Life Sciences

Contributing editor
Alexander Ehlers

2019

GETTING THE DEAL THROUGH

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Alexander Ehlers

Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft mbB

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This article was first published in January 2019
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Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 3780 4147
Fax: +44 20 7229 6910

First published 2009
Tenth edition
ISBN 978-1-78915-040-7

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

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Preface

Life Sciences 2019

Tenth edition

Getting the Deal Through is delighted to publish the tenth edition of *Life Sciences*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

Getting the Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on Serbia.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to Alexander Ehlers of Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft mbB, the contributing editor, for his continued assistance with this volume.

GETTING THE DEAL THROUGH

London
November 2018

Switzerland

Frank Scherrer
Wenger & Vieli Ltd

Organisation and financing of healthcare

1 How is healthcare in your jurisdiction organised?

The Swiss healthcare system is based to a great extent on mandatory health insurance. Mandatory basic health insurance can be contracted with a health insurance company of one's choice and there is the possibility of contracting additional private insurance. Apart from health insurance, there are other types of social insurance. Social insurance pays or reimburses the costs of healthcare providers (hospitals, physicians, pharmacists, etc). The private healthcare sector, which is not financed by social insurance, is also very important. The healthcare system has a federalist structure, and only certain areas are governed by federal law. Many competences and tasks have remained under the control of the 26 cantons (such as the running of public hospitals).

2 How is the healthcare system financed in the outpatient and inpatient sectors?

The healthcare system is mainly financed by social health insurance, private insurance, the Swiss Confederation, the cantons, the communities and the direct payments of patients. Inpatient treatment provided by a public hospital is mainly financed by health insurance and the cantons through flat-rate payments per case. Outpatient treatment is financed mainly by health insurance. The basic health insurance provides for a patient co-payment of, at present (in principle), 10 per cent to a maximum of 700 Swiss francs per year for adults. For both the outpatient and the inpatient sectors, private additional health insurance and direct payment of healthcare services are possible.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and healthcare professionals?

Advertising for medicinal products is governed by:

- the Law on Therapeutic Products (LTP);
- the Ordinance on Advertising for Medicinal Products;
- the Ordinance on Health Insurance (article 65, paragraph 2, and 68, paragraph 1, letter d);
- the Federal Act against Unfair Competition; and
- the Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code), issued by scienceindustries, an association of the Swiss chemical, biotech and pharma industries.

4 What are the main rules and principles applying to advertising aimed at healthcare professionals?

Advertising aimed at healthcare professionals (HCPs) is generally allowed for all medicinal products authorised in Switzerland. Advertising must not be misleading, inaccurate, against public policy or unethical, or incite excessive, abusive or inappropriate use of medicinal products.

Advertising aimed at HCPs must be in line with the latest product information approved by Swissmedic, the Swiss regulatory agency. Advertising must be accurate, balanced and provable. The claims must be based on and reflect the current state of scientific knowledge. They may only refer to clinical studies conducted in accordance with good clinical practice that are published or accepted for publication, or to meta-analyses or observational studies that are published in a scientifically recognised scientific journal. Publications must be quoted literally, completely and with the exact reference.

Advertisements must not indicate that a medicinal product does not have adverse effects or is without risk or harmless; appear to be an editorial; or indicate that a human medicinal product does not lead to dependency.

Advertising for prescription-only medicinal products on the internet must be limited to HCPs by means of password protection.

5 What are the main rules and principles applying to advertising aimed at the general public?

Advertising aimed at the general public is not allowed for prescription-only medicinal products. It is furthermore not allowed for medicinal products that are reimbursed by the 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 medicinal products. It must be in line with the latest Swissmedic-approved product information. It must be objective and without exaggeration and contain an invitation to consult the patient leaflet. Pharmaceutical products must be clearly presented as such. Quizzes, vouchers, testimonials and invitations to contact the marketing authorisation holder are not permitted.

