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

Chapter 8

SAUDI ARABIA

Nabil A Issa[1]

I OVERVIEW

The Kingdom of Saudi Arabia has continued to witness dramatic cultural and legal changes in recent years. The Ministry of Health (MOH) and Ministry of Investment of Saudi Arabia (MISA) recently approved certain liberalisations in relation to the operation of pharmaceutical warehouses.

Saudi Arabia is a critical jurisdiction for any party investing in the Middle East, partly because it is the largest economy in the Middle East and while oil wealth has brought new opportunities it has led to a growing occurrence of lifestyle diseases, such as diabetes and heart disease.[2] Although Saudi Arabia is working hard on a campaign to encourage daily exercise and is expected to impose tougher standards on imported food in relation to sugar and salt, it is not believed these lifestyle diseases will dramatically change in the short term. Moreover, similar to other countries around the world, Saudi Arabia is dealing with the issues in relation to the covid-19 pandemic. Saudi Arabia is challenged by a population demanding the latest technology and is establishing new medical colleges and partnering with international players. For example, Saudi Aramco Medical Services teamed up with Johns Hopkins to form Johns Hopkins Aramco Healthcare and Ashmore is bringing King's College London to Saudi Arabia. Even in the midst of the covid-19 pandemic, Gulf Capital was able to successfully exit an investment in radiology clinics in Saudi Arabia. A new healthcare city is currently being developed in Riyadh. Also, foreign private equity groups and operators such as Gulf Capital, TVM Healthcare, Mediterranea Capital, Investcorp, Fajr Capital, KIMS Healthcare and others have recently announced healthcare investments or intentions to invest in the Kingdom. Moreover, a number of healthcare groups have used the liberalisation of the healthcare sector to partially reorganise. The MOH is reviewing its next set of awards for dialysis clinics in Saudi Arabia. The MOH has retained a number of the world's leading consultants to explore implementing public–private partnerships and privatisations in the healthcare sector. The first privatisation of a healthcare centre was concluded in November 2019 when Soliman Fakeeh became a partial shareholder in Saudi Arabian Airline's medical centre. On 22 June 2021, the Saudi Food and Drug Authority (SFDA) prepared an update on the 'Transparency and Payments Disclosure Guidance for Medical and Food Companies' clarifying the limit and disclosure for training and education spending by food and drug companies on physicians and medical institutions.

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1 Nabil A Issa is a partner at King & Spalding LLP, which operates in cooperation with the Law Office of Mohammed AlAmmar.

2 See Correspondents, Saudi Arabia's Healthcare Market Witnessing Exponential Growth, *Khaleej Times*, 35, 27 August 2009.

The MOH is the regulator for most of the healthcare sector in Saudi Arabia. The Ministry of Defence, including the National Guard, maintains its own standards, but we understand this is expected to change soon and this responsibility will fall within the purview of the MOH.

The government of Saudi Arabia has established certain regulatory reforms to encourage investment in the healthcare sector by the private sector. The healthcare sector is undergoing constant change because of its high importance for Saudi Arabian nationals, and certain agencies have overlapping responsibilities, as described below.

II THE HEALTHCARE ECONOMY

The Council of Cooperative Health Insurance previously made it mandatory for all business owners to have medical insurance cover for their workers from the date of their arrival, and to hand them insurance cards within 10 days of their arrival in Saudi Arabia. According to the council's relatively new regulations, the insurance coverage becomes invalid only in the event of the beneficiary's death, cancellation or expiry of his or her insurance documents, or if he or she leaves Saudi Arabia on an exit-only visa. Married workers' medical insurance should cover pregnancy and childbirth. Article 7 of the Cooperative Health Insurance System also requires owners of private hospitals to provide medical insurance to their foreign workers.

