THE LIFE SCIENCES LAW REVIEW

TENTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

THE LIFE SCIENCES LAW REVIEW

TENTH EDITION

Reproduced with permission from Law Business Research Ltd
This article was first published in February 2022
For further information please contact Nick.Barette@thelawreviews.co.uk

Editor
Richard Kingham

THE LAWREVIEWS

PUBLISHER
Clare Bolton

HEAD OF BUSINESS DEVELOPMENT
Nick Barette

TEAM LEADER
Jack Bagnall

BUSINESS DEVELOPMENT MANAGERS
Rebecca Mogridge, Katie Hodgetts, Joey Kwok

BUSINESS DEVELOPMENT ASSOCIATE
Archie McEwan

RESEARCH LEAD
Kieran Hansen

EDITORIAL COORDINATOR
Isabelle Gray

PRODUCTION AND OPERATIONS DIRECTOR
Adam Myers

PRODUCTION EDITOR
Louise Robb

SUBEDITOR
Martin Roach

CHIEF EXECUTIVE OFFICER
Nick Brailey

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 978-1-83862-246-6

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

ARZINGER LAW OFFICE

AVVOCATI ASSOCIATI FRANZOSI DAL NEGRO SETTI

BÄR & KARRER

BIRD & BIRD (MEA) LLP

CASTRÉN & SNELLMAN ATTORNEYS LTD

CHANDLER MHM LIMITED

COVINGTON & BURLING LLP

ESTUDIO BECCAR VARELA

GENOME LAWYERS

GORODISSKY & PARTNERS LAW FIRM

JADEK & PENSA

JONES DAY

KABRAJI & TALIBUDDIN

KIM & CHANG

LATHAM & WATKINS

LEĜA ABOGADOS

MANNHEIMER SWARTLING ADVOKATBYRÅ

RODRIGO, ELÍAS & MEDRANO ABOGADOS

SÁNCHEZ DEVANNY

SHUSAKU YAMAMOTO

SPOOR & FISHER

TOZZINIFREIRE ADVOGADOS

VIEIRA DE ALMEIDA

WONGPARTNERSHIP LLP

CONTENTS

PREFACE

The tenth edition of *The Life Sciences Law Review* covers a total of 30 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, like its predecessor, was dominated by the covid-19 pandemic. Manufacturers of healthcare products continued to expedite 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. Manufacturers and international organisations have worked closely together in an effort to ensure equitable access to vaccines and other important healthcare products in low- and middle-income countries, but much work remains to be done. In the wake of the pandemic, it is to be hoped that governments learn from the lessons of covid-19, placing systems and structures in place for the next pandemic or other health emergency and expediting the development and approval of new healthcare products to deal with endemic health issues such as cancer, coronary heart disease and genetic disorders.

In times like 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 2022

Chapter 25

SWITZERLAND

Markus Schott[1]

I INTRODUCTION

Switzerland is home to a very significant and diverse life sciences industry with an emphasis on research and production. Apart from the two multinational companies, Novartis and Roche, which both have their headquarters in Basel, a large number of medium-sized and smaller companies, in both the medicines and the medical devices sectors, are based in different parts of Switzerland.

Approval, distribution and marketing of medicines and medical devices are almost exclusively regulated on the federal level by the Therapeutic Products Act (HMG). Pricing and reimbursement by way of mandatory social healthcare insurance is governed by a separate act on the federal level, the Health Insurance Act (KVG). Research on humans is regulated in a separate statute at federal level: the Human Research Act (HFG). The Act primarily aims at protecting human welfare, but also at creating favourable framework conditions for research on humans in Switzerland and ensuring quality and transparency of research on humans. The three Acts are implemented by a number of ordinances that contain more detailed provisions setting out the general rules of the Acts.

While the HMG is enforced mainly by the Federal Agency for Therapeutic Products (Swissmedic), the cantonal health departments have some supervisory powers as well. The competent authority for the enforcement of the KVG is the Federal Office of Public Health. Compliance of research with the HFG is supervised by cantonal ethics commissions and the Federal Office of Public Health.

II THE REGULATORY REGIME

The HMG draws a distinction between medicines and medical devices, which are regulated in separate chapters of the Act. While the rules regarding medicines include licensing obligations for the manufacturing, marketing, import, export and trade of medicines, the rules regarding medical devices are based on the principle of self-regulation by the person placing the device on the market. The HMG also regulates the prescription, dispensing and advertising of medicines as well as clinical trials.

