THE LIFE SCIENCES LAW REVIEW

Ninth Edition

Editor
Richard Kingham

THE LAWREVIEWS

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NINTH EDITION

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This article was first published in March 2021
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Editor
Richard Kingham

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Published in the United Kingdom
by Law Business Research Ltd, London
Meridian House, 34–35 Farringdon Street, London, EC4A 4HL, UK

www.TheLawReviews.co.uk

ISBN 978-1-83862-801-7

Printed in Great Britain by
Encompass Print Solutions, Derbyshire
Tel: 0844 2480 112

ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following for their assistance throughout the preparation of this book:

ANAND AND ANAND

ANTHIAZAMMIT LEGAL

AVVOCATI ASSOCIATI FRANZOSI DAL NEGRO SETTI

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CONTENTS

PREFACE

The ninth edition of *The Life Sciences Law Review* covers a total of 28 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

The past year has been dominated by the covid-19 pandemic, and this will undoubtedly be true of 2021 as well. Manufacturers of healthcare products have expedited the development and testing of drugs, biologics, diagnostics and personal protective equipment. Vaccines, many making use of novel technologies, have moved from the laboratory to the clinic and then to patients in record times; a matter of months rather than years or decades. Regulatory agencies have reviewed marketing applications with unprecedented speed and efficiency and international organizations have taken measures in an effort to ensure equitable access to medicines and vaccines in all countries.

In times such as these, it is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems that govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this year's publication will be especially helpful in this respect.

All of the chapters have been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
February 2021

Chapter 24

SWITZERLAND

Andreas Wildi and Celine Weber[1]

I INTRODUCTION

Switzerland harbours many sectors of the life sciences industry. Swiss research, development and production are well known in all corners of the planet. Switzerland is home to world leaders and is the origin of many groundbreaking ideas turned into successful start-ups, some set to become top players within a generation.

The Federal Institutes of Technology in Zurich and Lausanne, and the internationally recognised university hospitals in Geneva, Lausanne, Zurich, Basel and Berne contribute to this greatly.

Medicines and medical devices are mainly governed by the Federal Act on Medicinal Products and Medical Devices (the Therapeutic Products Act; TPA), which has recently been revised with regard to the provisions on integrity and transparency (the amended provisions came into force on 1 January 2020). There are numerous ordinances further specifying the provisions of the TPA. Reimbursement and pricing of medicinal products are subject to the provisions of the Federal Act on Mandatory Healthcare Insurance (KVG) and its main ordinances (KVV and KLV). While the Federal Act on Research involving Human Beings (the Human Research Act; HRA) contains provisions regarding research on humans, the Federal Act on Human Genetic Testing stipulates the conditions under which human genetic testing may be performed.

The Swiss Agency for Therapeutic Products (Swissmedic) and cantonal authorities are mainly responsible for enforcing the TPA and its ordinances. The Federal Office of Public Health (FOPH), part of the Swiss Ministry of Home Affairs, is the competent authority with regard to the enforcement of the KVG and TPA (the latter only when integrity and transparency in the collaboration between industry and healthcare providers are concerned). The enforcement of the HRA is the responsibility of cantonal ethics committees and the FOPH. Finally, the cantonal authorities are responsible for enforcing the Federal Act on Human Genetic Testing.

II THE REGULATORY REGIME

While medicines are tightly regulated by the TPA (Chapters 2 and 4) and numerous ordinances and must obtain a marketing authorisation, medical devices are governed by the principle of self-regulation. Medicines follow a genuine Swiss legislation, whereas medical devices are regulated in close accordance with European Union (EU) law. The legislation on

1 Andreas Wildi is a partner and Celine Weber is an associate at Walder Wyss Ltd.

medical devices will, however, be revised as a result of the new legislation in the EU. This revision will subject medical devices to a much stricter regime. It will enter into force in the course of the next two years.

i Classification

Medicines are products of chemical or biological origin that 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.[2]

Medical devices are products including instruments, apparatus, in vitro diagnostics, software and other goods or substances that are intended to have or are presented as having a medical use and whose principal effect is not obtained with a medicine.[3]

Foodstuffs are defined by the Federal Act on Foodstuffs and Utility Articles as all substances or products that are intended or may reasonably be expected to be consumed by human beings in a processed, partly processed or unprocessed state; medicines are not foodstuffs.[4] Health claims in connection with foodstuffs must comply with, among others, the provisions of the Ordinance on Information on Foodstuffs.

