HEALTHCARE | LAW REVIEW

Editor Sarah Ellson

ELAWREVIEWS

HEALTHCARE LAW REVIEW

The Healthcare Law Review Reproduced with permission from Law Business Research Ltd.

This article was first published in The Healthcare Law Review, - Edition 1 (published in September 2017 – editor Sarah Ellson)

For further information please email Nick.Barette@thelawreviews.co.uk

HEALTHCARE | LAW REVIEW

Editor Sarah Ellson

PUBLISHER Gideon Roberton

SENIOR BUSINESS DEVELOPMENT MANAGER Nick Barette

BUSINESS DEVELOPMENT MANAGERS Thomas Lee, Joel Woods

> ACCOUNT MANAGERS Pere Aspinall, Sophie Emberson, Laura Lynas, Jack Bagnall

PRODUCT MARKETING EXECUTIVE Rebecca Mogridge

RESEARCHER Arthur Hunter

EDITORIAL COORDINATOR
Gavin Jordan

HEAD OF PRODUCTION Adam Myers

PRODUCTION EDITOR
Gina Mete

SUBEDITOR Anna Andreoli

CHIEF EXECUTIVE OFFICER
Paul Howarth

Published in the United Kingdom by Law Business Research Ltd, London 87 Lancaster Road, London, W11 1QQ, UK © 2017 Law Business Research Ltd www.TheLawReviews.co.uk

No photocopying: copyright licences do not apply.

The information provided in this publication is general and may not apply in a specific situation, nor does it necessarily represent the views of authors' firms or their clients. Legal advice should always be sought before taking any legal action based on the information provided. The publishers accept no responsibility for any acts or omissions contained herein. Although the information provided is accurate as of August 2017, be advised that this is a developing area.

Enquiries concerning reproduction should be sent to Law Business Research, at the address above.

Enquiries concerning editorial content should be directed to the Publisher – gideon.roberton@lbresearch.com