The first stage of this compulsory insurance was introduced in 2006 and covered all workplaces with more than 500 people. This was followed by the next stage, introduced in the second half of 2007, which mandated all workplaces with fewer than 500 employees to also adopt the policy. Now, all companies with fewer than 500 employees that are renewing business licences must provide proof that expatriate medical insurance is available for all staff. This policy was a major shift in the Saudi market, although the main players in the industry – pharmaceutical companies, insurers and healthcare providers – are still at odds as to who benefits the most in the new landscape.

Eventually, all Saudi citizens will need to be covered by medical insurance, as the free medical healthcare programme is under stress from a large population with lifestyle diseases in an age of dwindling public resources. In preparation of the privatisation of public hospitals, Saudi Arabia is looking to create a form of insurance for those in the public sector.

The introduction of mandatory health insurance for expatriates, and insurance reform in general, has certainly shaken up the healthcare market in Saudi Arabia, providing a great amount of potential for pharmaceutical companies, laboratories, insurers and healthcare providers.

All Saudi Arabian insurance companies are required to be listed companies in Saudi Arabia. There are a number of insurance companies that are partly owned by foreign parties such as BUPA, Munich RE and AXA.

III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

Privately owned healthcare institutions, which offer treatment, diagnostic, laboratory, rehabilitation and nursing services (private healthcare institutions), are classified under the relevant regulations as one of the following:

a hospitals that are equipped to diagnose, treat and admit patients on an inpatient basis;

b general health centres prepared to diagnose and treat patients that offer at least three medical specialisations;

c specialised healthcare centres that focus on one medical speciality or more;
d physician office (clinics) prepared for treatment and diagnosis of patients;
e radiology centres for diagnostic imaging and radiology treatment;
f medical laboratories;
g same-day surgical facilities (i.e., ambulatory surgery centres) that are licensed to admit patients for minor and medium surgeries, provided that patients are discharged on the same day of admission;
h supporting medical services facilities that provide complementary medical and technical services and include: physical therapy centres, vision, nutrition centres, artificial limbs, or any other facilities that are classified as a supporting medical facility by the MOH; or
i medical transport services that include transport and first aid for patients before admission to hospitals in accordance with the standards and requirements of the Saudi Red Crescent Society.

The premises of all private healthcare institutions must be compliant with the medical and technical requirements historically designated by the MOH and must be equipped with the necessary medical equipment and furniture. In addition, a private healthcare institution must have appropriate systems for medical waste disposal, prevention of infection and medical records filing.

There is a wide range of both medical clinics and hospitals in Saudi Arabia. It is normally possible to obtain direct access to hospitals without the need for a referral.

There are strict data privacy laws that do not permit the storage of patient information outside Saudi Arabia.

There are some unusual approvals that may be required by a woman's husband or guardian prior to undertaking certain medical procedures. For example, a woman is required to obtain written permission from her husband or guardian prior to undertaking a hysterectomy, unless it is required in a life-threatening situation.

For certain procedures, it is common for Saudi Arabian nationals to obtain government approval and funding from the MOH for treatment outside Saudi Arabia. The United States and Germany are two of the most common destinations for treatment of Saudi Arabian nationals.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

Medical staff, including doctors and pharmacists, must be properly licensed by the MOH and the General Directorate of Health Affairs in accordance with the Healthcare Profession Practice Regulations, including any regulations or circulars published by the Saudi Commission for Health Specialties, which is the regulatory body responsible for licensing doctors.

In respect of employment, please note the following:

a each hospital must appoint a locally qualified doctor of Saudi nationality as a medical manager for the hospital (exceptions might be given for hospitals located in rural and remote areas);
b each hospital must appoint a pharmacist of Saudi nationality as a manager of the hospital's internal pharmacy on a full-time basis;
c the pharmacist officer responsible for drugs in the hospital's internal pharmacy, who is subject to surveillance, shall be a full-time pharmacist assistant of Saudi nationality. The internal pharmacy manager might hold this position; and

d each hospital must appoint an administrative manager of Saudi nationality, holding a university degree, to manage the hospital on a full-time basis.

