

THE HEALTHCARE LAW
REVIEW

SIXTH EDITION

Editor
Ulrich Grau

THE LAWREVIEWS

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REVIEW

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Editor
Ulrich Grau

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PREFACE

The sixth edition of *The Healthcare Law Review* covers six new jurisdictions and a total of 17 jurisdictions from Europe, North and South America and Asia. All chapters have been provided by leading experts in the field of healthcare law in their countries. The reviews have been prepared by the authors as a practical, business-focused analysis of recent changes and developments, their effects, and a look forward at expected trends. The reviews are intended to provide an overview of legal issues that are of interest for healthcare providers and related businesses.

The past two years have been dominated by the covid-19 pandemic. The pandemic not only affected all healthcare providers and staff working in health and social care but also scientists, public health officials and politicians throughout the world. Each country was hit hard by the pandemic, some countries were even overwhelmed, and major sources of the healthcare systems had to focus on maintaining the functioning of the health systems even in this exceptional situation. Therefore, all countries took additional exceptional measures to fight the pandemic. According to the reviews from the individual countries, these exceptional measures have now largely been scaled back or totally withdrawn, even though the pandemic is not yet over.

As a major result of the pandemic, many countries have geared their healthcare systems to ensure safe access to healthcare for citizens, even in extraordinary situations, through greater digitisation and use of telemedicine. This is not only about supplementing or replacing face-to-face doctor visits with communication options via telephone or video consultation. Many countries have also introduced electronic patient files, regulations for the exchange of health data and other digital communication channels. The next few years will show whether these innovations can also be successfully implemented in a healthcare reality that is no longer solely determined by a pandemic. A particular challenge in the future will also be to utilise the new digital tools not only within a national healthcare system in a single country, but also across borders. The European Union is already well on the way with the implementation of a European Health Data Space.

Even if individual countries solve their problems differently, we all can only benefit from knowing the different approaches to solving the problems and how successful the respective countries have been with their solutions in each case. I truly hope that the publication of *The Healthcare Law Review* will be particularly helpful in that respect.

I am more than happy to take over the editorship from Sarah Ellson from Fieldfisher LLP, London. I would like to sincerely thank her for her commitment over the past years. It is an extraordinary pleasure to work with this group of exceptional authors of *The Healthcare Law Review* in this edition and in the years to come to provide a practical overview of the

healthcare systems of the countries covered. We will continue our efforts to include more countries to this publication to be able to give a comprehensive worldwide approach to healthcare issues by each country.

Ulrich Grau

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August 2022

VIETNAM

Eli Mazur and Vu Tuan Duc¹

I OVERVIEW

After a year of implementing the covid-19 vaccination campaign, Vietnam has administered nearly 198.3 million doses of covid-19 vaccines to people living in the country, becoming one of six countries with the highest vaccination coverage in the world. Vietnam's healthcare industry is forecast to recover and grow strongly in 2022 due to increasing demand for healthcare and with social distancing measures now loosened.

This chapter provides a summary of Vietnam's developing healthcare system. This basic overview should be useful to academics, investors, attorneys and those with a general interest in the state of Vietnam's healthcare system (e.g., individuals considering Vietnam as a potential retirement destination).

II THE HEALTHCARE ECONOMY

i General

The current healthcare services available in Vietnam are a balance of powers between the government's investments in healthcare infrastructure, a strong demand for high quality health products and services and, at the same time, the ongoing implementation of universal healthcare coverage (UHC) as set out in Vietnam's 2012 Masterplan. On 8 June 2020, the National Assembly voted to pass and adopt the EU–Vietnam Free Trade Agreement (EVFTA) and the EU–Vietnam Investment Protection Agreement (EVIPA),² which will considerably increase trade and investment for pharmaceutical and medicinal products and medical devices³ from the European Union, as a result of a 99 per cent cut in tariffs and other trade barriers. As 55 per cent of drug demand in Vietnam is driven by patient and healthcare professional (HCP) demand for products manufactured in the EU, these new treaties will have a significant impact on the health of Vietnamese patients, the treatment of diseases in Vietnam and, hopefully, competition in the market, by lowering prices for such drugs.⁴

1 Eli Mazur is a partner and Vu Tuan Duc is an associate at YKVN.

2 Council Decision (EU) 2019/753 of 30 March 2020 on the conclusion of the Free Trade Agreement between the European Union and the Socialist Republic of Viet Nam.

3 See Annex 2-C of the EVFTA - Pharmaceutical/Medicinal Products and Medical Devices, Guide to the European Union–Vietnam Free Trade Agreement.

4 'Universal insurance is a feasible, achievable goal', Vietnam Social Security, 1 December 2021, available at <https://vss.gov.vn/english/news/Pages/vietnam-social-security.aspx?itemID=10175&CateID=198>.

ii The role of health insurance

In Vietnam, it is reported that as at 2020, the number of health insurance participants totalled 87.97 million, making up 90.85 per cent of the country's population,⁵ which ensures all individuals and communities access to good-quality health services that are affordable.⁶ At the same time, unfortunately, the inherent imbalance of supply and demand between the supply of and demand for hospital beds in Vietnamese hospitals remains unsolved.⁷ The number of patients needing treatment for diseases⁸ and overcrowded hospitals are still challenges that the Ministry of Health (MOH) aims to overcome.