ISBN 978-1-912228-00-3

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

ELAWREVIEWS

THE MERGERS AND ACQUISITIONS REVIEW

THE RESTRUCTURING REVIEW

THE PRIVATE COMPETITION ENFORCEMENT REVIEW

THE DISPUTE RESOLUTION REVIEW

THE EMPLOYMENT LAW REVIEW

THE PUBLIC COMPETITION ENFORCEMENT REVIEW

THE BANKING REGULATION REVIEW

THE INTERNATIONAL ARBITRATION REVIEW

THE MERGER CONTROL REVIEW

THE TECHNOLOGY, MEDIA AND TELECOMMUNICATIONS REVIEW

THE INWARD INVESTMENT AND INTERNATIONAL TAXATION REVIEW

THE CORPORATE GOVERNANCE REVIEW

THE CORPORATE IMMIGRATION REVIEW

THE INTERNATIONAL INVESTIGATIONS REVIEW

THE PROJECTS AND CONSTRUCTION REVIEW

THE INTERNATIONAL CAPITAL MARKETS REVIEW

THE REAL ESTATE LAW REVIEW

THE PRIVATE EQUITY REVIEW

THE ENERGY REGULATION AND MARKETS REVIEW

THE INTELLECTUAL PROPERTY REVIEW

THE ASSET MANAGEMENT REVIEW

THE PRIVATE WEALTH AND PRIVATE CLIENT REVIEW

THE MINING LAW REVIEW

THE EXECUTIVE REMUNERATION REVIEW

THE ANTI-BRIBERY AND ANTI-CORRUPTION REVIEW

THE CARTELS AND LENIENCY REVIEW

THE TAX DISPUTES AND LITIGATION REVIEW

THE LIFE SCIENCES LAW REVIEW

THE INSURANCE AND REINSURANCE LAW REVIEW

THE GOVERNMENT PROCUREMENT REVIEW

THE DOMINANCE AND MONOPOLIES REVIEW

THE AVIATION LAW REVIEW

THE FOREIGN INVESTMENT REGULATION REVIEW

THE ASSET TRACING AND RECOVERY REVIEW

THE INSOLVENCY REVIEW

THE OIL AND GAS LAW REVIEW

THE FRANCHISE LAW REVIEW

THE PRODUCT REGULATION AND LIABILITY REVIEW

THE SHIPPING LAW REVIEW

THE ACQUISITION AND LEVERAGED FINANCE REVIEW

THE PRIVACY, DATA PROTECTION AND CYBERSECURITY LAW REVIEW

THE PUBLIC-PRIVATE PARTNERSHIP LAW REVIEW

THE TRANSPORT FINANCE LAW REVIEW

THE SECURITIES LITIGATION REVIEW

THE LENDING AND SECURED FINANCE REVIEW

THE INTERNATIONAL TRADE LAW REVIEW

THE SPORTS LAW REVIEW

THE INVESTMENT TREATY ARBITRATION REVIEW

THE GAMBLING LAW REVIEW

THE INTELLECTUAL PROPERTY AND ANTITRUST REVIEW

THE REAL ESTATE M&A AND PRIVATE EQUITY REVIEW

THE SHAREHOLDER RIGHTS AND ACTIVISM REVIEW

THE ISLAMIC FINANCE AND MARKETS LAW REVIEW

THE ENVIRONMENT AND CLIMATE CHANGE LAW REVIEW

THE CONSUMER FINANCE LAW REVIEW

THE INITIAL PUBLIC OFFERINGS REVIEW

THE CLASS ACTIONS LAW REVIEW

THE TRANSFER PRICING LAW REVIEW

THE BANKING LITIGATION LAW REVIEW

www.TheLawReviews.co.uk

ACKNOWLEDGEMENTS

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

AL TAMIMI & COMPANY

BÄR & KARRER AG

BIOLATO LONGO RIDOLA & MORI

CLARO

DREW & NAPIER LLC

FASKEN MARTINEAU DUMOULIN LLP

FIELDFISHER LLP

FOLEY & LARDNER LLP

HAN KUN LAW OFFICES

KING & SPALDING LLP IN ASSOCIATION WITH THE LAW OFFICE OF MOHAMMAD AL-AMMAR IN RIYADH

MATHESON

RŪTA PUMPUTIENĖ LAW FIRM

SÁNCHEZ DEVANNY

URÍA MENÉNDEZ - PROENÇA DE CARVALHO

VEIRANO ADVOGADOS

CONTENTS

EDITOR'S P Sarah Ellson	REFACE	V
Chapter 1	BRAZIL Renata Fialho de Oliveira, Priscila David Sansone Tutikian, Fábio Luiz Barboza Pereira, Michele Lyra da Cunha Tostes, Andrea Piccolo Brandão and Vanessa Bertonha Felício	1
Chapter 2	CANADA	.13
	Lynne Golding, David Rosenbaum, Daniel Fabiano, Laurie Turner, Rosario Cartagena and Kimberly Potter	
Chapter 3	CHINA Min Zhu	.23
Chapter 4	ENGLAND Holly Bontoft and Sarah Ellson	.32
Chapter 5	GERMANYStefanie Greifeneder	.44
Chapter 6	IRELAND Tom Hayes, Rebecca Ryan and Michael Finn	.52
Chapter 7	ITALY Linda Longo and Giulia Gigante	.66
Chapter 8	LITHUANIARūta Pumputienė	.77
Chapter 9	MEXICO José Alberto Campos-Vargas	.86

Contents

Chapter 10	NEW ZEALAND	97
	Jonathan Coates, Aisling Weir and Catey Boyce	
Chapter 11	PORTUGAL	110
	Francisco Brito e Abreu and Joana Mota	
Chapter 12	SAUDI ARABIA	120
	Nabil A Issa	
Chapter 13	SINGAPORE	129
	Benjamin Gaw	
Chapter 14	SWITZERLAND	150
	Markus Wang and Jonas Bornhauser	
Chapter 15	UNITED ARAB EMIRATES	160
	Andrea Tithecott	
Chapter 16	UNITED STATES	173
	Lawrence W Vernaglia and Anna S Ross	
Appendix 1	ABOUT THE AUTHORS	191
Appendix 2	CONTRIBUTING LAW FIRMS' CONTACT DETAILS	203

Chapter 14

SWITZERLAND

Markus Wang and Jonas Bornhauser¹

I OVERVIEW

The Swiss healthcare ecosystem is rather complex, since it combines aspects of managed competition and corporatism in a decentralised regulatory framework. The system is characterised by the allocation of decision-making or decision influencing powers to (1) the three different levels of government (the Swiss Confederation, the 26 Swiss cantons and the 2352 municipalities in Switzerland); (2) the recognised private healthcare organisations, such as Swiss Red Cross, Swiss Patient Organisation, Swiss Cancer League and the organisation of the mandatory health insurance (MHI) providers; and (3) the Swiss citizens who can veto against or demand a reform through public referenda and plebiscite.²

The Swiss Confederation (i.e., the federal state) is only permitted to act in those fields in respect of which it is granted powers to do so by the Swiss Constitution. The most important fields are (1) the funding of the health system (through the MHI and other social insurances); (2) ensuring quality and safety of medicinal products and medical devices; (3) ensuring public health (control of infectious diseases, food safety, health promotion); and (4) research and training (third-level education) of non-physician health professionals.³ The most important piece of legislation by which the Swiss Confederation steers the Swiss healthcare system is the Federal Health Insurance Act (HIA),⁴ which sets the legal framework of the MHI system and in particular defines which services are to be paid by such system.

