH does not order an increase of the price on its own. This is only possible in a separate procedure upon request of the authorisation-holder.

When listing or reviewing the maximum reimbursement amount of a certain type of medical devices in the LIT, the FDHA assesses the average price of the different medical devices of this type that are on the market, whereas the price abroad must be taken into account. There are no specific reference countries determined by law and, as there is no regular review, the maximum amounts of the LIT do not always correspond with the current average market price.

4.4 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 are 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 and which is clearly in the focus.

The health insurer has to consult its independent medical adviser and decide within 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 him or herself or another lay person 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.

4.5 Cost-Benefit Analysis

The reinforcement of health technology assessments (HTA) is one of the government's "Healthcare 2020" priorities. Accordingly, the FOPH is implementing a HTA-programme to re-evaluate systematically medical services and products which are currently reimbursed under the compulsory health insurance. In accordance with HTA principles, the ordinary procedure for listing an original pharmaceutical product in the SL or a new type of medical devices in the LIT is divided into three stages: (i) assessment (evaluation of the FOPH/FDHA), (ii) appraisal (recommendation of the FPC/FCAIT), and (iii) decision (decree of the FOPH/FDHA). Additionally, the FDHA is currently undertaking a systematic review of the entire LIT as there has been no regular review of the LIT positions so far.

Cost-benefit analyses are applied in cases where pharmaceuticals or medical devices are reimbursed by the compulsory health insurance. An indirect cost-benefit analysis is applied with the criteria of the therapeutic cross-comparison: the pharmaceutical is thereby compared with other pharmaceuticals with the same indication or a similar mechanism of action and their costs per day or treatment are taken into account. For pharmaceuticals not included in the SL, but applied in individual cases, the health insurer must review whether the costs are within a reasonable therapeutic benefit when deciding upon the reimbursement. Finally, the maximum reimbursement amounts of the LIT correspond with the current average market prices of the types of medical devices, which constitutes a certain indirect cost-benefit analysis as well.

4.6 Regulation on the Prescribing Physicians and Dispensing Pharmacists

In general, physicians are free to prescribe any authorised pharmaceutical without regard to its price. However, if the physician prescribes a pharmaceutical which is not included in the SL, or which is listed but used outside the approved 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. 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 event of substitution, the pharmacist must inform the physician. In certain cantons of Switzerland, physicians are allowed to dispense pharmaceutical products directly to their patients (self-dispensation).

5. Promotion and Advertising

5.1 Governing Rules

The TPA governs promotion and advertising of pharmaceuticals and medical devices. Additional guidance is provided in the Ordinance on the Advertisement of Medicinal Products as well as in the Medical Devices Ordinance. In addition, the general rules of the Federal Act against Unfair Competition (AUC) are also applicable.

In principle, advertising aimed at healthcare professionals is allowed for any pharmaceutical authorised for marketing in Switzerland, provided that it is recognisable as advertisement and clearly separated from editorial contributions. However, advertisement is limited to the authorised indications and use of the pharmaceuticals, whereas references to studies are not limited to those mentioned in the product information. As such, the advertisement's statements have to comply with the pharmaceutical's product information authorised by Swissmedic. In addition, the advertisement must not be misleading, incite abusive, excessive or inappropriate use of pharmaceuticals, or be contrary to public morality and order. Moreover, the content must be accurate, truthful, well-balanced, and provable by up-to-date scientific findings. Advertising aimed at healthcare professionals is also allowed for any medical devices. Any misleading statements concerning the medical devices' efficacy and performance are prohibited.

Advertising of both pharmaceuticals and medical devices aimed at the general public is restricted. Advertising for pharmaceuticals on prescription is prohibited, whereas such an advertisement for over-the-counter pharmaceuticals is allowed. However, no advertisement is permitted for:

- pharmaceuticals containing narcotic or psychotropic substances;
- pharmaceuticals that may not, on account of their composition and their intended use, be used without the intervention of a doctor for the necessary diagnosis, prescription or treatment; and
- pharmaceuticals that are frequently the object of abuse or lead to addiction or dependence.

Further, advertising aimed at the general public for pharmaceuticals with a recommended dosage of more than 0.5g of pure alcohol are prohibited on radio and television. Advertisements for the public must be recognisable as such, may not be misleading, incite abusive, excessive or inappropriate use of pharmaceuticals, or be contrary to public morality and order. Additionally, exaggerations are prohibited and statements have to comply with the approved product information. Any advertising must include a direction to consult the patient leaflet and/or a healthcare professional.

Finally, advertising aimed at the general public is prohibited for medical devices subject to prescription only and for medical devices marketed for exclusive use by healthcare professionals. Statements on application, performance and efficacy in advertisement aimed at the public for all other medical devices are restricted to not making misleading statements and complying with the product information.