iii Funding and payment for specific services

The state budget is relatively low because of, among other things, poor income tax compliance and a weak property taxes levy, whereas the state's international debts are relatively high (particularly when contingent debts are included – e.g., potential government guarantees under build-operate-transfer contracts for infrastructure projects); thus, there is a need for a more active and robust private sector and for public–private partnerships (PPPs) in Vietnam. This will allow a deeper development of the Vietnamese healthcare sector in general – particularly as a low-middle income country – and a sustainable healthcare financing model. This will not be an easy transition, but the new Law on PPP Investment No. 64/2020/QH14 (National Assembly, 18 June 2020) and its guiding decree identifies medical examination and treatment facilities, preventive healthcare, and testing as PPP objectives in the healthcare sector, provided that there is investment of at least 100 billion dong. These regulations will lay the foundation for more detailed guidance on healthcare PPPs, which is expected to be issued by the MOH in the near future, to create a sustainable environment that encourages investment through continuous dialogue between government, industry and academia. Furthermore, the upcoming revision of the Health Insurance Law represents an opportunity for investing legislative and investor time in establishing the first stages of a 'government-industry dialogue to identify practical policy solutions to balance the budget realities and long-term sector development objectives'.⁹ In Vietnam, the pricing of healthcare services is publicly determined by the MOH and calculated each year based on a combination of market mechanics and socioeconomic realities.¹⁰ Thus, a locally produced drug will not necessarily be automatically subject to a low price required by law;¹¹ thus, the development of the healthcare sector, while addressing short-term state budget concerns, can also accommodate investors seeking long-term objectives of increasing profits on an annual basis.

5 EuroCham White Book 2019, pages 142–143.

6 'Universal health coverage in Viet Nam', World Health Organization, available at <https://www.who.int/vietnam/health-topics/universal-health-coverage>.

7 EuroCham White Book 2018, pages 134–135.

8 'The most common one being: hypertension, cancer, heart and vascular disorders, diabetes, chronic wounds, Chronic Obstructive Pulmonary Disorder (COPD) and asthma', EuroCham White Book 2018, pages 134–135.

9 EuroCham White Book 2019, pages 145–146.

10 'Healthcare service prices to be adjusted: Health Ministry', *Vietnam News*, 11 April 2018, available at <https://vietnamnews.vn/society/426075/healthcare-service-prices-to-be-adjusted-health-ministry.html>.

11 EuroCham White Book 2018, page 127.

III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

The framework for healthcare facilities in Vietnam consists of state healthcare facilities, private healthcare facilities and other healthcare facilities.¹² The state healthcare facilities are divided into four levels by administrative structure: central, provincial, district and commune.¹³ Vietnamese citizens paying for health insurance do not have to pay for medical services at public healthcare facilities. However, in many cases, Vietnamese people opt for private care as these facilities are better equipped. The main objective of the government is to provide affordable and universal access to healthcare for Vietnamese people.

The scope and role of practice of corporate and professional health and social care providers, including for state healthcare facilities, are found in Section 1, Part I of the Hospital Regulations issued with Decision 1895/1997/QD-BYT. According to Vietnamese law, a hospital is a facility for medical examination, treatment and healthcare for patients, which has the main tasks of:

- a* medical examination and treatment;
- b* training of officials;
- c* scientific research;
- d* directing routes;
- e* disease prevention;
- f* international cooperation; and
- g* economic management.

The applicable laws are, essentially, the Law on Medical Examination and Treatment and Decision 1895/1997/QD-BYT on Hospital Regulations. Corporate, professional healthcare and social healthcare providers are subject to several statutory limitations (e.g., delaying or refusing first aid, practising without, or owning false, certifications or licences, selling drugs or otherwise harming patients' rights).¹⁴

Vietnam does not have a separate healthcare system for older people. This means that they must participate in the health insurance system to receive benefits when receiving medical examinations and treatments. Recently, healthcare for older people became a priority in Vietnam. Several policies on healthcare for older people have been put into practice, such as the Vietnam National Action Programme for the Elderly for the period 2012–2020¹⁵ aiming to improve the quality of care for older people, as well as the Health Care for the Elderly Project for the period 2017–2025.¹⁶

Alternatively, Article 10.3 of the Law on Medical Examination and Treatment enables access to medical consultants through a referral system. Patients have the right to choose any representatives to perform and protect their rights and obligations during medical examinations and treatments. Consequently, in June 2019, the Vietnamese Deputy Minister of Health announced the launch of electronic health record (EHR) pilots in eight provinces and cities of Vietnam. These technological tools aim to improve the management of

12 Law on Medical Examination and Treatment No. 40/2009/QH12 (National Assembly, 23 November 2009), as amended from time to time (collectively, 'Law on Medical Examination and Treatment'), Article 81.1.