The Swiss federal government, the so-called Federal Council, and the Swiss parliament enact laws and ordinances that are to be implemented by the Swiss cantons. On a governmental level, the Federal Office of Public Health (FOPH), which is part of the Federal Department of Home Affairs (FDHA), is responsible for the development of national health policies. The responsibilities of the FOPH include other tasks, such as the supervision of mandatory health insurance, decisions on the reimbursement and the prices of therapeutic products and the regulation of university-educated medical and healthcare professions. It also represents the health policy interests of Switzerland in international bodies and with regard to other states.⁵

¹ Markus Wang is a partner and Jonas Bornhauser an associate at Bär & Karrer.

De Pietro et al, in: Quentin Wilm et al. (editors), Switzerland: Health system review, Health Systems in Transition, 2015 (cited: De Pietro et al., Switzerland: Health system review), 17(4):1–288, 19; Sturny Isabelle, in: International Profiles of Health Care Systems, The Swiss Health Care System, 2017 (cited: Sturny), 155-162, 155.

³ Articles 95, 117 and 118 of the Swiss Constitution; De Pietro et al., Switzerland: Health system review, 19.

⁴ De Pietro et al., Switzerland: Health system review, 19.

The Swiss healthcare system, Verband der forschenden pharmazeutischen Firmen der Schweiz (interpharma), accessible online at www.interpharma.ch/fakten-statistiken/4561-swiss-healthcare-system

The responsibility for the provision of healthcare services lies mainly with the 26 Swiss cantons. The cantons maintain and, together with the MHI, finance hospitals and nursing homes, which they also supervise. In addition, they are also competent to issue and implement certain health-related legislation. The cantons further finance a substantial part of inpatient care, provide subsidies to low-income households enabling such households to pay for insurance, and coordinate prevention and health promotion activities. The Swiss cantons work together on an institutional level through the Swiss Conference of the Cantonal Ministers of Public Health.

The competences and responsibilities of municipalities in the fields of healthcare and other social support services vary across Switzerland, depending on the related allocation of powers and tasks in the cantonal constitutions.

II THE HEALTHCARE ECONOMY

i General

Free healthcare services are available to all persons resident in Switzerland on the basis of the MHI system, irrespective of whether such residents are Swiss citizens or not, are employed or not, or work in the public or private sector. The MHI system, the basic social insurance covering the risk of illness, maternity and (if not covered by another insurance) accidents⁶ is regulated by the HIA, which entered into force in 1996. The basic principle set forth in the HIA provides that all persons resident in Switzerland have guaranteed access to good medical care. The basic MHI aims to ensure that the costs of required medical treatments are covered by the insurance.⁷

Every person employed in Switzerland is further covered by the mandatory accident insurance scheme for the health and economic consequences of work-related and non-work-related accidents, as well as occupational diseases (i.e., diseases that are caused in the course of occupational activity solely or principally by harmful substances or certain types of work according to a list issued by the federal government). Not covered by mandatory accident insurance are non-employed persons, such as children, students and pensioners. For these persons, coverage for accident is available as part of MHI.

Temporary non-resident visitors have to pay up front for care and must reclaim reimbursement under insurance coverage they may have in their home country.

ii The role of health insurance

Residents are legally required to insure themselves with an MHI provider. Persons moving to Switzerland have to do so within three months as from their arrival. Insurance is offered by about 60 competing non-profit MHI companies that are supervised by FOPH. Contrary to private insurers providing complimentary health insurance coverage, the MHI providers must accept all applicants, irrespective of age and irrespective of whether they are already ill or not.

⁽accessed on 19 July 2017) (cited: The Swiss healthcare system).

⁶ Article 1a HIA.

⁷ The Swiss healthcare system, Financing healthcare.

⁸ Articles 1a and 6 of the Federal Act concerning Accident Insurance.

⁹ Article 3 HIA.

¹⁰ Article 4 HIA.