5.2 Obtaining an Authorisation

Prior authorisation by Swissmedic is, according to Swissmedic's recently published practice, only required for advertisement for non-prescription pharmaceuticals on radio or television, as well as for advertisement of prescription pharmaceuticals in print media or on the internet, provided that the pharmaceutical concerned belongs to the group of analgesics, sleep-inducing medication, sedatives, laxatives, and anorectics (appetite suppressants) and cumulatively has, according to the product information, a potential for misuse or addiction.

5.3 Self-Regulatory Body

Various associations of the Swiss pharmaceutical industry have adopted the Code of Conduct of the Pharmaceutical

Industry ("Pharma Code") ruling the promotion of pharmaceuticals to healthcare professionals. Its Secretariat is entrusted with the supervision of compliance with the Pharma Code. There is no Swiss self-regulatory body ruling the promotion of medical devices.

5.4 Sanctions or Provisional Safety Measures

In the case of severe or repeated breaches of advertising regulations, the company concerned may be obliged for an appropriate period of time to submit any advertisement for pharmaceuticals for authorisation by Swissmedic. Further, Swissmedic may seize, hold in official storage, destroy or prohibit the use of illegal advertisements and publish such prohibition at the infringer's expense. It may, moreover, temporarily or permanently prohibit the advertising of specific pharmaceuticals. The breach of advertising regulations may lead to criminal sanctions of fines of up to CHF100,000 or imprisonment.

The Secretariat can, as its only sanction, request its signatories to discontinue their improper behaviour.

5.5 Enforcement by Competitors or by Third Parties/Bodies

Swissmedic and the Pharma Code Secretariat may act upon competitor's notification, but also upon third-party information or ex officio.

5.6 Sanctions Provided by the Self-Regulatory/State System

Proceedings in front of the Pharma Code Secretariat are planned to be completed within one month. Binding proceedings in front of Swissmedic and the state courts (including appeals) may last for several years. In order to achieve a prohibition of a competitor's advertising quickly, Swissmedic or the competent courts may deprive the suspensive effect of an ordered, but appealed prohibition. Also, injunctive relief may be available.

5.7 Restrictions Regarding Gifts and Sponsorships

Swiss law allows the grant of promotional gifts and other material benefits to HPCs only if those benefits are of modest value and are related to the medical practice. Federal authorities have established a value threshold of CHF300 per year and per individual recipient. Sponsorship to healthcare professionals, such as the granting of financial contributions to their continuing medical education, is allowed, provided that (i) there is no (direct or indirect) connection with the prescription or provision of pharmaceuticals, and that (ii) the participant pays a substantial contribution to the total educational costs (at least 20% for participants in education or 33% for all other participants). The general anti-bribery rules according to the Swiss Criminal Code (SCC) are cumulatively applicable to bribery cases in the healthcare sector.

It is currently not mandatory for pharmaceutical companies to disclose information about the material benefits granted to healthcare professionals or healthcare organisations. However, the industry's Pharma Co-operation Code requires its signatories to disclose pecuniary benefits granted to healthcare professionals or healthcare organisations annually, which information must remain accessible to the public for at least three years. In general, disclosure is made on an individual basis – ie, by identifying the recipient and the amounts paid, whereby the remuneration for the agreed service or consultancy tasks and the compensation for the service-provider's related costs shall be separated. Disclosure in aggregate form is sufficient if the healthcare professional or the healthcare organisation refuses to consent to individualised disclosure.

5.8 Most Common Issues

As the self-regulation on disclosure of payments made to healthcare professionals is relatively new, issues around the Pharma Co-operation Code's individual and aggregate disclosure give rise to many questions. In addition, the distinction between dispensing healthcare professionals and, for example, nurses (who do not have dispensing rights), is a common issue in this field.

5.9 Consumer Protection Rules

Advertising of pharmaceuticals and medical devices is also subject to the general consumer-protection rules of the AUC. Advertisement is considered not misleading if it respects the principles of truth and clarity as requested by TPA.

6. Manufacturing

6.1 Manufacturing Plants Subject to an Authorisation

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.

7. Distribution

7.1 Establishments Engaged in Wholesale

Wholesale of pharmaceuticals is 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 location. 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) on the Swiss or foreign market and whose place of business is in Switzerland must notify Swissmedic.

7.2 Different Classifications

Pharmaceuticals are divided into the following supply categories:

- supply once with a prescription from a doctor or veterinarian;
- supply with a prescription from a doctor or veterinarian;
- supply on technical advice from medical staff;
- supply on technical advice;
- supply without technical advice.

Please note that, based on the current revision of the Therapeutic Products Act and in order to enhance self-medication, it is planned to dissolve the 'supply on technical advice from medical staff' category and to re-assign the respective products to one of the other remaining categories (probably either the 'supply with a prescription from a doctor or veterinarian' category or the 'supply with technical advice' category).

