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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.

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Law & Practice

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Wenger & Vieli AG's life sciences team represents pharmaceutical and biotech companies on both industry-specific and general legal matters. Other clients include medical device, cosmetics and functional foods companies, as well as hospitals and physicians. Practitioners focus primarily on marketing authorisation, market access, advertising, manufacturing, distribution and health insurance reimbursement. The team also offers expertise in related matters, such as intellectual property, product liability, data protection and competition law. In addition, lawyers from the M&A and private equity departments provide specialist advice on takeovers and investments in the healthcare sector.

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1. Regulatory Framework

1.1 Key Legislation

Pharmaceuticals are mainly regulated by the Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products) (Heilmittelgesetz) of 15 December 2000 (LTP). Based on the LTP, several ordinances have been issued. The LTP and its related ordinances stipulate the conditions for obtaining a marketing authorisation and for authorisations required to manufacture, import, sell, trade and export pharmaceuticals as well as rules about the prescription, dispensing and advertising of pharmaceuticals. In many areas, Swiss legislation on pharmaceuticals follows EU regulation.

The Federal Health Insurance Act (Krankenversicherungsgesetz) of 18 March 1994 and related ordinances regulate the reimbursement and the pricing of pharmaceuticals reimbursed by the mandatory health insurance.

The LTP defines pharmaceuticals as products of chemical or biological origin which are intended to have or are 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; blood and blood products are also considered to be medicinal products. Products are assessed based on this definition in order to determine whether they are to be considered pharmaceuticals.

The LTP and its ordinances classify pharmaceuticals into different categories, which are partly subject to differing rules. The LTP differentiates between prescription-only and over-the-counter products, which are subject to different rules with regard to advertising and dispensation. Furthermore, there are certain special rules with regard to blood and blood products, allergen compounds and complementary and phyto-pharmaceutical substances. The law also provides for different rules with regard to the requirements for marketing authorisation and differentiates between phar-

maceuticals which are subject to the standard authorisation procedure and others such as, for example, pharmaceuticals with a known active ingredient or complementary medicines which are subject to a simplified procedure. Other categories of pharmaceuticals for which special rules exist are, for example, orphan drugs, biosimilars, co-marketing products and parallel imports. There are also pharmaceuticals which do not require marketing authorisation, such as pharmaceuticals manufactured ad hoc by pharmacies and hospitals for their own patients.

1.2 Regulatory Bodies

Marketing authorisations and licences to manufacture, import, trade or export pharmaceuticals are granted by the Swiss Agency for Therapeutic Products (Schweizerisches Heilmittelinstitut, Swissmedic). Authorisations to operate a hospital, a pharmacy or a drug store and to dispense medicinal products are granted by the cantons. To the extent provided for by federal law, Cantonal authorities are also responsible for monitoring and enforcing compliance with the federal regulations.

Reimbursement status for pharmaceuticals is granted and monitored by the Swiss Federal Office of Public Health (FOPH). The FOPH decides on the maximum price that is reimbursed for the pharmaceuticals.

1.3 Regulations

Medical devices are regulated by the LTP and the Ordinance on Medical Devices of 17 October 2001. The regulation of medical devices in Switzerland is in most respects similar to EU regulation. The Ordinance on Medical Devices defines medical devices as products, including instruments, apparatus, in vitro diagnostics, software and other goods or substances which are intended to have or are presented as having a medical use and the principal effect of which is not obtained with a medicinal product. Pharmaceuticals have a pharmacologic, immunological or metabolic effect on and lead to direct interaction with the human organism. The application of medical devices, however, results in physical effect only. The borderline between pharmaceuticals and medical devices is thus drawn based on the effect the product has on the human organism.

Nutritional products and cosmetics are regulated by the Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act, FSA) and its corresponding ordinances. Nutritional products are products which serve to maintain or build up the human body and are not promoted as pharmaceuticals. Nutritional products only serve to supply the body with substances necessary for the normal functioning and development of the human body without having a medicinal effect. For nutritional products only, a certain number of defined health-related claims are admissible. Cosmetics are products destined for external use on the human body, teeth or oral cavity only and serving, solely or predominantly, locally to protect, maintain, clean, perfume or deodorise sound body parts or change their appearance. Medicinal claims are not admissible for the promotion of cosmetics.

The borderline between pharmaceuticals and products such as cosmetics and nutritional products is drawn on the basis of the product's composition, its pharmacologic characteristics, its use and presentation and the risks it entails.

For certain products it is difficult to classify them as a pharmaceutical, nutritional product, cosmetic or medical device. In 2009, Swissmedic and the FOPH jointly issued a paper with criteria for the classification of such products.

If a company is of the opinion that the competent federal authority has wrongly classified its product, corresponding decisions can be challenged by the concerned company by way of appeal to the Federal Administrative Court. The appeal has to be filed within 30 days after notification of the respective decision. The appellant can claim breach of federal law, incomplete or incorrect establishment of the relevant facts or inappropriateness of the decision. Decisions of the Federal Administrative Court can be appealed further to the Swiss Federal Supreme Court. The appeal has to be filed within 30 days after notification of the decision of the Federal Administrative Court. The appellant can claim breach of law and clearly incorrect establishment of the relevant facts. Decisions of cantonal authorities can be challenged in accordance with the specific cantonal law applying to the case. Decisions of the highest cantonal court can be appealed to the Swiss Federal Supreme Court.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials are regulated by the LTP, the Federal Act on Research involving Human Beings (Human Research Act, HRA) of 30 September 2011 and the Ordinance on Clinical Trials in Human Research, as well as by the international ICH Guideline on Good Clinical Practice, ICH-GCP E6(R1), of 10 June 1996 and the WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, Brazil 2013.

Clinical trials with pharmaceuticals require authorisation by the competent ethics committee and Swissmedic. As an exception to this rule, clinical trials with pharmaceuticals authorised for marketing in Switzerland and administered within the scope of the authorised use do not need authorisation by Swissmedic. Swissmedic examines whether the pharmaceutical used in the trial complies with the requirements of Good Manufacturing Practice and with safety requirements. Swissmedic can inspect compliance with legal

rules at any time. The ethics committee is appointed and supervised by the cantons. The competent ethics committee ensures the protection and safety of the trial subjects, examines trials' compliance with ethical, scientific and legal requirements and may at any time request information and documents.

Clinical trials must comply with the rules of Good Clinical Practice and must pursue a scientifically relevant purpose. Trial subjects must consent to their involvement in the trial. The initiator of the trial is liable for damages suffered by trial subjects in connection with the trial. The sponsor must have its registered office in Switzerland or name a representative registered in Switzerland.

If the safety or health of the trial subjects is in danger the ethics committee can withdraw or suspend the authorisation for the trial or set additional requirements.

2.2 Approval and Authorisation

Depending on whether the pharmaceuticals involved in the trial are authorised for marketing and are used within the scope of the marketing authorisation, either the competent ethics committee only or both Swissmedic and the committee have to authorise the trial.

The clinical trial file must be submitted to the competent ethics committee by the investigator or the sponsor. The competent ethics committee is the committee of the canton in which the trial is conducted. If the trial takes place in more than one canton according to the same trial plan, the committee of the canton in which the trial co-ordinator is located is the leading committee and responsible for requesting information from other cantonal committees with regard to requirements in the respective canton.

The ethics committee confirms receipt of the application within seven days and informs of formal flaws in the file. The committee has to issue its decision within 30 days after receipt of the completed application. If the committee requests additional documents, the time limit is suspended until the complete information is received. In the case of multicentre trials, the leading committee has to issue its decision within 45 days. Authorisation is granted if the trial complies with ethical, legal and scientific requirements.

The file has to be submitted to Swissmedic by the sponsor. Swissmedic requires one hard copy and one electronic copy of the file containing the documents listed in the annex of the Ordinance on Clinical Trials in Human Research. Incomplete files will not be processed. Swissmedic will confirm receipt of the application within seven days and inform of formal flaws in the file. Swissmedic has to issue its decision within 30 days after receipt of the complete application. The time limit can be extended for another 30 days if the pharmaceutical is applied to human beings for the first time or if it is manufactured in a new process.

The trial file can be submitted to the competent committee and to Swissmedic simultaneously, if both approvals are required. The trial cannot start before the approval of both Swissmedic and the competent ethics committee has been granted. Essential changes in the trial plan have to be approved by Swissmedic and/or the committee prior to their implementation. The same deadlines apply as for the initial trial authorisation.