V NEGLIGENCE LIABILITY

The area of liability is still under development in Saudi Arabia. Saudi law consists of two types: the shariah or Islamic law (God-made law); and the government regulations, ministerial decrees and implementation rules (man-made law). Although the government regulations, decrees and rules are deemed to be subservient to the shariah,[3] in practice, the two types of law are sometimes in conflict. Further, as there is no recognised system of legal precedent in Saudi Arabia, the ability to resolve any conflict between the shariah and the government regulations remains problematic. In court cases, both types of law are usually applied and the courts' rulings may be supported by principles or regulations of either type – or a combination of the two. This makes it exceedingly difficult to predict with any degree of certainty the outcome of certain types of legal cases, including liability for medical negligence. The facts of the particular case, therefore, are perhaps more relevant to the dispute than would ordinarily be the case in Western jurisdictions.

Despite the generally unpredictable nature of the Saudi civil justice system, several important principles are nonetheless helpful in analysing claims in Saudi litigation or arbitration. A fundamental principle in Hanbali shariah[4] is that a contract between two parties constitutes the law between those parties – except to the extent it violates the shariah or public policy.

The shariah also contains many equity principles similar to those found in the common law of England and the United States. This includes a presumption of good faith in contract matters. It also includes the concepts of unjust enrichment and the voiding of contracts owing to incapacity, fraud and duress. The shariah, however, lacks many of the equitable remedies found in the common law, such as injunctive relief, which is exercised only in rare circumstances.

The shariah concept of damages is also important in determining potential liability in a commercial dispute. Under the shariah, only direct, proven damages are recoverable in cases involving tort or breach of contract. Thus, incidental and consequential damages will not be recognised. In addition, lost profits are generally not recoverable on the ground that they are speculative; only God could know what would, in fact, occur in any given situation. Thus, some of the consequential damages in a lawsuit in a Western jurisdiction may not be applicable in Saudi Arabia.

In general, there is the concept of 'blood money'. We note that under Saudi Arabian law, the maximum civil liability for wrongful death is 120,000 riyals for an adult Muslim male. This is established by General Organisation of Social Insurance, which provides workers' compensation coverage to employees.

In Saudi Arabia, the concept of blood money exists with respect to homicide, in which a crime victim's family may demand a sum of money for sparing the life of the killer. This may arise in a situation in which an employee of a medical institution was found to have

3 The Basic Law of 1992 declared the Holy Koran and the sunnah (traditions and sayings) of the Prophet Mohammed to be the Kingdom's Constitution.

4 The Hanbali school of Islamic jurisprudence is one of the four major schools, together with the Maliki, Hanafi and Shafi'i schools. The Hanbali is the predominant school in Saudi Arabia.

intentionally killed a person (rather than the death being deemed an accident). This would, of course, involve the Saudi Arabian criminal justice system. As a general rule, corporate criminal responsibility does not exist in Saudi Arabia, particularly for crimes such as homicide. The individuals responsible for the homicide rather than the corporation would be held accountable. We understand there are instances of medical professionals being held criminally liable for being grossly negligent where the negligence resulted in a death.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Saudi law previously treated foreign-owned entities in a manner that dramatically differed from local and Gulf Cooperation Council (GCC)-owned entities. Foreign-owned entities are entities that have any non-GCC foreign shareholders, even if the entities are incorporated in the GCC. There are, however, some differences including additional procedural steps during formation, restricting the activities of the foreign entity, demanding higher share capital to conduct business in certain sectors and imposing a higher income tax than local or GCC-owned entities. Foreigners and foreign-owned entities are taxed at 20 per cent of profit versus zakat at 2.5 per cent.