Cosmetics, when used as normally intended, come into contact with the body externally, and with teeth or mucous membranes externally, and belong to the category of 'utility articles'.[5] Health claims are prohibited for cosmetics.[6]

With regard to chemicals, substances are defined by the Federal Act on Protection against Dangerous Substances and Preparations as chemical elements and their compounds in the natural state or obtained by any production process, while preparations are defined as mixtures or solutions composed of two or more substances.[7] According to the Ordinance on Protection against Dangerous Substances and Preparations, said ordinance does not apply to medicines and medical devices.[8]

ii Non-clinical studies

The documentation of analytical, chemical and pharmaceutical test results in non-clinical trials – which is necessary to obtain a marketing authorisation for a specific medicine with a specific indication – must prove that the test procedures correspond with the current state of science and are validated. Studies carried out on animals or, where appropriate, on qualified or validated alternative models must (1) be in accordance with the rules and recommendations governing the protection of the animals used and ensuring impeccable test results; and (2) have been planned and implemented in accordance with the current state

2 Article 4 Paragraph 1 lit. a TPA.

3 Article 4 Paragraph 1 lit. b TPA; see also Article 1 MepV.

4 Article 4 Paragraph 1 and Paragraph 3 lit. d Federal Act on Foodstuffs and Utility Articles (LMG).

5 Article 5 lit. b LMG.

6 Article 47 Paragraph 3 Ordinance on Foodstuffs and Utility Articles (LGV).

7 Article 4 Paragraph 1 lit. a and c Federal Act on Protection against Dangerous Substances and Preparations.

8 Article 1 Paragraph 5 lit. c (2) Ordinance on Protection against Dangerous Substances and Preparations.

of science. Further, the marketing authorisation application for a new chemical entity must contain information and documents on pharmacodynamics, pharmacokinetics, toxicology and ecotoxicity.[9]

Non-clinical studies are subject to the Federal Act on Animal Protection, the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the Ordinance on Good Laboratory Practice.

iii Clinical trials

Clinical trials are mainly governed by Article 53 et seq. of the TPA, the HRA and the Ordinance on Clinical Trials in Human Research. Clinical trials of medicines and medical devices require prior authorisation from Swissmedic. However, clinical trials involving compliant medical devices applied in accordance with the intended use specified in the conformity assessment are exempted from mandatory authorisation.[10]

In addition to Swissmedic's authorisation, an authorisation from the responsible ethics committee is required.[11]

The sponsor is defined as a person or institution headquartered or represented in Switzerland that takes responsibility for organising a clinical trial, and in particular for the initiation, management and financing of the trial in Switzerland. The investigator on the other hand is the person responsible in Switzerland for the conduct of a clinical trial and for the protection of the participants at the trial site; an investigator who takes responsibility for organising a clinical trial in Switzerland is also a sponsor.[12]

Clinical trials must be conducted in accordance with the rules of Good Clinical Practice.[13]

The main principles in connection with clinical trials include the informed consent of the persons concerned, the primacy of individual interests over the interests of science and society, the requirement of a scientifically relevant topic, the principle of non-discrimination, the right of persons concerned to receive information on their health, the prohibition of the commercialisation of the human body and parts thereof, as well as compliance with certain scientific requirements. Furthermore, the person carrying out the clinical trial is liable for all damages suffered in connection with the project and must ensure that this liability is appropriately covered through insurance or in some other manner. In addition, the trial must be registered in a public registry and is subject to various notification and reporting obligations (e.g., completion or discontinuation of trial, adverse events, and safety and protective measures).[14]

9 Article 11 Paragraph 2 lit. a (1) and (2) TPA; Article 3 et seq. Ordinance on the Requirements Regarding the Marketing Authorisation of Medicinal Products (AMZV).

