

SWITZERLAND

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I OVERVIEW

The Swiss healthcare system is relatively complex. On the one hand, this is because there are public and private service providers. On the other hand, this is because the regulation is divided into three levels, namely federal, cantonal and communal level.² Even though several aspects are regulated at federal level, and are therefore uniform across Switzerland (such as mandatory health and accident insurances,³ or the combating of widespread human and animal diseases),⁴ certain essential parts are regulated at regional (i.e., mainly cantonal) level. The cantons are, for instance, responsible for ensuring that people have access to the healthcare services needed.⁵ For this purpose, the cantons maintain and supervise hospitals and nursing homes in their region and, together with the mandatory health insurance (MHI), also finance them.

The Swiss healthcare system is known not only for its complexity, but also for its quality, which is partly due to the dense network of healthcare providers. In 2020, 38,502 physicians were employed in Switzerland, which corresponds to a density of around 4.4 physicians per 1,000 inhabitants.⁶ Key institutions for the delivery of healthcare services are general practitioners (GPs), public and private hospitals, nursing homes and Spitex (home-care services). All institutions are subject to an operating licence, usually granted by the competent cantonal authority. Individual healthcare providers must meet certain qualification criteria to provide their services and also to invoice these through MHI.

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2 Switzerland is a federal state consisting of 26 cantons and 2,202 municipalities (status on 1 January 2020; see the Federal Statistical Office's website at <https://www.bfs.admin.ch/bfs/en/home/statistics/catalogues-databases/maps.assetdetail.11407588.html> (website last visited on 30 June 2021)).

3 Article 117 of the Federal Constitution of the Swiss Confederation (SR 101; FC).

4 Article 118 para. 2(b) FC.

5 Article 41 para. 1(b) FC.

6 The physician statistics created and published by the professional association of Swiss physicians (FMH) are available in German and French through the FMH's website at <https://www.fmh.ch/themen/aerzttestistik/fmh-aerzttestistik.cfm> (website last visited on 30 June 2021).

II THE HEALTHCARE ECONOMY

i General

As a matter of principle, healthcare services are provided to everyone residing in Switzerland, no matter whether the patient is a Swiss citizen or not. This is mainly thanks to the fact that the Swiss healthcare economy is based on an insurance model, which is why the different social insurances, in particular the MHI, play an important role.

ii The role of health insurance

In general, every person resident in Switzerland must be insured for medical care within three months of residing or being born in Switzerland by way of taking out MHI (also referred to as basic health insurance).⁷ Residents are free to choose among the insurance providers approved and supervised by the Federal Office of Public Health (FOPH).⁸ The cantons are in charge of ensuring that the insurance obligation is complied with and assigning persons who fail to comply with their duty to an insurer.⁹

Thanks to the MHI, all persons living in Switzerland have access to high-quality medical care covering the risks of illness, maternity and (if not covered by another insurance) accident from day one, as no waiting periods apply and as all licensed social health insurance providers are obliged to admit all applicants.¹⁰ In other words, MHI providers may not refuse to insure someone based on age, previous health problems or other reasons. A compensation mechanism by way of applying 'risk levies' ensures a fair allocation of risks among the insurers.¹¹

Employees working in Switzerland are further covered by mandatory accident insurance.¹² Persons not covered by mandatory accident insurance (such as self-employed persons or pensioners) may take out voluntary accident insurance. In this case, the MHI is usually extended so that it also provides coverage for the risk of an accident.¹³ Insurance benefits are generally granted in respect of occupational (work-related) accidents, non-occupational accidents and occupational diseases.¹⁴

Any person may take out supplementary insurance on a voluntary basis to cover healthcare services not reimbursed by MHI (e.g., care in a hospital's private ward). As contracts for supplementary health or accident insurance are governed by private law,¹⁵ premiums are risk-based and, in contrast to MHI, insurers may attach conditions to the insurance policy due to the insured's state of health.