Advertisements in a printed form or via electronic media for analgesics, sedatives, sleeping tablets, laxatives and anorectics must be submitted to Swissmedic for prior approval if the product information of the product mentions a potential for abuse or addiction.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

The most common infringements with regard to advertising rules are as follows:

- advertising without correct scientific basis;
- advertising for off-label use or medicinal products that have not yet been authorised;
- claims that are not correctly referenced;
- advertising that lacks the necessary minimum information;
- advertising that is not in accordance with the approved product information;
- advertising to the general public of prescription-only medicines; and
- in advertising to the general public, exaggerations, promises of therapeutic effect and advertising together with products other than medicinal products (cosmetics or food).

It should be noted that the surveillance of advertising aimed at HCPs is mainly performed by a body instituted by the Pharma Code, and not Swissmedic. Swissmedic must act if advertising endangers drug safety.

7 Under what circumstances is the provision of information regarding off-label use to healthcare professionals allowed?

Advertising for products that have not yet been authorised in Switzerland, or for off-label use of authorised products, is not allowed. According to the Pharma Code, pharmaceutical companies are, however, allowed to inform without direct or indirect advertising HCPs and the media about products or new indications, fields of use, dosages,

Galenic formulations or packages that have not yet been authorised in Switzerland. The trade name may be used, but always in connection with the international non-proprietary name of the active substance. The companies have to make it clear that the medicinal product, new indication, field of use, dosage, Galenic formulation or package has not yet been authorised by Swissmedic in Switzerland. Information as outlined above should be provided by independent speakers invited by pharmaceutical companies or professionals of the medical service or research department of the pharmaceutical companies.

8 Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sector?

The legal rules governing the collaboration of the pharmaceutical industry with HCPs are located in various acts and ordinances, mainly the following:

- the LTP, especially article 33 and the provisions on clinical trials and vigilance;
- the Ordinance on Advertising for Medicinal Products, especially article 11 on scientific congresses and promotional events;
- the Federal Law on Research involving Humans and the ordinances depending on it, especially the Ordinance on Clinical Trials;
- the anti-bribery provisions of the Swiss Criminal Code, article 322 ter to 322 decies, and of the Act against Unfair Competition, article 4a;
- the rules governing the employment and function of HCPs; and
- the Federal Act on Academic Medicinal Professions.

In principle, the same rules apply to physicians in the outpatient and inpatient sector. With regard to organisational rules and competences there are, however, important differences among employed and self-employed physicians.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

There are certain types of collaboration for which specific rules of best practice have been developed, and these are mainly set out in a publication of Swissmedic, the Pharma Code, the Code of Conduct of the Pharmaceutical Industry in Switzerland on cooperation with Healthcare Professional Circles and Patient Organisations (Pharma Cooperation Code), issued by scienceindustries, and a guideline of the Swiss Academy of Medical Sciences.

The main legal rule is article 33 of the LTP, which, in principle, prohibits the offering of financial advantages to physicians, pharmacists, druggists or healthcare establishments that employ such persons for prescribing or dispensing certain medicinal products; the rule also prohibits the acceptance of such advantages.

Financial advantages considered permissible are as follows:

- gifts of a modest value, which are relevant for the professional activity of the recipient (eg, prescription pads); according to practice, gifts are considered to be of a modest value if their total value is not more than 300 Swiss francs per year to each healthcare professional; and
- discounts that are customary in the relevant field or that are justified on business grounds (eg, volume discounts). If given on reimbursed products, such discounts must be passed on to the patient or the insurer that pays for the product.

According to article 11 of the Ordinance on the Advertising for Medicinal Products, hospitality related to scientific congresses or promotional events must be justifiable and must be subordinate to the main (scientific) purpose of the event. Accompanying persons must pay for their own costs.

With regard to the support for the participation of physicians in medical congresses, Swissmedic has issued a publication containing detailed rules. The basic rule is that – with some exceptions – physicians have to make a co-payment of at least 33 per cent of the direct costs of their participation (registration, accommodation, food and beverages, etc).

