

THE HEALTHCARE
LAW REVIEW

FIFTH EDITION

Editor
Sarah Ellson

THE LAWREVIEWS

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PREFACE

Welcome to the fifth edition of *The Healthcare Law Review*. In 2020, we made reference to the covid-19 pandemic and paid tribute to the commitment shown by all working in the sector: the healthcare professionals, the organisational leaders, all staff working in health and social care environments, and the scientists and public health officials seeking to navigate nations through this crisis. Little did we know how this would continue to dominate our lives throughout 2021 and what ingenuity and resilience it would ask of these professionals. This review provides an introduction to healthcare economies and their legal frameworks in 13 jurisdictions, with chapters including Cambodia, Malta and Vietnam. Every country will have been touched by the pandemic and, of course, each has responded in a different way. Some leading healthcare systems have been overwhelmed at times, many have been revealed as vulnerable and limited, and internationally governments and the private sector have shown their ability to innovate, expand capacity and ask more of their systems and professionals than was ever thought possible. The speed with which the vaccines have been developed has defied all previous expectations, and as the world works towards global vaccination we have a new vocabulary and a realisation that we will be expected to live with this new virus.

Our expert authors have reviewed and updated their chapters to reflect the ever-evolving situation in the jurisdictions covered in earlier editions. At the time of writing, many countries were still subject to emergency legislation and altered priorities. The legal position is subject to constant review as countries move through positions in relation to the scale and spread of the coronavirus and the roll-out of vaccination programmes. This review does not seek to navigate the rapidly changing pandemic-based positions, but this year's chapters reveal how underlying systems have changed and may be expected to adapt as a result. As previously, the book reveals both diverse areas of practice and the common challenges and similar approaches in very different countries.

Previous editions considered the rapid expansion of telehealth and telemedicine but few could have foreseen the 3,000 per cent increase in online consultations reported in a number of jurisdictions as we went into lockdown. Regulations, laws and reimbursement had to be revised or rewritten overnight. We will undoubtedly emerge with a newfound confidence about what care can and should be delivered remotely, where the risks that need to be regulated are, and where to prioritise face-to-face interactions between patients and healthcare professionals.

Scopes of practice have been revisited with professionals fulfilling roles outside their usual remit and the recently retired being brought back into practice, often in non-frontline roles, allowing current practitioners to step forward.

Every country wants a health system that cares for the sick and promotes the well-being of its people. Every nation wants to raise the bar to keep up with improving living standards

and expectations. However, every economy requires this to be done at an affordable price. Managing the costs of healthcare and workforce shortages, and ensuring a sustainable model of delivery, have been seen as key drivers in each of the countries covered in this publication. Countries around the world realise that excess deaths and heightened morbidity during the pandemic are not just from coronavirus. Many patients have not attended healthcare facilities for other illnesses or ongoing treatment, and getting care back on track at a time of economic recession with depleted resources and an exhausted workforce will be tough. The virus has asked huge questions of our healthcare systems, and populations will be re-evaluating expectations in the months and years ahead.

Integration between health and wider social care continues to be a key topic, and in countries where care-home mortality has been devastating, further questions are being raised about how social care is expected to operate in conjunction with existing hospital and hospice settings.

This publication identifies the broad characteristics of healthcare to be found in each jurisdiction. It considers: the role of insurance or public payers; models of commissioning; the interplay (or lack of it) between primary, secondary and social care; and the regulatory and licensing arrangements for healthcare providers and professionals.

These have been unprecedented times for the delivery of healthcare and have laid down challenges and opened opportunities. Each chapter describes a country's healthcare ecosystems. I would like to thank the many leading experts for the time and attention they have given to this project, and also the wider team at Law Business Research for their support and organisation.

Sarah Ellson
Fieldfisher LLP
London
August 2021

VIETNAM

Eli Mazur, Nguyen Thuy My and Nguyen Phuoc Hang¹

I OVERVIEW

As at 15 July 2021, Vietnam was undergoing the fourth wave of covid-19 with 12,620 cases of infection and 207 deaths due to the pandemic recorded.² However, 8,591 of the affected patients recovered and were discharged from hospitals thanks to the tireless efforts of healthcare professionals.