7 Article 3 para. 1 of the Health Insurance Act (SR 832.10; HIA).

8 Article 4 HIA.

9 Article 6 HIA.

10 Kieser/Lendfers, *Gesundheitsrecht in a nutshell*, Zürich/St. Gallen 2013, p. 85.

11 Article 16 et seq. HIA.

12 Article 1a para. 1 of the Accident Insurance Act (SR 832.20; AIA).

13 Article 1a para. 2(b) and Article 28 HIA.

14 Article 6 para. 1 AIA.

15 Supplementary private insurances are mainly regulated under the Insurance Contracts Act (SR 221.229.1; ICA); Kieser/Lendfers, *op. cit.*, p. 97.

iii Funding and payment for specific services

The funding of outpatient and inpatient healthcare services is regulated differently. The MHI system basically covers the costs of outpatient care, but only part of the costs of inpatient care. The costs for inpatient care are partially borne by the cantons.¹⁶ Due to this difference in payers, the principle ‘outpatient before inpatient’ applies.¹⁷ Additional funding is provided by other social insurance systems (such as the mentioned mandatory accident insurance, the old-age and survivors’ insurance, or the disability insurance).

MHI Funding

The MHI system, which covers most of the healthcare costs, is basically funded by premiums paid by the insured persons, usually on a monthly basis, but calculated on a daily basis.¹⁸ These premiums vary depending on the insured’s place of residence and age category.¹⁹ Choosing optional models provided by the insurer that limit the insured’s choice of service provider, such as HMO, GP or Telmed models, reduce the monthly premium to be paid.²⁰ Individuals on a low income are entitled to health insurance premium subsidies that are paid directly to the insurer by the insured’s canton of residence.²¹

In addition to the monthly premiums, insured persons pay a fixed annual amount towards the costs of services provided. This deductible (franchise) amounts to a minimum of 300 Swiss francs (for adults).²² The policyholder may choose a higher annual deductible in order to be granted lower premiums. The maximum annual deductible is limited by law to 2,500 Swiss francs (for adults).²³ The insured also pays at least 10 per cent of the costs exceeding the deductible in the form of a retention fee up to a maximum of 700 Swiss francs per year (for adults).²⁴ For hospital stays, an additional excess of 15 Swiss francs per day applies.²⁵

Services covered

The law and corresponding government-approved lists determine which healthcare services and treatments are reimbursed by MHI and which service providers may bill via the MHI. As a general rule, all services rendered must meet the principles of efficacy, utility and cost effectiveness.²⁶

The MHI typically covers the costs of services that serve to diagnose or treat an illness and its consequences, as well as maternity services.²⁷ These benefits include services provided by GPs and specialists, pharmacists, chiropractors, midwives, persons providing services under

16 Articles 25a para. 2, 41, 49a and 50 HIA.

17 Article 3c and Annex 1a of the Healthcare Services Regulation (SR 832.112.31; HSR).

18 Article 61 para. 1 HIA; decision of the Swiss Federal Tribunal (SFT) of 3 December 2015, 142 V 87.

19 Article 61 HIA.

20 Article 41 para. 4 in conjunction with Article 62 para. 1 HIA.

21 Article 65 HIA.

22 Article 64 para. 2(a) HIA in conjunction with Article 103 para. 1 of the Health Insurance Ordinance (SR 832.102; HIO).

23 Article 64 para. 3 HIA in conjunction with Article 93 para. 1 HIO.

24 Article 64 para. 2(b) and para. 3 HIA in conjunction with Article 103 para. 2 HIO.

25 Article 64 para. 5 HIA in conjunction with Article 104 para. 1 HIO.

26 Article 32 para. 1 HIA.

27 Article 1a para. 2 and Article 24 para. 1 HIA: The MHI covers the costs of the services referred to in Articles 25-31 HIA, subject to the conditions set out in Articles 32-34.

or by order of a medical practitioner and organisations employing such persons, laboratories, dispensing points for aids and appliances used for examination or treatment, hospitals, birth centres, nursing homes, spas, transport and rescue services, and establishments providing outpatient medical care by physicians, if meeting the qualification requirements as defined in the Healthcare Insurance Act (HIA).²⁸ Services covered include (1) examinations and treatments (including various preventive measures such as vaccinations or gynaecological screenings), (2) analyses and (3) medical rehabilitation measures.²⁹ Hospital stay coverage is limited to the standard of the general ward. The MHI also covers medically necessary transport and rescue costs and services of pharmacists in dispensing prescribed medicines.

Costs for dental treatment are only covered to a limited extent by MHI, for instance if such treatment is caused by a serious general illness or its consequences.³⁰ Dental treatment costs (e.g., for fillings of decayed teeth) are therefore generally born by the patient, unless they are covered by any other (private) insurance.