The largest share of the health costs is funded by the MHI system. In 2015, the share covered by the MHI system amounted to 35.3 per cent of the total health costs. ¹¹ Costs are further covered by direct financing of healthcare providers through the tax-financed budgets of the Swiss Confederation, the cantons and municipalities. The largest portion of such direct financing is made in the form of cantonal subsidies to hospitals providing inpatient acute care. In 2015, the share paid by the cantons amounted to 18.2 per cent of the total health expenditure. ¹² A further share of the costs is covered by the contributions to other social insurances also providing coverage for health-related risks, such as accident insurance, old-age insurance, disability insurance and military insurance. ¹³

iii Funding and payment for specific services

The healthcare services and products (medicinal products, medical devices and ancillary materials) payable by the MHI are defined by the FDHA. In doing so, it has to evaluate whether the services and products are (1) effective, (2) appropriate, and (3) cost-effective.¹⁴

The MHI system pays the costs of most general practitioners (GPs) and specialists, hospital care, home care services (Spitex), physiotherapy (if prescribed), and certain preventive services, including selected vaccinations, general health examinations and screenings for early detection of diseases for certain risk groups. Also covered are the cost of a comprehensive range of medicinal products and medical devices. Care for mental illness is paid by the MHI, if provided by certified physicians. The services of non-physician professionals, such as psychotherapy by psychologists, are only covered if prescribed by a qualified medical doctor and provided in its practice. Long-term care is only paid to the extent necessary medicinal services are concerned. Glasses, to the extent medically required, are partly paid. Procedures and methods used in complementary medicine (such as homeopathy) are covered by the MHI to some extent. Broadly excluded from the MHI is dental care.

Premiums vary for three different age categories and for different geographical regions, but are otherwise the same for every Swiss resident insured with a particular MHI company, independent of gender or health status. In addition, the premiums are not dependent on income. In principle, the insured persons have to pay the premiums themselves. There are no employer contributions. However, people with low income may request a premium reduction, which is subsidised by the Swiss Confederation and the canton of domicile. In 2016, cantonal average annual MHI premiums for adults with a minimum franchise of 300 Swiss francs per year and the standard insurance model with accident coverage ranged from 3,920 francs to 6,547 francs. The insurers offer specific insurance models, such as health maintenance organisation (HMO) models, which the insured persons may select to benefit from reduced premiums. Insured persons may also reduce the premiums by accepting

According to figures published by Federal Statistic Office, accessible online at www.bfs.admin.ch/bfs/en/home/statistics/health/costs-financing.html (accessed on 19 July 2017).

¹² According to figures published by Federal Statistic Office, accessible online at www.bfs.admin.ch/bfs/en/home/statistics/health/costs-financing.html (accessed on 19 July 2017).

¹³ Sturny, 156.

¹⁴ Article 32 HIA.

¹⁵ The Swiss healthcare system, Financing healthcare; Sturny, 155.

¹⁶ Swiss Federal Office of Public Health (FOPH), Statistik der obligatorischen Krankenversicherung 2014 (FOPH, 2016).

a higher franchise than 300 francs (presently franchises of up to 2,500 francs for adults and up to 600 francs for children are admissible). Chosen insurance models and selected franchises can be changed every year.

The insured persons have to pay 10 per cent of the cost of services received (above the franchise), including GP consultations, on their own, up to an annual cap of 700 francs for adults and 350 francs for children up to age of 18.¹⁷ Where generic drugs are available, patients have to pay 20 per cent of the price themselves if they want the original medicinal product. For hospital stays, patients have to pay an amount of 15 francs per inpatient day.¹⁸

Supplementary health insurance plans may be concluded on a voluntary basis and cover benefits that are not paid by the MHI, such as greater freedom with respect to the choice of doctor or hospital, payment of certain methods of complementary medicine that are not reimbursed by MHI or single room accommodation in hospitals. Such complementary insurances are offered by private insurers as well as by MHI insurers.¹⁹

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

The MHI system allows patients to go directly to specialists (i.e., free choice of doctor²⁰), unless they have opted for a special insurance model, such as HMO or Managed Care. (In 2012, approximately 20.8 per cent of all insured people were estimated to be insured by either an HMO plan or a physician network plan.)²¹ However, traditionally, the family doctor or GP is the first point of contact for patients. If the GP is not able to treat a disease, the patient is referred by the GP to a specialist or hospital. Patients are free to choose to receive their treatment in any hospital listed on the 'hospital list' of the canton in which they are domiciled or in which the hospital is located.²² Specialists often work in both hospitals and their own private practices. In some cantons, GPs and specialists are allowed to sell medicinal products to their patients; in others, they have to refer their patients to pharmacies in this respect.