13 See https://www.jstage.jst.go.jp/article/apjdm/4/2/4_23/_article.

14 Law on Medical Examination and Treatment, Article 6.

15 Issued after the Decision No. 1781/QD-TTg issued in 2012.

16 See www.longdom.org/articles/health-and-health-care-for-older-people-in-vietnam.pdf.

healthcare services thanks to direct access to blood group diseases, allergies and other relevant health data of Vietnamese patients.¹⁷ From April 2021, EHRs have been standardised and used nationwide in 50 provinces and cities, hospitals and health facilities across the country planned to be interconnected in the system from 1 July 2021, and it is expected that 90 per cent of the population will have their EHR at the end of 2022.¹⁸

According to Article 8 of the Law on Medical Examination and Treatment, patients have a right to confidentiality of their health status and private information given in their case history dossiers. A patient's data may be disclosed only when agreed by the patient or for professional information with practitioners directly treating the patient.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

In Vietnam, the provision of healthcare services and providers of these services is mainly governed by the Law on Medical Examination and Treatment as amended from time to time and other relevant guiding documents. Any institutional healthcare provider is required to obtain an operational licence appropriate for their operational scale and scope of activities.¹⁹ Similarly, any healthcare professional is required to have a practising certificate.²⁰ The operational licence and practising certificate shall be issued by the MOH and the provincial Department of Health (DOH) depending on the form of the institutional healthcare provider and the workplace of the healthcare professional.²¹

In addition, for the purpose of ensuring the quality of healthcare services provided for citizens, the MOH, the DOH, the Minister of the MOH and the Director of the DOH, in particular, are entitled to revoke these licences and certificates in some specific cases (e.g., as detailed in Section IV.ii) and have responsibilities for the establishment of advisory or inspection committees to advise during procedures for granting licences and certificates and inspecting any violations.²²

ii Institutional healthcare providers and healthcare professionals

Healthcare providers

Under Vietnamese law, an institution providing healthcare services can be organised under the following forms:

- a hospital;
- b medical assessment establishments;
- c general clinics;
- d specialised clinics;

17 'Ministry launches Electronic Health Record Software', *Viet Nam News Society*, 15 June 2018, available at <https://vietnamnews.vn/society/449935/ministry-launches-electronic-health-record-software.html>.

18 'E-medical records' data to be connected among hospitals from July 1', *Viet Nam News Society*, 6 April 2021, available at <https://vietnamnews.vn/society/919143/e-medical-records-data-to-be-connected-among-hospitals-from-july-1.html>.

19 Law on Medical Examination and Treatment, Article 42.2.

20 Law on Medical Examination and Treatment, Articles 2.6, 6.2 and 17.

21 Law on Medical Examination and Treatment, Articles 26 and 45.

22 Law on Medical Examination and Treatment, Articles 5, 26, 28.4, 29, 45, 47 and 48; Circular No. 41/2011/TT-BYT, as amended ('Circular 41'), Article 41.

- e* family doctor clinics;
- f* traditional medicine diagnosis and treatment clinics;
- g* obstetrics clinics;
- h* diagnosis establishments;
- i* health service establishments;
- j* commune-level health centres and equivalents; and
- k* other forms of medical examination and treatment centres.²³

To obtain an operational licence, an institutional healthcare provider must first satisfy all the conditions as prescribed in the applicable regulations, and prepare and submit the application dossier to the competent authorities for their review and inspection.²⁴ Then, the operational licence shall be issued.

Providing healthcare services is a conditional business line.²⁵ One of the conditions is that each healthcare service provider is required to be granted with appropriate licences before provision of such services. Providing medical examinations and treatment without an operational licence is a prohibited activity,²⁶ and there are no exceptions or exemptions. Institutional healthcare providers without a valid operational licence are subject to a monetary penalty of up to 100 million dong, and suspension of their operations for a period up to 24 months, assuming the provider obtains an operational licence in the interim period.²⁷

The procedure for obtaining operational licences includes three main steps: (1) submitting the application dossier to the competent authorities (i.e., the MOH or DOH); (2) reviewing the application dossier and conducting on-site inspections; and (3) depending upon the results arising from step 2, the competent authorities either issue the operational licence, request the revision and modification of the application dossier, or send a notice with reasons for not issuing an operational licence.²⁸

There are general conditions applied to all medical examinations and treatment establishments, such as having a fixed location (except for a mobile establishment) and adequate medical equipment and instruments appropriate for the scope of professional medical activities, and each healthcare facility must have one person in charge with technical expertise.²⁹ Moreover, each form of medical examination and treatment establishment has specific conditions on facilities and infrastructure, medical devices and qualifications of key personnel.

23 Law on Medical Examination and Treatment, Article 41.1.

24 Law on Medical Examination and Treatment, Article 47; Decree No. 109/2016/ND-CP (Government, 1 July 2016) promulgating the issuance of professional certificates for practitioners and the issuance of operational licences for medical examination, treatment establishment, as amended by Decree No. 155/2018/ND-CP (Government, 12 November 2018) ('Decree 109'), Articles 44 and 45; Circular 41, Articles 41 and 42.

25 Law on Investment No. 61/2020/QH14 (National Assembly, 17 June 2020), Annex 4.

26 Law on Medical Examination and Treatment, Article 6.2.

27 Decree No. 117/2020/ND-CP (Government, 28 September 2020) providing administrative penalty for violation against medical sector (Decree 117), Articles 39.6(a) and 39.7(c).

28 Law on Medical Examination and Treatment, Article 47; Decree 109, Articles 44 and 45; Circular 41, Articles 41 and 42.

29 Decree 109, Articles 23 and 23a.

The operational licence shall be revoked under any one of the following cases:³⁰

- a* the operational licence was issued *ultra vires*;
- b* the institutional healthcare provider fails to meet conditions specified under the Law on Medical Examination and Treatment;
- c* the institutional healthcare provider fails to operate after 12 months from the date of the issuance of their operational licence; or
- d* the institutional healthcare provider suspends its operations for 12 consecutive months or terminates its operation.