1 Markus Schott is a partner at Bär & Karrer.

i Classification

According to Article 4, Section 1(a) of the HMG, medicines are 'products of chemical or biological origin, which are intended to have or are presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps; blood and blood products are also considered to be medicines', and according to Article 4, Section 1(b), medical devices are 'instruments, apparatus, equipment, in vitro diagnostics, software, implants, reagents, materials and other goods or substances which are intended or claimed to have a medical use and whose principal effect is not obtained with a medicinal product'.

Foodstuffs, cosmetics and general consumer products are regulated by the Federal Act on Foodstuffs and Utility Articles (LMG). According to Article 4 of the LMG, foodstuffs are defined 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. Foodstuffs also include drinks, including water, intended for human consumption; chewing gum; all substances that are intentionally added to foodstuffs in the course of their manufacture, processing or treatment (see Article 4(2) of the LMG). Article 4(3) of the LMG further sets out a list of products not to be considered as foodstuff. Amongst others, medicinal products are not foodstuffs (see Article 4(2)(d) of the LMG).

The fundamental distinction between foodstuffs and medicines means that the marketing of foodstuffs may not claim any kind of therapeutic or prophylactic effect.[2]

According to Article 5 of the LMG, utility articles are defined as products that fall within one of several categories, among which 'personal hygiene articles and cosmetics, and articles that, when used as normally intended, come into contact with the mucous membrane of the mouth'.

The handling of chemicals (substances and preparations) is governed by the Federal Act on Protection against Dangerous Substances and Preparations, which is based on the principle of self-regulation. The handling of microorganisms is deemed equivalent to the handling of substances and preparations when they are used in biocidal products or plant protection products.

ii Non-clinical studies

To obtain a marketing licence from Swissmedic with regard to a specific medicine, it is necessary to submit to the authority all results of physical, chemical, galenic and biological or microbiological tests as well as of pharmacological and toxicological tests.[3] The application must comply with the requirements of the common technical document of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), in particular its Module 4 regarding non-clinical documentation. Consequently, when carrying out the studies, the relevant ICH guidelines must be taken into consideration.

Non-clinical studies must be in line with the requirements of the Federal Act on Animal Protection, according to which testing on animals is subject to a cantonal licence and must be in compliance with strict conditions to limit the impact on animal welfare. In a

2 'Health Claims'; Decision of the Federal Supreme Court of 8 May 2001, 2A.565/2000; Decision of the Swiss Federal Supreme Court of 22 January 2001, BGE 127 II 91; Isabelle Wildhaber and Thomas Poledna, 'The grey zone between medicinal products and foodstuffs: a guideline for a meaningful delineation in Swiss law', *Review of Swiss Law (ZSR)* 2010, Vol. 129, No. 1, pp. 51–78.

3 Article 11, Section 1(g) of the HMG.

controversial decision, the Federal Supreme Court has prohibited the use of rhesus monkeys for basic neurological research based on the principle of proportionality, in particular because the clinical benefit of the study was highly uncertain.[4]

The requirements regarding good laboratory practice are defined in the Ordinance on Good Laboratory Practice.

iii Clinical trials

Clinical trials are governed by the HFG, Articles 53 to 54 of the HMG, the Ordinance on Clinical Trials (KlinV) and the Ordinance on Clinical Trials with Medical Devices (KlinV-Mep). All clinical trials of therapeutic products must be carried out in accordance with the recognised principles of good clinical trial practice. According to the KlinV, trials with medicines have to comply with the requirements of the ICH guidelines on good clinical practice, and trials with medicinal devices have to comply with the requirements of the applicable European Union (EU) Directives[5] as well as the norm EN ISO 14155: 2011 of the International Organization for Standardization (ISO).[6]

The general conditions for conducting clinical trials with medicinal products are the explicit and free prior written consent of the trial subjects (informed consent),[7] the guarantee of full and complete compensation for injuries suffered in the course of the trial,[8] the endorsement of the trial by the competent ethics committee,[9] approval of the trial by Swissmedic,[10] and registration of the trial by the sponsor in a public register.[11] Clinical trials on minors, wards of court, persons incapable of consent, pregnant women and in emergency situations are subject to additional conditions.

The provisions regarding written consent of trial subjects (informed consent) as well as the guarantee of full and complete compensation for injuries suffered in the course of the trial also apply to clinical trials with medical products.[12] The sponsor of a clinical study further needs a licence from the competent ethics committee,[13] approval of the trial by Swissmedic[14] and registration of the trial by the sponsor in a public register.[15] The KlinV-Mep sets out exemptions from the licensing requirement for clinical trials with certain medical devices.[16]

The termination of the trial, as well as any change of the design of the trial, additional security measures and undesired incidents have to be notified to the competent ethics committee and to Swissmedic.