To fight the pandemic, on 8 March 2021 Vietnam launched its covid-19 vaccination campaign and approximately 4 per cent of the population have been vaccinated to date. The country is seeking around 150 million doses to cover 70 per cent of its population by the end of the first quarter of 2022.³

Owing to the complicated situation caused by the pandemic, Vietnam's healthcare system is facing various difficulties and is being continuously tested.

This chapter is a short summary of Vietnam's developing healthcare system. We have set forth a basic overview that 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 Vietnamese 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 by 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),⁴ which will considerably increase trade and investment for pharmaceutical/medicinal products

1 Eli Mazur is a partner and Nguyen Thuy My and Nguyen Phuoc Hang are managers at YKVN.

2 The figures are regularly updated by the Ministry of Health of Vietnam, available at <https://ncov.moh.gov.vn/>.

3 'Two Million Doses of Moderna Vaccines Donated by USA through the COVAX Facility Arrive in Viet Nam', UNICEF, 9 July 2021, available at <https://www.unicef.org/vietnam/press-releases/two-million-doses-moderna-vaccines-donated-usa-through-covax-facility-arrive-viet>.

4 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.

and medical devices⁵ from the European Union, as the 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 European Union, these new treaties will have a significant impact on the health of Vietnamese patients, the treatment of diseases in Vietnam, and hopefully, on competition in the market by lowering prices for such drugs.⁶

ii The role of health insurance

In Vietnam, as at 2019, 87.2 per cent of people enjoyed UHC,⁷ which ensures all individuals and communities access to good-quality health services that are affordable.⁸ At the same time, unfortunately, there is an imbalance of 'supply and demand' between supply and demand for hospital beds in Vietnamese hospitals.⁹ The number of patients needing treatment for diseases¹⁰ and the overcrowded hospitals are a challenge 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 BOT 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 a Vietnamese healthcare sector, in general – particularly for 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 identified (1) medical examination and treatment facilities, (2) preventive healthcare, and (3) 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'.¹¹ In Vietnam, the pricing of healthcare services is publicly determined by the MOH and calculated each year based on

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

6 'Direct import for Pharma Group', Vietnam Investment Review, 21 August 2019, available at <https://www.vir.com.vn/direct-imports-for-pharma-groups-70050.html>.

7 EuroCham White Book 2019, pages 142–143.

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

9 EuroCham White Book 2018, pages 134–135.

10 '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.

11 EuroCham White Book 2019, pages 145–146.

a combination of market mechanics and socioeconomic realities.¹² Thus, a locally produced drug will not necessarily be automatically subjected to a low price required by law,¹³ and, 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.

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.¹⁴ The state healthcare facilities are divided into four levels by administrative structure: central, provincial, district and commune.¹⁵ 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, is found in Section 1, Part I of the Hospital Regulations issued with Decision 1895/1997/QĐ-BYT. According to Vietnamese law, a hospital is a facility for medical examination, treatment and healthcare for patients, which has the main tasks of medical examination and treatment; training of officials; scientific research; directing routes; disease prevention; international cooperation; and economic management. The applicable laws are, essentially, the Law on Medical Examination and Treatment and Decision 1895/1997/QĐ-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).¹⁶

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 2012–2020¹⁷ aiming to improve the quality of care for older people, as well as the Health Care for the Elderly Project for the period 2017–2025.¹⁸

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 to protect their rights and obligations during medical examinations and treatments. Consequently, in June 2019, the Vietnamese Deputy Minister

12 '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>.

13 EuroCham White Book 2018, page 127.

14 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.