2.3 Registration and Publication of Results

The HRA provides for mandatory public registration of authorised clinical trials. The sponsor has to register the trial either with a primary registry accredited by the WHO or with the registry of the US National Library of Medicine as well as in the official Swiss public database (SNCTP Portal, www.kofam.ch/en/swiss-clinical-trials-portal/). Registration has to be made prior to conducting the trial, with the exception of Phase I trials which must be registered within one year after completion of the trial. Registered data must be in line with the application authorised by the competent ethics committee. Data registered in the international registry must be in accordance with the WHO Trial Registration Data Set (Version 1.2.1), data registered with the national database must contain additional data in accordance with annex 5 of the Ordinance on Clinical Trials in Human Research. Results of the trial do not have to be published.

3. Marketing Authorisations

3.1 Process for Obtaining Marketing Authorisation

Marketing authorisations are granted by Swissmedic. A marketing authorisation can only be granted to a company or person having its domicile, registered office or a branch office in Switzerland and holding a manufacturing, import or wholesale licence. Marketing authorisations can be granted based on the ordinary, the fast-track or the simplified procedure (see below). For certain pharmaceutical products (eg certain homeopathic and anthroposophical products) authorisation by way of a mere notification is possible. Authorisations granted according to one of these procedures entail identical rights to bring the pharmaceutical product on to the Swiss market. In addition to the common marketing authorisation it is possible to obtain a marketing authorisation for a limited period of time for pharmaceuticals against life-threatening diseases if there are no other treatment options available in Switzerland. For pharmaceutical products containing genetically modified organisms additional authorisation requirements apply.

The fees for the marketing authorisation vary depending on the nature of the product and the type of procedure. For a pharmaceutical product with a new active substance the fee is CHF70,000, for a pharmaceutical product containing an existing registered active substance (simplified procedure) the fee is CHF28,000 (if it brings an innovation) or CHF15,000 (if it does not bring an innovation). For certain categories of pharmaceutical products such as allergens, complementary and phyto-pharmaceuticals, veterinary medicines and co-marketing products different fees of below CHF10,000 apply.

Ordinary procedure
The application to Swissmedic for the marketing authorisation must be made using standard forms and the common technical document (CTD) format of the International Conference on Harmonisation. The required documents are listed in detail in the Ordinance on the Requirements for Marketing Authorisation of Medicinal Products and relating guidelines. Swissmedic recommends submitting data electronically. The conditions for granting marketing authorisation are high quality, safety and efficacy of the product. If a drug or process has already been authorised in another country that has a similar system of marketing authorisation, the results of the examinations carried out for that purpose have to be considered by Swissmedic. There is, however, no automatic recognition of foreign marketing authorisations. In the case of pharmaceutical products containing an active substance that has already been authorised, Swissmedic in principle assesses the evaluation reports of the foreign authorities. Swissmedic will not, however, make an assessment of the evaluation reports of the EMA or the FDA provided that these reports are not contradictory and Swissmedic has no essential concerns towards these evaluations.

The ordinary authorisation procedure takes at least one year. Swissmedic has issued a guideline setting out its internal targeted time periods and milestones, which are 30 days for the formal control, 120 days for the examination and establishment of the list of questions, 90 days for the advance notice of the decision and 90 days for the decision. If Swissmedic has queries, or requests further information or documents, the internal targeted time periods are stopped and the authorisation process can take longer.

Fast-track procedure
If there is no satisfactory treatment against a perilous or heavily disabling disease, and if the pharmaceutical product is of a high therapeutic value, a fast-track procedure is available at the applicant's request. The fast-track procedure must be applied for at least three months before the application for the marketing authorisation is filed. It enables registration to be completed within about four months. If Swissmedic has queries, the proceedings may take longer.

For medicinal products containing a new active substance and for extensions of the indication of such products, an accelerated procedure is available in which the deadlines are reduced by 20% against an increase of 100% of the fees.

Simplified procedure
A simplified procedure is available for certain types of pharmaceutical products, such as pharmaceutical products with active substances that have already been authorised, parallel imports from a country with an equivalent marketing authorisation system, orphan drugs and complementary and alternative pharmaceutical products. The procedure is mainly governed by the Ordinance on the Simplified Marketing Authorisation of Medicinal Products and Authorisation by Way of Notification.

3.2 Third-Party Data
Applications regarding pharmaceutical products with active substances that have already been authorised may be based on the documentation of a reference product already registered with Swissmedic, ie the results of the tests on the reference product serve as the basis for the application for the marketing authorisation. Based on the LTP, the applicant may rely on the data of the pharmacological, toxicological and clinical tests of the already authorised pharmaceutical product if the marketing authorisation holder of the original preparation gives written permission or if the protection period of ten years for the original preparation has expired. Under certain circumstances the applicant may also refer to literature. The marketing authorisation is subject to the simplified procedure (see above). The Ordinance on the Simplified Marketing Authorisation of Medicinal Products and Authorisation by Way of Notification specifies the documents which have to be submitted with the application and outlines the conditions for referral to third-party documents and literature.

3.3 Validity of Marketing Authorisation
Marketing authorisations are granted for renewable terms of five years. In order to renew the authorisation the marketing authorisation holder must submit a renewal application with supporting information at least six months before the expiry date.

Swissmedic will withdraw the marketing authorisation if the product is not effectively placed on the market within three years from the grant of marketing authorisation or not marketed for three consecutive years. Exceptions to this rule apply if a patent hinders the marketing of the pharmaceutical product (the period of three years only starts with the expiry of patent protection) and in cases of pharmaceuticals authorised in connection with an emergency situation and pharmaceuticals that are only exported (these are not subject to withdrawal).

Swissmedic can also withdraw, vary or suspend the marketing authorisation after a review proceeding if the legal requirements for the marketing authorisation (safety, quality and efficacy) are no longer met.

3.4 Paediatric Population

At present, there is no obligation for applicants to submit data of clinical trials in the paediatric population.

3.5 Varying a Granted Authorisation

Variations of an authorised pharmaceutical product are subject to approval by, or notification to, Swissmedic, depending on the type of variation. Substantial variations require a new marketing authorisation procedure, minor variations only have to be notified and variations that are in between have to be approved by Swissmedic. Appendices 7 to 9 of the Ordinance on Marketing Authorisation list the respective types of variations. The procedure for substantial variations takes approximately one year. In the notification procedure, the variation can be implemented if Swissmedic raises no objection after 30 days from receipt of the notification. The approval time for other variations depends on the type of variation and can take from a few months up to almost one year. The administrative fees for variations vary depending on the type of variation.

3.6 Transferring Authorisations from One Party to Another

A marketing authorisation or pending application can be transferred to another company. The prospective owner has to request the transfer from Swissmedic. This company must be domiciled in Switzerland and be in possession of a licence for import, manufacturing or wholesale. The application for a transfer must be made at least three months before the planned transfer date. Swissmedic has issued guidelines with regard to the procedure of the transfer of the marketing authorisation outlining the information and documents that must be handed in to Swissmedic. Swissmedic examines the application and issues a decree with regard to the transfer. The administrative fee for the transfer of a marketing authorisation is CHF1,000.

3.7 Access to Unauthorised Products

In certain limited situations, pharmaceuticals that are not authorised in Switzerland can be used for the treatment of patients. These situations are, for example: use within a clinical trial; use of pharmaceuticals lawfully manufactured by a pharmacy or a hospital pharmacy for its own patients; import of a pharmaceutical product in small quantities by the patient; import by healthcare professionals of a pharmaceutical product for which there is no treatment alternative in Switzerland from a country with an equivalent marketing authorisation system for an individual patient; or import by healthcare professionals of a pharmaceutical product for an individual patient based on a special authorisation by Swissmedic. It is also possible to obtain a marketing authorisation for a limited period of time for pharmaceuticals against life-threatening diseases if there are no other treatment options available in Switzerland.

3.8 Ongoing Obligations

The holder of a marketing authorisation has various obligations. They must make sure that the pharmaceuticals comply with the marketing authorisation and that they meet the requirements of their regulatory licences. They must establish a pharmacovigilance system, and will have various notification and reporting obligations to Swissmedic. The holder of a marketing authorisation for a pharmaceutical with a new active substance, for example, has to submit to Swissmedic periodic safety update reports during the five years after marketing authorisation has been granted.

3.9 Post-Marketing Obligations

The LTP gives Swissmedic the power to grant a marketing authorisation subject to conditions or associated with obligations. Such conditions or obligations can be further evaluation of the product, eg in Phase IV trials. Post-marketing obligations can also be imposed by Swissmedic during the term of the authorisation and in connection with the renewal of the marketing authorisation. Post-marketing obligations must be proportionate and adequate with regard to the aim of the measures.