10 Article 54 Paragraph 1 and 2 lit. b TPA.

11 Article 45 Paragraph 1 HRA; Article 24 et seq. Ordinance on Clinical Trials in Human Research (KlinV).

12 Article 2 lit. c and d KlinV.

13 Article 5 Paragraph 1 and Annex 1 number 2 KlinV.

14 Article 4 et seq., Article 19 et seq., Article 46 and Article 56 HRA; Article 3 et seq., Article 10 et seq., Article 37 et seq. and Article 64 et seq. KlinV.

iv Named-patient and compassionate use procedures

In Switzerland, there are two main possibilities to use non-authorised medicines. A medical professional may, under certain circumstances, import non-authorised medicines, which are either authorised or part of a clinical trial in a comparable jurisdiction, for the treatment of an individual patient.[15]

Furthermore, Switzerland defines and allows compassionate use, whereby it may temporarily authorise the sponsor of a clinical trial approved in Switzerland to use medicines used in clinical trials on certain persons or on a certain group of persons outside of the clinical trial.[16]

A treatment with a non-authorised medicine is reimbursed by the compulsory healthcare insurance scheme if the medicine is authorised for the relevant indication in a country with an authorisation system recognised by Swissmedic as equivalent, and if either (1) the use of the medicine is an indispensable condition for another treatment covered by compulsory health insurance and if that treatment is clearly in the foreground; or (2) the use of the medicine is expected to have a great therapeutic benefit against a disease that is fatal or that could result in serious and chronic health impairments, and if no other effective and approved treatment is available owing to a lack of therapeutic alternatives.[17]

The reimbursement requires prior approval by the healthcare insurance after consultation with the medical examiner, and the costs must be proportionate to the therapeutic benefit.[18]

v Pre-market clearance

The commercial distribution of medicines requires a marketing authorisation by Swissmedic, whereas medical devices may, in principle, be put on the Swiss market without a marketing authorisation.[19]

A marketing authorisation for a medicine is granted by Swissmedic if it is of high quality, safe and effective, if the applicant is the holder of an authorisation to manufacture, import or conduct wholesale trade, and if the applicant has a registered address, registered office or a branch office in Switzerland.[20]

The marketing authorisation is issued for five years. Its renewal is generally unlimited in terms of time.[21]

A simplified procedure ensures fast access to certain categories of medicines:

a medicines with known active pharmaceutical ingredients;

b medicines whose active substances are used in a medicine that, at the time of submission of the application, has been authorised for at least 10 years in at least one EU or European Free Trade Association (EFTA) country and that is comparable in terms of indications, dosage and method of administration;

15 Article 49 Ordinance on the Authorisations of Medicinal Products (AMBV). See also Article 48 AMBV with regard to the import of non-authorised medicines by individuals for their private use.

16 Article 9b Paragraph 1 TPA; Article 52 et seq. AMBV.

17 Article 71c Paragraph 1 in conjunction with Article 71a Paragraph 1 lit. a and b KVV.

18 Article 71d Paragraph 1 and 2 KVV.

19 Article 9 Paragraph 1 and Article 45 TPA.

20 Article 10 Paragraph 1 TPA. See also Article 11 and Article 16 et seq. TPA.

21 Article 16 Paragraph 2 and Article 16b Paragraph 2 TPA.

c non-prescription medicines with an indication that, at the time of submission of the application, has been proven to have been used medically for at least 30 years, of which at least 15 years have been in EU and EFTA countries;
d medicines that, at the time of submission of the application, are proven to have been authorised as medicines for at least 15 years in a canton;
e complementary medicines;
f herbal medicines;
g medicines prepared by a hospital pharmacy or in the hospital's own radiopharmaceutical unit for the needs of the hospital;
h medicines prepared by the army and used in the context of the coordinated army medical corps;
i important medicines for rare diseases; and
j veterinary medicines, which are intended exclusively for animals not kept for the production of foodstuffs.[22]

Complementary medicines without indication, the active substances of which are included in lists of special therapeutic directions, may be placed on the market solely on the basis of a notification to Swissmedic. The same holds true for other medicines or groups of medicines for which, because of their low-risk potential, a simplified marketing authorisation procedure proves to be disproportionate.[23]