8. Import and Export

8.1 Governing Rules

The Swiss Customs Code and its implementing ordinances govern the import and export of goods in general, whereby the customs authorities are held to ensure that a therapeutic product that is imported for release in the Swiss market conforms to the legislation pertaining to pharmaceuticals and medical devices.

8.2 Governmental Entities

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.

8.3 Importer of Record

The importer must be a holder of pharmaceutical manufacturing licences or a qualified healthcare professional. Imports by private persons are admissible for small doses and for private use only.

8.4 Prior Authorisations

Pharmaceuticals to be imported must as a rule 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.

8.5 Non-Tariff Regulations and Restrictions

Non-tariff restrictions are set forth on 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 forth the restrictions in detail.

8.6 Exportations of Intangibles

In practice, the exportation of intangibles is not controlled, unless the software or the related technology is exported on data storage items (such as discs or similar). Nevertheless, dual-use intangibles may be subject to export controls, regardless of whether they are exported in data storage items, via the internet or otherwise.

8.7 Control of Exports of Dual-Use Goods

Dual-use products are controlled in Switzerland; the jurisdiction is part of all relevant international treaties in this regard.

8.8 Provisions on Trade/Regulatory Facilitation

Switzerland is part of 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.

8.9 Economic Sanctions

Switzerland applies all UN sanctions. We have not come across sanctions that encompass pharmaceuticals and medical devices.

9. Patents

9.1 Laws

The Federal Act on Patents for Inventions (PatA) sets out 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 germ-line genetic identity of human beings. Also excluded from patentability are methods for treatment by surgery or therapy and diagnostic methods.

9.2 Patentable Subsequent Medical Uses

Only new inventions are patentable. Accordingly, any pharmaceutical substance or composition that forms part of the 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;
- 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, neither through Swiss national patents nor 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 patent or subsequent granted patents. A patient taking the pharmaceutical product for the patented use is not considered to infringe directly 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). Moreover, a physician prescribing or a pharmacist dispensing the pharmaceutical 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 even if the pharmaceutical is then dispensed for patented use (cross-label use).

9.3 Mechanisms for Patent Term Extension

Supplementary protection certificates (SPC), extending the term of protection for medicinal and plant protection products, are available for Swiss national and European patents with protection for Switzerland. 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, minus five years. It is valid for a maximum of five years. Requirements for a 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. The Swiss Patent Court applies the so-called infringement test and assesses whether the product defined in the SPC would infringe the rights deriving from the basic patent. If this is not the case, the SPC implies a valid protection for the pharmaceutical product. By contrast, for the disclosure test which is applied by the EU courts, it must also be assessed whether the product itself is disclosed in the claims of the basic patent.

9.4 Infringement

Liable under civil and criminal law is:

- 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 (i) his or her patent rights have been violated or a violation is anticipated, and (ii) the violation threatens to cause not easily reparable harm to the applicant. The court may refrain from ordering interim measures if the opposing party provides appropriate security.

9.5 Specific Defences to Patent Infringement

Research and experimental use exceptions are recognised under Swiss patent law and apply to both pharmaceuticals and medical devices. Scientific or experimental research for gaining further insights into the patented invention is allowed even if the focus of the experiments is commercial. 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 (Bolar exception), except stockpiling.

Compulsory licences are available in a case of 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 (use of a patented biotechnological invention as an instrument or means for research), for diagnostic tools and for the export of pharmaceutical products. Compulsory licences are granted and revoked by civil courts on request and only if efforts by the applicant to obtain a contractual licence on appropriate market terms within a reasonable period of time have been unsuccessful. The proprietor of the patent has the right to appropriate remuneration.

9.6 Bringing Proceedings for Patent Infringement

Under Swiss patent law, 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. Civil action can be filed without any need to attempt conciliation before a conciliation authority; the issue of warning letters is also not required. 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, then decide about the infringement claim.

9.7 Procedures Available to a Potential Generic Entrant

A generic entrant with proven interest can claim the nullity or partial nullity of a patent if the invention is obvious, not novel or not disclosed in a way that a person skilled in the art could understand it based on the patent (declaratory action). Declaratory action is not a requirement for generic products wanting to enter the Swiss market; in principle, a market authorisation, and even a listing in 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. Patent protection on original products is not considered by the regulatory authorities and can be challenged only in civil or penal proceedings.

10. IP Other Than Patent

10.1 Legislation and Procedures

Swiss legislation on counterfeit directly applies to pharmaceuticals and medical devices, under the PatA 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 counterfeit 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 Customs authorities at the border or in a custom warehouse is also very effective. Switzerland recently agreed to implement the Medicrime Convention of the Council of Europe, aiming at preventing the counterfeiting of medical products.