3.10 Third-Party Access to Pending Application

Pending applications for marketing authorisations fall under official secrecy. However, the granting of orphan drug status is published before the marketing authorisation is granted. The granting of a marketing authorisation is published in the monthly Journal of Swissmedic with the essential information on the product and the product information is published under www.swissmedicinfo.ch. The refusal to grant a marketing authorisation is not published.

3.11 Third-Party Access to Additional Information

Based on the Swiss Freedom of Information Act (Öffentlich keitsgesetz) third parties can ask to access official documents. No access is granted to, for example, documents of a pending administrative proceeding or to business secrets of the applicants. Personal data also needs to be protected in the event that information is made accessible.

The application for access to official documents has to be addressed to the authority which created or received the documents as primary addressee. Where access is requested to official documents which contain personal data and if the authority is considering granting access, the person concerned is given the opportunity to submit comments within ten days. The authority has to make a decision within 20 days after receipt of the application. This time period may be extended for 20 more days. The decision can be questioned

by applying for mediation with the Swiss Federal Data and Information Commissioner. There is, furthermore, the possibility of a judicial appeal procedure.

4. Pricing and Reimbursement

4.1 Setting and Controlling Prices

Pharmaceutical products which are reimbursed by the basic health insurance are subject to a price control by the Swiss Federal Office of Public Health (FOPH). There is no price control for non-reimbursed products. Finished pharmaceutical products must, in principle, be shown on the list of specialisms (SL) established by the FOPH for being reimbursed in the basic health insurance. The SL price determined by the FOPH is the maximum price that can be invoiced by healthcare providers and that will be reimbursed by the health insurance companies. The SL price may not be increased without consent of the FOPH. When determining the SL price the FOPH also determines the ex-factory price of the pharmaceutical company. The repartition of the margin between the ex-factory price and the SL price amongst the wholesalers on the one hand and pharmacies, hospitals and self-dispensing doctors on the other is not regulated by law.

The SL price is regularly reviewed. In particular, there is a review every three years, at patent expiry and in the case of extension of the indication. Several aspects of the price determination and review proceeding are currently under revision and judicial review.

There is no comparable price control for medical devices. The distributors of medical devices are free to set their prices. Basic health insurance, however, only reimburses certain predetermined maximum amounts for certain types of medical devices. For medical devices applied by the patients themselves or by other laypersons, these amounts are listed in the list of instruments and tools (Mittel- und Gegenständeliste) established by the Federal Department of Home Affairs. The reimbursement of medical devices applied or implanted by healthcare providers is regulated in the tariff agreements governing the respective healthcare services.

4.2 Initial Price Negotiations

The marketing authorisation holder must make an application to the FOPH for listing a product in the SL. The three conditions for SL admission are efficacy, usefulness and economy. At present, the economy for original preparations is in principle assessed on the basis of the following two criteria:

- the average ex-factory price (without VAT) in nine reference countries (Germany, France, Austria, Denmark, The Netherlands, the UK, Belgium, Finland and Sweden); and
- the prices of drugs with the same indication or a similar mode of action (therapeutic cross-comparison). If the pharmaceutical product constitutes a considerable therapeutic advancement, an innovation premium is granted.

According to the current implementation regulations, the SL price may as a maximum exceed the average ex-factory price of the nine reference countries by 5%. This maximum does not apply if the product is of significant importance for medical care or if the comparison with prices abroad is only possible with fewer than three countries.

In its application to have a drug listed in the SL, the marketing authorisation holder must indicate the requested price. If the FOPH considers the price too high, it indicates an alternative price, which the applicant can accept or reject. Often, it follows a price discussion. If no acceptable price for both sides can be found, the applicant can ask for a formal decision that can be appealed to the Federal Administrative Court and finally to the Federal Supreme Court.

The SL prices of generics are determined in relation to the prices of their reference products. Depending on the sales volume of the original preparation (and its co-marketing preparations), the prices of generics need to be between 10% and 60% lower than the original.

4.3 Public Funds

Under the mandatory health insurance system, the health insurance companies reimburse finished pharmaceutical products prescribed by physicians (or under certain circumstances, chiropractors) which are listed on the SL and which are used within their indication. The listing in the SL may be subject to certain conditions regarding reimbursement (limitations).

The costs of a product that is not listed on the SL, or is listed on the SL but is used off-label or outside a limitation of reimbursement have to be reimbursed by the mandatory health insurance in the following situations:

- in a compassionate-use situation if there is no effective and authorised treatment alternative; and
- in the situation of a "treatment complex" (ie when there is a narrow connection between medical services that are reimbursed and services that are not, or are only partially reimbursed when the non-reimbursed services are a necessary condition for the treatment, or are of considerable importance for the success of the treatment).

In both situations, the physician of confidence of the respective health insurance company has to be consulted and the health insurance company has to approve reimbursement in advance and determines the extent of reimbursement.

Voluntary additional private health insurance also covers pharmaceuticals that are not listed in the SL.

For other social insurances, such as insurance in the event of accident or invalidity, the scope of reimbursement of medicinal products may be different.

4.4 Cost-Benefit Analysis

As previously mentioned, one of the criteria to determine the price of a pharmaceutical product is the comparison with the prices of drugs with the same indication or a similar mode of action (therapeutic cross-comparison). This comparison should include a cost-benefit analysis. This has been highlighted in a recent decision of the Swiss Federal Court (9C_417/2015).

A formalised health technology assessment is presently not in place for determining the prices of pharmaceutical products. The FOPH has, however, recently formulated a "health technology assessment" programme and intends to extend, step by step, its HTA activities over the coming years. The focus of this programme is to be on the re-evaluation of the reimbursement of certain products or services with the goal of deleting them from the catalogues of reimbursed products or services or restricting reimbursement.

4.5 Restrictions on Costs Grounds

All products listed on the SL fulfil the condition of economy. Physicians may therefore prescribe all these products without regard to their price. If a product is not reimbursed, physicians must inform the patient about this and may only prescribe it in agreement with the patient. The general principle of economy, however, also applies to the activities of healthcare professionals. If the total costs they cause to health insurance considerably exceed the costs of comparable healthcare professionals, a review proceeding may be initiated by santésuisse that may lead to claims for repayment of certain amounts.

4.6 Payment to Dispensing Pharmacists

Pharmacists are remunerated through the sales margin of the pharmaceutical product and certain lump sum payments that are added to their sales price. In principle, the sales margin consists in the difference between the selling price of the pharmacist (that may not exceed the public price listed in the SL) and the price at which the pharmacist bought the product from the wholesaler or marketing authorisation holder. The lump sums that are added to the sales price for certain services of the pharmacists are determined in a tariff agreement between the associations of the health insurance companies (santésuisse) and the Swiss Pharmacists Association.

Pharmacists in principle have to dispense the pharmaceutical that has been prescribed by the physician. If a generic is available, pharmacists have the right to substitute the original unless the physician has expressly written on the prescription that a substitution is excluded for medical reasons.

5. Promotion and Marketing

5.1 Governing Rules

Advertising for pharmaceutical products is governed by the LTP, the Ordinance on Advertising for Medicinal Products, the Ordinance on Health Insurance (with regard to pharmaceuticals reimbursed by health insurance) and the Federal Act against Unfair Competition (AUC).

The LTP provides for different classifications of pharmaceuticals relevant for the distribution and promotion of pharmaceuticals. The law differs between over-the-counter (lists C to E) and prescription-only pharmaceuticals (lists A and B).

Advertising aimed at healthcare professionals is generally allowed for all pharmaceuticals authorised for marketing in Switzerland. Advertising must, however, not be misleading, inaccurate, against public policy or unethical, or incite excessive, abusive or inappropriate use of pharmaceuticals, and must be in line with the latest product information approved by Swissmedic. Advertising must be accurate, balanced and provable and claims must be based on and reflect the current state of scientific knowledge.

Advertising aimed at the general public is not allowed for prescription-only pharmaceuticals and for pharmaceuticals reimbursed by basic health insurance. Advertising aimed at the general public must not be misleading, inaccurate, against public policy or unethical, or incite excessive, abusive or inappropriate use of pharmaceuticals. It must be in line with the latest product information approved by Swissmedic, must be objective and without exaggeration and contain an invitation to consult the patient leaflet. In certain limited situations, advertisements must be submitted to Swissmedic for prior approval.

Advertising for medical devices is regulated differently by rules set out in the Ordinance on Medical Devices. The Ordinance stipulates that advertising for medical devices which are dispensed directly to the general public or are used directly by the general public may only contain statements on its application, efficiency and efficacy which are in line with the product information. Misleading statements with regard to efficacy and efficiency respectively are not allowed. Advertising aimed at the general public is not allowed for prescription-only medical devices or medical devices marketed for application by healthcare professionals only.