When Saudi Arabia joined the World Trade Organization (WTO) in December 2005, the Saudi government agreed to open to foreign investment several areas that were previously closed. Pursuant to Royal Decree No. M/54 dated 21/09/1426H, the documentation in relation to Saudi Arabia's accession to the WTO was approved. In terms of the WTO, medical services are generally open. Technically, MISA maintains that the only restrictions in terms of foreign investment in the healthcare sector are 'services provided by midwives and nurses, physical therapy services and quasi-medical services internationally classified at CPC 93191', which are on the Negative List. In accordance with the WTO, the ownership of entities engaged in medical care was meant to be open if the foreign entity entered into a joint venture with a properly licensed Saudi party.

In addition to the above-mentioned restrictions in accordance with the Negative List, the MOH and SFDA have their own set of rules and restrictions. The Council of Ministers Resolution No. 683151 dated 10/03/1436 H (1 January 2015 G) is the most current version of the Regulations for Private Healthcare Institutions (the Private Healthcare Regulations). The MOH now permits foreign ownership of hospitals, medical centres and pharmacies (although pharmacies must be at least partially owned by a Saudi pharmacist). Ownership, however, must be by a foreign party owning and operating healthcare facilities outside of Saudi Arabia.

Non-GCC nationals can also own entities providing ancillary services such as waste management, IT support and sterilisation services. Consistent with Saudi Arabia's desire to encourage in-country manufacturing, parties manufacturing medical devices and pharmaceutical products (and directly selling such manufactured medical devices and pharmaceutical products) can also be non-GCC national owned, though they will have to comply with MISA's requirements to receive a foreign investment licence for manufacturing.

The foreign investment status of most healthcare sectors is that they are open to foreign ownership.

On 15 April 2020, the Cabinet of Saudi Arabia issued a resolution approving the Pharmaceutical and Herbal Establishments and Substances Regulation (the New

Pharmaceutical Law), providing a liberalisation on the ability of foreign nationals or companies to directly own certain pharmaceutical businesses in Saudi Arabia. The New Pharmaceutical Law was enacted on 16 April 2020 pursuant to Royal Decree number (M/108) of 2020.

The New Pharmaceutical Law repeals and replaces the Pharmaceutical Establishments and Substances Regulation which was enacted in 2004 (the Old Pharmaceutical Law).[5] While this article will compare certain aspects under the Old Pharmaceutical Law and the New Pharmaceutical Law, the primary purpose of this article is to discuss certain changes relating to foreign ownership.

i Restrictions on foreign ownership

Under the Old Pharmaceutical Law, the ownership of certain pharmaceutical businesses including medicinal consultation and pharmaceutical-substance analytical centres and pharmaceutical wholesale warehouses (the Pharmaceutical Businesses), was strictly limited to Saudi nationals. As a result of such restriction, foreign investors were unable to directly invest in any of these Pharmaceutical Businesses. Historically, foreign investors had indirect investments in Pharmaceutical Businesses through side agreements or schemes or arrangements with local Saudi Arabian nationals. Such arrangements, while not uncommon in Saudi Arabia, are illegal and impose significant risks on the foreign investor's interests in the business.

Under the New Pharmaceutical Law, the restrictions on foreign ownership of certain Pharmaceutical Businesses have been removed, consequently allowing foreign investors to directly own any of the specified Pharmaceutical Businesses in Saudi Arabia.

As a result of the regulatory changes introduced under the New Pharmaceutical Law, many of the existing arrangements will potentially terminate and we expect foreign investors will restructure their business operations in Saudi Arabia, in accordance with the New Pharmaceutical Law. However, foreign investors must ensure that any such restructuring or termination of any such arrangement is done in accordance with any specific contractual arrangements and in compliance with Saudi Arabian law.

ii Lower 'localisation' requirements

In addition to permitting foreign ownership of Pharmaceutical Businesses, the New Pharmaceutical Law dispensed with certain 'localisation' requirements, which were required under the Old Pharmaceutical Law. For example, the Old Pharmaceutical Law required pharmaceutical wholesale warehouses to be managed by a licensed pharmacist who is a Saudi Arabian national. Such requirement no longer exists under the New Pharmaceutical Law.