The fees as of 1 January 2021 are as follows:

a authorisation of a medicine with a new active substance: 80,000 Swiss francs;
b authorisation of a medicine with a known active substance: 50,000 Swiss francs;
c authorisation of a herbal medicine with a new active substance: 30,000 Swiss francs;
d authorisation of a medicine in the simplified procedure: 100 to 80,000 Swiss francs;
e renewal of an existing authorisation and change into authorisation unlimited in time: 500 Swiss francs; and
f authorisation of orphan drugs: fee is waived (grant of orphan drug status: 3,000 Swiss francs).[24]

Medical devices may be put on the market if they do not endanger the health of users, consumers, patients or third parties when used in accordance with their intended use. Claims for their performance or effectiveness must be provable. The person placing a medical device on the market must be able to prove that the device satisfies the fundamental requirements set forth by the applicable EU Directives and that it has been submitted to the prescribed procedures for assessing conformity. Only a small group of medical devices is subject to a mandatory notification obligation before putting them on the market for the first time.[25]

22 Article 14 et seq. TPA.
23 Article 15 TPA.
24 Article 4 Paragraph 1, Article 9 lit. a and Annexes 1 and 2 Ordinance of the Swiss Agency for Therapeutic Products on its fees.
25 Article 45 et seq. TPA; Articles 4, 6 and 9 et seq. MepV.

vi Regulatory incentives

Upon application, the Intellectual Property Institution grants a supplementary protection certificate for medicines, which is valid after expiry of the maximum term of the patent for a period equal to the period that elapses between the date of patent filing and the date of the first marketing authorisation, minus five years. It is valid for five years at the most.[26]

Document protection is granted for 10 years for medicines with a new active ingredient. Document protection is also granted for 10 years for a new indication in the case of a considerable therapeutic improvement and for three years for a new indication, application, dosage form, dose strength or dosage recommendation of a medicine with a known active ingredient. Document protection is also granted to paediatric medicines (10 years) and orphan drugs (15 years).[27]

Medicines for paediatric use benefit from a six-month extension of the supplementary protection certificate, subject to certain conditions.[28]

Patent-protected medicines may be manufactured and exported to developing countries to combat public health problems, subject to certain conditions (compulsory licences).[29]

vii Post-approval controls

Any person manufacturing or distributing therapeutic products (i.e., medicines or medical devices) must establish a notification system. He or she must notify Swissmedic of any adverse event or reaction that (1) is or may be attributable to the therapeutic product itself, its use or labelling; or (2) may endanger or damage the health of the consumer, the patient or a third party. That person must also notify Swissmedic of any quality defects and any further findings and assessments that could influence the basis of evaluation. Such notifications must be made in accordance with the recognised rules of good vigilance practice.[30]

The marketing authorisation is transferable.[31] The rules regarding amendments to approvals (known as variations) have been largely harmonised with EU law.[32]

Swissmedic may revoke the marketing authorisation if the medicine is not actually placed on the market within three years of granting the authorisation or if it is no longer actually on the market during a period of three successive years after it has been placed on the market. If the authorisation holder intends not to place a paediatric medicine on the market, such intention is published by Swissmedic together with the information that the authorisation documentation can be obtained free of charge from the marketing authorisation holder.[33]

viii Manufacturing controls

Manufacturers of medicines require a licence from Swissmedic, whereas manufacturers of medical devices are not required to obtain such a licence.[34]

26 Article 140a et seq. Federal Act on Patents for Inventions (PatG).
27 Article 11a et seq. TPA; Article 30 Ordinance on Medicinal Products (VAM).
28 Article 140n et seq. PatG.
29 Article 40d PatG.
30 Article 59 TPA.
31 Article 10 VAM.
32 Article 21 et seq. VAM; Article 22a et seq. AMZV.
33 Article 16a TPA; Articles 11 and 13 VAM.
34 Article 5 Paragraph 1 lit. a TPA.

Manufacturing licences are issued if the necessary technical and operational conditions are fulfilled and if an appropriate system of quality assurance exists.[35]

The licence is unlimited in time in principle and specifies in particular the qualified person, the authorised activities and the business locations.[36]

The manufacture of medicines must conform to the recognised rules of good manufacturing practice.[37]

ix Advertising and promotion

Whereas the TPA contains provisions regarding advertising of both medicines and medical devices, the ordinances applicable to advertising of medicines and medical devices differ. Advertising of medicines is subject to the Ordinance on Advertising of Medicinal Products (AWV), whereas advertising of medical devices is subject to Article 21 of the Ordinance on Medical Devices (MepV).

