Life Sciences 2021

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LEXOLOGY
Getting The Deal Through

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Published by
Law Business Research Ltd
Meridian House, 34-35 Farringdon Street
London, EC4A 4HL, UK

First published 2009
Twelfth edition
ISBN 978-1-83862-360-9

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

Life Sciences
2021

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Lexology Getting The Deal Through is delighted to publish the twelfth edition of *Life Sciences*, which is available in print and online at www.lexology.com/gtdt.

Lexology 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 Lexology 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 new chapters on Canada, China, the European Union, Israel, and South Korea.

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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.

Lexology 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 the contributing editor, Alexander Ehlers of Ehlers, Ehlers & Partner, for his continued assistance with this volume.

LEXOLOGY
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London
November 2020

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This article was first published in December 2020
For further information please contact editorial@gettingthedealthrough.com

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Switzerland

Frank Scherrer and Dominique Roos
Wenger & Vieli Ltd

ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

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. Only specific areas are governed by federal law. Many competences and tasks are under the control of the 26 cantons (such as the running of public hospitals).

Financing

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 through flat-rate payments per case and the cantons. 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.

Basic structures

3 | What are the basic structures of the provision of care to patients in statutory and private care?

Statutory care (basic health insurance) provides for a quite extensive, though limited catalogue of reimbursed healthcare services. They are provided by public or private hospitals, physicians, pharmacists or other recognised healthcare providers. The basic health insurance system generally allows a free choice of healthcare providers. Private care offers certain additional healthcare services, like alternative medicine or in the field of hospital accommodation. There are very many types of private health insurance policies. Public hospitals also provide services for privately insured patients.

HEALTHCARE SERVICES

Authorisation

4 | What steps are necessary to authorise the provision of health services, and what law governs this?

The provision of most health services requires a licence from the canton that is mostly regulated in the cantonal Health Act. There are various conditions relating, among others, to education and experience. The requirements regarding education and experience are regulated in various legal texts at federal and cantonal level.

Only certain categories of health service providers are recognised as healthcare services providers under the Health Insurance Act so that their services are reimbursed under the statutory health insurance system. These are mainly hospitals, physicians and pharmacists. The recognition of healthcare services providers is regulated in articles 35 to 40 of the Health Insurance Act. Some cantons have adopted additional provisions restricting the recognition of healthcare services providers for a certain period.

Structure

5 | Which types of legal entities can offer healthcare services?

Healthcare services can be provided under different legal structures. Physicians' cabinets and pharmacies are often run as sole proprietorships or partnerships. Like hospitals, they can also be run as legal entities such as in the form of a corporation or limited liability company. Hospitals are often entities governed by public law, sometimes also foundations or associations. The personal regulatory obligations of the medicinal persons managing the establishment are independent from the type of legal entity.

Services of foreign companies

6 | What further steps are necessary for foreign companies to offer health services?

Foreign companies wishing to offer health services in Switzerland need a licence like Swiss companies if they are offering health services on Swiss territory. In the Canton of Zurich, for example, such companies need to have at least a registered branch office in the Canton.

ADVERTISING

Legislation

7 | Which legislation governs advertising of medicinal products to healthcare professionals?

Advertising for medicinal products to healthcare professionals is governed by:

- the Law on Therapeutic Products;
- the Ordinance on Advertising for Medicinal Products;

- the Federal Act against Unfair Competition; and
- the Code of Conduct of the Pharmaceutical Industry in Switzerland, issued by scienceindustries, the association of the Swiss chemical, biotech and pharma industries.

Main principles

8 What are the main rules and principles applying to advertising of medicinal products 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.

Advertising of medical devices

9 Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

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 only 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.

The main difference is that in the field of medical devices advertising is mainly limited by the principle that advertising must not be misleading, while in the field of medicinal products, the legislature has issued much more protective legislation for lay persons.

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

10 What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

Digitisation in healthcare has different speeds depending on the sector. While diagnostic and data processing and data presentation equipment and software are developing very fast and are leading-edge technology, projects like the electronic patient file or recognised electronic signature are slowly moving. In Switzerland, there are rather few legal developments specifically in this field.

The revision of the Data Protection Act of 25 September 2020, which is expected to come into force in 2022, will have a major impact also in the healthcare sector. The revision brings the content of the Swiss Data Protection Act closer to that of the General Data Protection Regulation. Important impacts will be the obligation to establish a record of data processing activities and the requirement to complete a data protection impact assessment for high-risk activities, which will often be relevant when personal data requiring special protection is processed on a large scale, such as health data.

Provision of digital health services

11 Which law regulates the provision of digital health services, and to what extent can such services be provided?

There are no specific laws governing digital health services such as telemedicine. Instead, digital health services need to be assessed based on various different laws. One main principle is that physicians based on their mandate contract with the patient have to apply the diligence that can be expected from them based on their education and experience. This rule is also laid down in article 40 letter a of the Act on Academic Medicinal Professions. Cantonal health laws require that the treatment of patients be done personally and in principle through immediate contact (eg, section 12 paragraph 3 of the Health Act of the Canton of Zurich). The professional rules of the Swiss Association of Physicians merely prohibit the regular treatment solely based on a digital contact.