Despite the foregoing, the New Pharmaceutical Law requires that pharmaceutical and herbal manufacturing plants operating in Saudi Arabia have a licensed scientific office, and that the manufacturing plant and the scientific office be managed by a pharmacist who is a

5 According to the Cabinet resolution approving the New Pharmaceutical Law, pharmacies and herbal substance sale stores remain subject to the Old Pharmaceutical Law. A specific regulation in respect of pharmacies and herbal substance sale stores is anticipated.

Saudi Arabian national. Moreover, the New Pharmaceutical Law limits the promotion and the introduction of pharmaceutical and herbal substances in Saudi Arabia to Saudi nationals.[6] These localisation requirements have been retained from the Old Pharmaceutical Law.

The table below compares the foreign ownership restrictions and localisation requirements under the Old Pharmaceutical Law and the New Pharmaceutical Law.

Pharmaceutical business	Old Pharmaceutical Law	New Pharmaceutical Law
Pharmaceutical wholesale warehouses	Must be owned and managed by a Saudi pharmacist	May be 100% foreign owned and managed
Pharmaceutical and herbal manufacturing plants	Technical manager must be a Saudi pharmacist	Technical manager must be a Saudi pharmacist
Medicinal consultation and analytical centres	Must be owned and managed by a Saudi pharmacist	May be 100% foreign owned and managed
Promotion and introduction of pharmaceutical and herbal products	Limited to Saudi pharmacist	Limited to Saudi pharmacist
Scientific Office	Must be managed by a Saudi national	Must be managed by a Saudi national

iii Pharmacies and herbal substance sale stores

Notwithstanding the regulatory changes under the New Pharmaceutical Law and the proposed foreign ownership exemptions, the New Pharmaceutical Law excluded pharmacies and herbal substance sale stores from its scope of application. As such, ownership of these establishments is yet, legally speaking, still limited to Saudi nationals. Nonetheless, we understand that the Saudi Arabia MOH has occasionally permitted foreign ownership of pharmacies and herbal substance sale stores outside the six largest cities in Saudi Arabia on a case-by-case basis.[7] The intention for this exemption is to promote foreign investment into rural, under-developed areas in Saudi Arabia. As set out above, a new regulation is anticipated in respect of pharmacies and herbal substance sale stores. It is yet to be seen whether foreign ownership of these establishments will be permitted under the anticipated regulation.

The changes introduced under the New Pharmaceutical Law are exciting and welcomed. Foreign investors should consider how to potentially benefit from these changes. We will provide a further update once the regulation in respect of pharmacies and herbal substance sale stores is issued.

iv Potential exceptions

Foreign investors should consider alternative, enforceable structures to access the healthcare sector. For example, to date some foreigners have accessed the Saudi Arabian healthcare sector by investing in certain healthcare investment funds established pursuant to the Investment Funds Regulations of the Saudi Arabian Capital Market Authority (CMA). These funds have invested in sectors as diverse as pharmacies, clinics and small, medium-sized and large hospitals. In addition, we are aware that the MOH and the CMA have, to date, not objected to investors who meet the qualified foreign financial institutions' requirements for acquiring listed securities of entities operating in the healthcare sector.

6 The New Pharmaceutical Law entitles the Chairman of the Saudi Food and Drugs Authority to waive this requirement if there is a shortage of Saudi pharmacists. Under the Old Pharmaceutical Law, the Minister of Health had this authority.