4 Decision of 7 October 2009, BGE 135 II 405.
5 93/42/EEC and 90/385/EEC.
6 Article 5, Section 1 and Attachment I of the KlinV.
7 Articles 16 to 18 of the HFG and Articles 7 to 9 of the KlinV.
8 Articles 19 to 20 of the HFG and Articles 10 to 14 of the KlinV.
9 Article 45 of the HFG and Articles 24 to 29 of the KlinV.
10 Article 54 of the HMG and Articles 30 to 34 of the KlinV.
11 Article 56 of the HFG and Articles 64 to 67 of the KlinV.
12 Article 4 of the KlinV-Mep.
13 Article 45 of the HFG and Articles 10 to 15 of the KlinV-Mep.
14 Article 54 of the HMG and Articles 16 to 20 of the KlinV-Mep.
15 Article 56 of the HFG and Article 49 of the KlinV-Mep in conjunction with Articles 64 to 67 of the KlinV.
16 Article 7 of the KlinV-Mep.

iv Named-patient and compassionate use procedures

According to Article 9, Section 4 of the HMG, Swissmedic may authorise, for a limited period, the distribution or dispensing of medicines not authorised for marketing to treat life-threatening diseases if such an authorisation is compatible with the protection of health, if a significant therapeutic benefit is to be expected from the administration of these medicines, and if no other comparable medicine exists. Also, based on Article 20, Section 2 of the HMG, small quantities of non-authorised medicines may be imported by patients or medical professionals under certain conditions.

By definition, a medicine that is not authorised for marketing cannot be included in the list of medicines to be reimbursed by the mandatory health insurance (see Section III). Based, however, on Article 71b of the Ordinance on Health Insurance (KVV), such costs may be reimbursed if, in the individual case at hand, they are adequate with regard to the therapeutic benefit.

v Pre-market clearance

The distribution of a medicine in Switzerland – irrespective of whether the medicine requires a prescription or may be sold over the counter – requires a marketing authorisation from Swissmedic.[17] Such marketing authorisation is issued if the applicant proves:

a that the medicine is of high quality, safe and effective;
b that the applicant is licensed for manufacture, import or wholesale trade; and
c that its registered address, registered office or a branch office is in Switzerland.[18]

In case of complementary medicines without indication, the marketing authorisation is issued if the applicant proves that the medicines are of high quality, and credibly demonstrate that the medicinal product in question does not pose a risk to the safety of consumers.[19]

The marketing authorisation is valid for five years but can be renewed as long as the conditions for issuing the marketing authorisation are met.[20]

Besides the ordinary licence procedure, the statute provides for a simplified licence procedure that applies if this is compatible with the quality, safety and efficacy requirements provided for by Swiss law.[21] In particular, this is the case with regard to:

a medicines made with known active pharmaceutical ingredients:
- medicinal products whose active substances are used in a medicinal product which, when the application was submitted, has been authorised as a medicinal product for at least 10 years in at least one EU or European Free Trade Association (EFTA) country and which is comparable in terms of indications, dosage and method of administration;
- non-prescription medicinal products with indications which, when the application was submitted, have been proven to have been used medically for at least 30 years, and for at least 15 years in EU and EFTA countries;
- medicinal products which, when the application was submitted, have been authorised as medicinal products for at least 15 years in a canton;

17 Article 9 of the HMG.
18 Article 10 of the HMG.
19 ibid.
20 Article 16 of the HMG.
21 Article 14 of the HMG.

b complementary medicines;
c herbal medicines;
d medicinal products prepared by a hospital pharmacy or in the hospital's own radiopharmaceutical unit for the needs of the hospital;
e medicines prepared by the army and used in the context of the coordinated army medical corps;
f important medicines for rare diseases; and
g veterinary medicines that are intended exclusively for animals not kept for the production of foodstuffs.

Following the submission of the required documents, the application is examined by Swissmedic, which decides whether the marketing authorisation is to be issued based on the quality of the manufacturing, the medicine's efficacy and its safety.[22] The marketing authorisation may be withdrawn if the medicine has not been marketed within the last three years.[23]

The entire authorisation procedure (ordinary licence procedure) takes between 10 and 12 months and between four and five months if the expedited procedure is chosen by the applicant.