The Pharma Cooperation Code provides that the signatory companies have to disclose financial advantages granted to HCPs or healthcare organisations (HCOs) on a company website. Disclosure has to be made in principle on a named basis, listing the value of the advantages granted per calendar year to the respective HCP or HCO per category. In cases where the HCP or HCO does not agree to the named disclosure, disclosure needs to be made on an aggregate basis.

10 What are the most common infringements committed by manufacturers with regard to collaboration with healthcare professionals?

Besides improper advertising, infringements committed by manufacturers with regard to collaboration with HCPs in general relate to undue financial advantages. Only a few decisions of Swissmedic and the courts, however, have been published in this field. A revision of the rules on financial advantages is pending.

11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

The main rules and principles contained in the Pharma Cooperation Code are as follows:

- companies shall respect the independence of patient organisations with regard to their political position, their methodology and their activities;
- all partnerships between patient organisations and companies should be based on mutual respect;
- the companies shall neither ask patient organisations to promote certain medicinal products nor respond to corresponding requests by patient organisations;
- the aims, the scope and the agreement of support and partnerships should be transparent and documented in writing;
- a list showing support offered on an individual basis has to be published by companies;
- the aim is for patient organisations to be supported by more than one pharmaceutical company. Pharmaceutical companies may not require patient organisations to let them provide financial or other support as the only pharmaceutical company either overall or for their individual projects; and
- service agreements with patient organisations essentially have to comply with the same requirements as service agreements with HCPs.

12 Are manufacturers' infringements of competition law pursued by national authorities?

Competence for the enforcement of the Cartel Act lies with the Swiss Competition Commission. The number of cases involving pharmaceutical manufacturers is small. The Swiss Competition Commission in 2009 imposed fines on Pfizer, Eli Lilly and Bayer for alleged resale price maintenance through the provision to pharmacists of recommended resale prices for their non-reimbursed medicinal products Viagra, Cialis and Levitra. The Federal Administrative Court annulled the decision of the Competition Commission in its decision of 19 December 2017, essentially finding that resale price maintenance had not been established. This decision has been appealed to the Federal Supreme Court, where the case is now pending.

Infringements of the Act against Unfair Competition are usually brought forward in a civil procedure; only in very limited circumstances will the authorities act ex officio.

13 Is follow-on private antitrust litigation against manufacturers possible?

The Swiss Cartel Act contains provisions on private lawsuits in the case of breach of cartel law. Private antitrust litigation, however, only plays a very modest role in antitrust enforcement in Switzerland.

14 What are the main mandatory anti-corruption and transparency rules applicable to pharmaceutical manufacturers?

The main mandatory anti-corruption rules applicable to pharmaceutical manufacturers are article 33 of the LTP mentioned in question 9 and the anti-bribery provisions of the Swiss Criminal Code, article 322 ter to 322 decies. The anti-bribery provisions are in line with the Criminal Law Convention on Corruption of the Council of Europe and therefore

very similar to other modern anti-corruption laws. As per 1 July 2016, the provisions against bribery in the private sector were strengthened and became offences that are prosecuted ex officio.

The main mandatory transparency rule is article 322 decies of the Swiss Criminal Code that requires that certain advantages need to be approved by the organisation of the recipient for being legal. There are many other transparency rules in various acts and ordinances at the federal, cantonal and municipal levels.

Compliance – medical device manufacturers

15 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Advertising of medical devices and collaboration with patient organisations are currently not as rigorously regulated as advertising for medicinal products. The Ordinance on Medical Devices contains one provision on advertising that sets the following rules (in article 21):

- advertising for medical devices that are intended for the direct distribution to or use by the public must be limited to statements contained in the product information with respect to use, capabilities and efficacy;
- misleading claims of efficacy or capabilities are prohibited; and
- advertising to the general public is prohibited with regard to medical devices that are subject to prescription or are exclusively distributed for use by HCPs.