Advertising of medicines is defined in the AWV as all information, marketing and incentivising measures aimed at promoting the prescription, supply, sale, consumption or use of medicines. General information on health and diseases without any direct or indirect references to individual medicines is not, however, considered to be advertising. The packing material and the drug information do not fall within the provisions of the AWV either.[38]

The provisions regarding advertising of medicines clearly distinguish between advertising directed at healthcare professionals (HCPs) and advertising directed at the general public. Generally speaking, it is permitted to advertise all types of medicines if the advertising is directed exclusively at HCPs. However, it is only permitted to advertise non-prescription medicines to the general public.[39]

With regard to medical devices, Article 21 MepV states that advertising to the general public is prohibited for medical devices that are placed on the market for the exclusive use by professionals.

Advertising is deemed unlawful if it is misleading or contrary to public order and morality, if it may incite an excessive, abusive or inappropriate use of medicines or if it is for medicines that may not be placed on the market nationally or cantonally.[40]

Furthermore, advertising directed at the general public is deemed unlawful for medicines that contain narcotic or psychotropic substances and for medicines that may not, on account of their composition and their intended use, be used without the intervention of a doctor for the necessary diagnosis, prescription or treatment, as well as for medicines that are frequently the object of abuse, or lead to an addiction or dependence.[41]

The infringement of the regulations on the advertising of medicines may entail criminal sanctions.[42]

In addition, Swissmedic may take all administrative measures necessary to enforce the TPA. In particular, it may seize, hold in official storage, destroy or prohibit the use of illegal

35 Article 6 Paragraph 1 TPA.

36 Article 40 and 42 AMBV.

37 Article 7 Paragraph 1 TPA; Article 4 Paragraph 2 and Annexes 1 and 2 AMBV.

38 Article 1 Paragraph 2 lit. a and c; Article 2 lit. a AWV.

39 Article 31 Paragraph 1 and Article 32 Paragraph 2 lit. a TPA; Article 3 et seq. and Article 14 et seq. AWV.

40 Article 32 Paragraph 1 TPA.

41 Article 32 Paragraph 2 TPA.

42 Article 87 Paragraph 1 lit. b and Paragraphs 2–6 TPA.

advertising media, and publish the prohibition at the expense of the responsible parties as well as temporarily or permanently prohibit the advertising of a specific medicine in the event of serious or repeated infringements of the provisions of the TPA, and publish the prohibition at the expense of the responsible parties.[43]

x Distributors and wholesalers

Any person engaged in the wholesale trade of medicines must possess a licence issued by Swissmedic, which is issued if the necessary technical and operational conditions are fulfilled and an appropriate system of quality assurance exists. The licence is also issued if the applicant already possesses a manufacturing or import licence for medicines.[44]

Brokers and agents require a licence for the distribution of medicines as well.[45]

The licence is unlimited in time in principle and specifies in particular the qualified person, the authorised activities and the business locations.[46]

Furthermore, anyone who dispenses medicines requires a cantonal licence.[47]

In principle, mail-order trade in medicines is prohibited. However, cantons may issue a licence under certain conditions.[48]

xi Classification of products

In connection with the marketing authorisation, Swissmedic classifies medicines into four categories (A, B, D and E) depending mainly on their safety and their undesirable effects. Generally speaking, categories A and B contain prescription-only medicines, whereas category D contains over-the-counter medicines in pharmacies and drug stores, and category E contains medicines sold without any restrictions.[49]

Category A and B medicines may be dispensed by doctors or pharmacies. Category A medicines may, however, only be dispensed once.[50] Certain category B medicines may, under certain conditions, be dispensed by pharmacists without a prescription.[51]

Category D medicines may be dispensed by pharmacies and drug stores after professional advice, whereas category E medicines can be sold anywhere without restrictions.[52]

The former category C (over-the-counter medicines that may be dispensed by pharmacies after professional advice by a healthcare professional) has been abolished, starting from 1 January 2019, and all the medicines that were in it have been reclassified into category D or B. However, until completion of said reclassification, category C will continue to exist until all reclassifications are legally binding, which may take several years if such reclassifications are appealed.[53]