7 Riyadh, Jeddah, the Holy City of Mecca, the Holy City of Medina, Al-Ahsa and Ta'if.

v New joint venture structures

Foreign investors often prefer to undertake a joint venture with a local partner but are uncomfortable with Saudi Arabian law. Foreign investors are increasingly using the new Abu Dhabi Global Market (ADGM) jurisdiction to incorporate an English law special purpose vehicle (SPV) and then have the SPV own the operating company in Saudi Arabia. It is now possible to deem the ADGM SPV a Saudi Arabian tax resident, making it attractive to Saudi Arabian parties, who pay lower tax than foreign parties, while giving foreign parties English law certainty for their joint ventures in Saudi Arabia. Other parties are using CMA funds and ADGM/Dubai International Financial Centre funds as joint venture vehicles and currently these provide significant tax advantages to the foreign party.

VII COMMISSIONING AND PROCUREMENT

The MOH and the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) are the primary parties involved in the commissioning of a new hospital.

The registration process and procedural steps for obtaining a sector-specific regulatory licence to set up a hospital in Saudi Arabia can be divided into three key steps: (1) obtaining MOH's preliminary approval; (2) obtaining the approval of the Ministry of Commerce and Investment (MOCI); and (3) obtaining final approval from the General Directorate of Health Affairs and the CBAHI. Pharmaceutical companies are also required to obtain licences from the MOH and the MOCI and approval by MISA will also be required if the company is partly foreign owned.

Investors must first obtain a preliminary approval from the MOH. At this stage, the MOH requires information about the applicant investors, including, in the case of corporate investors, the constitutive documents (i.e., the commercial registration and articles of association) of each applicant. The MOH also requires information describing in brief the investment plan (including number of hospitals and beds, proposed project sites, construction plan, management structure, expertise of the involved parties and the implementation plans). The MOH will review the application and may request further documents or clarifications. This process will normally take one to two weeks from the date of submitting the required documents.

After successfully obtaining the MOH's initial approval, the corporate entity must be incorporated in Saudi Arabia to conduct the intended licensed activities (e.g., developing and operating hospitals). At this stage, the investors must obtain the necessary approvals from the MOCI.

After incorporation of the appropriate investment vehicle, the MOH will request copies of the constitutive documents of the investment vehicle (i.e., articles of association and the commercial registration) and a land-ownership deed for the project site. The MOH will then refer the application to the relevant General Directorate of Health Affairs (GDHA).

Construction plans and other sketches for each hospital must be submitted to the relevant GDHA for approval. Construction work cannot commence before obtaining the approvals from the Projects and Maintenance Department at the MOH, the relevant municipality and the Civil Defence. A technical study must be submitted to the Civil Defence certifying the compliance of sites with the related technical specifications and requirements. This study must be prepared by an engineering consultancy office, accredited by the Civil Defence and specialising in safety and fire protection. The Civil Defence Regulations set out the required specifications in respect of project sites, structures and equipment. The hospital

will also be expected to enter into a contract with a specialised licensed entity for the safe disposal of medical waste and obtain a report from a specialised licensed entity evidencing (1) the installation of radiation safety measures and other necessary measures for the hospital radiotherapy departments; (2) compliance with specifications and standards; and (3) the availability of radiation protection measures and measures for early detection of radiation leakage. Upon completion of the construction work, the relevant MOH committee will inspect the hospital buildings and preparatory work and issue an inspection report within two weeks of the date of the application, and the applicant will be provided with a reference letter to the Ministry of Labour to apply for recruitment visas. The MOH will issue the final approvals after the necessary number of staff have been recruited and after the hospital has obtained the necessary professional licences and approvals for professionals hired in Saudi Arabia. A hospital is required to recruit a certain number of resident doctors, specialists, consultants, pharmacists, technicians, nurses and medical staff, based on its size.

Investors are often surprised by the number of regulators involved with the licensing of a business operating in the healthcare sector. In addition, parties acquiring hospitals or clinics have found that the hospitals or clinics (particularly if more than 10 to 15 years old) sometimes have outstanding issues or reports from the local Civil Defence, municipality or health department, and are operating on temporary licences. Healthcare facilities that do not comply with the latest regulations could face costly and lengthy processes to bring their facilities into compliance.