5.2 Breaches of the Promotional Rules

Swissmedic is responsible for enforcing the rules on advertising. Its decisions can be appealed to the Federal Admin-

istrative Court. If advertising practises constitute a breach of the Federal Act against Unfair Competition (AUC), this can be brought before the civil courts. Advertising for pharmaceuticals aimed at healthcare professionals is also regulated by the Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code), issued by scienceindustries, the association of the Swiss chemical, biotech and pharmaceutical industries. The surveillance of advertising aimed at healthcare professionals is mainly performed by the secretariat of the Pharma Code and not by Swissmedic. If a case cannot be solved or if a signatory of the Pharma Code does not comply with a decision of the secretariat, the case will be brought to the attention of Swissmedic. Swissmedic must act in any case if advertising endangers drug safety. Decisions by Swissmedic and by a state court overrule decisions of the private body instituted by the Pharma Code.

5.3 Sanctions for Breaching Promotional Rules

Infringements of the advertising regulations can be sanctioned by the secretariat of the Pharma Code by instructing the party to stop the breach and to correct its effects if possible.

Swissmedic, moreover, can ban the use of, confiscate, hold in official storage and destroy promotional material and reprimand and set deadlines for repair. In severe or repeated cases of infringements Swissmedic can prohibit advertising for specific pharmaceuticals for a limited or unlimited period of time. Swissmedic can also impose fines for infringement.

The regulations on advertising directed to medicinal persons are primarily enforced by the secretariat of the Swiss Pharma Code, often also based on complaints from competitors. Swissmedic mainly intervenes if breaches of advertising regulations threaten public health. The regulations on advertising directed to the public are enforced by Swissmedic. Competitors and third parties can notify the secretariat of the Pharma Code or Swissmedic about infringements of advertising regulations.

Competitors can also bring a lawsuit before the civil courts in case of breach of rules of the AUC. Such lawsuits are not very frequent.

5.4 Length of Breach Proceedings

Proceedings of the secretariat of the Pharma Code should not take more than one month unless there are good reasons for an extension. The secretariat grants the opportunity to respond to the complaint within an adequate period of time.

Proceedings before Swissmedic and the state courts can take up to several years. It is possible that Swissmedic or the competent court may order that an appeal will not have suspensive effect regarding a prohibition ordered, ie the appeal to the next instance will not have the effect that the advertising in question can be further used.

If a competitor brings a lawsuit based on the AUC, under certain circumstances it can request the prohibition of the advertising by way of injunctive relief.

5.5 Restrictions on the Provision of Gifts/ Sponsorship

The LTP prohibits the offer and acceptance of financial or other advantages to individual medical practitioners or healthcare establishments. As an exception to this rule, gifts of a modest value, relevant to the professional activity of the recipient, are allowed. According to practice, gifts are considered to be of a modest value if their total value is not more than CHF300 per year per healthcare professional. Under certain conditions, it is also permitted to grant discounts to healthcare professionals. Swissmedic has issued a publication containing detailed rules on physicians' participation in medical congresses sponsored by the industry.

The Swiss Criminal Law and the AUC may also apply on dealings with healthcare professionals.

Sponsorships and support to healthcare organisations for educational or research purposes are generally admissible under the above cited rules.

5.6 Requirement to Disclose Details of Payments

There is no legal requirement to disclose payments to healthcare professionals or healthcare organisations. The Pharma Co-operation Code, which is based on the EFPIA Code, does, however, oblige its signatories to publish annually the payments made during the calendar year to healthcare professionals or healthcare organisations (except for research purposes). The publication has to be made within six months from the end of the calendar year on the company website. In principle, payments must be disclosed naming the recipient and specifying the amounts paid per category. As an exception to this rule, it is, under certain circumstances, possible to disclose payments in aggregate form. For data protection reasons, a disclosure in aggregate form is also necessary if the healthcare professional or healthcare organisation in question refuses to give its consent to individualised disclosure.

6. Manufacturing

6.1 Process for Obtaining an Authorisation

Manufacturing licences are as a rule granted by Swissmedic. Hospital pharmacies and other establishments holding a retailing licence may have to apply for a manufacturing licence of their canton. The applicant must be located in Switzerland and must meet the conditions outlined in the Ordinance on Establishment Licences. The key stages of the authorisation

process are application, inspection and grant of licence. Depending on the size of the facilities, the complexity of the products and of the manufacturing techniques, inspections may take several days. The fee for examining the application is CHF500, plus the fee for the inspection (which includes preparing and writing a report and is calculated at CHF200 per inspector per hour). The fee issuing the licence certificate is CHF100. Licences are valid for renewable terms of five years.

6.2 Competent Authority

Compliance with the conditions for a manufacturing licence is monitored by Swissmedic and the cantons, which have powers in their respective areas defined in the LTP and related ordinances. Regular inspections are, in principle, conducted every two years. Inspections can however also be performed any time during a licence term and are charged at the rate of CHF200 per inspector per hour. Swissmedic and the cantons can also, without incurring costs, take samples, request essential information and documents, and ask for any necessary help. Subject to the principles of proportionality and of public interest the authorities can generally take any administrative measures necessary to enforce the LTP. The LTP lists measures that Swissmedic or the competent authorities of the cantons may take such as:

- raise objections and set an appropriate time period for re-establishment of the lawful situation;
- suspend or revoke the licence (this decision will be published by Swissmedic);
- close down the establishment;
- seize, hold in official storage or destroy medicinal products which endanger health or which do not conform to the LTP; and
- prohibit the distribution, supply, import, export and trade of medicinal products, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage.

Apart from administrative measures, criminal sanctions can also be imposed by Swissmedic and the competent cantonal courts.

6.3 Regulatory Measures

Swiss legislation provides for several means to combat the counterfeiting and illegal distribution of medicines. The LTP prohibits the distribution of medicinal products that are not authorised and provides for severe sanctions. The customs authorities are entitled to hold back shipments of pharmaceutical products at the Swiss border or in a customs warehouse if they suspect an infringement of the LTP. Customs authorities must then call upon the enforcement authorities (Swissmedic or cantonal authorities) to make further enquiries and take the necessary measures. Swissmedic has made combating the illegal trade of medicinal products a priority and is in close contact with foreign authorities. Switzerland signed the Medicrime Convention of the Council of Europe in 2011. Changes of the law necessary for its ratification are currently being prepared.

Swissmedic and the cantons monitor compliance with manufacturing and marketing authorisations. They verify by periodic inspections that the conditions for the authorisations are met. Swissmedic and the cantons can also, without incurring costs, take samples, request essential information and documents, and ask for any necessary help. Swissmedic and the competent authorities of the cantons can generally take any administrative measure necessary to enforce the LTP. For breaches of the manufacturing licence, Swissmedic can raise objections and set an appropriate time period for re-establishment of the lawful situation, suspend or revoke the licence (this decision will be published by Swissmedic), close down the establishment, seize, hold in official storage or destroy pharmaceuticals which endanger health or which do not conform to the LTP, prohibit the distribution, supply, import, export and trade in foreign countries of pharmaceuticals, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage. Apart from such administrative measures, Swissmedic and the competent cantonal courts can also impose criminal sanctions.

7. Distribution

7.1 Obtaining an Authorisation to Engage in Wholesale Trade

Wholesale licences are granted by Swissmedic. The applicant must be located in Switzerland and must meet the conditions outlined in the Ordinance on Establishment Licences. Switzerland has adopted the EU Guidelines on Good Distribution Practice of Medicinal Products which need to be implemented by Swiss distributors. Depending on whether the distributor intends to market the products, the wholesale licence must include the authorisation for batch release. Key stages of the authorisation process are application, inspection and grant of licence. The fee for examining the application is CHF500, plus the fee for the inspection (which includes preparing and writing a report and is calculated at CHF200 per inspector per hour). The fee issuing the licence certificate is CHF100. Licences are valid for renewable terms of five years.

7.2 Competent Authority

Compliance with the conditions for a wholesale licence is monitored by Swissmedic and the cantons, which have powers in their respective areas defined in the LTP and related ordinances. Regular inspections are, in principle, conducted every two years. Inspections can, however, also be performed at any time during a licence term and are charged

at a rate of CHF200 per inspector per hour. Swissmedic and the cantons can also, without incurring costs, take samples, request essential information and documents, and ask for any necessary help. Subject to the principles of proportionality and of public interest the authorities can generally take any administrative measure necessary to enforce the LTP. The LTP lists measures that Swissmedic or the competent authorities of the cantons may take such as:

- raise objections and set an appropriate time period for re-establishment of the lawful situation;
- suspend or revoke the licence (this decision will be published by Swissmedic);
- close down the establishment;
- seize, hold in official storage or destroy medicinal products which endanger health or which do not conform to the LTP; and
- prohibit the distribution, supply, import, export and trade of medicinal products, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage.