Residential (institutional) long-term care is provided by medical nursing homes or nursing departments of old-age or disability homes, while home-care nursing services are provided by the Spitex services. The contributions of the MHI system for care in nursing homes depend on the level of need determined in assessments and do not necessarily cover the total costs. The amount paid by the system for Spitex services depends on the type and duration of the care provided. Responsible for the organisation of long-term care are the Swiss cantons, which may delegate responsibility to municipalities.²³

In April 2017, a new act governing the national electronic patient record entered into force. The act aims to increase care coordination, quality of treatment, patient safety and efficiency in the healthcare system. Insured persons may voluntarily opt for such a record and decide who shall have access to information pertaining to their treatment-related information. The records are being stored in decentralised form. Health service providers will have to take

¹⁷ Article 64 para. 2 HIA.

¹⁸ Sturny, 156.

¹⁹ The Swiss healthcare system, Financing healthcare.

²⁰ Article 41 para. 1 HIA.

²¹ De Pietro et al., Switzerland: Health system review, 155.

²² Article 41 para. 1 bis HIA.

²³ De Pietro et al., Switzerland: Health system review, 186 f.

part in certified communities to be able to read the records. While hospitals and long-term care institutions are legally required to join and offer their services using an electronic patient record, ambulatory providers are not.²⁴

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

In Switzerland, licensing and supervision of institutional healthcare providers and health professionals is mainly the responsibility of the cantonal authorities.

ii Institutional healthcare providers

Each hospital and other inpatient service provider (rehabilitation, psychiatric, geriatric and long-term care) requires an operating licence granted by the canton in which it operates. Licences are granted if the hospital or inpatient service provider fulfils the licence requirements defined in cantonal legislation. Requirements cover in particular issues such as medical supervision, hygiene, structure, hospital pharmacy and quality management.²⁵

In addition, hospital and inpatient service providers need a permission to provide services that are reimbursable by the MHI system. The related requirements that need to be fulfilled are defined in Article 39 of the HIA. Such requirements include, in particular, organisational requirements (such as, sufficient personnel and adequate medical equipment), the obligation to treat all patients in need of care and the inclusion in the cantonal hospital list, which is the main instrument of the cantons to steer sufficient, but cost-efficient provision of inpatient and acute care services by hospitals and other inpatient service providers.

iii Health professionals

In Switzerland, generally three groups of health professionals need to be distinguished: (1) university-trained health professionals (physicians, dentists, pharmacists, chiropractors and veterinary surgeons); (2) psychological professionals, including psychotherapists and clinical psychologists; and (3) non-university trained health professionals, including nurses and midwives.

University-trained health professionals

The cantonal departments of health are responsible for the licensing of university-trained health professionals in independent practice. The general conditions for licensing are set forth in the Federal Act on Medical Professions (AMP). The licence requirements defined in the AMP include a university diploma, a recognised specialisation title, a good personal reputation, proficiency in a national language and good health condition. Any applicant fulfilling these requirements is entitled to obtain the cantonal licence. The cantons are obliged to register licensed university-trained health professionals in the national register of medical professionals. Licensed university-trained health professionals have the right to practice without supervision and to run their own practice. Healthcare professionals have

²⁴ Sturny, 160.

²⁵ De Pietro et al., Switzerland: Health system review, 57.

²⁶ Article 36 AMP.

²⁷ Art. 51 et seq. AMP.

to be re-accredited by cantons every 10 years (and every three years after the age of 70).²⁸ Physicians further need a cantonal approval and register number to practise at the expense of the MHI (ZSR-Number). Moreover, self-employed physicians are required to take out professional liability insurance.²⁹ Employed physicians, in particular, physicians in hospitals, are insured via their employer.

University-trained health professionals with qualifications obtained abroad may provide their services without special licence under the conditions outlined in Annex III of the treaty between the Swiss Confederation and the European Union concerning the Free Movement of Persons dated 2 June 1991or Annex K of the EFTA treaty of 4 January 1960.³⁰

With the object to control increasing healthcare costs by limiting the number of newly practising physicians, a temporary ban on the opening of new practices was implemented back in 2001. After being lifted for a short period in 2012, it has been re-enacted until 2019, leaving, however, the cantons discretion whether and to which extent they want to enforce it. As a result, some cantons do not apply the ban at all, and others restrict admission of new providers only in certain special fields (e.g., only GPs and paediatricians). Cantons may choose to restrict physicians only in private practice or also in the outpatient departments of hospitals (see also Section VI in this regard).³¹

Psychological professionals

Pursuant to the Federal Act on Psychological Professions (APP), the cantons are further responsible for the licensing of psychological professionals. Comparable to the AMP, the APP stipulates the requirements of education, specialisation, cantonal licensing and continuing education.³² A register for psychological professionals (similar to the register of medical professionals) is planned;³³ the corresponding implementing ordinance has, however, not yet been enacted.