Article 33 of the LTP on the prohibition of financial advantages in its current wording does not apply to medical devices. The industry association of medical device manufacturers and distributors, Swiss Medtech, has, however, issued a code of conduct that provides for similar, more detailed and partly stricter rules than article 33 of the LTP. For example, medical device manufacturers may not grant any more financial support for congress participation to individual HCPs. The general anti-bribery provisions of the Criminal Code and the Act against Unfair Competition apply also to manufacturers and distributors of medical devices.

Pharmaceuticals regulation

16 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The rules on the granting of marketing authorisations and the placing of medicines on the market are set out in the LTP and various ordinances depending on it, in particular the Ordinance on the Requirements for Marketing Authorisation of Medicinal Products, the Ordinance on the Simplified Marketing Authorisation of Medicinal Products and Authorisation by Way of Notification, the Ordinance on the Simplified Marketing Authorisation of Complementary and Herbal Medicinal Products, the Ordinance on Establishment Licences and the Ordinance on Medicinal Products.

17 Which authorities may grant marketing authorisation in your jurisdiction?

Marketing authorisations are granted by Swissmedic.

18 What are the relevant procedures?

The relevant procedures are the ordinary, pre-announcement, fast-track and simplified procedures. A marketing authorisation can only be granted to a company or person having its domicile, registered office or a branch office in Switzerland. The applicant must also have a manufacturing, import or wholesale licence.

Ordinary procedure

The application to Swissmedic for a marketing authorisation for a human medicinal product must be made using standard forms and the common technical document (CTD) or eCTD or eDok when data is submitted electronically. The required documents are listed in detail in the Ordinance on the Requirements for Marketing Authorisation of Medicinal Products and guidelines issued under it. Swissmedic recommends submitting data electronically.

The conditions for granting a marketing authorisation are that the product is of a high quality and is safe and effective. 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 should be considered by Swissmedic (article 13 LTP). There is, however, no automatic recognition of foreign marketing authorisations. In the case of medicinal products containing an active substance that has already been authorised, Swissmedic, in an article 13 proceeding, limits itself, in principle, to assessing the evaluation reports of the foreign authorities. Swissmedic will not, however, make an assessment of the evaluation reports of the European Medicines Agency or the Food and Drug Administration, provided that these reports are not contradictory and Swissmedic has no essential concerns towards these evaluations.

The normal authorisation process takes about a year at minimum. Swissmedic has issued a guideline setting out its internal targeted time periods and milestones. If Swissmedic has queries, or requests further information or documents, the internal targeted time periods are stopped and the authorisation process can take longer.

Procedure with pre-announcement

If the applicant informs Swissmedic well in advance (five to eight months) of the date of filing the application for marketing authorisation, Swissmedic offers, under certain conditions, a 20 per cent faster process. The fees for the proceeding are then doubled.

Fast-track procedure

If there is no treatment, satisfactory or otherwise, against a perilous or heavily disabling disease, and if the medical preparation 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.

Simplified procedure

A simplified marketing authorisation procedure is available for certain types of medicinal products, such as:

- medicinal products with active substances that have already been authorised in Switzerland;
- parallel imports from a country with an equivalent marketing authorisation system;
- orphan drugs;
- medicinal products whose active substance has been used in a medicinal product authorised in one or more EU or EFTA countries for at least 10 years and which are comparable with regard to indication, dosage and mode of application;
- non-prescription medicinal products with indication that, at the time of submission of the application, are proven to have been used medically for at least 30 years, at least 15 years of which are in EU and EFTA countries;
- certain radiopharmaceuticals and antidotes; and
- complementary and herbal medicinal products.

The procedure is mainly governed by the Ordinance on the Simplified Marketing Authorisation of Medicinal Products and Authorisation by Way of Notification and the Ordinance on the Simplified Marketing Authorisation of Complementary and Herbal Medicinal Products.