43 Article 66 Paragraphs 1 and 2 TPA.
44 Article 28 TPA; Article 2 lit. l and Article 11 et seq. AMBV.
45 Article 4 Paragraph 1 lit. e TPA; Article 24 et seq. AMBV.
46 Articles 40 and 42 AMBV.
47 Article 30 Paragraph 1 TPA.
48 Article 27 TPA.
49 Article 23 et seq. TPA; Article 40 et seq. VAM.
50 Article 41 et seq. VAM.
51 Article 45 VAM.
52 Article 43 et seq. VAM.
53 Article 88 VAM.

xii Imports and exports

Any person who, in a professional capacity, imports or exports ready-to-use medicines intended for distribution or dispensing, requires a licence issued by Swissmedic. The same holds true for anyone who, in a professional capacity, trades medicines in foreign countries from Switzerland, without their entering into Switzerland.[54]

The licence is unlimited in time in principle, and specifies in particular the qualified person, the authorised activities and the business locations.[55]

xiii Controlled substances

Advertising directed at the general public is deemed unlawful for medicines that contain narcotic or psychotropic substances as referred to in the Narcotics Act.[56]

The import of medicines is generally limited to medicines that have been authorised or that are not subject to authorisation.[57] As a general rule, opium for smoking and the residues created in its production or use, diacetylmorphine and its salts, hallucinogens such as lysergide (LSD 25) and narcotics containing an effective concentration of cannabinoids may not be cultivated, imported, produced or placed on the market. However, the FOPH may issue exceptional licences, subject to certain conditions. For the import, production and placing on the market of one of the mentioned narcotics that is an active ingredient in an authorised medicine, a licence from Swissmedic is required.[58]

The export of medicines and their foreign trade from Switzerland is generally prohibited if they are prohibited in the target country or if circumstances suggest that they could be intended for illegal purposes.[59]

xiv Enforcement

As a general rule, both Swissmedic and cantonal authorities – in certain situations the FOPH – are responsible for market surveillance, for conducting inspections and for enforcing the TPA.[60]

Swissmedic may take all administrative measures deemed necessary and institute criminal proceedings, which are conducted by Swissmedic and the FOPH, and which may involve further federal or cantonal authorities.[61]

The Code Secretariat is the self-regulatory body that is responsible for the implementation of the Pharma Code and the Pharma Cooperation Code, which are relevant and often referred to self-governing codices by the pharmaceutical industry. Both codes contain provisions regarding procedures in case of a breach of a code.

54 Article 18 TPA; Article 11 et seq. and Article 21 et seq. AMBV.
55 Articles 40 and 42 AMBV.
56 Article 32 Paragraph 2 lit. b TPA.
57 Article 20 Paragraph 1 TPA.
58 Article 8 of the Narcotics Act.
59 Article 21 Paragraph 1 TPA.
60 Articles 58, 60, 82 et seq. and Article 90 TPA.
61 Articles 66 and 90 TPA.

III PRICING AND REIMBURSEMENT

Healthcare insurance is compulsory for all people residing in Switzerland. It is regulated mainly by the KVG. A medicine or a medical device is eligible for reimbursement by the compulsory healthcare insurance scheme, if an accordant application has been filed with the FOPH. The list of specialities covers ready-to-use medicines, whereas the list of means and objects (MiGeL) covers medical devices used by patients. The KVG stipulates that to be included on such a list a product must prove to be effective, appropriate and economical.[62]

Prices for medicines are determined by the FOPH. It determines the ex-factory price of a product by conducting, on the one hand, a therapeutic cross-comparison in which it considers the treatment costs of already-approved medicines for the same condition. On the other hand, it carries out an international price comparison, considering the price of the same medicine in nine reference countries (Austria, Germany, Denmark, Sweden, France, Finland, Netherlands, the United Kingdom and Belgium). The therapeutic cross-comparison and the international price comparison are weighed equally in setting the final price. An innovation premium may be granted if the product represents a significant therapeutic advance. The price of every medicine in the list of specialities is reviewed every three years.[63]

The maximum prices contained in the MiGeL for medical devices indicate how much the compulsory healthcare insurance scheme will reimburse for a medical device that falls within a specific MiGeL position. Any costs beyond the maximum price must be borne by the patient.[64]