Purely cosmetic surgeries are generally not covered by MHI, as cosmetic issues usually do not qualify as illness and do not require medical treatment. Exceptions apply on a case-by-case basis, for instance to the correction of macromastia (breast hypertrophy) causing physical or psychological complaints and, thus, qualifying as disease requiring treatment.³¹

With regard to hospital care, each canton has an approved Hospital List. Only services provided by (public and private) hospitals on this list are covered by MHI.³²

iv Pricing

Inpatient services are priced and reimbursed by MHI based on flat rates per case. The rates are related to performance and based on uniform structures throughout Switzerland.³³

Outpatient services are charged (and reimbursed by MHI) based on standard rates agreed between professional associations of physicians and MHI-associations, and are then approved by the Federal Council.³⁴ The relevant tariff (TARMED) is currently being renegotiated.

Prescribed medicines as well as aids and appliances (such as crutches, inhalers, or prostheses) are covered by MHI at the prices set out in the List of Pharmaceutical Specialities and up to the limit specified in the Aids and Appliances List, respectively.³⁵ Pharmacists may dispense generics to listed branded medicines unless the physician has specifically prescribed the branded product. It should be noted that the 10 per cent co-payment retention fee of the insured under the MHI is usually raised to 20 per cent if an equivalent medicine exists that costs less (by a defined margin).³⁶

28 Article 35 HIA.

29 Articles 25 et seq. HIA.

30 Article 31 HIA.

31 See, for example, decision of the SFT of 15 November 1995, 121 V 211 (regarding breast reduction surgery; in this case, MHI-coverage was denied).

32 Article 39 para. 1(e) HIA.

33 Article 49 para. 1 HIA.

34 Article 46 para. 4 HIA.

35 Article 52 para. 1 HIA in conjunction with Articles 20 et seq. and 30 et seq. as well as Annex 2 HSR.

36 Article 52 para. 1 HIA in conjunction with Article 38a HSR.

III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i Main service providers

Healthcare services are mainly provided by GPs, public and private hospitals, nursing homes (e.g., for rehabilitation or the elderly and the disabled) and Spitex (home-care services).

All healthcare service providers must meet certain qualification requirements in order to carry out their services, be acknowledged for reimbursement under MHI and be licensed under cantonal law.

ii Freedom of choice

For outpatient treatment and unless otherwise agreed (e.g., under a HMO model), the insured person is free to choose among the authorised service providers that are suitable for the treatment of the illness. The insurer will cover the costs according to the tariff applicable to the chosen service provider.³⁷

For inpatient treatment, the insured person is free to choose from among the hospitals on the Hospital List of its canton of residence. The policyholder may also choose a hospital on the Hospital List of another canton.³⁸ In such case, the MHI will only cover the costs of accommodation and treatment up to the amount that would be charged by a hospital on the Hospital List of the canton of residence, unless the treatment is carried out at such other location for medical reasons (e.g., emergency or specialised treatment).

Despite this general freedom of choice, patients usually address their GP first, who then refers them to a specialist or orders investigative measures (such as X-rays, CTs or MRTs).

iii Access to medical records

On 15 April 2017, the Electronic Patient File Act (EPFA)³⁹ regulating the framework conditions for the introduction of the electronic patient file (EPF) entered into force. The EPF is a collection of personal documents with information about health. The information can be accessed at any time via a secure internet connection by both patients and healthcare professionals. Patients decide who can access which information and under which circumstances.⁴⁰ Use of the EPF is entirely voluntary for the patients (i.e., an EPF is only established if the patient gives his or her written informed consent).⁴¹

It was planned to introduce the EPF from 15 April 2020 onwards. However, due to challenging data protection and security requirements, the EPF's implementation proved to be more complex and has only started to be introduced step-by-step since spring 2021.

37 Article 41 para. 1 HIA.

38 Article 41 para. 1bis HIA.

39 SR 816.1.

40 Article 9 EPFA.

41 Article 3 para. 1 EPFA.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

It is important to distinguish between the following ‘licences’: (1) professional or operating licences (granted if all health regulation requirements as discussed in this section are met) and (2) social security-related authorisations (e.g., admittance to bill at MHI expense by being listed on the cantonal Hospital List).⁴²

i Regulators

The cantons are mainly in charge of licensing and supervising institutional healthcare providers and healthcare professionals.