For certain medicinal products (eg, certain homeopathic and anthroposophical products), authorisation by way of a mere notification procedure is possible.

Swissmedic may grant a marketing authorisation of limited duration based on reduced requirements for medicinal products against life-threatening or seriously disabling diseases if this is compatible with the protection of health, if a significant therapeutic benefit can be expected from the administration of these products and if no equivalent medicinal product is available in Switzerland.

19 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Article 16a of the LTP states that Swissmedic will withdraw the marketing authorisation of a medicinal product if it is not effectively brought into circulation within three years from the grant of the marketing

Update and trends

On 18 March 2016, Parliament decided a major revision of the LTP. The major part of the revision will enter into effect as per 1 January 2019. The revision relates to many areas of the law, including regarding incentives for marketing authorisation of medicinal products for children and orphan drugs; the extension of regulatory data protection; facilitation of market access for medicinal products authorised in the EEA and of complementary and herbal medicines; facilitation of access to medicinal products that are not (yet) authorised in Switzerland; changes to the dispensation competences of pharmacists and drugstores; and furtherance of self-medication. The safety of pharmaceutical products shall be increased, for example, by the requirement of a pharmacovigilance plan, the application of good vigilance practice and additional notification requirements. Transparency shall be increased by additional publications of Swissmedic about authorised medicinal products, for example, by the publication of a public assessment report (SwissPAR). The provisions of the revised LTP on financial advantages offered to healthcare professionals will not come into effect before 2020.

authorisation or not marketed for three consecutive years. If a patent hinders the marketing of the medicinal product, the three-year period starts with the expiry of patent protection. Pharmaceuticals authorised in connection with an emergency situation and pharmaceuticals that are only exported are not subject to such withdrawal.

20 Which medicines may be marketed without authorisation?

The LTP provides for the following catalogues of human medicines that may be marketed without authorisation:

(i) medicinal products manufactured by hospitals or public pharmacies based on a prescription by a physician for a specific person or a specific circle of persons (magistral formula) – the medicinal product can be manufactured ad hoc or for stockpiling, but only dispensed based on a prescription by a physician;
(ii) medicinal products manufactured ad hoc or for stockpiling by hospitals, public pharmacies, drugstores or other establishments with a manufacturing licence based on a special monograph of the pharmacopoeia or another recognised dispensary for dispensation to their own clients (officinal formula);
(iii) non-prescription medicinal products manufactured ad hoc or for stockpiling by hospitals, public pharmacies, drugstores or other establishments with a manufacturing licence based on their own formula or on a formula published in learned literature and within the dispensing competence of the person responsible for the manufacturing and for dispensation to his or her own clients;
(iv) medicinal products for which no alternative equivalent medicinal product is authorised or available and that are manufactured for stockpiling by hospitals based on a hospital internal list of medicinal products and for dispensation to their own clients;
(v) medicinal products for clinical trials; and
(vi) medicinal products that cannot be standardised.

Manufacturing of the medicinal products listed under points (i) to (iv) can be delegated to an establishment with a manufacturing licence, and there are qualitative and quantitative limits for manufacture of these medicinal products.

21 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

Until the end of 2018, there was no specific regulation on named patient programmes initiated by pharmaceutical manufacturers before a marketing authorisation was granted. Under certain conditions, physicians and pharmacists could import certain medicinal products that were not authorised in Switzerland for the treatment of named patients or for emergency situations (article 36 of the Ordinance on Establishment Licences). This possibility will, in principle, be maintained under the revised law. In the same way as before, physicians and pharmacists will be allowed (without a specific authorisation by Swissmedic) to import medicinal products that are not authorised in Switzerland but in a country with a comparable marketing authorisation system (currently Australia, the EEA member states, Japan, Canada, New Zealand, Singapore and the United States) for named patients or for emergency situations. In addition, physicians and pharmacists will also be allowed to import medicinal products that have not (yet) obtained marketing authorisation in such a country but are authorised for use in a clinical trial. In the latter situation, a risk analysis has to be established and reported to the competent cantonal authorities prior to importation.