The fees for a marketing authorisation depend[24] on the licensing procedure:
a the fees for licensing a medicine with a new active substance are 80,000 Swiss francs;
b the fees for licensing a medicine with an existing registered active substance are 50,000 Swiss francs;
c for renewing an existing authorisation the fees are 500 Swiss francs; and
d there is no fee for market authorisations of products granted orphan drug status.[25]

As a general rule, the marketing of medical devices is not subject to a marketing authorisation. Rather, the person placing the device on the market has to ensure that it does not endanger the health of the user, the consumer, the patient or a third party, and that any claims regarding its performance or effectiveness are provable.[26] Moreover, the device has to comply with the fundamental requirements according to internationally harmonised standards of the European Committee for Standardization and of the ISO. Such conformity has to be assessed and documented either with a self-declaration or by a notified body recognised by Swissmedic. Furthermore, manufacturers of medical devices or their authorised representatives and importers must register the information required by part A of Annex VI to the EU Medical Device Regulation (EU-MDR) with Swissmedic.[27] Registration of medical devices on the Swiss market shall enter into force at a later stage only.[28]

22 Article 16 of the HMG.
23 Article 16a, Section 1(a) of the HMG.
24 Article 4, Section 1, and Appendixes 1 and 2 of the Ordinance on the fees of the Swiss Agency for Therapeutic Products.
25 Article 14, Section 1(f) of the HMG; Article 9 of the Ordinance on the fees of the Swiss Agency for Therapeutic Products.
26 Article 45 of the HMG.
27 Article 55 of the Ordinance on Medical Products (MepV).
28 Article 17 and 101 of the MepV.

vi Regulatory incentives

Comparable with the situation in the European Union under Regulation (EC) 469/2009, Swiss law provides for supplementary protection certificates (SPCs), which allow the extension of patent protection for medicines.[29] SPCs take effect on 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 market authorisation minus five years. The maximum term is five years.[30] Similar to Article 36 of Regulation (EC) 1901/2006, Swiss law provides for a six-month extension of SPCs granted in relation to medicines for paediatric use.[31]

Implementing the requirements set out in Article 39 of the TRIPS Agreement,[32] and in contrast with the respective regime in the EU, Article 11a HMG grants a data exclusivity period for first applicants of medicines in relation to the results of the pharmacological, toxicological and clinical tests used in the marketing authorisation application process. The exclusivity period is 10 years for original products, and three years for new indications, modes of administration, dosage forms or dosages. For a new indication, this period of protection shall be set by the Agency, on request, at 10 years if it is expected to bring a significant clinical benefit in comparison with existing therapies and if it is backed up by extensive clinical trials. On request, Swissmedic shall grant a ten-year document protection for a medicinal product specifically and exclusively for pediatric use in accordance with the pediatric investigation plan, provided that no document protection exists for another medicinal product authorised by Swissmedic with the same active substance for the same specific pediatric use. In the case of an important orphan medicinal product, Swissmedic shall, on request, grant document protection for a period of 15 years.

Simplified authorisation procedures apply to certain medicines for rare diseases.[33] Differently from the situation in the EU under Regulation (EC) 141/2000, the orphan drug status under Swiss law does not entail any marketing exclusivity.

Swiss patent legislation provides for compulsory licences that – under restrictive conditions – allow the manufacture of patent-protected medicines and their export to developing countries that require these products to combat public health problems, in particular those related to HIV and AIDS, tuberculosis, malaria and other epidemics.[34] So far, however, such compulsory licences have not acquired any practical relevance.

vii Post-approval controls

According to Article 59 of the HMG, any person manufacturing or distributing ready-to-use medicines or medical devices must put in place a system of notification. It must notify Swissmedic of any adverse event or reaction that is or may be attributable to the therapeutic product itself, its use or to incorrect labelling or instructions, or which may endanger or harm the health of the consumer, the patient, or a third party. Furthermore, any person manufacturing or distributing therapeutic products must notify Swissmedic of any quality

29 Article 140a et seq. of the Swiss Patent Act.

30 Article 140e of the Swiss Patent Act.

31 Article 140t of the Swiss Patent Act.

32 The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.

33 For products granted 'orphan drug status' (Article 14, Section 1(f) of the HMG).

34 Article 40d of the Swiss Patent Act.

defects and any further findings and assessments that could influence the basis of evaluation for granting the respective authorisation. Such notifications must be in accordance with the recognised rules of good vigilance practice.[35]

viii Manufacturing controls

According to Article 5, Section 1 of the HMG, the manufacturing of medicines is subject to a prior authorisation by Swissmedic (but not the manufacturing of medical devices). If the applicant can prove that it meets the required technical and operational conditions and that an appropriate system of quality assurance is in place, it is entitled to a licence. All medicines have to be produced in accordance with the recognised rules of good manufacturing practices (GMP), which are defined in the Ordinance on Authorisations in the Medicinal Sector (AMBV). According to this Ordinance's Appendix 1, the following international rules on GMP are relevant: EU Directives 2003/94/EEC and 1991/412/EEC, EudraLex Volume 4, and the Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products of 8 October 1970 (under the Pharmaceutical Inspection Co-operation Scheme PIC/S).

ix Advertising and promotion

Advertising and promotion of medicines is primarily regulated by Articles 31 to 33 of the HMG and in more detail in the Ordinance on Advertising of Medicines (AWV). Advertisement of medical devices is governed by Article 69 of the MepV.