Furthermore, the provisions on patient–doctor confidentiality have to be respected.

Authorities

12 Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The authorities responsible for compliance with data protection and privacy are mainly the federal and cantonal data protection officers. Their tasks are laid down in the federal or cantonal data protection acts. The federal data protection officer has published several guidance documents on data protection in the healthcare sector (eg, a guidance for the processing of personal data in the medical field in 2006 or explanations on the processing of personal data in medical cabinets).

Requirements

13 What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

Health data is personal data that is particularly worthy of protection. Therefore, there are elevated requirements regarding the information of the data subjects on the collection and processing of this data. An explicit consent of the data subjects is as a rule required. Patient–doctor confidentiality also requires that patient data is safely stored and protected against access by non-authorised third parties. There is no regular need for a qualified data protection officer.

The revision of the Data Protection Act of 25 September 2020, which is expected to come into force in 2022, establishes the requirement of a data protection impact assessment for likely high risk activities, which will often be relevant when personal data requiring special protection is processed on a large scale, such as health data.

Common infringements

14 What are the most common data protection and privacy infringements committed by healthcare providers?

The most common data protection and privacy infringements committed by healthcare providers are a lack of up-to-date protection of electronic patient data against unauthorised access and a lack of sufficient informed consent for further use of patient data.

COLLABORATION

Legislation

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

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

- the Law on Therapeutic Products (LTP), especially articles 55 and 56 and the provisions on clinical trials and vigilance;
- the Ordinance on Integrity and Transparency in the Field of Therapeutic Products;
- the Ordinance on Advertising for Medicinal Products;
- 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, articles 322ter to 322decies, 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. However, with regard to organisational rules and competences, there are important differences among employed and self-employed physicians.

Collaboration with healthcare professionals

16 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 have been developed. These are mainly set out in article 55 LTP, the Ordinance on Integrity and Transparency in the Field of Therapeutic Products, the Code of Conduct of the Pharmaceutical Industry in Switzerland and the Code of Conduct of the Pharmaceutical Industry in Switzerland on cooperation with Healthcare Professional Circles and Patient Organisations (the Pharma Cooperation Code), issued by scienceindustries.

Article 55 LTP prohibits to offer, request, grant or accept undue financial advantages to healthcare practitioners or healthcare organisations in relation to prescription-only medicinal products and certain medical devices still to be determined by the Federal Council.

The following exceptions apply:

- support contributions for research, further education and training, provided that certain criteria are met;
- invitations to educational events, provided that the participant makes a co-payment of at least 33 per cent, unless he or she actively participates in the event (eg, by holding a presentation);
- compensation for equivalent services in return, in particular for such services in connection with orders and deliveries of therapeutic products;
- price discounts or refunds granted on the purchase of therapeutic products, provided that they do not affect the choice of treatment; and
- gifts of a modest value, relevant for the professional activity of the recipient (eg, prescription pads or any other article for daily professional use); gifts are considered to be of a modest value if their total value is not more than 300 Swiss francs per year per healthcare professional. Industry codes, which are based on the EFPIA codes, are more restrictive and prohibit any gifts to healthcare professionals, with the following reservations:
  - objects, information and training materials of moderate value, which are also beneficial to patients; and
  - writing implements and pads of modest value, provided to healthcare professionals on the occasion of an educational event, which must not bear any references to the company or to particular medicinal products.

The Pharma Cooperation Code provides that the signatory companies to it 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.

Collaboration with patient organisations

17 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.

The Pharma Cooperation Code provides that the signatory companies to it have to disclose financial advantages granted to patient organisations.

Common infringements

18 What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

Besides improper advertising, infringements committed by manufacturers with regard to collaboration with HCPs in general relate to undue financial advantages. However, only a few decisions of the authorities and the courts have been published in this field.

Collaboration on medical devices

19 Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

Article 55 of the LTP on the prohibition of undue financial advantages in its current wording does not apply to medical devices. However, the industry association of medical device manufacturers and distributors, Swiss Medtech, has issued a code of conduct that provides for similar, more detailed and partly stricter rules than article 55 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.

Parliament has already passed a revision of article 55 LTP that will extend the rules on undue financial advantages to medical devices. The date that this revision will enter into effect has not yet been determined.

COMPETITION LAW

Authority enforcement

20 Are infringements of competition law by healthcare providers pursued by national authorities?

Infringements of cartel law by healthcare providers can be pursued by the Swiss Competition Commission. Civil actions in court are also possible. To date, there have been few cartel cases involving healthcare providers. This may be related to the fact that the Cartel Act, according to article 3, does not apply if the legislator wanted to exclude certain markets, goods or services from competition, for example, by granting undertakings special rights for executing public tasks. In the healthcare sector there are a number of such rules.