The revised law also provides for specific provisions on 'compassionate use programs' authorised by Swissmedic. According to the new article 9b paragraph 1 LTP, Swissmedic may temporarily authorise the sponsor of a clinical trial in Switzerland to use trial medication (that has not yet received a marketing authorisation) on certain persons or certain categories of persons outside of the clinical trial.

Pricing and reimbursement of medicinal products

22 To what extent is the market price of a medicinal product governed by law or regulation?

Medicinal products that are reimbursed by the basic health insurance are subject to governmental price control. The prices of non-reimbursed products are free and are not government-controlled.

A finished medicinal product (whether prescription-only or non-prescription) must, in principle, be listed on the speciality list (SL) established by the Federal Office of Public Health in order to be reimbursed in the basic health insurance. When deciding on the admission of a medicinal product to the SL, the Federal Office of Public Health determines its list price. This price is the maximum price that can be invoiced by healthcare providers and that will be reimbursed by health insurance companies. About 80 per cent of the sales of pharmaceutical products in Switzerland relate to products listed on the SL.

If a medicinal product is not listed on the SL or is listed on the SL but used off-label or outside a limitation of reimbursement, it must be taken over by the health insurance companies in basic health insurance if there is no effective and authorised treatment alternative and a high therapeutic benefit can be expected from its use. In this situation, the health insurance companies determine the reimbursed amount and negotiate a cost participation with the pharmaceutical company concerned.

23 Must pharmaceutical manufacturers negotiate the prices of their products with the public healthcare providers?

For reimbursed medicinal products, the SL established by the Federal Office of Public Health lists the maximum ex-factory price and the SL price. Healthcare providers can negotiate a lower price than the ex-factory price with the pharmaceutical manufacturers. Sometimes rebates are granted, namely to hospitals. For non-reimbursed products, prices can be negotiated among pharmaceutical manufacturers and healthcare providers.

24 In which circumstances will the national health insurance system reimburse the cost of medicines?

Under the basic health insurance, health insurance companies pay or reimburse finished medicinal products prescribed by physicians for outpatient treatment (or, under certain circumstances, chiropractors) that are listed on the SL if they are used within their indication. The SL listing may be accompanied with limitations regarding reimbursement.

In two exceptional situations, the costs of a product that is either not listed on the SL, or is listed on the SL but used off-label or outside a limitation of reimbursement, are taken over by the basic health insurance: 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 very 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.

In the inpatient sector, the costs of medicines are mainly paid through, and included in, flat-rate payments per case. For certain medicines, separate supplementary fees can be invoiced by the hospital to the health insurance companies.

Optional additional private insurance usually also covers authorised medicinal products that are not listed in the SL.

25 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The competent body is the Swiss Federal Office of Public Health. It decides on the admission of finished medicinal products to the SL. A medicinal product is only admitted to the SL if the applicant can show its efficacy, usefulness and economy. The relevant criteria for fixing the SL price of an original product are the prices of drugs having the same indication or a similar mode of action and the average price of the product in other countries. Currently, the prices in nine reference countries – Germany, Denmark, England, the Netherlands, France, Austria, Belgium, Finland and Sweden – are used for this comparison. For determining the SL price, the Federal Office of Public Health adds a distribution margin to the ex-factory price determined according to the two criteria described above. The fulfilment of the conditions for admission to the SL is in principle reviewed every three years. A review of the conditions for admission to the SL also takes place immediately after the expiration of the patent protection, as well as in the following situations: authorisation of a new indication by Swissmedic, restriction of an indication by Swissmedic, request for changing a limitation and request for a price increase. The SL prices of generics are determined in function of the prices of their reference products.

26 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

There are no statutory rules obliging manufacturers or distributors to give certain discounts. Healthcare providers must pass on discounts that they have received on medicinal products or in relation to services reimbursed by the basic health insurance to the debtor of the healthcare product or service (insurance or patient).