Advertising of medicines is defined as all information, marketing and incentivising measures aimed at promoting the prescription, supply, sale, consumption or use of medicines.[36] Advertising directed exclusively at persons prescribing or dispensing medicines is permitted for all types of medicines. Advertising directed to the general public is only permitted for non-prescription medicines.[37] For medical devices that need to be applied by a healthcare professional, advertising directed to the general public is prohibited.[38] Mere factual information on human health and diseases that does not, directly or indirectly, make reference to a certain medicine is, however, not considered advertising.[39] The same applies for package information leaflets and information on medical products to healthcare professionals.[40]

Any advertising for medicines that (1) is misleading or contrary to public policy and morality; (2) may incite to an excessive, abusive or inappropriate use of medicines; or (3) relates to medicines (or indications thereof) that are not admitted to the Swiss market (nationally or cantonally), is prohibited.[41] Promotion of off-label use, namely, the use of a medicine for indications or treatments other than listed on its approved label, is not permitted.[42]

Medicine advertising directed to the general public (which is only permissible for non-prescription medicines) must contain explicit and easily legible information that the medicine is authorised by Swissmedic and the advice to read the package information

35 Article 59 of the HMG.

36 Article 2 of the AWV.

37 Article 31, Section 1 and Article 32, Section 2(a) of the HMG and Article 14 of the AWV.

38 Article 69, Section 3 of the MepV.

39 Article 1, Section 2(c) of the AWV.

40 Article 1, Section 2(a) of the AWV.

41 Article 32, Section 1 of the HMG; Article 5, Section 1 of the AWV.

42 Article 5, Section 1 of the AWV e contrario.

leaflets.[43] Advertising on radio, television and in cinemas must end with specific warnings.[44] Advertising for certain sensitive categories of drugs, such as anorectics or sedatives, is subject to an advance clearance requirement if the drug information mentions a potential for abuse or addiction.[45]

Comparative advertising (including advertisements comparing prices) is, if correct, permissible if directed exclusively to healthcare professionals, but not if directed to the general public.[46] Medicine samples may be furnished to healthcare professionals only upon written request and in small quantities. Samples must be clearly and permanently labelled as 'free samples' and must not be larger than the smallest commercially available package. Sale of samples by the healthcare professionals is prohibited.[47] Samples provided to consumers may not contain more than one recommended daily dose and may only be distributed through the channels authorised to distribute such products.[48]

In case of non-compliance, Swissmedic may take administrative measures to re-establish compliance with the law. This may include the seizure and destruction of the non-compliant advertising materials as well as the suspension or revocation of the respective licences and marketing authorisations.[49] In addition, infringements of the regulations on the advertising of medicines are subject to criminal sanctions.[50]

Besides the aforementioned medicine-specific regulations, the general legal framework regarding advertising and promotion must be observed. In particular, the limits set by the Unfair Competition Act, which generally prohibits unfair marketing activities, such as false statements, passing-off and the like, must be followed.

According to the Swiss Academy of Medical Sciences' Code on the 'Collaboration between Medical Professionals and the Industry' of 2013, researchers responsible for, or taking part in, a trial may not – for the sake of their independence and credibility – take part in marketing promotions for the product or procedure investigated.[51]

x Distributors and wholesalers

The wholesale of medicines (but not of medical devices) requires a licence.[52] This licence will be issued by Swissmedic if the necessary professional and operational conditions are met, and if an appropriate system of quality assurance is in place. If the applicant is already in possession of a manufacturing or import licence for medicines, it will also be eligible for a wholesale licence. Brokers and agents are also subject to the licensing requirement for the distribution of medicines.[53] The licence may not be transferred to any other person or to any

43 Article 16, Section 5(c) of the AWV.

44 'This is an authorised medicine. Please take advice from a health professional and read the patient information'; see Article 17 of the AWV.