Additionally, an operational licence may be suspended for up to 24 months in the event of certain violations, including if the institutional healthcare provider:

- a* fails to satisfy the eligibility requirements after obtaining the operational licence;
- b* employs HCPs who do not have practising certificates or have had practising certificates revoked or suspended;
- c* lends out, borrows or rents their operational licence;
- d* provides medical examination and treatment services beyond the scope of their operational licence, except for emergency treatment; and
- e* applies new methods for medical examination and treatment without the approval of the MOH Minister or DOH Director.³¹

A healthcare establishment subjected to a penalty is entitled to complain about such decision or decision in accordance with procedures prescribed in the Law on Complaints and Denunciations.³² In particular, it can file a complaint with the same authority that issued the penalty, or it may file a petition with the administrative court. In practice, violations (e.g., provision of medical examination and treatment services beyond the scope of the operational licence, except for an emergency treatment,³³ or not satisfying the conditions on facilities as required by law)³⁴ are often detected in private healthcare facilities, especially private clinics.

Healthcare professionals

Extensive regulation is applied to all HCPs providing healthcare services in Vietnam. HCPs comprise doctors, assistant doctors, nurses, midwives, technicians, herbalists, and owners of family herbal remedies or treatment methods.³⁵ Under Vietnamese law, pharmacists are not considered HCPs but are governed by the Pharmaceutical Law.

HCPs are entitled to practise technical techniques in accordance with the scope of their practising certificates.³⁶ The individual practitioner's scope of practice is determined by a range of factors that gives him or her the authority to perform a particular role or task. The

30 Law on Medical Examination and Treatment, Article 48.

31 Decree 117, Article 39.

32 Law on Medical Examination and Treatment, Article 79.

33 See <https://cuocsongantoan.vn/de-bac-si-nuoc-ngoai-hoat-dong-chui-mot-benh-vien-tai-tp-hcm-vua-bi-xu-phat-17152.html>.

34 See <http://sao.baophapluat.vn/tin-tuc/chi-tiet/bac-ninh-thu-hoi-giay-phep-vo-thoi-han-phong-kham-da-khoa-quoc-te-nhan-ai-6832/>; <https://dantri.com.vn/suc-khoe/ha-noi-thu-hoi-giay-phep-hoat-dong-kham-benh-chua-benh-cua-phong-kham-sai-pham-20190524155053922.htm>; <https://kinhtechnghoan.vn/tp-hcm-xu-phat-9-co-so-benh-vien-tu-nhan-vi-pham-quy-dinh-ve-kham-chua-benh-65392.html>.

35 Law on Medical Examination and Treatment, Article 17.

36 Law on Medical Examination and Treatment, Article 25.2(c).

scope of practice for HCPs in Vietnam is determined under Circular No. 35/2019/TT-BYT (MOH, 30 December 2019) pursuant to which several important factors are considered including, among other things, the quality of medical examination and treatment and patient safety; professional licences and certificates; and available support and resources. Failure to practise in accordance with his or her permitted professional scope might subject a healthcare professional to a monetary penalty of up to 40 million dong and the suspension of his or her practising certificate for a period of up to 24 months.³⁷

By law, HCPs must obtain practising certificates from the MOH or the provincial DOH, depending on their workplace and nationality, in order to practise in Vietnam.³⁸ The practising licence has an indefinite term and is valid nationwide.³⁹ To obtain the practising certificate, healthcare practitioners must satisfy certain requirements, including:

- a* having regulatory medical qualifications;
- b* having confirmation of practice experience;
- c* having certificates for practising medical examination and treatment; and
- d* not being prohibited from professional practice or work related to medical or pharmaceutical professions under any judgement or decision of a court, or as the result of being criminally prosecuted, serving penal sentences, etc.⁴⁰

In cases of revocation, healthcare professionals may apply for re-registration of their practising certificate provided that they comply with all above requirements and obtain the certificate on completing continuous medical education.⁴¹

If a foreigner practitioner wishes to practise healthcare in Vietnam, this person must have the following to obtain a practising certificate:

- a* relevant professional qualifications and practical experience;
- b* a certificate of language proficiency in medical examination, and medical treatment from a licensed education establishment;
- c* a criminal record or equivalent document certified by competent authorities of the practitioner's home country;⁴² and
- d* a work permit issued by a competent labour authority.⁴³

iii Negligence liability

In Vietnam, medical errors fall under the category of professional and technical errors in medical examination and treatment. According to the law and courts' approach, the legal responsibility due to professional and technical errors will be incurred by individual healthcare professionals rather than the institutional healthcare establishments.⁴⁴ Indeed,

³⁷ Decree 117, Articles 38.7(c) and 38.8(d).

³⁸ Law on Medical Examination and Treatment, Article 26.2; and Decree 109, Article 9.1(b).

³⁹ Law on Medical Examination and Treatment, Article 25.2.

⁴⁰ Law on Medical Examination and Treatment, Article 18.

⁴¹ Law on Medical Examination and Treatment, Article 20.

⁴² Criminal record (also known as criminal record certificate, police certificate, police check, judicial curriculum vitae or judicial record card in other jurisdictions) means a certificate issued by a state agency managing the criminal record database, to prove whether or not an individual has a previous criminal conviction.

⁴³ Law on Medical Examination and Treatment, Article 19.