Medicine quality and access to information

27 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

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 competences of Swissmedic and the customs authorities to block counterfeited or illegally traded medicinal products and to investigate breaches of the law are broad. Swissmedic has made combating the illegal trade of medicinal products a priority and is in close contact with foreign authorities.

Besides the LTP, the legislation on intellectual property also offers means to counter the counterfeiting and illegal distribution of medicines.

In 2011, Switzerland signed the Medicrime Convention of the Council of Europe. On 29 September 2017, Parliament empowered the Federal Council to ratify the Convention and decided on certain changes to the LTP and the Code of Criminal Procedure for implementing it. At the time of writing of this article, it was planned that these changes and changes to the implementing ordinances shall come into effect on 1 January 2019.

28 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

Advertising for prescription-only medicines to the general public is prohibited in Switzerland. The Swiss Federal Court has confirmed this prohibition in several decisions. In contrast, information on illnesses and treatment options is admissible. The product information for prescription-only medicines (information for professionals and patient leaflet) is not to be regarded as advertising and can be made freely available, including on the internet. Swissmedic makes it available on its website, www.swissmedicinfo.ch.

Since 1 June 2015, the Federal Office of Public Health for reimbursed products makes available a summary of the basis for the assessment of the efficacy, usefulness and economy of a product in case of admission on the SL and changes of the indication or limitation.

Pharmaceutical companies are intensifying initiatives to make health-related information on illnesses and treatment options available to the general public, and also to advertise themselves as companies.

29 Outline major developments to the regime relating to safety monitoring of medicines.

The revision of the LTP that was decided on 18 March 2016 and will come into effect on 1 January 2019 (see the 'Update and trends' section) provides for an extension of the reporting obligations, the implementation of 'good vigilance practices' and pharmacovigilance planning, and for quality assurance measures in the medication process.

Vaccination

30 Outline your jurisdiction's vaccination regime for humans.

There is no general obligation to vaccinate in Switzerland. Currently, the cantons can foresee such an obligation. Only very few cantons have imposed an obligation to vaccinate, for example, against diphtheria. The Act on Epidemics of 28 September 2012, which came into force on 1 January 2016, gives the Confederation the competence to impose an obligation to be vaccinated on certain groups of exposed persons if they want to continue their exposed activity. The importation and batch release of vaccines are in principle subject to authorisation by Swissmedic on an individual basis. The vast majority of vaccines are prescription-only medicinal products. The Federal Office of Public Health and the Federal Commission for Questions related to Vaccinations establish a vaccination plan each year. The vaccinations according to the vaccination plan and certain other vaccinations are reimbursed by the social health insurance.

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Banking Regulation
Cartel Regulation
Class Actions
Cloud Computing
Commercial Contracts
Competition Compliance
Complex Commercial Litigation
Construction
Copyright
Corporate Governance
Corporate Immigration
Corporate Reorganisations
Cybersecurity
Data Protection & Privacy
Debt Capital Markets
Dispute Resolution
Distribution & Agency
Domains & Domain Names
Dominance
e-Commerce
Electricity Regulation
Energy Disputes
Enforcement of Foreign Judgments
Environment & Climate Regulation
Equity Derivatives
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Financial Services Compliance
Financial Services Litigation
Fintech
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Government Investigations
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High-Yield Debt
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Mediation
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Ports & Terminals
Private Antitrust Litigation
Private Banking & Wealth Management
Private Client
Private Equity
Private M&A
Product Liability
Product Recall
Project Finance
Public M&A
Public-Private Partnerships
Public Procurement
Rail Transport
Real Estate
Real Estate M&A
Renewable Energy
Restructuring & Insolvency
Right of Publicity
Risk & Compliance Management
Securities Finance
Securities Litigation
Shareholder Activism & Engagement
Ship Finance
Shipbuilding
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Sovereign Immunity
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ISBN 978-1-78915-040-7