10.2 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 the following:

- signs that are in the public domain;
- shapes that constitute the nature of the goods themselves or shapes of the 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. Further, the use of "Swiss-made" designations and the Swiss cross, as indications of origin for therapeutic products, is limited by the new "Swissness" legislation.

10.3 Importation and Distribution Restrictions

The principle of international exhaustion applies and parallel imports of pharmaceuticals or medical devices into Switzerland cannot be restricted based on the TmPA. Please note 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 PatA.

10.4 IP Protection

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. A design is protected to the extent that it is new and has individual character. Figurative representations or three-dimensional shapes may also be registered as trade marks.

10.5 Data Exclusivity

Data exclusivity is granted by law for the original pharmaceutical's files for a period of ten years, provided that the pharmaceutical received Swissmedic's marketing authorisation. After this period's end, a generic pharmaceutical manufacturer may rely on this data in its application for marketing authorisation. Confidential data on medical devices may rely on protection as trade secrets pursuant to the AUC and the SCC.

11. Competition Law

11.1 Activities Constituting Infringement

Until the year 2000, pharmaceutical distribution was regulated by Sanphar, the pharmaceutical industry association. Sanphar had established a market regulation which stipulated maximum margins and rebates for all market players (manufacturers, wholesalers and retailers). The Swiss Competition Commission (ComCo) held in 2000 that the market regulation was an unlawful horizontal price-agreement which infringed cartel law. Subsequently, the market regulation and the association itself were dissolved.

In 2006, the Secretariat of the ComCo (Secretariat) opened an investigation against the three pharmaceutical companies Pfizer, Bayer and Eli Lilly. The companies had published non-binding retail price recommendations for their pharmaceutical products Viagra, Cialis and Levitra which were followed by more than 80% of the pharmacies and self-dispensing doctors. The prescription-only pharmaceutical products in question were not listed in the SL and, therefore, no price control applied. In view of the ComCo, the widely followed price recommendations qualified as unlawful concerted practices and, therefore, the ComCo imposed fines of CHF5.7 million against the involved companies in 2009. This decision was widely criticised in legal literature, mainly because the ComCo did not prove that the companies set incentives or imposed pressure to ensure that the non-binding recommendations were followed. In 2013, the FAC set the decision of the ComCo aside. It held that the Cartel Act is not even applicable, mainly because the regulatory prohibition of advertising prescription-only pharmaceuticals excludes competition in general. The Federal Supreme Court did not share this view, annulled the decision in 2015 and demanded the FAC to apply the Cartel Act to the case at hand. The procedure is still pending in front of the FAC.

The General Electric Company (USA) and its subsidiaries GE Healthcare GmbH (GE Germany) and GE Medical Systems AG (GE Switzerland) submitted a voluntary report to the Secretariat in 2014, which revealed the following: GE Germany sells certain ultrasound scanners in Germany directly with its own sales organisation as well as with independent sales partners. In Switzerland, GE ultrasound scanners are only distributed by GE Switzerland. Since April 2008, there had been agreements between GE Germany and its German sales partners about absolute territorial allocations prohibiting sales outside these territories. German dealers were not allowed to sell ultrasound scanners to Swiss clients in response to their sales enquiries (so-called passive sales). The Secretariat found these agreements to be unlawful agreements affecting competition. In an amicable settlement approved by the ComCo in 2016, GE Germany and Switzerland undertook not to enter into any agreements prohibiting passive sales in the future and to amend accordingly all contracts with German sales partners if necessary. No sanction was imposed because the investigation was initiated based on the voluntary report and GE co-operated in every respect.

After receiving several reports regarding misconduct in the distribution of pharmaceutical products in Switzerland, in 2010 the Secretariat opened a preliminary investigation concerning all trading levels in the sale of pharmaceutical products. Within this context, it examined the conduct of the most important pre-wholesaler in Switzerland Alloga, which belongs to the Galenica group. In 2015, the Secretariat published a final report on this topic. It stated that Alloga likely has a market-dominant position as a pre-wholesaler of pharmaceuticals and that there are indications that Alloga has abused this position by requesting securities from its customers (ie, wholesalers) which might constitute inappropriate business conditions. The Secretariat did not open a formal investigation because Alloga accepted a series of measures proposed by the Secretariat. As another result of the preliminary investigation, in 2012 the Secretariat opened a formal investigation into the commercialisation

of electronic medical information required by wholesalers and retailers for the distribution, dispensing and accounting of authorised pharmaceutical products. In March 2017, the ComCo imposed a fine of CHF4.5 million against HCI Solutions, a subsidiary of the Galenica group, because it abused its market-dominant position by preventing competitors from accessing the market of electronic medical information and by demanding its commercial partners (ie, pharmaceutical manufacturers) to accept additional services if they wanted their medical information included in the database. HCI Solutions challenged this decision in the FAC.