⁴⁴ 'Compensation And Dispute Settlement In Medical Examination And Treatment Service Contracts According To Vietnamese Law', 15 June 2020, available at <http://www.lapphap.vn/Pages/TinTuc/210525/>

under the determination of a professional council – established by either the institutional healthcare establishment where the healthcare professional is working or by the in-charge healthcare provincial authority – a potentially negligent healthcare professional can be suspended from practising for having committed a violation of regulations on responsibilities for care and treatment of patients, a violation of professional and technical regulations and professional ethics, or an infringement of patients' rights.⁴⁵ The professional and technical error asserted must have resulted in a serious consequence to the health or the life of a patient. The healthcare professional will, therefore, lose his or her practising certificate unless the accident occurred and:

- a the healthcare professional has complied with professional and technical regulations in the medical examination and treatment;
- b it was an emergency case in which technical devices and equipment were lacking and qualified healthcare professionals were unavailable; or
- c during a force majeure event.⁴⁶

Under the Law on Medical Examination and Treatment, a healthcare establishment is required to purchase liability insurance for their healthcare professionals (including, among others, doctors, doctor assistants, nurses and midwives).⁴⁷ Thus, in addition to individual responsibility allocated to the HCP, the relevant healthcare establishment or its insurer (where applicable) is required to compensate for any losses and damage incurred by patients and their relations.⁴⁸ Furthermore, according to law, a conclusion of the professional council in relation to the professional and technical errors serves as a basis for the litigation agencies (e.g., courts, prosecutors) to consider in dispute settlement. If patients or their relations disagree with the professional council's conclusion, they can lodge a complaint to the supervisory authority (i.e., the in-charge healthcare provincial authority if the professional council is established by the institutional healthcare establishment, or the MOH if the in-charge healthcare provincial authority established the professional council) or submit a claim to the competent court. As a matter of litigation practice, despite receiving a conclusion from the professional council, the conclusions of a few competent agencies (e.g., the Forensic Medicine Center of Ho Chi Minh City, the National Institute of Forensic Medicine) have been used as the basis for hearings at the court of first instance.

The *Hoa Binh* case is one of the most relevant cases regarding the liability of institutional and individual healthcare providers in Vietnam.⁴⁹ In 2017, nine out of 18 patients who were all receiving dialysis treatment at an artificial kidney unit of Hoa Binh General Hospital simultaneously died after having manifested vomiting, itching and dizziness. Prosecutors judged the causes of such incident were the machines' water supply tubes not being purified correctly and the equipment and water quality not being properly inspected before the dialysis

Boi-thuong-thiet-hai-va-gjai-quyet-tranh-chap-trong-hop-dong-dich-vu-kham--chua-benh-theo-phap-luat-Viet-Nam.html.

45 Law on Medical Examination and Treatment, Articles 29.1(d), 29.3 and 73.1.

46 Law on Medical Examination and Treatment, Article 73.2.

47 Law on Medical Examination and Treatment, Article 78.

48 Law on Medical Examination and Treatment, Article 76.1.

49 Jail sentences announced in Hoa Binh deadly medical incident, source: <https://vietnaminsider.vn/jail-sentences-announced-in-hoa-binh-deadly-medical-incident/> | Doctor Hoang Cong Luong was sentenced to 30 months in prison, source: <https://e.vnexpress.net/news/news/doctor-in-dialysis-deaths-gets-a-year-off-jail-term-3940689.html>.

treatment was commenced. The managing doctor of the active resuscitation department was prosecuted for ‘unintentionally committing fatal actions’. The People’s Court of Hoa Binh province eventually sentenced the managing doctor to 30 months’ imprisonment.

V OWNERSHIP OF HEALTHCARE BUSINESSES

There are two kinds of healthcare systems running concurrently in Vietnam: one is the government hospitals, and the other is the private sector, which is owned by foreign and domestic investors. Overcrowding, shortage of medical staff and obsolete equipment for surgery and intensive care units are significant challenges in the healthcare system in Vietnam. Although Vietnam was considered a ‘poor country’ in 2013,⁵⁰ it now compares favourably to its South East Asian counterparts; its overall quality of care, in particular for basic primary care, appears surprisingly good, as evidenced by its success managing the coronavirus pandemic.

In addition to improving the government hospitals, facilitating the rise of private hospitals is the quickest and most feasible solution to improve the overall healthcare system. To promote the strengths of the private sector, the government has issued several policies to socialise healthcare and encourage private investment, especially investing in the high-end segment. In particular, among other things, investors can invest in healthcare establishments, pharmaceuticals, medical devices and medical training units. Foreign investments of up to 100 per cent are allowed in each of these sectors with certain conditions on the capital requirements, and many other tax incentives have been put in place. Besides the required minimum investment capital, foreign investors are subject to the same compulsory conditions for establishing healthcare facilities as Vietnamese investors, including but not limited to the scale of the facilities, quality of the facilities, medical equipment, organisation and personnel.

In addition to lifting the limitation on foreign ownership, several other incentives have been granted to inbound investment for healthcare services such as:

- a* the application of lower corporate income tax rates for a certain period of time;
- b* the exemption or reduction of import tax on goods imported that are used as fixed assets, raw materials or supplies for healthcare projects; and
- c* other exemptions, including a reduction of land rents and land levies.

Government policies and incentives for healthcare services have proven to have a positive effect on the Vietnamese healthcare system. In the past few years, the private sector has grown rapidly. A large number of private healthcare facilities have been established, and the number of beds per 10,000 people increased from 23.56 in 2011 to about 29 in 2021 and is now projected to be 29.5 in 2022.