45 Article 23 of the AWV and Swissmedic Journal 08/2016 p. 644 et seq.

46 Articles 7 and 22(c) of the AWV.

47 Article 10 of the AWV.

48 Article 19 of the AWV.

49 Article 66 of the HMG.

50 Article 87 of the HMG.

51 Clause I.10.

52 Article 28 of the HMG.

53 Article 4, Section 1(e) HMG; Article 24 et seq. AMBV.

other site.[54] The licence is in principle unlimited in time but can be limited.[55] The wholesale of medicines is only permissible with respect to medicines that have a marketing authorisation for Switzerland. In addition to the requirements for the issuance of the licence, a company that is engaged in the wholesale trade of medicines must also respect the recognised principles of good distribution practice.[56]

Any person dispensing medicines in a pharmacy, a drugstore or another retail trade establishment must have a cantonal licence for retail trade.[57] The cantons lay down the conditions and procedures for granting this licence. While mail-order trade with medicinal products is prohibited in general, the cantons may issue licences for mail-order trade if certain conditions are met, in particular if there is a prescription for the medicinal product, and appropriate consultation as well as sufficient medical supervision of the effect of the medicinal product are guaranteed.[58]

xi Classification of products

Swiss law differentiates between four categories of medicines: categories A, B, D and E depending on the risk represented by the product.[59] In general, categories A and B contain prescription-only products, category D contains over-the-counter medicines in pharmacies and drug stores and category E contains medicinal products without any sales restrictions. Each medicine is classified in the authorisation process by Swissmedic.[60]

Category A medicines are subject to a more stringent prescription requirement, which means that a medical prescription only allows for a one-time supply of the prescribed medicine. Category B medicines are subject to a prescription that allows for a repeated supply of the prescribed medicine. Category C medicines do not need a prescription but may only be supplied after the advice of a medical person has been obtained. For category D medicines, no prescription is necessary. Category D medicines may only be supplied, however, after expert advice has been obtained. Category E medicines can be supplied without any restrictions.[61] It is permissible to promote prescription-only medicines to professionals, but not to consumers.[62]

xii Imports and exports

According to Article 18 et seq. of the HMG, a licence granted by Swissmedic is required by any person who, in a professional capacity, imports or exports ready-to-use medicines intended for distribution or dispensing, or who trades medicines in foreign countries from Switzerland, without such medicines entering Switzerland. This licence will be issued if the necessary professional and operational conditions are met, and if an appropriate system of

54 Article 40 of the AMBV.
55 Article 9b, Section 1 of the HMG and Article 53 et seq. of the AMBV.
56 Article 15 of the AMBV.
57 Article 30 of the HMG.
58 Article 27 of the HMG.
59 Article 23 et seq. of the HMG; Article 40 et seq. of the Ordinance on Medicinal Products (VAM).
60 Article 40 of the VAM.
61 Article 23 to 27 of the VAM.
62 Article 14 of the AWV.

quality assurance is in place. The licence may also be issued to applicants who already possess a manufacturing licence for medicines or, with regard to export and trade abroad, to applicants already possessing a licence for the import or wholesale trade of medicines.

xiii Controlled substances

Medicines containing narcotic or psychotropic substances as referred to in the Federal Narcotics Act may not be promoted to consumers.[63] Moreover, according to Article 21 of the HMG, the export of medicines or trade in medicines abroad is prohibited if such medicines are prohibited in the target country. In principle, the import of medicines is only permitted with regard to medicines that are licensed for distribution in Switzerland or that do not require such licence.

xiv Enforcement

Swissmedic and the competent cantonal authorities (generally the department of health) are responsible for the supervision of manufacturing, distribution and marketing activities. They supervise the Swiss market in general as well as the individuals manufacturing, distributing and marketing medicines. A specific investigation is opened if either Swissmedic or the cantonal authorities discover any violation during their supervision or if a violation is notified to them.

Swissmedic and the cantonal authorities may perform any necessary investigation into a specific incident, and the parties involved have the obligation to fully cooperate in this investigation. In particular, Swissmedic or the cantonal authorities may take samples, demand information and essential documents and request any necessary help for this purpose. Swissmedic, or, in the case of a serious and immediate threat to health, the cantonal authorities, may take all necessary administrative measures to remedy a breach of the applicable rules.[64]

III PRICING AND REIMBURSEMENT

Consumer prices and ex-factory prices of medicines and medical devices to be reimbursed by the mandatory health insurance are determined by the Federal Office of Public Health upon application of the respective distributor. To be eligible for reimbursement, medicines and medical devices need to be included in specific lists: the list of specialities for ready-to-use medicines; or the list of means and objects for medical devices. In both cases, to be listed, the applicant must demonstrate that the respective product is effective, economical and suitable.[65]