11.2 Pay-for-Delay Agreements

There is as yet no case law addressing pay-for-delay agreements in Switzerland.

11.3 Life Cycles Strategies Versus Generic Drug Companies

There is as yet no case law addressing life cycle strategies of originators versus generic pharmaceutical companies in Switzerland.

11.4 Proceedings for Breach of Competition Law

The ComCo and its Secretariat are responsible for administrative proceedings regarding the enforcement of Swiss competition law. Anyone can give information about a potential breach to the Secretariat, which will then conduct a preliminary investigation. The Secretariat can also commence such a preliminary investigation on its own initiative. If there are sufficient indications that an unlawful restriction exists, the Secretariat opens a formal investigation in consultation with a member of the presidency of the ComCo. The Secretariat publishes the opening of a formal investigation. As the investigation is based on the principles of administrative procedures, the Secretariat establishes the facts ex officio and, therefore, the Secretariat has the power to conduct investigative measures, such as order production of documents and information, carry out witness hearings or conduct dawn raids. The Secretariat issues a draft decision on which the parties can comment. The ComCo will then issue its final decision and can impose fines up to 10% of the turnover that the company achieved in Switzerland in the preceding three financial years. The ComCo may refrain from a fine or grant a reduction to companies who co-operatively helped to disclose the infringement. The decision may be appealed to the FCA and the Federal Supreme Court.

Swiss competition law provides also the possibility for private enforcement. A person affected by an unlawful restraint may file a claim with the civil courts and is entitled to request the elimination or desistance of the hindrance, damages and satisfaction, and surrender of unlawfully earned profits. Currently, private enforcement is very seldom used in Switzerland. Even though that there is no possibility to claim damages and unlawfully earned profits, the administrative procedure with the ex officio fact-finding and the limited cost risk for the complainant is regularly more attractive.

11.5 Most Relevant Proceedings

The decision of the ComCo to qualify the market regulation of Sanphar as an unlawful horizontal price agreement was an important decision for the pharmaceutical industry. After this decision, the prices of pharmaceuticals not listed in the SL should be determined by the free operation of the market. According to the ComCo, this goal was not reached (at least for certain pharmaceuticals) because of the widely followed price recommendations. When the FAC (and thereafter potentially the Supreme Court) finally take a decision on the merits in this case, this might have another impact on the pharmaceutical industry.

12. Transactions/Collaborations

12.1 Important Legal Provisions

Acquisitions in the life sciences sector follow general rules of transactions. Representations and warranties in life sciences' share and asset deals should cover at least the following issues: (i) intellectual property rights and know-how, (ii) marketing authorisations, (iii) licence agreements, (iv) potential product liability, and (v) regulatory and anti-corruption compliance.

Co-operation by joint ventures exists both as contractual or corporate joint ventures. Parties are free in the choice of the legal set-up. Key issues to be addressed are commonly: (i) scope of the joint venture, (ii) non-competition, (iii) management, (iv) ownership of intellectual property rights, know-how and marketing authorisations, and (v) termination mechanism and consequences.

Licence agreements in the life sciences sector are quite complex and a number of specific issues are relevant, such as: (i) definition of licensed intellectual property rights or know-how, (ii) holder of marketing authorisations, (iii) exclusivities (for research, manufacturing and distribution activities), (vi) confidentiality, (v) product supply, (vi) sharing data and data protection, (vii) exploitation of co-operation results and (viii) regulatory compliance.

When entering into other commercial agreements (such as supply, distribution, or research and development agreements), the regulatory life sciences' framework – as well as data protection, advertising, unfair competition and antitrust law – must be kept in mind. Notably, the agreements must ensure that the principles and guidelines of Good Manufacturing Practices (GMPs) and the regulatory responsibilities are met.

12.2 Customary Agreements to Bridge the Valuation Gap

There are several customary options to bridge a valuation gap between buyer and seller. Earn-out clauses are commonly used, as the expected development of the target after closing is often difficult to assess. The goals, which trigger payments, can be regulatory milestones, the achievement of financial goals (eg, products sales) or other value-creating events. Thereby, parties should address milestone obligations in order to prevent any abuse. An alternative to bridge valuation gaps is to grant options for the seller to gain shares in the purchaser upon certain conditions.

12.3 Purchase Price Adjustments

In terms of purchase price adjustments, completion as well as locked-box models are commonly used.

12.4 Deal Protection Terms

In the course of a transaction, the parties usually agree on several protection measures. Transactions in the life sciences sector typically involve crucial and valuable information and know-how and, especially in the due diligence process, disclosed information must be kept absolutely confidential. Specific confidentiality agreements generally include penalty clauses. Also, parties commonly agree on a period of exclusive negotiations. As an additional protection, the parties have the possibility to agree on "break fees". The break fee typically obliges the parties to pay compensation when certain conditions are met that prevent the negotiations from succeeding.