While the country progresses economically, personal income and the standard of living are increasing exponentially as people become better educated and exposed to higher quality services offered in other countries. Annually, Vietnamese people travel abroad for medical treatment and spend up to US\$2 billion on medical tourism.⁵¹ This further highlights the

50 Ranking 135th in the world in 2013 (according to World Bank data) based on GDP per capita, see PwC Report ‘The Vietnamese healthcare industry: moving to next level’ source: <https://www.pwc.com/vn/en/advisory/deals/assets/the-vietnamese-healthcare-industry-moving-to-next-level-pwc-vietnam-en.pdf>.

51 ‘A rising trend in overseas treatment in Vietnam’, B&Company, 15 September 2019, available at <http://b-company.jp/en/2019/09/16/a-rising-trend-on-overseas-treatment-from-vietnam-citizens>.

new challenge for the Vietnamese healthcare system; namely, to compete internationally. It also sparks a desire for the private sector to create more efficient treatment facilities to bring Vietnamese healthcare closer in line with regional and international standards. However, based on the government's track record in healthcare policy, it is plausible to anticipate that the government will need to promote the healthcare system and attract foreign investment in healthcare services in Vietnam with a bundle of attractive policies, which will increase the volume of foreign investment in Vietnamese healthcare services, especially in the high-end segment. If not, Vietnam will continue to subsidise the wallets of doctors abroad, and the less fortunate will bear the burden of such a system.

VI MARKETING AND PROMOTION OF SERVICES

Due to the significant impact on individual and social well-being, healthcare services are considered an essential structure that requires the government's leadership. Consequently, healthcare promotions, advertising and other forms of marketing are strictly controlled by the state to prevent misleading messages and harm to patients as the result of healthcare advertisements.

Under Vietnam's regulations on advertising, healthcare businesses are categorised as a 'special service' and, hence, they must be strictly controlled with specific limitations and prohibitions, in particular:

- a* a prohibition on advertisement inaccuracies regarding the capabilities, professional qualifications or marketing beyond the scope of professionally licensed operations inscribed in the practising certificates and operational licences;⁵²
- b* a prohibition on advertisements taking advantage of traditional medicine or other medical knowledge to falsely advertise treatment methods and medicines;⁵³
- c* a requirement that individuals and organisations providing medical examinations and treatment services, which are advertised, must obtain regulatory certificates or licences for such activities issued by the competent authority;⁵⁴
- d* a requirement that healthcare advertisements are in accordance with licences for operation of medical examination and treatment in favour of institutional healthcare establishments or medical practising certificates in favour of healthcare practitioners, and contain certain regulatory information including, among other things, information regarding licensed healthcare establishments and the scope of professional activities provided in such licences;⁵⁵ and
- e* healthcare advertisements must be approved by the competent authority (i.e., the MOH or provincial DOH).⁵⁶

52 Law on Medical Examination and Treatment, Article 6.7.

53 Law on Medical Examination and Treatment, Article 6.7.

54 Law on Advertisement No. 16/2012/QH13 (National Assembly, 12 June 2012) as amended by Law No. 35/2018/QH14 (National Assembly, 20 November 2018), Article 20.4(e).

55 Decree No. 181/2013/ND-CP (Government, 21 February 2013) providing details for implementation several articles of Law on Advertisement, as amended from time to time (Decree 181), Article 9.1.

56 Decree 181, Article 12.1 and Circular No. 09/2015/TT-BYT (Ministry of Health, 25 May 2015) regarding provisions on confirmation of advertising contents in special products, goods, services under management of the Ministry of Health as amended by Circular No. 25/2018/TT-BYT (Ministry of Health, 28 September 2018), Article 12.

If healthcare advertising violates the aforementioned requirements, depending on the nature and severity of such violation, the healthcare professionals and establishments involved may be subject to a monetary fine of up to 80 million dong and suspension of their operational certificates for up to six months, and their advertisements must be removed.⁵⁷

Although Vietnamese law clearly states several requirements for healthcare advertisements and administrative sanctions, in practice there still may be a number of circumstances in which healthcare practitioners and establishments violate provisions on healthcare promotions and advertising for the purposes of maximising their profits, regardless of adverse impact on individuals' well-being. Recently, the state has used a range of compliance and enforcement tools to address and tackle non-compliant advertising including, but not limited to, implementing inspections on a regular basis and applying administrative penalties. For instance, the Inspection Division of the Department of Health of Ho Chi Minh City issued a decision regarding a monetary penalty of 61 million dong and forced removal of advertisements that exceeded the scope of licensed activities applicable to a clinic due to its non-compliant advertisements.⁵⁸

VII PROCUREMENT OF SERVICES AND GOODS

Owing to the characteristics of the healthcare system in Vietnam, the concept of commissioning is not recognised within the Vietnamese legal framework regulating healthcare. In particular, healthcare establishments must be established according to the law and organised in, among others, one of the following forms:

- a* general and specialised hospitals;
- b* general and specialised clinics;
- c* family medical facilities;
- d* maternity wards;
- e* medical service providers; and
- f* commune-level health stations.⁵⁹

Most of the general and specialised hospitals in Vietnam are established by the state. Hence, those hospitals are well connected to the social security system of Vietnam. Furthermore, the state hospitals are categorised as either being on the provincial or national level and subject to direct management, respectively, of the MOH or DOH.