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

Private enforcement

21 Is follow-on private antitrust litigation against healthcare providers possible?

The Swiss Cartel Act contains provisions on private enforcement in the case of breaches of antitrust law. However, private antitrust litigation only plays a very modest role in antitrust enforcement in Switzerland.

Anti-corruption and transparency

22 What are the main anti-corruption and transparency rules applicable to healthcare providers?

The main anti-corruption rules applicable to healthcare providers are article 55 of the Law on Therapeutic Products (LTP) and the Ordinance on Integrity and Transparency in the Field of Therapeutic Products as well as the anti-bribery provisions of the Swiss Criminal Code, articles 322ter to 322decies. 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 (article 4a of the Act against Unfair Competition) were strengthened and became offences that are prosecuted ex officio.

The main mandatory transparency rule is article 56 LTP, which requires that rebates granted in selling therapeutic products (ie, medicinal products and medical devices) must be transparently displayed on the invoice and in the books of the selling and purchasing entity or person. Another important transparency rule is article 322decies of the Swiss Criminal Code, which requires that certain advantages need to be approved by the organisation of the recipient to be legal. There are many other transparency rules in various acts and ordinances at the federal, cantonal and municipal levels.

The Code of Conduct of the Pharmaceutical Industry in Switzerland on cooperation with Healthcare Professional Circles and Patient Organisations issued by scienceindustries obliges pharmaceutical companies adhering to it to disclose transfers of value to healthcare providers, healthcare organisations and patient organisations.

PRICING AND REIMBURSEMENT

Price regulation

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

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

A ready-to-use 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 to be reimbursed in the basic health insurance (unless it is paid by hospitals out of a diagnosis-related group flat-rate). 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 is 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 against a fatal or severe and chronic illness, 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.

For medical devices, the health insurance companies pay a certain fixed amount per device that is listed in the list of aids and equipment independently of the price of the specific medical device in question.

Negotiations between manufacturers and providers

24 Must pharmaceutical and medical device manufacturers negotiate the prices of their products with 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. Prices of medical devices can also be negotiated. For non-reimbursed products, prices can be negotiated among pharmaceutical manufacturers and healthcare providers.

Reimbursement

25 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 ready-to-use 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 situation when there is no effective and authorised treatment alternative against a fatal or severe and chronic illness and a high therapeutic benefit can be expected from its use, 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 after having negotiated a cost-contribution with the manufacturer.

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 may also cover certain authorised medicinal products that are not listed in the SL.

Price adjudication

26 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 with 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: authorising a new indication by Swissmedic, restricting an indication by Swissmedic, requesting changing a limitation and requesting a price increase. The SL prices of generics are determined in the function of the prices of their reference products.

Discount

27 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

There are no statutory rules obliging manufacturers or distributors of medicinal products 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).

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UPDATE AND TRENDS

Key developments of the past year

28 Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

A major revision of the law on medical devices has been decided adapting Swiss law to the EU Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). The MDR will come into effect on 26 May 2021, and the provisions on IVDR on 26 May 2022. The respective revisions of Swiss law will also come into effect on these dates. Currently, there is also a revision of the mutual recognition agreement with the EU on the recognition of conformity assessments being negotiated. However, the outcome of these negotiations is uncertain.

Owing to the revision of the Law on Therapeutic Products, the entry into force of the Ordinance on Integrity and Transparency in the Field of Therapeutic Products and the Code Consolidation of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Code of Conduct of the Pharmaceutical Industry in Switzerland and the Code of Conduct of the Pharmaceutical Industry in Switzerland on cooperation with Healthcare Professional Circles and Patient Organisations were also revised. The revised codes will enter into force on 1 January 2021.

Parliament decided to amend article 55 of the Law on Therapeutic Products to regulate undue benefits related to medical devices. This will require an amendment of the Ordinance on Integrity and Transparency in the Field of Therapeutic Products. The revision is likely to come into effect in 2022.

Parliament is currently discussing various projects for a revision of the pricing and reimbursement rules, especially for generic products.

Coronavirus

29 What emergency legislation, relief programmes and other initiatives specific to your practice area has been implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

The Federal Council and the authorities of the cantons have issued various ordinances since 13 March 2020 in response to the covid-19 pandemic. In

addition to various other measures, the authorities issued specific rules in the medicinal products and medical devices sector, including:

- empowering the Swiss Agency for Therapeutic Products (Swissmedic) to grant exemptions from the requirements for the import and authorisation of medicinal products;
- granting exceptional authorisations for disinfectants;
- empowering Swissmedic to allow deviations from the manufacturing and batch release process for medicinal products;
- restricting the distribution of certain medicinal products;
- implementing reporting obligations regarding quantities of in vitro diagnostics held in stock;
- covering the costs of covid-19 tests used in accordance with the test criteria of the Federal Office of Public Health; and
- launching a Swiss covid-19 app.

These rules are subject to change. The most current situation can be seen on the website of the Federal Office of Public Health.

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ISBN 978-1-83862-360-9