Apart from administrative measures, Swissmedic and the competent cantonal courts can impose criminal sanctions.

7.3 Authorisation to Trade in Pharmaceutical Products

The Ordinance on Establishment Licences defines wholesale distribution as procurement of products to persons entitled to trade, process, dispense or apply such products. Accordingly, the requirement of a wholesale licence is not subject to the condition that the distributor physically stores or handles the products. A wholesale licence, therefore, has to be obtained if the distributor takes legal ownership of the products but does not physically handle or store them itself.

7.4 Other Operators Required to Hold Licences/ Authorisations

Manufacturing, import, export, transit, wholesale, trade with drugs in foreign countries and the taking of blood samples for transfusions or manufacturing of pharmaceuticals require corresponding establishment licences. Wholesale includes all activities of procurement of pharmaceuticals (finished or unfinished), such as obtaining, importing, exporting, keeping, stocking, offering, delivering, promoting and transferring or allocating (with or without consideration) pharmaceuticals. Any person conducting any of these activities has to obtain a wholesale licence. The procedure and fees are as outlined above.

7.5 Procedure for Marketing Imported Medicines

Subject to certain exceptions, only products with a marketing authorisation from Swissmedic can be brought on to the market in Switzerland. For pharmaceutical products authorised in a country with a comparable marketing authorisation system, Swiss law provides for a simplified marketing authorisation procedure (parallel imports). Patent protection is not taken into account in the marketing authorisation procedure. The patent holder can invoke the civil courts for protecting its rights. In addition, the distributor is required to apply for an import or wholesale licence with the authorisation for batch release.

7.6 Restrictions on Sales of Medicines at a Distance

The LTP in principle bans mail order distribution. This ban applies to all forms of orders at distance (in writing, by email, over the internet etc). The cantons can, however, grant authorisations to run a mail order pharmacy if certain conditions are met including: the applicant must own a cantonal retailing licence and must guarantee that proper advice is given to patients, that the effects of the drug are adequately monitored and that all the risks specific to mail order distribution must be addressed with adequate safety measures. The patient must supply a doctor's prescription for any drug ordered, whether it is a prescription or non-prescription drug.

8. Patents

8.1 Applicable Laws

The relevant legislation in this field is the Swiss Federal Act on Patents for Inventions (Patents Act, PatA) and the corresponding ordinance (Ordinance on Patents for Inventions, Patents Ordinance, PatO). Switzerland is also a member state of TRIPS and the Paris Convention.

The issues most commonly encountered by pharmaceutical products are the same as for other patentable products, namely failure to meet the novelty requirement, lack of an inventive step or the infringement of existing patents. The most challenging issues lie outside the legislation, namely in the relationship of patent protection and other legislation such as the legislation on reimbursement and on restraints of competition.

In order for an invention to be patentable, it must meet the novelty requirement, be non-obvious to a person skilled in the art (for example involve an inventive step) and must meet the industrial applicability requirement. In addition to these general patentability requirements, there are patentability requirements specific to pharmaceuticals with respect to patents for second and subsequent medical uses. Under Article 2 PatA inventions the exploitation of which is contrary to human dignity or that disregard the integrity of living organisms, or that are in any other way contrary to public policy or morality are not patentable. In particular, no patent may be granted for processes for cloning human beings and the clones obtained thereby; processes for forming hybrid organisms by using human germ cells, human

totipotent cells or human embryonic stem cells and the entities obtained thereby; processes of parthenogenesis by using human germinal material and the parthenogenetic entities obtained thereby; processes for modifying the germ line genetic identity of human beings and the germ line cells obtained thereby, unmodified human embryonic stem cells and stem cell lines.

8.2 Second and Subsequent Medical Uses

New uses of known substances or compositions may be protected under the Patent Act as second medical uses if the use for a specific surgical, therapeutic or diagnostic method is deemed to be new and the substance or composition is intended only for such use (Article 7c PatA). A subsequent medical use of a substance or composition may be patentable even if forming part of the state of the art provided that it is distinct from the first medical use (Article 7c PatA) and that it is intended for use in the manufacture of a means to a surgical, therapeutic or diagnostic end (Article 7d PatA). The scope of protection in these cases is limited to the specific medical use. New dosage regimes are patentable provided that the statutory patentability criteria, for example novelty, inventive step and industrial applicability, are fulfilled. The same applies to the use for new or selected patient populations.

The manufacturing of and trading with a ready-for-use pharmaceutical product, including a package leaflet pointing out the new medical use, would be considered an infringement. The same applies to marketing and trading with the protected substance/composition not produced by the patent owner. The prescription or the dispensing of the protected substance/composition not produced by the patent owner of the new medical use by a doctor or pharmacist is not considered an infringement according to a recent decision by the Swiss Federal Supreme Court (BGE 137 III 170). Also, the use of the protected substance/composition not produced by the patent owner for a new medical use by the patient is not considered an infringement because this action does not constitute a commercial act under Article 8 PatA.

8.3 Pharmaceutical Patent Infringement

According to Art. 8 PatA the patent confers on its owner the right to prohibit others from commercially using the invention. Use includes, in particular, manufacturing, storage, offering, placing on the market, importing, exporting and carrying in transit, as well as possession for any of these purposes. Carrying in transit may only be prohibited, however, if the proprietor of the patent is permitted to prohibit importation into the country of destination.

Applying for marketing authorisation does not infringe a patent as such an application is not considered a commercial use of the patent. This is specifically mentioned in Article 9 para 1 lit. c PatA which states that the effects of the patent do not extend to acts necessary for obtaining marketing authorisation for a medicinal product in Switzerland or in countries with equivalent medicinal product control (Bolar exemption, see below).

Any person who uses a patented invention unlawfully may be held liable under civil and criminal law (Article 66 PatA). Any patent owner who is threatened with or has their rights infringed may demand an injunction or that the unlawful situation be remedied (Article 72 PatA). To be actionable, the threat of infringement must be imminent, for example there must be a serious risk of an infringement.

8.4 Specific Defences

Article 9 PatA sets forth exceptions to the effect of a patent. It includes:

- a private use exception: the effects of the patent do not extend to acts undertaken within the private sphere for non-commercial purposes.
- a research exception: the effects of the patent do not extend to acts undertaken for research or experimental purposes in order to obtain knowledge about the subject-matter of the invention including its uses; in particular, any scientific research concerning the subject-matter of the invention is permitted.
- so-called "Bolar exemption": the effects of the patent do not extend to acts necessary for obtaining marketing authorisation for a medicinal product in Switzerland or in countries with equivalent medicinal product control.
- an educational exception: The effects of the patent do not extend to the use of the invention for teaching purposes at educational institutions.

Further, the effects of the patent do not extend to the use of biological material for the purpose of the production or the discovery and development of a plant variety; or to biological material that is obtained in the field of agriculture due to chance or is technically unavoidable.

As regards compulsory licences, three years from the date of the grant of the patent, or at the earliest four years after the filing of the patent application, any person with a legitimate interest may apply to the court for the grant of a non-exclusive licence to use the invention if the owner of the patent has not sufficiently exploited it in Switzerland by the time of the action and cannot justify such lack of exploitation (Article 37 PatA). In these cases and at the request of the plaintiff, the court may grant a licence immediately after the action has been filed without prejudice to the final judgment providing that the plaintiff provides prima facie evidence that they have an interest in the immediate use of the invention and that they provide adequate security to the defendant. Furthermore, a court may grant a compulsory licence based on public interest if a patent owner refuses to grant a third-party licence to use the invention without sufficient reason (Article

40 PatA). Any person who intends to use a patented biotechnological invention as an instrument or means for research is entitled to a non-exclusive licence (Article 40b PatA). We have found no evidence that a compulsory licence based on public interest has ever been granted. With respect to inventions concerning a diagnostic product or procedure for humans, a non-exclusive licence will be granted to remedy a practice held to be anti-competitive in court or administrative proceedings (Article 40c PatA). The provision regarding compulsory licences under Article 40c PatA also seems to remain a dead letter as the process for obtaining such a licence is complex and time-consuming. Parties wishing to obtain a compulsory licence usually require that licence much sooner than the proceedings would allow for.

8.5 Parties that can Bring Infringement Proceedings

Any person threatened with or being subjected to a patent infringement, for example the owner of a patent, may demand an injunction that the infringer stops or remedies the unlawful situation (Article 72 PatA).