A buyer is usually interested in not paying the entire purchase price at closing. The parties might agree that the purchase price is (partly) held back. Besides the advantage of paying later (liquidity reason), the buyer can then offset any claims in case of a violation of the representations and warranties. To balance, the seller normally insist on an escrow agreement. In an escrow arrangement, the buyer pays a part of the purchase price to an escrow agent which holds the money on behalf of the parties and only pays out the money pursuant to contractually agreed conditions.

12.5 Local Antitrust Approval

If a planned concentration of companies reaches the following two turnover thresholds, it must be notified in Switzerland to the ComCo before their implementation if for the last business year preceding the concentration (i) the companies involved reported together a worldwide turnover of at least CHF2 billion or a turnover in Switzerland of at least CHF500 million, and (ii) at least two of the companies involved reported individual turnovers in Switzerland of at least CHF100 million.

A notification is also mandatory, irrespective of any threshold, if the ComCo has found that one of the companies involved has a dominant market position in Switzerland and also the concentration concerns that market or an adjacent market.

If a merger is closed without approval by the ComCo, the company that was required to file can be charged with a fine of up to CHF1 million.

12.6 Tax Treatment of Asset Deals Versus Share Deals

A share deal is usually more attractive for a Swiss tax-resident seller. If a company sells a shareholding of at least 10%, the difference between the sales proceeds and the investment costs are generally virtually tax-exempt, due to the participation reduction. If an individual sells a shareholding held as a private asset, the capital gain is generally not subject to income tax. Therefore, transactions involving private individuals as sellers are very often structured as share deals.

Share deals are subject to Swiss securities transfer tax if a Swiss securities dealer is involved as a party or as an intermediary, unless an exemption applies.

From the buyer's perspective, a share deal has two major disadvantages. First, a share deal generally does not allow the buyer to eliminate future taxable profits in the target by setting them off with the financing costs for the acquisition. A merger of the target company with the acquisition vehicle bearing the finance costs within a few years after the acquisition and other debt push-down arrangements in order to finance the acquisition costs directly via the target are generally scrutinised under the tax avoidance scheme (ie, tax deductibility of finance costs may be denied at the level of the target). Second, the acquirer takes over the target company with all its potential tax (and non-tax) liabilities. Therefore, a share deal usually requires a substantial tax due diligence and tax indemnifications in order to cover the tax risks economically taken over by the buyer.

An individual seller holding the shares as private asset usually insists on a specific provision requiring the purchaser not to distribute funds from the target that were distributable and not required for business purposes at the time of the acquisition within the next five years in order to avoid reclassification of the tax-free capital gain into taxable income.

An asset deal generally gives rise to income taxation of all hidden reserves pertaining to the assets sold. Real estate transfer taxes and/or real estate gains taxes may apply to Swiss real estate. For Swiss VAT purposes, an asset deal can usually be structured as a transfer of a going concern, which generally does not give rise to payment of any VAT. While the buyer generally does not take over any tax risks from the seller, it takes over the seller's VAT basis of assets transferred as a going concern.

An asset deal has the huge advantage for the purchaser that it allows a step-up in the tax basis of the acquired assets and for tax-effective depreciations in the following years. Moreover, an asset deal allows financing the acquisition costs directly via the proceeds from the acquired business. The identification of tax issues and the negotiation of the tax language in an asset deal is generally much simpler than for a share deal. From a Swiss tax perspective, it is usually important to agree on a purchase price allocation for both the seller and the acquirer.

12.7 Protection of Licensees

The opening of insolvency or bankruptcy proceedings are not a reason for immediate termination of licence agreements on rights belonging to the bankrupt estate of the debtor if the licence contract does not provide for such a termination right. However, there may be specific cases where the bankruptcy of one party may constitute a reason for the other party to terminate the agreement for cause.

With the opening of the bankruptcy proceedings, long-term agreements remain in force only for the contractual term or until the end of the next notice period. However, the bankruptcy administrator can decide to continue to comply entirely or partly with the licence obligations of both the licensor and licensee that have fallen into bankruptcy. The bankruptcy administration can also assign the licensor's contractual rights. The creditor can still demand that security be furnished. The bankruptcy administrator has also no right for an early termination of a licence agreement in the case of a bankruptcy proceeding – in composition proceedings this remains possible.

Licences that have been registered against the correspondent trade marks, patents or designs in Swiss registers are assumed to "survive" the bankruptcy and composition proceedings (ie, they remain valid). In such a case, the licensee is entitled to continue exploiting and a potential successor of the licensor has to comply with the licence agreement.