Non-university trained health professionals

Presently, no specific regulations exist for non-university health professionals (i.e., nurses, midwives, nutritionists, physiotherapists, occupational therapists, medical laboratory officers, specialists in medical radiology, dental hygienists, podiatrists and ambulance officers). Currently, these professions are regulated as any other profession by the State Secretariat for Education, Research and Innovation, which belongs to the Federal Department of Economic Affairs, Education and Research. A draft for a Federal Act on Health Professions has been passed by the Swiss parliament, but is not expected to enter into force before the beginning of 2020. An important role for the training and qualification of non-university trained health professionals play the guidelines issued by OdASanté, an organisation founded by the cantons and the federal employer associations in the health sector.³⁴

²⁸ De Pietro et al., Switzerland: Health system review, 56.

²⁹ Article 40 let. h AMP.

³⁰ Article 35 AMP.

³¹ De Pietro et al., Switzerland: Health system review, 56-57.

³² Article 24 APP.

³³ Article 38 APP.

³⁴ De Pietro et al., Switzerland: Health system review, 62-63.

V NEGLIGENCE LIABILITY

i Overview

The relationship between a healthcare professional in private practice and the patient is qualified under Swiss law as a mandate, governed by the provisions of the Swiss Code of Obligations. In case of a mistreatment, the acting private healthcare provider is liable to the patient for any damage suffered, provided the patient can prove that it has suffered a damage as a consequence of a mistreatment or lack of the required diligence owed by the treating health professional and provided the health professional acted with fault (which is assumed). Public law institutions, such as public hospitals and physicians employed by them, are liable based on public laws, namely the state liability acts. Substantive conditions for liability thereunder are similar to those under private law.³⁵ In case of a split treatment relationship (e.g., where a self-employed physician operates in a public hospital assisted by health professionals employed by the hospital), the civil law claims may asserted by the patient also in the framework of the public proceedings.³⁶

In Switzerland, conflicts between harmed patients and healthcare institutions and professionals respectively are often resolved by out-of-court-settlements. In this regard, the Swiss Patient Organisation (SPO) and the Swiss Patient Federation (DVSP) play an important role. For their members, SPO and DSVP provide legal advice and support in filing complaints and negotiating settlements. Pursuant to the DVSP, nearly 95 per cent of all patient complaints are resolved out of court.³⁷

ii Notable cases

In two recent cases, the Swiss Federal Supreme Court has further clarified the question regarding the burden of proof with respect to the failure of the treating physician to act diligently when treating a patient and, thus, one of the key requirements of negligence liability. In a decision rendered in 2016,³⁸ it reiterated the principle that the treating physician does not owe a success (restoration of the patient's health), but only a treatment that is in line with the rules of acknowledged medical standards and diligence. Lack of success does not imply a lack of diligence and, therefore, lack of diligence must be proved by the patient. This also applies if the treatment results in another physical damage. While a physician is under an obligation to take all measures reasonably required to avoid such other physical damage and the occurrence of such new damage may suggest a maltreatment, it is still up to the patient to prove that the physician has not complied with his or her obligation to act diligently. In another case,³⁹ the court held that it is up to the treating physician to proof that he has adequately informed the patient of the risks of a treatment and obtain the patient's consent for the treatment. However, in those cases in which the physician may rely on a implied or hypothetical consent (e.g., in cases of urgency), it is up to the patient to show that it would have rejected the treatment had it been aware of the risks the treatment entails.

³⁵ Gächter Thomas/Rütsche Bernhard, Gesundheitsrecht – ein Grundriss für Studium und Praxis, 3rd ed., Basel 2013 (cited: Gächter/Rütsche), marginal note 395.

³⁶ Gächter/Rütsche, marginal note 391 et seq.

³⁷ De Pietro et al., Switzerland: Health system review, 75.

Decision of the Swiss Federal Supreme Court dated 26 September 2016, 4A_216/2016.