Article 75 PatA also entitles the person who holds an exclusive licence to bring such action unless this is expressly excluded by the licence agreement.

The remedies that are available are:

- action to stop and eliminate any infringing activity (Article 72 PatA); and/or
- action for damages according to the Swiss Code of Obligations (Article 73 PatA); and/or
- action for declaratory judgment that a patent infringement has taken or is taking place (Article 74 lit. 2 PatA);
- action for account of profits according to the Swiss Code of Obligations (based on a claim of unjustified enrichment as permitted by the Federal Supreme Court in the leading case BGE 129 III 422).

In the event of a conviction, the court may order the forfeiture and sale or destruction of the unlawfully manufactured products or equipment, devices and other means that primarily serve their manufacture (Article 69 PatA). If the court orders a sale, the net proceeds from the sale shall firstly be used for the payment of the fine, then the payment of the investigation and court costs, and finally for the payment of a final unappealable award of damages to the injured party and to cover its litigation costs; any surplus will go to the former owner of the goods sold. Even in the event of the dismissal of the action or an acquittal, the court may order the destruction of the equipment, devices and other means intended primarily for the infringement of the patent.

The seizure of the allegedly infringing products may also be requested. If the proprietor of a patent that is valid in Switzerland or a licensee of such a patent who is entitled to institute civil or criminal proceedings has clear indications of the imminent import, export or transit of goods which infringe that patent, they may request the Customs Administration in writing to refuse the release of the goods. The applicant may also submit a written request to the Customs Administration to destroy the goods (Article 86f PatA).The applicant must provide all the information available to them that is necessary for the Customs Administration's decision; this includes a precise description of the goods (Article 86b PatA). If the Customs Administration, as a result of such an application, has grounds to suspect that certain goods intended for import, export or transit infringe a patent valid in Switzerland, it will notify the applicant and the declarant, holder or owner of the goods accordingly. It will withhold the goods for a maximum of ten working days (to be counted from the time of notification), in order for the applicant to obtain injunctive relief. Where justified by circumstances, it may withhold the goods for a maximum of 10 additional working days (Article 86c PatA). The Customs Administration is also authorised to notify the proprietor of a patent that is valid in Switzerland if they suspect the imminent import, export or transit of goods infringing a patent. In such cases, the Customs Administration is authorised to withhold the goods for three working days in order that the person entitled may file an application to institute proceedings. The destruction of the goods requires the consent of the declarant, holder or owner and consent is deemed to be given if the declarant, holder or owner does not expressly object to the destruction within the legal time limits (Article 86g and 86c PatA).

Article 77 of the Patent Act also permits the request for injunctive relief such as measures to secure evidence, to preserve the existing state of affairs or to enforce provisionally claims for omission and remedy. Further, a plaintiff may request that a precise description be made of the alleged unlawful processes used or of the allegedly unlawful products manufactured.

A person wilfully committing a patent infringement may, upon complaint by the injured party, also be held criminally liable (custodial sentence of up to one year or monetary penalty, Article of 81 PatA). The right to file such a complaint lapses after six months from the day on which the injured party gains knowledge of the offender. If the offender acts for commercial gain, prosecution is ex officio and subject to a higher penalty (a custodial sentence of up to five years or monetary penalty).

The typical procedure in patent infringement proceedings is the normal procedure for civil law suits or criminal action. In order immediately to stop the infringing action a plaintiff will regularly request injunctive relief and then proceed with the ordinary procedure asking for all or part of the

remedies described above. Since 1 January 2012 the Federal Patent Court has been the Court of First Instance in charge of adjudicating civil law disputes concerning patents. Before 2012 the cantonal courts were competent for these cases. The Federal Patent Court is exclusively competent in patent infringement and validity matters. Other civil actions relating to patents (such as disputes pertaining to patent licence agreements or the rights to a patent) can also be brought before the Federal Patent Court. Patent cases are mainly conducted in written form and judgments are mainly based on written evidence.

A defendant may invoke invalidity of a patent as a defence in ongoing court proceedings or independently bring a nullity action (Article 26 PatA). A nullity action may be brought by any person with a proven interest (Article 28 PatA).

8.6 Procedures Available to Potential Generic Entrant

As is the case for other protected goods, there are no specific procedures available. If the general procedural requirements are met, a potential generic entrant could bring an action for a declaratory judgment that the generic does not infringe a specific patent. The claimant is required to show a legal interest in the judgment. To do so, the claimant must show that an actual controversy of sufficient immediacy and reality exists. Trying to obtain a declaratory judgment at a very early stage of the potential market entry might prove difficult because a court could find the legal interest to be lacking. Another disadvantage of such a proceeding would be the length of court proceedings and appeals.

Clearing the way is not a requirement for a generic market entry. The authorisation procedure for pharmaceuticals does not take account of patent protection. Making sure that no patents are infringed remains the full responsibility of the potential generic entrant.

8.7 Patent Term Extension

The patent term is not extendible but the Swiss Intellectual Property Institute shall on application grant a supplementary protection certificate ("SPC") for the active ingredients or combination of active ingredients of medicinal products (Article 140a of PatA).

The certificate is granted if, at the time of the application, the product as such, a process for manufacturing it or a use of it is protected by a patent and official authorisation has been granted for placing the product on the market in Switzerland as a medicinal product.

The owner of the patent has the right to the certificate and only one certificate shall be granted for each product. Should two or more owners of a patent file applications for the same product based on different patents, the certificate may be granted to each applicant (Article 140c of PatA). The protection of a certificate extends, within the limits of the scope of protection conferred by the patent, to any use of the product as a medicinal product that has been authorised before the expiry of the certificate. The certificate grants the same rights as the patent and is subject to the same restrictions (Article 140d of PatA).

The certificate takes effect on expiry of the maximum term of the patent for a period equal to the period between the date of filing of the patent (Article 56 of PatA) and the date of the first authorisation to place the product on the market as a medicinal product in Switzerland, minus five years (Article 140e of PatA). The certificate is valid for a maximum term of five years. There is a time limit for filing the application and the filing must be made within six months of the first authorisation to place the product on the market in Switzerland as a medicinal product, or within six months of the grant of the patent if this was granted later than the first authorisation.

In the event that the time limit is not met, the Institute shall refuse the application (Article 140f of PatA). The certificate is subject to the payment of an application fee and renewal fees, which must be paid in advance in one single payment for the full term of the certificate.

Any person may bring an action to have the certificate declared null and void (Article 140k of PatA).

9. IP Other than Patents

9.1 Restrictions on Trade Marks

There are no specific restrictions under trade mark law and the general restrictions apply, ie any pharmaceutical trade mark that is descriptive or misleading cannot be registered as a trade mark. The official non-proprietary or generic name ("INN") given to a pharmaceutical substance, as designated by the World Health Organization (WHO), cannot be trademarked under Swiss law as it is deemed generic. Modifications of INNs can be registered if the name of the pharmaceutical is deemed distinctive. Whether such name has achieved distinctiveness is judged from the perspective of the relevant public.

Also, the term pharmaceutical and common abbreviations or short forms such as "pharm" or "pharma" are deemed to indicate pharmaceutical use of products or pharmaceutical services. It is prohibited to use these terms in connection with trade marks for poisonous substances, drinks and foodstuffs. Such use would be deemed misleading to the public.

The LTP and the corresponding ordinances do not contain any provisions regarding the trade marks for pharmaceuti-

cals. The brand of a pharmaceutical, however, must be submitted to Swissmedic by the applicant in marketing authorisation proceedings. Swissmedic, according to Article 7 para 3 of the Ordinance on Pharmaceuticals, is entitled to reject the application if the brand in question is contrary to public order or morality or if it is deemed misleading or to create confusion with existing brands.

9.2 Legislation and Procedures

Swiss legislation provides for several means to combat the counterfeiting and illegal distribution of medicines. The LTP prohibits the distribution of medicinal products that are not authorised and provides for severe sanctions. The customs authorities are entitled to hold back shipments of pharmaceutical products at the Swiss border or in a customs warehouse if they suspect an infringement of the LTP (Article 66 para 4 of the LTP). In addition, the Patent Act (see above), the Trademark Protection Act and the Act against Unfair Competition provide means to combat the counterfeiting and illegal distribution of medicines.

Under Article 69 of the Trademark Protection Act (TmPA), on complaint of the injured party, any person who unlawfully labels goods or services with the trade mark of another person in order to mislead and thereby give the impression that the goods or services are original goods or services and/or offers or places goods or services on the market as original goods or services, or offers or provides original services that unlawfully bear the trade mark of another is liable to a custodial sentence (not exceeding one year) or a monetary penalty. If the offender acts for commercial gain, prosecution is initiated ex officio and the penalty is a custodial sentence (not exceeding five years) and a monetary penalty. Any person who imports, exports, carries in transit or stocks goods that they know are intended for fraudulent use in the course of trade is liable, on complaint of the injured party, to a fine of up to CHF40,000.