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

16 Law on Medical Examination and Treatment, Article 6.

17 Issued after the Decision No. 1781/QĐ-TTg issued in 2012.

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

of Health announced the launch of electronic health records (HER) pilots in eight provinces and cities of Vietnam. These technological tools aim to improve the management of healthcare services thanks to direct access to blood group diseases, allergies and other relevant health data of Vietnamese patients.¹⁹ From April 2021, HER has been standardised and used nationwide in 50 provinces and cities, and there are plans for the system to be connected with hospitals and health facilities across the country from 1 July 2021.²⁰

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 are 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 (the operational licence).²¹ Similarly, any healthcare professional is required to have a practising certificate (the practising certificate).²² The operational licence and the 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.²³

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 of licences and certificates and inspect any violations.²⁴

ii Institutional healthcare providers

Under Vietnamese Law, an institution providing healthcare services can be organised under the following forms: hospital; medical assessment establishments; general clinics; specialised clinics, family doctor clinics; traditional medicine diagnosis and treatment clinics; obstetrics clinics; diagnosis establishments; health service establishments; commune-level health centres

19 '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>.

20 '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>.

21 Law on Medical Examination and Treatment, Article 42.2.

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

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

24 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.

and equivalents; and other forms of medical examination and treatment centres.²⁵ To obtain an operational licence, an institutional healthcare provider must first satisfy all the conditions as prescribed in applicable regulations, prepare and submit the application dossier to the competent authorities for their review and inspection.²⁶ Then, the operational licence shall be issued.

Providing healthcare services is a conditional business line.²⁷ 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 activity²⁸ and there are no exceptions or exemptions. The 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.²⁹

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 from Step 2, the competent authorities issue either the operational licence, request to revise and modify the application dossier, or send a notice with reasons for not issuing an operational licence.³⁰

There are general conditions applied to all medical examinations and treatment establishments, such as having a fixed location (except for a mobile establishment), having 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.³¹ Moreover, each form of medical examination and treatment establishment has specific conditions on facilities and infrastructure, medical devices, and qualifications of key personnel.

The operational licence shall be revoked under any one of the following cases:³²

- 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.

25 Law on Medical Examination and Treatment, Article 41.1.

26 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.

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

28 Law on Medical Examination and Treatment, Article 6.2.

29 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).

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

31 Decree 109, Articles 23 and 23a.

32 Law on Medical Examination and Treatment, Article 48.

Additionally, an operational licence may be suspended for up to 24 months in the event of certain violations, including if the institutional healthcare provider: (1) fails to satisfy the eligibility requirements after obtaining the operational licence; (2) employs HCPs who do not have practising certificates or have practising certificates revoked or suspended; (3) lends out, borrows or rents their operational licence; (4) provides medical examination and treatment services beyond the scope of their operational licence, except for emergency treatment; and (5) applies new methods for medical examination and treatment without the approval of the MOH Minister or DOH Director.³³ A healthcare establishment subjected to a penalty is entitled to complain about such decision or decisions in accordance with procedures prescribed in the Law on Complaints and Denunciations.³⁴ 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,³⁵ or not satisfying the conditions on facilities as required by law)³⁶ are often detected in private healthcare facilities, especially private clinics.

iii 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.³⁷ 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.³⁸ The individual practitioner's scope of practice is determined by a range of factors that gives them the authority to perform a particular role or task. The 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 others: (1) quality of medical examination and treatment and patient safety; (2) professional licences and certificates; and (3) 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 their practising certificate for a period of up to 24 months.³⁹

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.⁴⁰ The practising licence has an indefinite term and is valid nationwide.⁴¹ For obtaining the

33 Decree 117, Article 39.

34 Law on Medical Examination and Treatment, Article 79.

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

36 See <http://sao.baophaplaut.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://kinhtechungkhoan.vn/tp-hcm-xu-phat-9-co-so-benh-vien-tu-nhan-vi-pham-quy-dinh-ve-kham-chua-benh-65392.html>.