³⁹ Decision of the Swiss Federal Supreme Court dated 19 August 2015, 4A_137/2015.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Traditionally, independent physicians in Switzerland were self-employed. However, as a result of the trend towards group practices, physicians started to organise themselves as unregistered partnerships, and since 2001, due to a revision of the HIA,⁴⁰ it is permissible for physicians to practise (together with other physicians) organised as legal entity (i.e., as limited liability company or joint stock company) if, in particular, the following requirements are fulfilled:

- each physician employed by a limited liability company or joint stock company needs a professional licence for physicians;
- each of the employed physicians is obliged to perform the healthcare services personally (no delegation of responsibilities);
- c the employed physicians remain functionally responsible towards the patients;
- d corporate bodies may not give professional instructions;
- e the employed physicians have to take appropriate professional liability insurance either directly or via the legal entity they work for; and
- f a cantonal approval to practise at the expense of the MHI system and a ZSR-Number must be obtained.⁴¹

In some cantons, to organise a medical practice in the form of a legal entity, operating the practice additionally requires a licence for medical practices. Legal entities holding such an operating licence are obliged to notify changes regarding the operationally and professionally responsible persons (i.e., the responsible body) as well as changes of the legal entity.

i Hospitals

Public hospitals are mainly owned and operated by the cantons or the municipalities. However, more and more public hospitals are operated by independent institutions (about 34 per cent of all public hospitals in 2013) or joint stock companies (about 31 per cent).⁴²

Also, privately owned hospitals may be included in cantonal hospital lists and are then allowed to provide services reimbursable by the MHI system. As result, private hospitals are (at least in theory) able to compete on a level playing field with public hospitals, and patients have the choice to be treated in private hospitals included in the cantonal hospital lists. However, (new) private organisations that intend to operate a hospital can find it hard to get in local cantonal lists. Private hospitals may be managed either on a profit-making or not-for-profit basis.⁴³

Almost 70 per cent of general acute inpatient hospitals in Switzerland are publicly owned or subsidised. Specialised hospitals, on the other hand, such as hospitals for surgical, gynaecological or paediatric care, are mainly privately owned. Emergency services are provided by public or subsidised non-profit hospitals.⁴⁴ There is a tendency to form larger (public and private) hospital organisations with several sites to increase efficiency in management and purchasing in both public and private hospitals.

⁴⁰ Article 36a HIA.

⁴¹ Kaufmann Markus, Die Arztpraxis als Aktiengesellschaft oder GmbH – Zulässigkeit und Vorteile, in: Der Luzerner Arzt, Ausgabe 2010/2 (Nr. 81), 32; De Pietro et al., Switzerland: Health system review, 56.

⁴² De Pietro et al., Switzerland: Health system review, 172.

⁴³ Civitas: The Institute for the Study of Civil Society, The Swiss Healthcare System (2002), accessible online at www.civitas.org.uk/pdf/Switzerland.pdf (accessed on 24 July 2017), 1-11, 3.

⁴⁴ De Pietro et al., Switzerland: Health system review, 170.

VII COMMISSIONING AND PROCUREMENT

Commissioning and procurement of care services is mainly in the responsibility of the Swiss cantons. As far as inpatient care is concerned, the cantonal hospital planning and eventually the hospital list are the major instruments for steering sufficient, but cost-effective, institutional healthcare provisions in the respective cantons. The cantons are required to coordinate their planning.⁴⁵ In the fields of highly specialised medicines, the cantons are even obliged to plan on a country-wide level.⁴⁶ The hospital lists are reviewed and updated periodically by the cantons. Commissioning and procurement of non-institutional healthcare services by physicians have hardly been regulated in Switzerland to date, but are essentially left to the market, subject to the above-mentioned temporary restrictions regarding the opening of new practices (see Section IV.iii). However, this may change, in particular, with respect to GPs in some remote regions of Switzerland, where interest to open a new practice or take over an existing practice is low, and it is likely that no sufficient coverage will exist in the foreseeable future.

The main instrument for ensuring that new specific services and treatments are introduced and made available to the patients is the list of healthcare services and products reimbursable by the MHI system, which is maintained on a federal level by the FDHA (see Section II.ii above).

VIII MARKETING AND PROMOTION OF SERVICES

In Switzerland, the restrictions on advertising applicable to healthcare services differ depending on the person of the advertiser. Specifically, the AMP and APP stipulate that advertisements of healthcare professionals governed by the respective acts (see Section IV.iii) need to be objective and meet a public need and must not be misleading or obtrusive. Anatomism may include warnings, reprimands and fines up to an amount of 20,000 francs. Public and private hospitals, as well as emergency departments, on the other hand, are authorised to advertise their services without such restrictions. Since the distinction between self-employed physicians and hospitals can hardly be justified, part of the doctrine considers similar restrictions on hospital advertising adequate.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

Coming years will bring new developments in Switzerland, in particular, in the fields of organ donation and pre-implantation diagnostics.