The customs authorities are authorised to notify the proprietor of a trade mark entitled to institute proceedings for preliminary injunctions (Article 56 of TmPA) if there is any suspicion of the imminent import, export or transit of goods that unlawfully bear a trade mark or an indication of source. The customs authorities are authorised to withhold the goods for three working days, in order for the trade mark owner to institute proceedings under Article 71 of TmPA which allows the trademark owner to request the customs authorities in writing to refuse the release of the goods and to destroy them (Article 72c of TmPA).

The sale of counterfeit products also violates the Act against Unfair Competition (AUC) which prohibits the false and misleading declaration of goods. The AUC provides relief through civil as well as criminal proceedings.

9.3 Importation and Distribution Restrictions

There are no specific restrictions under trade mark law to import and distribute non-counterfeit, genuine pharmaceutical products from other markets, region or countries, except that the product must have been put lawfully on these markets. As regards such parallel imports into Switzerland, according to rules developed by the Swiss Federal Supreme Court, the principle of international exhaustion applies. Under patent law, however, the principle of regional exhaustion applies (Article 9 para 1 of PatA). Furthermore, the patent owner's consent for parallel imports to Switzerland is always required if the price of the product in question is determined by public authorities in Switzerland or the country of origin. The LTP requires that a parallel importer obtains a marketing authorisation for the pharmaceuticals imported from countries with an equivalent marketing authorisation system.

9.4 IP Protection

It is possible to obtain a registration for a figurative or 3D mark under Swiss trade mark law as well as design protection under the Swiss Design Act. The general rules for these types of registrations apply. As regards figurative and 3D marks, if the shapes in question constitute the nature of the goods themselves or the shapes of the goods or their packaging are technically necessary, they are excluded from trade mark protection. The Act against Unfair Competition may also provide additional protection against the copying of trade dress or designs.

10. Competition Law

10.1 Activities Constituting Infringement

The Swiss Competition Commission ("ComCo") decided in the year 2000 that the market regulations established by the Sanphar association infringed Cartel law. The market regulations provided for, amongst others, rebate band widths for manufacturers and wholesalers and margins for pharmacies and self-dispensing doctors. Soon after this decision, the Sanphar association was dissolved.

In 2010, ComCo held that price recommendations for pharmacy prices of the drugs Viagra, Cialis and Levitra amounted to unlawful resale price maintenance. As these drugs are not reimbursed, there is no price control by FOPH. The reasons for the decision of ComCo were that the recommendations were followed by more than 80% of pharmacies and that the retail prices were entered into a very widely used IT system. The three companies in question were fined a total of over CHF5 million. The Administrative Federal Court in 2013 annulled the decision of ComCo, holding that the Cartel Act was not applicable because the prohibition of advertising for prescription-only pharmaceutical products and the "shame factor" would exclude price competition amongst

pharmacies. On appeal by ComCo, the Federal Supreme Court annulled the decision of the Administrative Federal Court on 28 January 2015 and remanded the case to the Administrative Federal Court for assessing the case under the Cartel Act. The proceeding is still pending before the Administrative Federal Court.

In a case of 2006, ComCo had investigated whether Pharmion and Lipomed had abused a market dominant position when asking a certain price for Thalidomide. It came to the conclusion that there had been no abusive pricing.

Since September 2010, ComCo has been conducting a preliminary investigation regarding the distribution of pharmaceutical products in Switzerland. On 11 May 2015, the secretariat of ComCo adopted a final report on the partial aspect of the preliminary investigation regarding allegations of abuse of market dominance against Alloga, the biggest prewholesaler in Switzerland, which belongs to the Galenica group. The allegations were raised by Amedis, a wholesaler and customer of Alloga, belonging to the Phoenix group, and concerned the requirement by Alloga towards Amedis to provide a bank guarantee of CHF20 million for securing open claims. In its preliminary investigation, ComCo had found indications that Alloga is market-dominant in the distribution channel of pharmaceutical products via prewholesalers and that it had abused this position through the requests to Amedis to provide securities and their amount and duration. ComCo did not, however, open an investigation as Alloga had accepted certain guidelines proposed by ComCo regarding requests for security.

10.2 Pay-for-Delay Agreements
There is no case law on pay-for-delay agreements.

10.3 Life Cycle Strategies
There is no case law on life cycle strategies of originators versus generic drug companies.

10.4 Proceedings for Breach of Competition Law
The competent administrative authority for the enforcement of Swiss competition law is ComCo. ComCo acts on its own accord or upon complaint by anyone. The procedure is governed by the principles of ex officio establishment of the facts and decision of the authority.

Private parties may also sue other parties in civil courts. Any person hindered by an unlawful restraint of competition from entering or competing in a market is entitled to request the elimination of or desistance from the hindrance, damages and satisfaction and/or surrender of unlawfully earned profits in accordance with the provisions on agency without authority. The proceeding follows the ordinary proceedings in civil law suits with few particularities.

11. Transactions/Collaborations

11.1 Key Contractual Terms
In addition to the standard key terms of the respective transactions, the following terms are key:

- share sales: determination and adaptation of purchase price, reps and warranties regarding the IP rights, know-how, licences, marketing authorisations, regulatory dossiers, manufacturing and distribution, pharmacovigilance system, continuing business clauses regarding clinical trials, regulatory proceedings, IP rights and terms of sale.
- asset sales: exact description of the assets sold and purchased, including businesses or parts of a business, assumed and excluded liabilities, contracts, employees, etc, licences granted by the parties, otherwise same clauses as for share sales. (It should be noted that marketing authorisations can usually be transferred under certain conditions, whilst this is not the case for licences for manufacturing, import, export, wholesale, etc. Often a transition phase is necessary for implementing the transfers of the marketing authorisations, changes in the manufacturing chain and/or packaging and labelling of the products.)
- joint ventures, using a corporate vehicle: subject matter/area of the JV, contribution of each partner, corporate organisation, ownership of IP, co-operation in the marketing.
- licence agreements: definition of the licensed IP and Know-how, regulatory responsibilities, pharmacovigilance responsibilities, supply of products, consideration with possibly milestone payments, ownership of IP rights.

11.2 Customary Deal Terms to Bridge the Valuation Gap
Customary clauses for bridging the valuation gap between buyer and seller are earn-out clauses, contingent value rights, eg put/call options and appraisal clauses.

11.3 Purchase Price Adjustments
Customary purchase price adjustments clauses are completion accounts and locked boxes.

11.4 Deal Protection Terms
Customary deal protection clauses are exclusivity and break fees.

11.5 Local Antitrust Approval
A planned concentration of undertakings has to be notified to ComCo before its implementation if in the financial year preceding the concentration:

- The undertakings concerned together reported a worldwide turnover of at least CHF2 billion, or a turnover in Switzerland of at least CHF500 million; and
- At least two of the undertakings concerned each reported a turnover in Switzerland of at least CHF100 million.

Notification is also mandatory if, in proceedings under the Cartel Act, one of the undertakings concerned has in a final and non-appealable decision been held to be dominant in a market in Switzerland, and if the concentration concerns either that market or an adjacent market or a market upstream or downstream thereof.

11.6 Tax Treatment of Asset Deals Versus Share Deals

An asset deal enables the buyer to obtain a step-up in the tax basis of the assets acquired and to allocate the acquisition costs at the same level as the operating business. On the other side, the sales proceeds from the asset deal are allocated and taxed in the company selling the assets and the shareholder of that company is again taxed when the sales proceeds are distributed as dividends, whereby participation relief (Swiss tax-resident corporate shareholders) or partial taxation (Swiss tax-resident individual shareholders, holding their shares as private means) might be available.

Contrary to the asset deal in a share deal, the buyer effectively bears any historical and future ongoing tax and non-tax liabilities of the target company. No step-up in basis is available. Acquisition costs cannot be placed at the operating level. Swiss tax-resident individuals who own their shares in the target company as private means might achieve a tax-free capital gain. Swiss tax-resident corporate shareholders might also benefit from the participation relief.