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Decrees by Swissmedic and the FOPH can be appealed to the Federal Administrative Court. The latter's decisions can be appealed to the Federal Supreme Court.[65]

Both Swissmedic and cantonal authorities may institute criminal proceedings. On the federal level, such proceedings are conducted by Swissmedic and the FOPH and may involve further authorities.[66]

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

The TPA states that persons prescribing, dispensing, using or purchasing for this purpose prescription medicines, and organisations employing such persons shall not claim, be promised or accept any undue advantage for themselves or for the benefit of a third party. Similarly, it is prohibited to offer, promise or grant an undue advantage to any such person or organisation for their benefit or for the benefit of a third party. Not considered undue advantages are: (1) advantages of modest value relevant to medical or pharmaceutical practice; (2) contributions for research, education and training, provided that certain criteria are met; (3) compensation for equivalent services, in particular in connection with orders and deliveries of therapeutic products; and (4) discounts or refunds granted on the purchase of

62 Article 32 KVG.

63 Articles 65b and 65d KVV; Article 34a *bis* et seq. Ordinance on the Indemnification by Compulsory Healthcare Insurance (KLV).

64 Article 44 Paragraph 1 KVG; Article 24 Paragraph 2 KLV.

65 Article 84 Paragraph 1 TPA.

66 Articles 66 and 90 TPA.

therapeutic products, provided they do not influence the choice of treatment.[67] Furthermore, all discounts and refunds granted on the purchase of therapeutic products must be shown in the supporting documents and invoices and in the accounts of both the selling and purchasing persons and organisations and must be disclosed to the FOPH on request.[68]

HCPs who receive discounts or benefits from other HCPs or persons or companies supplying medicines or medical devices must pass these on to the healthcare insurer or the insured person, either wholly or the majority of it (subject to certain conditions).[69]

The Pharma Code and the Pharma Cooperation Code contain provisions regarding the relationship between the pharmaceutical industry and prescribers as well. Further self-regulatory codes include the Guidelines of the Swiss Academy of Medical Sciences on Collaboration between Medical Professionals and the Industry and the code enacted by H+, the Swiss Hospital Association.

The Pharma Cooperation Code contains the obligation to publicly publish, on a yearly basis, all monetary and in-kind benefits that they have given to HCPs and healthcare organisations in the previous year.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

The general liability regime, including both contractual and non-contractual liability (including product liability), applies in relation to persons injured by medicines or medical devices. Swiss law does not provide a specific liability system for such cases. However, in cases where injuries are suffered in connection with medical treatment at public hospitals, cantonal state liability rules are applicable.

In connection with medical research on humans, the person carrying out the clinical trial is liable for all damages suffered in connection with the project and must ensure that this liability is appropriately covered through insurance or in some other manner.

The Federal Act on the Medical Profession stipulates that persons who exercise a university medical profession in the private sector and under their own professional responsibility are obliged to take out adequate professional liability insurance.[70]

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

There are no provisions in Swiss competition law specifically addressing the life sciences sector. However, within the scope of their responsibility to enforce general competition and antitrust provisions, the Swiss Competition Commission (COMCO) and the Swiss courts do monitor and pass decisions on competition law matters within the life sciences sector. In a recent case, COMCO fined three pharmaceutical companies for alleged unlawful agreements affecting competition. The three companies had been issuing non-binding price recommendations for medicines. The case has been adjudicated by both the Federal Administrative Court and the

67 Articles 55 and 86 Paragraph 1 lit. h TPA; Article 1 et seq. Ordinance on Integrity and Transparency in the Field of Therapeutic Products (VITH).

68 Articles 56 and 87 Paragraph 1 lit. h TPA; Article 10 VITH; see, however, the exception for low-risk therapeutic products in Article 56 Paragraph 3 and Article 10 Paragraph 2 VITH.