Depending on the healthcare services' demand, patients can decide the healthcare establishment or hospital they wish to visit themselves based on the techniques and professions of such hospitals or references by the provincial or general hospital, rather than engaging a commissioning service. For example, with respect to common diseases, patients tend to visit the general hospital that is near to their homes or workplaces or otherwise more convenient for them. Medical treatment expenses will be fully or partially covered by their

57 Decree No. 38/2021/ND-CP (Government, 29 March 2021) regarding administrative penalties for violation on culture and advertising sectors, Article 56.

58 '61-million fine for a clinic to give an ad on hymenorrhaphy (hymenoplasty)' *Zing News*, 30 September 2019, available at <https://zingnews.vn/phat-61-trieu-dong-phong-kham-quang-cao-va-mang-trinh-post995898.html>.

59 Decree 109, Article 22.1.

social insurance. In some cases where the patient requires more intensive care (e.g., cancer, trauma and orthosis, otolaryngology), he or she will visit a specialist hospital for examination and treatment.

Given the foregoing practice, commissioning of healthcare services in Vietnam is neither common nor recognised by the Vietnamese legal framework.

VIII REIMBURSEMENT OF SERVICES AND GOODS

Under the Social Health Insurance scheme, insured members can receive benefits from any health facilities that have contracted with the Vietnam Social Security (VSS). The contracted health facilities include both public and private hospitals, with public providers being dominant.

The contracted providers are responsible for providing services for insured members and claiming the expenditure from the VSS using a fee-for-service (FFS) mechanism (i.e., the provider is reimbursed for each service provided). Subsequently, the VSS reviews the claims and reimburses the providers. In addition to FFS, capitation payments (i.e., the provider is paid in advance at a predetermined fixed rate to provide a defined set of services for each individual enrolled with the provider for a fixed period) were applied only for primary care providers from 2004, and payment by diagnosis-related group (i.e., the provider is paid at a fixed rate per discharge based on diagnosis, treatment and type of discharge) was defined by the 2008 Healthcare Insurance Law but has never been implemented in practice except for during the pilot period in 2009.

On the other hand, patients can pay for treatment themselves and claim reimbursement from the VSS afterwards.

IX DIGITAL HEALTH DEVELOPMENTS

Digital health in Vietnam is at an early stage of development, and limited to the adoption of the EHR, as discussed Section III.

X CORONAVIRUS

As of 7 June 2022, Vietnam's MOH confirmed a total of 10,726,045 cases of covid-19. However, 9,513,981 of the affected patients have recovered and been discharged from hospitals. The MOH reported that as of 6 March 2022, one year after implementing the covid-19 vaccination campaign, Vietnam has administered nearly 198.3 million doses of vaccines to people living in the country, becoming one of the six countries with the highest vaccination coverage in the world.⁶⁰

In parallel with the fight against the pandemic, the government has introduced the application of a vaccine passport, which is a certificate showing the bearer has completed a course of vaccination against covid-19 and is regulated by the Law on the Prevention and Control of Infectious Diseases and the International Health Quarantine Regulation. Bearers of vaccine passports do not have to undergo quarantine or take covid-19 tests when going

60 'Vietnam begins granting vaccine passports, with 500,000 issued on first day', 16 April 2022, available at <https://en.vietnamplus.vn/oneyear-covid19-vaccination-successful-shield-campaign/223202.vnp>.

abroad. On 20 December 2021, the MOH issued Official Dispatch No. 8938/BYT-DP providing instructions about procedures for verification of covid-19 vaccination information and covid-19 vaccination. As of April 2022, nearly 500,000 Vietnamese people have vaccine passports.⁶¹

The MOH has proposed changing the stringent 5K message on prevention measures⁶² to V2K (meaning vaccination, mask and hand washing/disinfection) after consulting with the National Steering Committee for COVID-19 response. However, the 5K message will be reintroduced if new virus strains emerge and affect people's health, as stated by the Vice Minister for Health. According to the MOH, the pandemic has been brought under control nationwide; however, it is still on the list of Group A infectious diseases (extremely dangerous diseases), and therefore measures such as wearing masks and vaccination shall not be removed.

XI FUTURE OUTLOOK AND NEW OPPORTUNITIES

After 10 years of implementation, the Law on Medical Examination and Treatment has created an important legal framework for the care and protection of people's health through the management of medical activities, ensuring the rights of patients. However, it has exposed a number of shortcomings and limitations, making it no longer suitable given the current reality. The amended version of the Law on Medical Examination and Treatment is under discussion, and shall contain three chapters more than the current Law. It is expected to be built around 'placing patients at the centre'.⁶³

One significant growth opportunity in Vietnam is inbound medical tourism. Indeed, according to the MOH, many patients from other ASEAN countries choose Vietnam, more specifically Phu Quoc Island, Vung Tau, Nha Trang or Da Nang,⁶⁴ for some specific medical services (e.g., cosmetic surgery, dental care). Foreigners find Vietnam's healthcare attractive thanks to its 'political stability, affordability, and relatively good medical care'. At the same time, however, Vietnamese people travel abroad when it comes to specific and technical healthcare (e.g., complex medical treatment).⁶⁵

Moreover, as only 8.3 per cent of the population in Vietnam reaches the age of 65, the healthcare services dedicated to the elderly are insufficient to ensure suitable and adapted care. Vietnam must improve more quickly to comply with the evolution of life expectancy and enhancing life expectancy by ensuring a sustainable healthcare environment for its

61 'Vietnam begins granting vaccine passports, with 500,000 issued on first day', 16 April 2022, available at <https://tuoitrenews.vn/news/society/20220416/vietnam-begins-granting-vaccine-passports-with-500000-issued-on-first-day/66667.html>.