The key licensing bodies and their responsibilities differ from canton to canton. In the canton of Zurich, for instance, the Department of Health is generally in charge of ensuring the availability of sufficient and economically viable healthcare services and of granting the respective licences.⁴³

ii Institutional healthcare providers

Institutional healthcare providers offering inpatient services are mainly (1) hospitals and clinics and (2) nursing homes. They are generally organised on a regional level and all require an operating license from the canton in which they operate. The requirements to be met are defined by cantonal law and mainly relate to disposing of sufficient qualified personnel and appropriate management.⁴⁴

Institutional healthcare providers that offer outpatient services are mainly (1) outpatient medical care institutions (in the form of a legal entity or sole proprietorship), (2) Spitex (or other professional nursing services) and (3) rescue services companies. These providers also require a cantonal or, if applicable based on cantonal law, municipal operating licence or authorisation.

Sanctions such as fines of up to 50,000 Swiss francs, or in the case of repeated offences or acting for financial gain, up to 500,000 Swiss francs, apply to providers that operate without a licence.⁴⁵

iii Healthcare professionals

The regulation on healthcare professionals is rather complex, but has recently become somewhat clearer with the entry into force of the Healthcare Professions Act (HPA).⁴⁶ Based on the HPA, seven healthcare professions that were so far subject to differing cantonal laws are now subject to uniform federal regulations on training and licensing requirements. The cantons remain responsible for issuing professional licenses to practise the relevant profession independently and autonomously and for supervision. These new uniform requirements were implemented with regard to nursing, physiotherapy, occupational therapy, midwifery, nutrition and dietetics, optometry and osteotherapy.⁴⁷

42 See, for example, Article 39 para. 1(e) HIA and Section II.iii., above.

43 See the Department of Health's website at <https://gd.zh.ch/internet/gesundheitsdirektion/en/home.html> (website last visited on 30 June 2020).

44 See, e.g., § 36 of the Zurich Health Act (LS 810.1; Zurich HA); Kieser / Lendfers, *op. cit.*, p. 76.

45 § 61 para. 1(a) and para. 2 Zurich HA.

46 SR 811.21.

47 Article 2 para. 1 HPA.

The qualification requirements that physicians, dentists, chiropractors, pharmacists and veterinarians ('university-trained professionals') must meet are regulated under the Medical Professions Act (MPA).⁴⁸ The requirements applying to psychological professionals (including psychotherapists) are regulated under the Psychological Professions Act (PPA).⁴⁹

All other medical professionals (such as speech therapists or dental technicians) are subject to regulations under cantonal laws.

The above-mentioned applicable laws determine the requirements for each profession with respect to training (education, specialisation), (cantonal) licensing and continuing education.⁵⁰ They also regulate the prerequisites for acknowledging healthcare professionals who obtained qualifications abroad.⁵¹ Cantonal licences are generally granted to healthcare professionals in order to practise under their own professional responsibility if such person meets the professional requirements according to the applicable legislation (e.g., the MPA), is trustworthy and assures proper exercising of his or her profession.⁵²

All persons practising under their own professional responsibility whose profession is regulated under the MPA, PPA or HPA must take out or maintain professional liability insurance in accordance with the nature and extent of the risks associated with their activity.⁵³ Disciplinary and criminal sanctions apply for non-compliance with this insurance or any other professional obligation.⁵⁴ Usually, cantonal law also prescribes the taking out and maintenance of professional liability insurance for the professions regulated thereunder.⁵⁵

V NEGLIGENCE LIABILITY

The prerequisites of negligence liability differ depending on whether the healthcare services are provided in fulfilment of a public service (e.g., by a public regional hospital), or on the basis of private law (either based on a mandate contract⁵⁶ or in tort) (e.g., by a private practitioner).

This distinction is not only relevant with regard to liability requirements, but also with respect to determining (1) against whom a claim must be made (as cantonal public law may require that claims are only brought against the canton and not against the healthcare provider), (2) which procedural rules apply and (3) which court is competent to hear the case.⁵⁷

48 Article 2 para. 1 MPA (SR 811.11).

49 SR 935.81.

50 Article 1 para. 3 MPA; Article 1 para. 2 PPA; Article 1 HPA.

51 Article 1 para. 3(d) MPA; Article 1 para. 2(e) PPA; Article 2 para. 2(c) HPA.

52 See, for instance, § 4 para. 1 Zurich HA.

53 Article 40(h) MPA; Article 27(f) PPA; Article 16(g) HPA.

54 Article 43 et seq. MPA; Article 30 et seq. PPA; Article 19 et seq. HPA.

55 See, for instance, § 12 para. 2 Zurich HA.

56 Contracts between patients and (private) healthcare providers generally qualify as mandate in the sense of Articles 394 et seq. Swiss Code of Obligations (SR 220; CO); see, e.g., Widmer Lüchinger, *Medical Liability in Switzerland*, in: *Medical liability in Europe: a comparison of selected jurisdictions*, Berlin 2011, p. 547-609, n. 77, PDF-version available at <https://edoc.unibas.ch/17739/> (website last visited on 30 June 2021).