69 Article 56 Paragraph 3 and 3 *bis* KVG; Article 76a et seq. KVV.

70 Article 40 lit. h of the Federal Act on the Medical Profession.

Federal Supreme Court, with the former overturning COMCO's fine, stating that unlawful agreements regarding prices require elements such as pressure, the promise of specific benefits and a lack of transparency, none of which were deemed to be present in the case at hand, and the latter then siding with COMCO, stating that the conditions for concerted behaviour had been met.[71] The case has now been re-adjudicated by the Federal Administrative Court, which adhered to its original verdict. Interestingly, the Federal Administrative Court held that the sales market of a prescription drug cannot be compared with that of a regular consumption good, especially when considering factors such as advertising, competition and price freedom.[72]

ii Transactional issues

While the Swiss pharma industry is host to many mergers, acquisitions and other strategic transactions, none have given rise to further scrutiny from a competition law standpoint in recent years. Swiss regulatory framework and intellectual property legislation allow for considerable flexibility, further facilitating such transactions or collaborations.

VIII CURRENT DEVELOPMENTS

The revised provisions in the TPA on integrity and transparency in connection with therapeutic products that came into force on 1 January 2020 aim to prevent the corruption of HCPs by manufacturers of medicines and medical devices, to increase transparency on granted discounts as well as to better enforce the obligation of HCPs to pass on received discounts. It remains to be seen whether the new legislation will have the desired effects or whether HCPs will insist on no longer receiving discounts because such discounts increase their administrative work and do not benefit them.

The legislation on medical devices is currently being revised so as to harmonise it with the new EU regulation. The revised provisions will enter into force in the course of the next two years.

Governmental (FOPH) reimbursement and pricing of medicines and of medical devices – whereby the focus is on medicines – faces similar challenges compared with the challenges in many other jurisdictions. The revenue expectations of an innovative industry must match the coverage capabilities of the social security system (i.e., the mandatory healthcare insurance scheme in Switzerland). Multi-indication pricing, pricing of IP-protected technologies versus generic technologies, and pricing of new technologies that do not match existing categories of medicine, medical procedure or medical device are challenges on the operational level. First proposals for new KVG provisions addressing some of the current pricing issues were introduced to stakeholders by the FOPH in 2018. It will most likely be years before the two chambers of parliament adopt new KVG provisions regarding the life sciences sector (i.e., its pricing), if ever.

Meanwhile, the three-yearly price reviews of medicines by the FOPH pose several questions that have led to numerous appeals before the Swiss Administrative Court; indeed,

71 Decision of the Federal Administrative Court B-360/2012 of 3 December 2013; Decision 2C-79/2014 of the Federal Court of 28 January 2014.

72 Decision of the Federal Administrative Court B-843/2015 of 19 December 2017, consid. 6.

some provisions of the KVV and KLV were altered as from 1 March 2017. In 2020, the Federal Administrative Court has rendered various relevant decisions in that regard, providing guidelines for the price-revision practice.

Appendix 1

ABOUT THE AUTHORS

ANDREAS WILDI

Walder Wyss Ltd

Andreas Wildi studied medicine at the University of Zurich and graduated as medical doctor (MD). Later on, he completed his law degree at the University of St Gallen HSG (MLaw). Andreas Wildi has worked for the Swiss government, where he led the pharmaceutical reimbursement and pricing unit in the Federal Office of Public Health. Furthermore, Andreas Wildi has worked as EMEA market access law director for Janssen Pharmaceuticals (Johnson & Johnson). He is now a partner at Walder Wyss Ltd. His key practice areas are Swiss and international reimbursement and pricing law of pharmaceuticals and other therapeutic products, as well as regulatory issues of pharmaceuticals, medical devices, special nutrition, cosmetics, genetic testing, stem cells and blood products. Andreas has published widely on legal issues arising from pharmaceuticals and healthcare.

CELINE WEBER

Walder Wyss Ltd

Celine Weber completed her law studies at the universities of Zurich, Geneva, Paris X Nanterre and New South Wales in Sydney (BLaw 2010, Master in Life Sciences Law 2012). She is an associate at Walder Wyss Ltd and her key practice areas are medical law, regulatory law in life sciences (pharmaceuticals and medical devices, specialist nutrition, cosmetics, genetic testing, stem cells and blood products etc.), health insurance law and competition law. She regularly publishes in these fields.

WALDER WYSS LTD

Seefeldstrasse 123
PO Box
8034 Zurich
Switzerland
Tel +41 58 658 58 58
Fax: +41 58 658 59 59
andreas.wildi@walderwyss.com
celine.weber@walderwyss.com
www.walderwyss.com

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ISBN 978-1-83862-801-7