37 Law on Medical Examination and Treatment, Article 17.

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

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

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

41 Law on Medical Examination and Treatment, Article 25.2.

practising certificate, the healthcare practitioners must satisfy certain requirements, including: (1) having regulatory medical qualifications; (2) having confirmation on practice experience; (3) having certificates for practising medical examination and treatment; and (4) 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.⁴² In case of revocation, the healthcare professional 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.⁴³

If a foreigner practitioner wishes to practise healthcare in Vietnam, this person must have the following to obtain a practising certificate: (1) relevant professional qualifications and practical experience); (2) a certificate on language proficiency in medical examination, and medical treatment from a licensed education establishment; (3) a criminal record or equivalent document certified by competent authorities of the practitioner's home country;⁴⁴ and (4) a work permit issued by a competent labour authority.⁴⁵

V NEGLIGENCE LIABILITY

In Vietnam, medical errors fall into 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.⁴⁶ Indeed, 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 (1) a violation of regulations on responsibilities for care and treatment of patients, (2) a violation of professional and technical regulations and professional ethics, or (3) an infringement of patients' rights.⁴⁷ 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 their practising certificate, unless the accident occurred and (1) the healthcare professional has complied with professional and technical regulations in medical examination and treatment, or (2) it was an emergency case in which technical devices and equipment were lacking and qualified healthcare professionals were unavailable, or (3) during a force majeure event.⁴⁸

42 Law on Medical Examination and Treatment, Article 18.

43 Law on Medical Examination and Treatment, Article 20.

44 Criminal record (also known as 'criminal record certificate', 'police certificate', 'police check', 'judicial curriculum vitae', '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.

45 Law on Medical Examination and Treatment, Article 19.

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

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

48 Law on Medical Examination and Treatment, Article 73.2.

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, midwives).⁴⁹ 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 damages incurred by patients and their relations.⁵⁰ 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 the 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 getting 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.⁵¹ 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: (1) the water supply for filtering; (2) haemodialysis; and (3) the equipment had not been properly inspected. 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.

VI 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 2013,⁵² 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.

49 Law on Medical Examination and Treatment, Article 78.

50 Law on Medical Examination and Treatment, Article 76.1.

51 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>.

52 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>.

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: (1) application of a lower corporate income tax rates for a certain period of time; (2) exemption or reduction of import tax on goods imported, which are used as fixed assets, raw materials, or supplies for healthcare projects; and (3) other exemptions, including 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 both in size and number. A large number of private healthcare facilities have been established, and the number of beds per 10,000 people has increased from 23.56 in 2011 to about 29 in 2018.

While the country progresses economically, personal income and standard of living increase exponentially as people are becoming 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.⁵³ That further highlights the new challenge of the Vietnamese healthcare system; namely, to compete internationally. It also sparks a desire by the private sector to create more efficient treatment facilities to bring Vietnamese healthcare closer to 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.

VII COMMISSIONING AND PROCUREMENT

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 one of the following forms, among others: (1) general and specialised hospitals; (2) general and specialised clinics; (3) family medical facilities; (4) maternity wards; (5) medical service providers; and (6) commune-level health stations.⁵⁴ Most of the general and specialised hospitals in Vietnam are established by the state. Hence, those hospitals are well connected to

53 '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>.

54 Decree 109, Article 22.1.

the social security system of Vietnam. Furthermore, the state hospitals are categorised as either being on the provincial or national levels 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, which is near to their homes or workplaces or otherwise more convenient for them. Medical treatment expenses will be fully or partially covered by their 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 MARKETING AND PROMOTION OF SERVICES

Due to the significant impact on individual and social well-being, healthcare services are considered as 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: (1) a prohibition on advertisement inaccuracy for the capabilities, professional qualifications, or marketing beyond the scope of professionally licensed operations inscribed in the practising certificates and operational licences;⁵⁵ (2) a prohibition on advertisement taking advantage of traditional medicine or other medical knowledge to falsely advertise treatment methods and medicines;⁵⁶ (3) 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;⁵⁷ (4) 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 others, information regarding

55 Law on Medical Examination and Treatment, Article 6.7.

56 Law on Medical Examination and Treatment, Article 6.7.

57 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).

licensed healthcare establishments and the scope of professional activities provided in such licences;⁵⁸ and (5) healthcare advertisements must be approved by the competent authority (i.e., the MOH or provincial DOH).⁵⁹

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, suspension of their operational certificates for up to six months and their advertisements must be removed.⁶⁰

Though Vietnamese law clearly states several requirements for healthcare advertisements and administrative sanctions, in practice, however, 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 has 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.⁶¹

IX CORONAVIRUS

Wearing masks and social distancing help to reduce the chances of being exposed to the virus or spreading it to others. However, vaccines play a fundamental role in stopping the covid-19 pandemic.⁶² The importation and manufacture of vaccines for emergency purposes is critical.