57 Widmer Lüchinger, *op. cit.*, n. 8.

i Prerequisites

The prerequisites of negligence liability under private law (contract or tort) are as follows: (1) breach of contract or, in tort, unlawfulness (e.g. medical intervention non-lege artis or breach of the duty to inform), (2) fault (intention or negligence; fault is presumed in case of breach of contract), (3) damage (pecuniary loss), (4) natural and adequate causality (i.e., there must be a causal link between the breach of contract/wrongful conduct and the damage suffered, whereby such damage must not be too remote).⁵⁸ Patients who suffer damage are free to bring their claims based on contract law and in tort, if the prerequisites of both kind of liabilities are fulfilled.

As indicated above, liability of public legal entities, such as public regional hospitals, is governed by (cantonal) public law. The prerequisites of this 'state liability' are similar to the prerequisites mentioned above under private law, with the exception of fault, which is not a requirement under most cantonal legislations.⁵⁹ Usually, the liability of physicians employed by such public hospitals is also governed by cantonal public law, but this depends on the legislation of the canton where the hospital is located.⁶⁰ As a default rule, private law rules apply.

ii Notable cases

Many negligence liability cases do not become public as they are usually dealt with by way of amicable out-of-court settlement. This is not only due to the complexity and associated costs usually involved in such disputes, which often require obtaining one or more expert opinions, but also due to the rather heavy burden of proof the patient needs to meet. Furthermore, the accused healthcare provider often has an interest in keeping such cases secret and, thus, out of court.

Issues frequently addressed in negligence liability court cases relate to the prerequisites of sufficient informed consent, contributory negligence and the burden of proof.

A notable case in the recent past dealt with the question of hypothetical consent.⁶¹ In this decision, the Swiss Federal Tribunal (SFT) confirmed its jurisprudence that the burden of proof is on the physician to establish that a patient was sufficiently informed and consented to the medical intervention. In the absence of such consent, the physician may argue hypothetical consent. Despite the physician also bearing the burden of proof for this assertion, the patient must provide credible evidence or at least personal reasons why he or she would have opposed the medical intervention, in particular if he or she had known the risks. The SFT further confirmed that to determine whether hypothetical consent may be assumed, the circumstances of each individual case, notably the personal and concrete situation the patient finds his or herself in, are decisive. Consequently, one may only make an argument based on the hypothetical reaction of a 'reasonable patient' if the patient in question (as in the case at hand) does not assert any personal reasons that would have led him or her to reject the proposed medical treatment. In this case, the SFT confirmed that

58 See Article 97 para. 1 CO regarding liability based on contract law and Article 41 para. 1 CO regarding liability in tort.

59 Widmer Lüchinger, op. cit., n. 100.

60 Widmer Lüchinger, op. cit., n. 98.

61 Decision of the SFT of 1 April 2019, 4A_353/2018.

the court of lower instance had rightfully assessed and assumed that the patient would have agreed to the surgical intervention even if she had been fully informed about the alternative treatment methods (not involving surgery).⁶²

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Switzerland's public hospitals are usually owned and operated by either the cantons or the municipalities. Recently, however, more and more public hospitals are organised as and operated by private legal entities (e.g., stock corporations).⁶³ This new development has led to controversial legal questions, such as whether also these hospitals are still subject to public procurement laws.⁶⁴

Next to the public hospitals, there are institutions organised under private law that are predominantly privately owned. According to statistics published by the association of private hospitals, *Privatkliniken Schweiz*, in 2018, private hospitals contributed a share of 24 per cent of nursing days to inpatient healthcare throughout Switzerland.⁶⁵

Private practitioners are either self-employed or organised in outpatient medical care institutions (in the form of a legal entity or sole proprietorship).