13. Investigations/White Collar

13.1 Focus of Investigations

The grant, offer or promise of material benefits to persons who prescribe or dispense pharmaceuticals or to the organisations which employ them is prohibited under Swiss law. Also, rebates on pharmaceuticals are permitted only if commercially and economically justified discounts, as rebates on volume or for other economic reasons. Similar codes of conduct apply in respect of prescription medical devices. As a result, penal and regulatory authorities appear to concentrate their investigations firstly on the rebates granted by the medical and pharmaceutical industry to HCPs, and secondly on the education grants involving HCPs.

13.2 Important 'Do's' and 'Don'ts'

Investigations require clear "dawn raids" guidelines and a good management of personnel resources. Responsible persons must be in place and documents and materials must be made available within the shortest time possible. Trade secrets must be protected from disclosure. During the investigation, transparent co-operation with the prosecution authorities is of the utmost importance.

13.3 Distinct Characteristics of Investigations

There is essentially no difference between an investigation in the pharma/medical device sector and an investigation in another sector in Switzerland.

14. Product Liability

14.1 Specific Legal Regime

With the exception of clinical trials where special rules apply, there is no specific legal regime as regards the liability for injuries caused by pharmaceuticals or medical devices. The general provisions and principles of tort law are contained mainly in the Federal Act on Product Liability (PLA) and Article 41 et seqq. of the Swiss Code of Obligations (CO) apply.

The general and cumulatively applicable prerequisites for a potential liability based on the PLA are:

- damages (not covered are damages to the defective product itself and damages to items of property not intended for private use or damages of an amount of up to CHF900);
- a defective product; and
- an adequate causal link between the defectiveness of the product and the damage caused.

Defectiveness is thereby defined as the product in question not providing the safety which, taking all circumstances into account, an "average user" (either the public or HCPs for prescription-only therapeutic products) is entitled to expect. Circumstances to be taken into account are the way the product is presented to the public or the HCP (including information provided in the package leaflet), the use to which it could reasonably be expected to be put and the point in time when the product was put into circulation.

Under general tort law (Article 41 et seqq. CO), in addition to damages, an unlawful (tortious) act and adequate causation, also fault (intent or negligence) must be given for potential liability.

Potentially liable under the PLA is the "producer" defined as the manufacturer (person who produced the finished product, a basic material, or a component), the quasi-manufacturer (person who represents him- or herself as the

manufacturer by putting their name, trade mark or other distinguishing feature on the product) or the importer. In a second stage and if the 'producer' cannot be identified, the supplier is liable unless he or she informs the damaged person of the producer's name or of the person who supplied him or her with the product.

Potentially liable under the general tort principles of the CO is any natural or legal person culpably committing a tortious act.

14.2 Standard of Proof for Causation

The standard for proof of causation is "overwhelming likelihood", whereby the burden of proof is incumbent upon the claimant. It should, however, be noted that this standard of proof may be lowered under specific circumstances. A claimant can basically only invoke presumption of causation in an actual case of lack of proof. The means to rebut such a presumption are very limited and are at the court's discretion.

14.3 Specific Defences

There are no specific defences available regarding liability for pharmaceuticals or medical devices. Most relevant for therapeutic products is the proof of state-of-the-art development and manufacturing of the product at the time the product was put into circulation ("development risk defence").

14.4 "Regulatory Compliance Defence"

A "regulatory compliance defence" is not acknowledged under Swiss law in the sense of per se excluding liability. Regulatory compliance is, however, considered as being an indication that the product did provide the safety which, taking all circumstances into account, a person was entitled to expect.

14.5 Market Share Liability

It is the claimant's burden of proof to establish precisely which product (ie, which pharmaceutical or which medical device) caused his or her alleged medical condition in order to receive compensation for damages.

If claimant may establish causation for more than one product, the respective manufacturers are jointly and severally liable. It is within the judge's discretion to decide – based on the evidence provided – how to allocate the effective bearing of damages among the manufacturers. In any case, market shares will not play a role in this decision as any form of market-share liability is unknown to Swiss law.

If only one of several pharmaceuticals or medical devices is responsible for an alleged medical condition of the claimant, but the claimant cannot establish which one, then there is no sufficient causal link to entitle the claimant to compensation for damages.

14.6 General Statute of Limitation Period

The statute of limitation period for all products falling under the PLA (ie, inter alia for pharmaceuticals and medical devices) is three years after the day upon which the damaged person became aware, or should reasonably have become aware, of the damage, the defect, and the identity of the producer. Claims under the PLA are in any case forfeited if no law suit is filed within ten years after the day upon which the producer put the product causing the damage into circulation.

The general statute of limitation period for all claims based on the CO is one year from the date on which the injured party became aware of the loss or damage and of the identity of the person liable for it. In any event, a claim is time-barred ten years after the date on which the loss or damage was caused. Longer periods apply if the action for damages is derived from an offence for which criminal law envisages a longer limitation period.