Quite often these issues arise when facilities were constructed before purpose-built healthcare facilities were the norm. At one point it was not unusual for parties to operate out of converted villas and other facilities that were not purpose-built to service the healthcare sector. It should come as no surprise that many older medium-sized or regional medical centres also started life as something other than a hospital and, over time, were slowly expanded. Often, these facilities will not fully comply with the latest rules issued by the relevant health regulator, Civil Defence or municipality relating to ingress or egress, fire safety, ventilation, width of hallways, number and size of elevators, size of patient rooms, waiting rooms, sanitation and waste disposal requirements for each medical facility. We have seen various acquisitions halted once a potential buyer understands the significant cost of making the necessary changes if a new owner will not be grandfathered under a previous exception.

If an investor is considering a first-time acquisition in the regional healthcare sector, it is often advisable to appoint an expert consultant to evaluate the condition of the target facility and to determine whether any expenditure on upgrading the facility will be necessary for compliance with regulatory requirements, so that this can be taken into consideration as the opportunity is assessed.

VIII MARKETING AND PROMOTION OF SERVICES

Saudi Arabia recently announced various regulations limiting the ability of pharmaceutical companies to provide entertainment or otherwise influence doctors or healthcare systems. There is now a reporting requirement that all parties providing 'financial support' in relation to consultations, lecture fees, education, training, hospitality, etc. of over 250 riyals over three months or over 1,000 riyals in a year must report this to the Saudi Food and Drug Authority.

IX CORONAVIRUS

Saudi Arabia has been working with various international parties to secure the necessary number of doses of vaccinations for its residents and citizens. Saudi Arabia also initially only gave one dose of the AstraZeneca and Pfizer vaccines when it was attempting to vaccinate a larger percentage of its population with limited doses. Saudi Arabia regularly monitors the progress of various countries and has severely limited the ability of its citizens to leave the country and of parties to visit from various jurisdictions. Saudi Arabia is continuously re-evaluating which countries' residents or citizens may enter into Saudi Arabia. It is also continually reviewing the policy as to which vaccinations by visiting parties are approved. Currently Saudi Arabia has only approved AstraZeneca, Pfizer, Moderna and Johnson & Johnson vaccines. Parties who have not been vaccinated with an approved vaccine are not permitted entry into Saudi Arabia.

X FUTURE OUTLOOK AND NEW OPPORTUNITIES

We continue to see a tremendous interest in telemedicine, particularly in the field of dermatology. There has been a focus on this area as the Saudi public continues to desire best-in-class services.

We continue to see tremendous interest by medical providers and private equity houses focusing on Saudi Arabia. Ashmore recently raised a significant fund to invest in hospitals in Saudi Arabia. A number of hospitals, dental clinics, etc. are expanding through raising new funds or through initial public offerings.

Following the recent steps to liberalise the healthcare sector, we expect to see growing foreign investment in medical centres, radiology clinics and other types of medical facilities throughout Saudi Arabia.

Furthermore, Saudi Arabia has been looking to increase foreign investment in large hospitals. There are also a number of privatisations expected in this sector.

XI CONCLUSIONS

Saudi Arabia is currently liberalising its regulations to encourage more foreign participation in the healthcare sector in Saudi Arabia. There continue to be tremendous opportunities for investment in this sector and we expect these will only accelerate with the expected announcement by the government of the partial or full privatisation of a number of medical centres and hospitals.

Appendix 1

ABOUT THE AUTHORS

NABIL A ISSA

King & Spalding LLP in cooperation with the Law Office of Mohammed AlAmmar

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Nabil regularly represents clients on healthcare transactional matters in Saudi Arabia and the United Arab Emirates. He is especially known for developing innovative shariah-compliant CMA funds and investment structures for real estate and private equity investments in Saudi Arabia and the United Arab Emirates. Proficient in Arabic and fluent in English, Nabil is a regular author and presenter on healthcare regulations and investments in the Middle East.

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