A drug (including a vaccine) without a marketing authorisation in Vietnam may be licensed for import if it serves the emergency purpose of preventing and eliminating epidemics,⁶³ provided that it (1) has been licensed in at least one other country, and (2) approved by the MOH as suitable for urgent epidemic control.⁶⁴ Indeed, as at mid-July 2021, the MOH had issued several decisions on conditional approval of vaccines for emergency use

58 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.

59 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.

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

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

62 'How quickly could COVID-19 vaccines stop the pandemic?', World Health Organization, 28 October 2020, available at [https://www.who.int/news-room/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines](https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines).

63 Pharmaceutical Law No. 105/2016/QH13 (National Assembly, 6 April 2016) (Pharma Law), Article 60.2(c).

64 Decree No. 54/2017/ND-CP (Government, 8 May 2017) providing guidelines for implementation of the Pharma Law, as amended by Decree No. 155/2018/ND-CP (Government, 12 November 2018), Article 67.

in covid-19 prevention on the basis of Article 60.2(c) of the Pharma Law for the following vaccines: AstraZeneca, Sputnik V, Vero Cell (or SinoVac), Moderna, Pfizer-BioNTech and Janssen.⁶⁵

In parallel with the fight against the pandemic, the Vietnamese government is considering other measures to help the economy to recover. One of the measures is 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 would not have to undergo quarantine or take covid-19 tests when going abroad. Currently, the competent authorities are studying the international practices, evaluating the feasibility and proposing a pilot solution for vaccine passports.⁶⁶

X FUTURE OUTLOOK AND NEW OPPORTUNITIES

One of the significant growth opportunities 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,⁶⁷ for some specific medical services (e.g., cosmetic surgery, dental care). Foreigners find the attractiveness in Vietnam's healthcare thanks to its 'political stability, affordability, and relatively good medical care'. At the same time, nevertheless, Vietnamese people travel abroad when it comes to specific and technical healthcare (e.g., complex medical treatment).⁶⁸

Moreover, as only 8.3 per cent of the population in Vietnam reaches the age of 65, the healthcare services dedicated to the elderly shows insufficiency for ensuring suitable and adapted care. Vietnam must improve faster to comply with the evolution of life expectancy and enhancing life expectancy by ensuring a sustainable healthcare environment for its patients.⁶⁹ 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.

65 'Viet Nam approves Janssen COVID-19 vaccine for emergency use', Online Newspaper of The Government of The Socialist Republic of Viet Nam, 15 July 2021, available at <http://news.chinhphu.vn/Home/Viet-Nam-approves-Janssen-COVID19-vaccine-for-emergency-use/20217/44640.vgp>.

66 'Vietnam's top leaders consider vaccine passport', *Hanoitimes - Economic and Urban Newspaper*, 13 June 2021, available at <http://hanoitimes.vn/vietnams-top-leaders-consider-vaccine-passport-317727.html>.

67 '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/>.

68 '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>.

69 '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>.

XI CONCLUSIONS

Vietnam's healthcare system has made major 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 is 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.

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For nearly two decades, Eli has been a trusted adviser 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 group, as well as a partner in YKVN's project finance practice group. Over the years, Eli has acted for lenders and sponsors on a number of the largest projects to reach financial close in Vietnam, including, but not limited to, Mong Duong II. Eli is presently engaged in both traditional and green energy projects in various stages of project development and financing.

In 2018, Eli was recognised as a 'leading lawyer' in corporate and M&A by *AsiaLaw*, as well as in 2018–2020 as the 'top pharmaceutical adviser' in Vietnam by three different organisations.

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My remains the trusted counsel for several leading global pharma MNCs with operations in Vietnam, as well as the pharmaceutical association in Vietnam. She 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, which maintain full legal compliance and optimise commercial results.

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