VII COMMISSIONING AND PROCUREMENT

To ensure that Swiss residents have access to a sufficient range of inpatient medical hospital services, the cantons are responsible for hospital planning in line with their needs.⁶⁶ This planning work results in the cantonal Hospital Lists, which specify the service contracts of the hospitals relevant to care. As indicated in Section II.iii, the remuneration of inpatient treatment is covered proportionally by the relevant canton and the social insurers (mainly the MHI).⁶⁷ The Hospital Lists are regularly updated and the current lists are available through the website of the Conference of the Cantonal Directors of Health, which supports the cantons in coordinating and cooperating with each other in their hospital planning.⁶⁸ In turn, within the scope of their service contracts, all listed hospitals are subject to an admission obligation with regard to insured persons residing in their canton of operation.⁶⁹

In contrast to the statutorily determined planning of inpatient care, the cantons have no legal obligation to carry out or coordinate outpatient care, but may in fact do so by using their admission control powers (e.g., by granting or not granting new licences).

62 Decision of the SFT of 1 April 2019, 4A_353/2018, consid. 2.2.

63 See, e.g., the website of the association of Zurich hospitals ('Verband Zürcher Krankenhäuser') for statistics regarding the canton of Zurich, according to which 79 per cent of the Zurich hospitals are organised under private law, 60 per cent of which in the form of stock corporations: <https://www.vzk.ch/gesundheitspolitik/dossiers/rechtsform> (website last visited on 30 June 2021).

64 Decision of the SFT of 21 February 2019, 145 II 49 ('Spital Wetzikon'; subjection to public procurement laws was affirmed).

65 Statistics published within the annual brochure 2020 of the association 'Privatkliniken Schweiz', available at <http://www.privatehospitals.ch/> (website last visited on 30 June 2021), pp. 16-17.

66 Article 39 para. 2 HIA.

67 Article 49a para. 1 HIA.

68 See the website of the Conference of the Cantonal Directors of Health at <https://www.gdk-cds.ch/de/gesundheitsversorgung/spitaeler/planung> (website last visited on 30 June 2021).

69 Article 41a HIA.

VIII MARKETING AND PROMOTION OF SERVICES

In contrast to rather strict regulations on the marketing and promotion of health-sensitive products such as pharmaceuticals, foodstuffs, or cosmetics, the advertisement of healthcare services is much less regulated.⁷⁰

Service providers exercising a profession regulated by the MPA, PPA or HPA (see Section IV.iii) must comply with the legal requirements on marketing and promotion set out therein. The MPA, for instance, stipulates that university-trained professionals, operating under their own professional responsibility, may only market and promote their services if such advertisement is objective, meets public needs and is neither misleading nor intrusive.⁷¹ Sanctions may include warnings, reprimands, fines of up to 20,000 Swiss francs, a ban on practising the profession under one's own professional responsibility for a maximum of six years (temporary) or a definitive ban to practice in this sense.⁷²

With regard to services provided by hospitals and nursing homes, there may be applicable provisions under cantonal law that must be followed. Usually, the general rules on advertising apply (i.e., advertising must be true to the facts and must not be misleading).⁷³

IX CORONAVIRUS

Fighting the covid-19 pandemic since spring 2020 and the social distancing measures introduced in that context has brought e-health and digital forms of patient care (such as telemedicine) into focus, which will likely further accelerate digitalisation in the Swiss healthcare economy. Some of the legal bases for use of such new technologies already exist or can be applied by analogy. Some legal bases have yet to be created by revising existing laws or enacting new ones. This applies in particular to human research projects, where the use of digital or artificial intelligence applications is still viewed rather critically.

With regard to outpatient treatment, also the tariff regulating MHI compensation (the TARMED) would need to be adapted, as was done selectively and for a limited time during the fight against covid-19 based on the FOPH's recommendation. During this time, for instance, physiotherapists were allowed to bill a limited number of hours for the care of their patients via video call.⁷⁴ However, given that even the implementation of the EPF posed major challenges (see Section III.iii), it will probably still take some years before the Swiss healthcare system is ready to enter the digital age.

70 See, e.g., David / Reutter, *Schweizerisches Werberecht*, 3rd ed. Zurich 2015, n. 99 et seq. and n. 938 et seq.

71 Article 40(d) MPA; see similar provisions in Article 27(d) PPA (for psychological professionals) and Article 16(e) HPA (for the seven professions regulated by the HPA).

72 Article 43 para. 1 MPA; Article 30 para. 1 PPA; Article 19 para. 1 and 2 HPA (here, sanctions do not include a temporary or definitive ban from practising the profession).