The statute of limitation period must be invoked by the defending party; such a period will not be considered by courts ex officio. Consequently, the defending party may also waive their right to argue that a claim is time-barred.

14.7 Information Against Manufacturers

No specific claims for information against manufacturers of pharmaceuticals or medical devices or against public authorities are available.

14.8 Available Damages

Under the PLA, only material damages exceeding CHF900 and material damages caused to items of private use as well as bodily injuries ("personal damages") may be claimed.

Under the CO, all damages, such as personal and material damages to all kind of objects (whether in private use or not), including loss of gain as well as so-called "normative damages" as household and nursing damages, may be claimed. Damages are generally not available if damage has not yet materialised. In addition, and applicable both under the PLA and under general tort law, one may claim moral tort compensation; however, under Swiss law, this is moderate in amount.

Punitive damages are not available under Swiss law, but judgments providing for punitive damages may be enforced at the judge's discretion.

14.9 Maximum Limit on Damages

There are no maximum limits of damages available for one claimant and/or available from one manufacturer.

14.10 Recent Decisions

One of the few recent published drug liability cases is a case considering a birth-control pill (Decision of the Supreme Court 4A_365/2014; 4A_371/2014). A young girl had taken this birth-

control pill and had suffered a pulmonary embolism and has been, since then, severely disabled. The patient claimed that undesirable side-effects of the pill had caused her personal injury. The Commercial Court Zurich and the Federal Supreme Court, however, found that the pill taken was not defective in the sense of the PLA. The courts particularly found that not mentioning in the package insert addressed to the patient the enhanced risk to suffer from thrombosis, embolisms or similar undesirable side-effects compared to so-called "second generation" birth-control pills did not constitute an instruction error by the pharmaceutical company. At hand, a respective risk comparison was, however, contained in the professional information directed to physicians prescribing the respective pill, which aspect was also taken into account by the courts. It was further held that a manifested undesirable side-effect itself does not per se render a pharmaceutical product defective.

This decision is particularly important for producers of pharmaceuticals (and also of medical devices), as it accepts the "learned intermediary" doctrine.

14.11 Trial
Trials are held by a judge. Jury trials are unknown to Swiss law.

14.12 Disclosure Obligation
Actual discovery is unknown to Swiss law. The parties are, however, under a duty to co-operate in the taking of evidence and may also be ordered to disclose certain documents that are considered relevant to the case. If that party then fails to co-operate, a court is free to weigh such behaviour against that party.

Also, actual pre-trial discovery is not available. Article 158 of the Civil Procedure Code provides for a precautionary taking of evidence if the applicant shows credibly that the evidence is at risk or that he or she has a legitimate interest.

14.13 Potential Changes to Legal Regime
Currently, there are no discussions regarding potential changes in the legal liability regime for pharmaceuticals.

Pestalozzi
Loewenstrasse 1
8001 Zurich
Switzerland

Tel: +41 44 217 91 11
Fax: +41 44 217 92 17
Email: Lorenza.ferrari@pestalozzilaw.com
Web: www.pestalozzilaw.com

15. Privacy & Data Protection

15.1 Legislation and Regulation
The Federal Act on Data Protection (DPA) and the Ordinance to the Federal Act on Data Protection (ODPA) govern privacy and data protection in Switzerland. The DPA is currently under revision and will likely take effect by the end of the summer 2018. In addition, cantonal laws also apply to data collected by cantonal bodies and institutions.

15.2 Regulatory Bodies
The Federal Data Protection and Information Commissioner (FDPIC) supervises compliance with the DPA and investigates alleged infringements. In civil cases, civil courts will also enforce data privacy rights and obligations.

15.3 Health Related Information
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 about the collection of sensitive personal data, disclose sensitive data to third parties only if justified by law, by consent or by an overriding interest, as well as involving specific notification and registration obligations with the FDPIC.

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

15.4 Sanctions
The current DPA provides for fines of up to CHF10,000 for certain breaches of the data privacy legislation. For a person accessing electronic patient records without authorisation, fines of up to CHF100,000 can be imposed. Additionally, the FDPIC may, provided it revealed in an investigation that a natural/legal person in the private sector does not comply with the DPA, render non-binding recommendations on data protection measures. Civil proceedings for breach of privacy are cumulatively permitted.

15.5 Special Requirements for Cloud Platforms
There are no specific statutory provisions for cloud platforms. However, the general provisions of the DPA have to be complied with – eg, data subjects must be informed about the data processing in the cloud and implementation of data 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 – use of either the EU standard contractual clauses or the FDPIC's template agreement for outsourcing of data processing is recommended. Furthermore, both the data controller and the data processor must respect

the right to obtain information and the right of data deletion or correction.

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 abroad. Therefore, security measures and their control should be all the more stringent and comprehensive.