In Switzerland, the demand for organs for transplantations is by far higher than the number of available organs. While the proportion of deceased donators tends to remain at the same level, the number of individuals waiting for an organ is constantly rising. Therefore, the federal government launched an action plan in 2013, named 'More Organs for Transplantations'. With this plan, the federal government aims to increase the number of

⁴⁵ Article 39 para. 2 HIA.

⁴⁶ Article 39 para. 2 bis HIA.

⁴⁷ Articles 40 let. d AMP and 27 let. d APP.

⁴⁸ Article 43 para. 1 lets. a – c; Article 30 para. 1 lets. a – c APP.

⁴⁹ David Lucas/Reutter Mark A., Schweizerisches Werberecht, 3rd ed., Zurich/Basel/Geneva 2015, 492.

donators from 13 to 20 per million inhabitants by 2018. This goal shall be achieved through a collective implementation of various measures. By now, some measures have already been realised, namely the development of the 'Swiss Donation Pathway', which describes the donation process and helps to create checklists for quick detections of donators. Furthermore, the SwissPOD study is continued in an improved way and is expanded on the emergency departments.⁵⁰ Finally, general awareness of the public shall be increased with the aim of significantly increasing the number of persons who opt-in for a donation by introducing a donation pass.

Pre-implantation genetic diagnosis (PID) is a medical procedure in which embryos are genetically analysed before inserting them into the uterus. In Switzerland, PID was generally forbidden. However, in 2016, the Swiss people accepted in a referendum a change in the respective legislation, the Federal Act concerning Medically Supported Reproduction (AMSR), providing for a liberalisation of PID. The revised law shall, in particular, ensure that couples involving a person in respect of which the risk exists that a child may, as a result of genetic reasons, become ill or handicapped, can make use of PID on favourable terms. Furthermore, it shall help couples that are incapable of getting pregnant naturally to have children. The revised AMSR, as well as the implementing ordinance, will enter into force on 1 September 2017.

X CONCLUSIONS

The Swiss MHI system and the combination of managed competition and corporatism has helped to create and maintain a healthcare system at a very high level, covering the entire country and ensuring that all people resident in Switzerland have free access to first-class medical treatment. On the other side, the split responsibilities between the different government levels, as well as the fact that demand for medical services is, due to the MHI system, hardly influenced by cost considerations, make it difficult to control healthcare costs, which have significantly increased over the past years. Therefore, the focus of the policy and legislative initiatives will continue to be on measures to stop, or at least slow down, cost increases in the fields of healthcare. While already-implemented measures mainly focused on the prices of medicinal products, one may expect that in the near future reimbursement of specific medical treatments with questioned efficiency will be re-assessed and eventually excluded from reimbursement. Further, the federal government has announced to analyse the methods by which other European countries, in particular, Germany and the Netherlands, try to steer the increased demand for healthcare services, namely by the means of budgets or measures controlling the amount for services provided.

Aktionsplan mehr Organe für Transplantationen im Rahmen der Bundesrätlichen Strategie Gesundheit 2020, Bundesamt für Gesundheit BAG, www.g2020-info.admin.ch/de/create-pdf/?project_id=54 (visited on 20 July 2017).

Appendix 1

ABOUT THE AUTHORS

MARKUS WANG

Bär & Karrer AG

Markus Wang studied law at the University of St Gallen (lic. iur.; Dr. iur.) and the London School of Economics (LLM) and was admitted to the Bar in 1996. He heads Bär & Karrer's life sciences and intellectual property departments. His practice covers a wide range of contentious and non-contentious intellectual property issues, as well as regulatory matters in the life sciences and healthcare field. Dr Wang lectures intellectual property law at the University of Fribourg.

IONAS BORNHAUSER

Bär & Karrer AG

Jonas Bornhauser has studied at the University of Zurich (lic. iur., Dr. iur.) and at Nottingham Law School (LLM), and was admitted to the Bar in 2009. He is an associate and a member of Bär & Karrer's intellectual property department, with a practice covering a wide range of contentious and non-contentious trademark, copyright, patent and other IP-related issues, in particular, matters related to the pharmaceutical and life science industry.

BÄR & KARRER AG

Brandschenkestrasse 90 CH-8027 Zurich Switzerland

Tel: +41 58 261 5000 Fax: +41 58 261 5000 markus.wang@baerkarrer.ch jonas.bornhauser@baerkarrer.ch www.baerkarrer.ch

191



Strategic Research Sponsor of the ABA Section of International Law



ISBN 978-1-912228-00-3