11.7 Protection of Licensees

The bankruptcy law does not explicitly deal with IP rights and licensees are not protected in the case of insolvency of a licensor. Upon bankruptcy proceedings being opened, the total assets of the debtor, ie including patents, trade marks and other IP rights, form part of a sole mass (Article 197 para 1 of the Bankruptcy Act). In general, a contract will not automatically be terminated when bankruptcy proceedings are opened. Under Article 211 of the Bankruptcy Act, however, all contractual claims are converted into monetary claims of corresponding value unless the bankruptcy administrator chooses to prevent this conversion by fulfilling the contract in question. The contract then remains in force. As regards long-term agreements such as licence agreements, the bankruptcy administrator may also decide to enter into only a part of a contract (Article 211a para 2 of the Bankruptcy Act).

Under Articles 82 and 83 of the Code of Obligations, the licensee would be entitled to hold back licence fee payments unless there is sufficient certainty that the licensee may exploit the licence as stipulated in the contract.

12. Investigations/White-Collar

12.1 Focus of Investigations

Investigations are mainly conducted by Swissmedic in the case of breaches of the LTP, in particular illegal trade with pharmaceuticals or breach of the advertising provisions, including undue financial advantages. The criminal prosecution authorities may also conduct investigations if cases regarding the breach of the LTP are transferred to them or in case of other criminal offences, eg in cases of bribery. There are only a few investigations and decisions for bribery in the pharmaceutical sector in Switzerland.

In the case of breaches of the advertising provisions, Swissmedic focuses on the internal responsibilities for signing off the advertising in question.

12.2 Important 'Do's' and 'Don'ts'

The appropriate behaviour in investigations depends on the type of the investigation, the investigating authority and the situation of the company or persons being investigated. Normally, it is advisable that the facts and, if necessary, the scientific or economic background, are explained openly. In criminal or administrative criminal investigations it is advisable that a person being interrogated does not recognise liability.

12.3 Recent Landmark Cases

There have been no recent landmark cases in Switzerland.

12.4 Distinct Characteristics of Investigations in Pharma Sector

In the pharma sector, most often it is Swissmedic which conducts the investigation.

13. Product Liability

13.1 Regime for Injury Caused by Pharmaceutical Products

Product liability of pharmaceutical manufacturers is governed by the Product Liability Act and general tort law. There is no special regime as regards liability for injury caused by pharmaceuticals and no special regime is presently in discussion. For clinical trials with pharmaceuticals, there are special rules.

13.2 Prerequisites for Potential Liability

The liability of the manufacturer for defective products according to the Product Liability Act is strict. The prerequisites for liability are damage (only personal injury or damage to things for private usage), a product defect and adequate causation (of the damage by the defective product). A product is defective if it fails to provide the safety which a person is entitled to expect, taking into account all circumstances.

The level of safety that can be expected has to be determined by the judge in each single case. For pharmaceuticals, the product information is essential in this respect.

Liability based on general tort law is fault-based. The prerequisites for liability are damage, the breach of a protective legal provision, adequate causation (of the damage by the breach of the protective legal provision) and a fault of the liable person (intent or negligence).

The breach of statutory obligations does not, per se, render the manufacturer liable towards the consumer, but only under the conditions of the PLA or general tort law mentioned above.

The potentially liable persons are primarily the manufacturer and the importer. This is most often the marketing authorisation holder. Under the PLA the following persons are deemed to be manufacturers: of course, the effective manufacturer (in whole or in part) of the defective product, any person who applied their name or trade mark to the product and any person who imported the product for commercial distribution. If the manufacturer according to this definition cannot be determined, any person who supplied the product is considered to be the manufacturer unless this person indicates the manufacturer or their supplier.

13.3 Standard of Proof for Causation

The claimant must prove adequate causation. This means, according to the Federal Supreme Court, that a cause must be appropriate to cause a result of the kind that has occurred or to facilitate considerably the occurrence of such a result, based on general experience of life and the usual course of events. The standard of proof of adequate causation is overwhelming likelihood (Decision of the Federal Supreme Court, BGE 133 III 81, E.4.2.2).

13.4 Market Share Liability

In principle, the burden of proof for causation lies on the claimant. If the claimant can establish adequate causation for several pharmaceutical products, the manufacturers of these products are jointly and severally liable. The internal repartition of the damage amongst the manufacturers is in the discretion of the judge.

13.5 Defences for Fault-Based or Strict Liability

There are no statutory defences specific for liability for pharmaceuticals. The general defences under the PLA are (Article 5 of the PLA):

- the manufacturer did not market the product.
- the product was not defective when it was put into circulation.
- the defect is attributable to compliance with compulsory, official regulations.
- the defect was not identifiable on the basis of scientific and technological knowledge at the time the product was put into circulation ("development risks defence").
- the manufacturer did not manufacture the product for a business purpose or within the framework of their professional activity.
- the manufacturer had produced only base material or part of the product and the defect was caused by the construction of the product, in which the base material or part was incorporated, or by the instruction given by the manufacturer of that product.

13.6 Regulatory Compliance Defence

There is no "regulatory compliance defence." ie liability cannot be excluded merely because all regulatory requirements have been complied with. As defectiveness is assessed based on all circumstances, compliance with regulatory requirements and the assessments of the experts of the regulatory authorities will need to be taken into account, however.

13.7 Limitation Period

The limitation period for product liability claims under the PLA is three years from the day when the injured person acquired or could have acquired knowledge of the damage, the defectiveness and the person of the manufacturer. Claims under the PLA are in any case time-barred if no law suit is filed within ten years from the day when the product in question was marketed. There are no different limitation periods for certain categories of persons.

The limitation period for product liability claims under general tort law is one year from the day when the injured person acquired knowledge of the damage and the person liable, or ten years from the day of the damaging act or omission. In the case of a longer limitation period for a criminal act, this longer period would apply.

13.8 Recoverable Damages

Under the PLA, the injured person may only claim for compensation of personal damages and material damage to things for private usage. This limitation does not apply for liability under general tort law. Punitive damages are not available in Switzerland. Damages can be allocated even if the exact amount of the damage cannot yet be exactly defined; however, the damage must already have materialised.

Under general tort law, amends for pain and suffering are available. The amounts are generally moderate. In cases of severe violations of physical integrity they range up to about CHF100,000 to CHF200,000.

13.9 Maximum Limit on Damages

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

13.10 Recent Decisions

The Swiss Federal Supreme Court in 2015 decided a case regarding the contraceptive Yasmin. The plaintiff claimed compensation from Bayer, the marketing authorisation-holder of Yasmin, for the damages caused by the pulmonary embolism which she had suffered. The plaintiff and her health insurance company claimed that Yasmin had caused the embolism and that the drug was a defective product because the patient leaflet did not sufficiently state the risks of the product. The Federal Supreme Court considered that, in the case of prescription drugs, the question of whether the product offers the safety that can be expected can only be answered based on the expectations of the healthcare professional as the patients lack the necessary expertise to decide on the appropriate treatment. The mere fact that drugs may have unwanted side-effects does not render them defective if the product information for healthcare professionals mentions them. In the case of Yasmin, the product information addressed to healthcare professionals contained the necessary information. Therefore, the court ruled that the marketing authorisation holder was not liable.

This decision is important not only for the pharmaceutical industry but for product liability law in general, as it accepts the learned intermediary doctrine.

13.11 Trial

Court proceedings are decided by judges. There are no jury trials.

13.12 Obligation to Disclose Documents

Under Swiss law, there is no pre-trial discovery as in other jurisdictions. In the evidentiary proceeding of a pending lawsuit, the court may order a party to produce certain documents or other evidence. If the party refuses to do so, the court may weigh this behaviour against that party.

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The Federal Code of Civil Procedure provides for the possibility of precautionary taking of evidence by the court if the applicant credibly shows that evidence is at risk or that he or she has a legitimate interest (Article 158 of the CPC).

13.13 Class/Group Action Procedure

There is no class action procedure available in Switzerland. Several claimants can ask that their respective claims be joined and the proceedings conducted together, but the claims remain separate and are judged separately.

13.14 Funding of Claims

Generally, claims have to be funded by the claimant. Contingency fees or conditional fees for attorneys-at-law are not allowed and constitute a violation of professional rules. Legal aid from the state is available to any person who does not have sufficient financial resources under the condition that his or her case does not seem devoid of any chances of success. Legal aid may be granted for all or part of the case and comprises an exemption from the obligation to pay advances and provide security, an exemption from court costs and the appointment of an attorney by the court if this is necessary to protect the rights of the party concerned. It does not relieve the party concerned from compensating to the opposing party in the event that the claim is unsuccessful.

There are a number of companies offering legal expense insurances. There are also a few third-party litigation funding companies on the market which fund claims on a case-by-case basis for part of the gain. However, this is a rather new branch of business and the experience with this instrument in Switzerland is very limited.

13.15 Potential Changes to Legal Regime

There have been no material discussions regarding potential changes in the legal regime for liability for pharmaceutical products.