62 The 5K message comprises *khau trang* (face masks), *khử khuẩn* (disinfection), *khoang cach* (distancing), *khong tu tap* (no gatherings), and *khai bao y te* (health declarations).

63 'Deputies debate revision of Law on Medical Examination and Treatment', 13 June 2022, available at <https://en.vietnamplus.vn/deputies-debate-revision-of-law-on-medical-examination-and-treatment/229187.vnp>.

64 'Vietnam's tourism: Sector Opportunities for Investors 2020', *Vietnam Briefing*, 13 December 2019, available at <https://www.vietnam-briefing.com/news/vietnams-tourism-sector-opportunities-investors-2020.html/>.

65 'Fostering Medical Tourism on the Agenda of the Health Ministry Conference', *Vietnam Briefing*, 18 December 2019, available at <http://vietnamnews.vn/society/570009/fostering-medical-tourism-on-the-agenda-of-healthministry-conference.html#T24z5mDwtm8mkYsH.99>.

patients.⁶⁶ As a positive sign of such developments, intelligent tools are being increasingly implanted within Vietnamese medical structures, such as ‘nurse robots’ in some of Ho Chi Minh City’s hospitals. These robots notably can recognise faces, give directions and basic medical advice, prevent wrongful forms of behaviour, communicate in several languages and programme medical appointments. High-technology equipment is considered Vietnam’s priority for development and shows positive results in terms of hospital management and patient monitoring.

XII CONCLUSIONS

Vietnam’s healthcare system has made significant positive developments over the past three decades. In 2000, Vietnam was on the list of the least developed countries in the world, whereas in 2020 Vietnam was classed as a middle-income country. Its healthcare system and its healthcare outcomes are largely reflective of this singular economic achievement. In addition to serving as a poster child of the World Bank and the World Health Organization, Vietnam’s most recent successes managing the coronavirus epidemic reflect the advanced state of its healthcare infrastructure. However, in the coming decade, additional foreign investment in private hospitals and clinics will be necessary to ensure that Vietnam’s outbound medical tourism comes to an end. This is a great opportunity for foreign investors seeking opportunities in Vietnam.

⁶⁶ ‘Vietnam to become Super-aging Country by 2050’, *Vietnam Plus*, 12 December 2019, available at <https://en.vietnamplus.vn/vietnam-to-become-superaging-country-by-2050/165321.vnp>.

ABOUT THE AUTHORS

ELI MAZUR

YKVN

Eli Mazur has been a trusted adviser for nearly two decades for multinational companies operating in Vietnam, including in the life sciences and healthcare sectors.

Eli is the founding partner of YKVN's life sciences practice, where he acts, or has acted, for Pfizer, Sanofi, Roche, Merck, MSD, Bayer, Ferring, AstraZeneca and many other multinational pharmaceutical companies, including both Fortune 500 healthcare companies and domestic pharmaceutical companies with international ambitions.

As the retained counsel for over six years for EUROCHAM's pharma group – the industry's only association or committee that has a significant impact on the promulgation, implementation and regulation of Vietnamese law in the pharmaceutical sector – Eli advised the pharma group on legal compliance and submitting sector comments on the new Pharmaceutical Law and its implementing regulations.

Eli originally came to Vietnam in 2003 as a senior research associate with the Vietnam programme, Harvard University, and led the law and public policy programme at the Fulbright economics teaching programme in Ho Chi Minh City. Before joining YKVN LLC in 2010, Eli spent more than three years in the Vietnam project finance practice of Freshfields Bruckhaus Deringer. Eli is a fluent speaker of the Vietnamese language, having spent his first three years in Vietnam learning the language.

From 2018 to 2022, Eli has been recognised as the top pharmaceutical adviser in Vietnam by three different organisations.

Eli is a US qualified lawyer and a registered foreign lawyer in Vietnam, and is highly regarded by clients as a problem solver, a crisis mitigation expert and a commercially oriented, practical adviser, with the ability to add true value to a company's bottom line with, among other things, his ability to assist clients develop and maintain successful long-term commercial partnerships in Vietnam.

VU TUAN DUC

YKVN

Vu Tuan Duc is a key member and manager of YKVN's elite healthcare and pharmaceutical practice. Duc is unique among Vietnamese lawyers, as his entire legal training and career has been dedicated to advising clients in the innovative pharmaceutical sector. After years of advising pharma MNCs with operations in Vietnam, Duc has not only built strong connections with clients but also possesses a deep understanding of the industry, legal

framework, and the central and provincial agencies and officials with the responsibility for interpreting and implementing the regulations. Duc's familiarity with the pharmaceutical industry enables him to distil the 'essence' of regulations and give quality, practical and value-added commercial advice to his clients.

Duc remains the trusted counsel for several leading global pharma MNCs with operations in Vietnam, as well as the pharmaceutical association in Vietnam. He is an expert in advising on legislative developments and policy (such as the new pharmaceutical law, and implementing decrees, circulars and official letters) and assisting clients to adjust business models that maintain full legal compliance and optimise commercial results.

YKVN

Suite 1102 The Metropolitan
235 Dong Khoi Street, District 1
Ho Chi Minh City
Vietnam
Tel: +84 28 3822 3155
eli.mazur@ykvnlaw.com
duc.vu@ykvnlaw.com
www.ykvnlaw.com

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