73 Articles 2 and 3 of the Unfair Competition Act (SR 241; UCA).

74 See para. 3.3 of the FOPH's factsheet entitled 'Kostenübernahme für ambulante Leistungen auf räumliche Distanz während der COVID-19-Pandemie', dated 20 May 2020 and replacing the factsheet of 6 April 2020; the factsheet is no longer applicable and the related FOPH recommendations have been revoked as of 22 June 2020, see <https://www.bag.admin.ch/bag/en/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov/regelung-krankenversicherung.html> (website last visited on 30 June 2021).

X FUTURE OUTLOOK AND NEW OPPORTUNITIES

Further developments and new opportunities alongside increased digitalisation are expected with regard to medical cannabis. Under current Swiss law, cannabis is considered a prohibited narcotic and is subject to a comprehensive traffic ban.⁷⁵ This means that cannabis may not be cultivated, produced, imported or distributed. Consequently, the medical use of cannabis is also limited and is only possible with an exceptional permit from the FOPH. As the demand for treatment with cannabis has risen considerably in recent years and as almost 3,000 exceptional authorisations were granted by the FOPH in 2018 alone,⁷⁶ the Swiss Parliament passed an amendment of the Narcotics Act on 19 March 2021 to lift the traffic ban on medical cannabis.⁷⁷ Based on the amended Narcotics Act, the traffic ban on cannabis will be limited to non-medical ('recreational') use, an exemption permit will no longer be necessary and medical cannabis will be subject to the authorisation and monitoring system of the Swiss Agency for Therapeutic Products (Swissmedic). The amended Narcotics Act is not expected to enter into force before 2022.⁷⁸

Another challenge related to the increased digitisation of healthcare is cyber threat. The Swiss legislator has recently introduced a new cybersecurity provision applicable to healthcare institutions (such as hospitals) in the revised Medical Devices Ordinance.⁷⁹ As cyber threats are likely to continue to increase, taking appropriate measures is and will be of serious consideration not only to healthcare institutions, but to all other involved stakeholders as well (e.g., insurance providers, GPs etc.).

XI CONCLUSIONS

Experience over the past months while combating the covid-19 pandemic has shown that the Swiss healthcare system, although complexly organised, basically functions well. However, the high costs of healthcare are a recurring topic of discussion. Accordingly, the revision of the TARMED and the possible introduction of cost-reducing flat rates per case with respect to outpatient care are being hotly debated today and will probably continue to be so in the near future. This is particularly true as on 30 June 2021 the Federal Council decided that the TARDOC, which was supposed to replace the TARMED, could not be approved in its present form.⁸⁰

75 Cannabis products with a THC-content of less than 1 per cent are not subject to the Narcotics Act (SR 812.121; NA) and are therefore increasingly being used commercially. This is particularly true for CBD-products.

76 See Swissmedic's website at https://www.swissmedic.ch/dam/swissmedic/en/dokumente/recht/pharmakop%C3%B6e/betmg_revision_cannabisarzneimittel.pdf.download.pdf/09_Gesetzes%C3%A4nderung%20Cannabisarzneimittel_Adrian%20Gschwend.pdf (website last visited on 30 June 2021).

77 See the FOPH's website at <https://www.bag.admin.ch/bag/de/home/medizin-und-forschung/heilmittel/med-anwend-cannabis/gesetzesaenderung-cannabisarzneimittel.html> (website last visited on 30 June 2021).

78 See Swissmedic's website at https://www.swissmedic.ch/dam/swissmedic/en/dokumente/recht/pharmakop%C3%B6e/betmg_revision_cannabisarzneimittel.pdf.download.pdf/09_Gesetzes%C3%A4nderung%20Cannabisarzneimittel_Adrian%20Gschwend.pdf (website last visited on 30 June 2021).

79 Article 74 Medical Devices Ordinance (SR 812.213).

80 See the Federal Council's press release of 30 June 2021 available at <https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-84250.html> (website last visited on 30 June 2021).

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Janine Reudt-Demont is a life sciences and healthcare specialist at Niederer Kraft Frey. Her experience covers the regulation of all aspects of the medtech and pharmaceutical industry. Janine also counsels clients on questions of distribution, product liability and product safety laws, including recalls. In addition to her advisory expertise, she regularly represents clients in court proceedings, arbitration, mediation and before administrative bodies.

Janine has extensive experience in handling product recalls and in advising as well as defending companies against product liability claims, including representation before state courts. Janine is also very experienced in counselling companies of all industries on questions of healthcare and data protection laws.

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