The regime regarding pricing of medicines has been revised several times over the last decade to reduce drug prices in Switzerland; for the last time per 1 March 2017. According to the current rules, ex-factory prices of medicines are determined based on (1) a comparison with the average price of the same medicine in certain other countries (Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Sweden and the United Kingdom) and (2) a comparison with similar medicines contained in the list of specialities.[66] Moreover,

63 Article 32, Section 2(b) of the HMG.

64 Article 66 of the HMG.

65 Article 32 of the KVG.

66 Article 65b KVV, Articles 34 and 34a *bis* of the Ordinance on the Indemnifications of Mandatory Health Insurance.

if the medicine in question is superior compared to the existing medicines and marks an innovative step, a mark-up on the price is granted by the authority.[67] The consumer price is determined based on the ex-factory price plus a fixed addition for the cost of distribution of the medicine.[68]

On 21 March 2012, the Federal Council had amended the ordinances implementing the KVG to tighten the regime of price reviews regarding medicines to be reimbursed by the mandatory health insurance. According to the amendments, such periodic price reviews by the Federal Office of Public Health (which occur every three years after listing of the medicine) are only to be based on the comparison with the prices of the same medicines in the reference countries, and the comparison with similar medicines in Switzerland is to be disregarded henceforth. A number of pharmaceutical companies challenged the respective price reduction decisions before the Federal Administrative Court for violations of the KVG and constitutional rights and principles. In April 2015, the Swiss Federal Administrative Court admitted the appeals and ruled that it was incompatible with the provisions of the KVG to exclude the comparison with similar medicines in Switzerland from price reviews. The appeal of the Federal Office of Public Health against this decision was rejected by the Swiss Federal Supreme Court in its judgment dated 14 December 2015.[69] This judgment has triggered amendments of the existing pricing regime to the effect that the comparison with similar medicines available in Switzerland must be taken into account as a general rule again. The changes entered into force on 1 March 2017.

The prices for medical devices are set out in the list of tools and objects (MiGeL). The maximum prices contained in the MiGeL 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 have to be borne by the patient.[70]

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Decisions of Swissmedic or the Federal Office of Public Health can be appealed to the Federal Administrative Court and finally to the Federal Supreme Court. Decisions of cantonal authorities are subject to appeals to cantonal administrative courts and to the Federal Supreme Court. While all courts and tribunals are entitled and under an obligation to review the correct application of the applicable law, the judiciary's powers are restrained with regard to technical matters of which the competent authorities have a better understanding.

Criminal prosecution for severe cases of non-compliance with the duties under the HMG falls either within the competence of Swissmedic or within the competence of the cantonal authorities. In both cases, court appeals are also possible.

67 Article 65b, Section 6 of the KVV.

68 Article 67, Section 1 *bis* of the KVV.

69 Decision of 14 December 2015, 9C_417/2015.

70 Article 44, Section of the KVG; Article 24, Section 2 of the Ordinance on the Indemnification by Compulsory Healthcare Insurance (KLV).

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

According to Article 55, Section 1, persons who prescribe, dispense, use or purchase for this purpose prescription medicinal products, 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 forbidden 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 that are of relevance to medical or pharmaceutical practice; (2) support for research, education and training, provided that certain criteria are met; (3) compensation for equivalent services in return, in particular for those provided in connection with orders and deliveries of therapeutic products; and (4) price discounts or refunds granted on medical purchases, provided they have no influence on the choice of treatment.[71]

Healthcare professionals who receive discounts or benefits from other healthcare professionals or persons or companies supplying medicinal products or medical devices that are eligible for reimbursement are basically obliged to pass them on to the healthcare insurer or the insured person, either wholly or at least in the majority.[72]

The relationship between the pharmaceutical industry and prescribers is addressed in more detail in several codes of conduct that are enacted by organisations of the respective industry or profession (and that are only binding for members of the respective organisations). The most important codes are: the Pharma Code; the Pharma Cooperation Code of the Pharmaceutical Industry in Switzerland; and the Guidelines of the Swiss Academy of Medical Sciences on Collaboration between Medical Professionals and the Industry. They, inter alia, address the scope of permissibility of promotional and educational events and research sponsoring. A further code of conduct that is of relevance in this respect is the one enacted by H+, Switzerland's hospitals association. It focuses on the issue of discounts granted by the pharmaceutical industry to hospitals, which are – by nature – large buyers.

Article 56 of the HMG sets off a duty of transparency according to which all discounts and rebates granted on purchases of medicinal products shall be shown on the receipts and invoices and in the accounts of both the selling and the purchasing persons and organisations and shall be disclosed to the competent authorities on request. The details of this duty of transparency are set out in the VITH.[73] The Pharma Cooperation Code, which is based on a number of international codes, stipulates an obligation for its signatories to publish on an annual basis all monetary and in-kind benefits that have been provided to healthcare professionals and healthcare organisations.

71 Article 55, Section 2 of the HMG and Article 1 et seq. of the Ordinance on Integrity and Transparency in the Field of Therapeutic Products (VITH).

72 Article 56, Section 3 and 3 *bis* of the KVG; Article 76a et seq. of the KVV.

73 Article 10 et seqq. of the VITH.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Swiss law does not provide for a specific liability system in relation to persons injured by medicines or medical devices. Instead, the general liability regime, including both contractual and non-contractual liability (including the manufacturer's liability) applies. In respect to injuries suffered in connection with medical treatment at public hospitals, cantonal state liability rules are applicable.

Self-employed medical professionals (e.g., physicians, dentists, pharmacists) must take out adequate liability insurance.[74]

Regarding research on humans, the HFG stipulates a specific liability including an obligation to provide adequate insurance of the sponsors of clinical trials.[75]

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

Swiss competition law does not provide for any regulation specific to the life sciences sector and therefore the general rules apply. However, some regulations in the life science sector derogate the competition law, such as the maximum prices for prescription drugs as fixed by the Federal Office of Public Health in the list of specialties and the restriction of parallel imports of drugs into Switzerland (due to the need to get Swissmedic's approval for such parallel imports). So far, the life science sector has not been the main focus of the Swiss Competition Commission or the courts. This should, however, not be mistaken for the Competition Commission neglecting enforcement of competition law in the life science sector. Its activities have focused on phase I merger control cases where it adopted the remedies imposed by the European Commission. The Competition Commission also prohibited the vitamins cartel, and it prohibited the use of price recommendations for prescription drugs that are not included in the list of specialties. An appeal against this decision is currently pending. Other competition law cases in the life sciences sector deal with joint tariffs and joint negotiations between insurers and service providers.

ii Transactional issues

Both the regulatory framework and legislation on intellectual property, including rules concerning the transfer or licensing of patent rights, transferring marketing authorisations, implementing co-marketing or co-promotion arrangements, leave the parties considerable flexibility to structure any transaction or collaboration according to their needs.

VIII CURRENT DEVELOPMENTS

On 19 May 2021 the newly revised MepV and the new KlinV-Mep entered into force to harmonise the Swiss regulation with the new EU Medical Device Regulations, the MDR and IVDR. In the context of aligning Swiss medical devices legislation to the new EU regulation, the MRA (Mutual Recognition Agreement) between Switzerland and the EU also needs to be updated so that barrier-free market access and joint surveillance can be ensured. So far, the MRA has not been updated and is not expected to be updated any time soon because of

74 Article 40(h) of the Swiss Act on Medicinal Professions.

75 Articles 19 and 20 of the HFG.

general blocking points in the development of the bilateral relationship between Switzerland and the EU. The lack of an updated MRA affects the mutual market access to – and trading of – medical devices, coordinated market surveillance activities and the sharing of information between authorities or the mutual recognition of certificates of conformity.

Appendix 1

ABOUT THE AUTHORS

MARKUS SCHOTT

Bär & Karrer

Markus Schott is the co-head of the firm's life science group and one of Switzerland's leading lawyers in the field of life sciences. Markus Schott has broad experience in all kinds of regulatory law matters including governmental licences, authorisations and supervision, pricing regimes, sanctions and industry codes. He advises and represents pharmaceutical and medtech companies, laboratories, hospitals and other actors in the healthcare, cosmetics, food and beverage sectors, research institutions and governmental agencies.

He also drafts expert opinions and also has an exceptional track record representing clients in court proceedings. As such, he regularly acts as party counsel before the Federal Administrative Tribunal and the Federal Supreme Court.

Markus Schott teaches public economic law as a law professor at the University of Zurich. He regularly publishes and speaks on conferences in his fields of expertise, and he has written important parts of the commentary on the Federal Act on Medicines and Medical Devices (2nd edition 2022) as well as an edited textbook of the Swiss law on therapeutic products (2022). He is listed in the categories of life sciences and healthcare in *Who's Who Legal*.

BÄR & KARRER

Brandschenkestrasse 90
8002 Zürich
Switzerland
Tel: +41 58 261 54 77
markus.schott@baerkarrer.ch
www.baerkarrer.ch/en

ISBN 978-1-83862-246-6