

THE HEALTHCARE
LAW REVIEW

Editor
Sarah Ellson

THE LAWREVIEWS

THE HEALTHCARE LAW REVIEW

The Healthcare Law Review

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SAUDI ARABIA

*Nabil A Issa*¹

I OVERVIEW

Saudi Arabia has witnessed dramatic economic changes in recent years. With the introduction of compulsory health insurance for those working in the private sector, the healthcare landscape has opened up for a wide range of healthcare players, such as laboratories, pharmaceutical companies, insurers and healthcare providers, all of whom are still looking to take advantage of the growing market. There is also continuous improvement in education, which is leading to increase in healthcare awareness.

Saudi Arabia 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 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. The Ministry of Health has awarded significant contracts to Diaverum and DaVita to operate dialysis clinics in Saudi Arabia. The hospitals of Saudi Arabia are often performing some of the world's most complicated medical procedures, including organ transplants, separation of conjoined twins and neurosurgery.

The Ministry of Health is the regulator for most of the healthcare sector in Saudi Arabia. The Ministry of Defence, including the National Guard, maintains its own standards.

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 to Saudi Arabian nationals, and certain agencies have overlapping responsibilities, as described below. Moreover, as part of Saudi Arabia's well-publicised Vision 2030, it is transforming its public sector and exploring privatising certain aspects of its healthcare sector. Currently, there are a number of foreign investment restrictions, which will be discussed in this chapter.

1 Nabil A Issa is a partner at King & Spalding LLP in association with the Law Office of Mohammad Al-Ammar in Riyadh.

2 See Correspondents, Saudi Arabia's Healthcare Market Witnessing Exponential Growth, KHALEEJ TIMES, 35, 27 August 2009.

II THE HEALTHCARE ECONOMY

i General

The Council of Cooperative Health Insurance has made it mandatory for all business owners to cover their workers with medical insurance from the date of their arrival and hand them insurance cards within 10 days of their arrival in the Saudi Arabia. According to the council's new regulations, the insurance coverage becomes invalid only in case of the beneficiary's death, cancellation or expiration 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 expats, 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 specialty 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;

- b* 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 Ministry of Health; 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 Ministry of Health 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 of Saudi Arabia without the written permission of the concerned patient.

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.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

Medical staff, including doctors and pharmacists, must be properly licensed by the Ministry of Health 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 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 shariah⁴ 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' or *diya* exists with respect to homicide, in which a crime victim's family may demand a sum of money in order to spare the life of a killer. This may arise in a situation in which an employee of a medical institution were found to have 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 and such action resulting in a death.

3 The Basic Law of 1992 declared the Holy Qur'an 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 shari'a is the predominant school in Saudi Arabia.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Currently, Saudi law treats foreign-owned entities in a manner that dramatically differs from local and Gulf Cooperation Council (GCC)-owned entities. Foreign-owned entities are entities that have any non-GCC foreign shareholders, even if such entities are incorporated in the GCC. Examples of some differences are demanding 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. As per 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, the Saudi Arabian General Investment Authority (SAGIA) maintains 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. As per 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. We understand Saudi Arabia has not yet complied with such commitment, so will require new implementing regulations prior to Saudi Arabia opening up most areas of healthcare.

In addition to the above restrictions as per the Negative List, the Ministry of Health (MoH) and Saudi Food & Drug Authority (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 Private Healthcare Regulations provide that essentially all areas of healthcare, other than hospitals, are reserved for Saudi Arabian nationals. We have been advised by the MoH that non-Saudis are only allowed to own hospitals with a minimum of 100 beds and provided the medical director of the hospital is a Saudi national. In our experience, the MoH generally grants licences to foreigners only if the foreign-owned hospital has at least 150 beds, or at least 100 beds if the foreign party is acquiring an existing hospital or it is a specialty hospital, which the MoH agrees is focused on an area of importance to Saudi Arabia. The hospital medical director must be a qualified Saudi physician. The head of the pharmacy must also be a Saudi Arabian pharmacist. Further, the application for private hospitals requires that the Administrative Director be a Saudi Arabian national. Note that a hospital with even 1 per cent foreign ownership is required to obtain a SAGIA licence and falls under the Private Healthcare Regulations. We understand that SAGIA and the MoH may soon announce a relaxation allowing for partial foreign investment of up to 75 per cent of medical centres on a case-by-case basis, and if such meets certain minimum foreign investment guidelines.

Please note the following in regards to healthcare sectors that are and are not currently open to foreign investment.

i Private clinics or centres

Owners of private clinics or centres must be 100 per cent Saudi parties. These include dialysis clinics, radiology clinics and polyclinics.

ii Dental clinics

Owners of dental clinics must be 100 per cent Saudi parties. We understand individual non-Saudi GCC national dentists may also potentially be licensed to own and operate dental clinics.

iii Foreign ownership in other healthcare-related arenas

Non-Saudis are allowed to have 100 per cent ownership in managing and operating companies engaged in medical maintenance, non-medical maintenance, hygiene, sterilisation, security, IT services, leasing of medical equipment, medical waste management and monitoring clinical trials.

iv Medical device manufacturers

Foreign investment in medical device manufacturing is generally permitted. Approvals are required from the SFDA.

v Pharmaceutical manufacturers

Pharmaceutical manufacturers are regulated by the Institutions Pharmaceuticals Regulations, under which foreigners can establish manufacturing plants (pharmaceuticals and medical devices) in Saudi Arabia, with 100 per cent ownership under an industrial licence. Approvals are required from the SFDA.

vi Pharmacies

Only Saudi Arabian nationals are permitted to own pharmacies and pharmaceutical establishments in Saudi Arabia, and such must be at least partly owned by a Saudi Arabian pharmacist. The regulations set forth certain conditions that pharmacy owners must satisfy. These include:

- a* being licensed by the MoH to practise as a pharmacist;
- b* employing a Saudi national as a manager; and
- c* meeting the specifications for a pharmacy that were historically set out by the MoH.

The regulations also limit the number of pharmacies that can be owned by one individual or company to no more than 30 pharmacies.

vii Laboratories

As per the Law on Private Laboratories issued pursuant to Council of Ministers Decision No. 29 dated 25/01/1423H (7 April 2002 G), which provides that licensing may be granted for laboratories provided that: (1) the applicant for the licence is 100 per cent Saudi, (2) the applicant undertakes to assign a Saudi to be the laboratory technical manager, and (3) the applicant undertakes to provide necessary academically qualified specialists and use proper equipment and instruments.

viii Foreign ownership of property

A non-Saudi entity may not own real estate in Saudi Arabia before it establishes a commercial presence in the country. The ownership rules applicable to GCC nationals are regulated in

Saudi Arabia by the Ownership of Real Estate by GCC Nationals Regulations; non-Saudi non-GCC nationals' ownership of real estate is regulated by the Regulation on the Ownership and Investment of Real Estate by Non-Saudis.

Additionally, property ownership by a company that is wholly or partially owned by non-Saudi nationals within the boundaries of the designated holy cities of Mecca and Medina is not permitted.

Finally, individual foreigners who hold residency permits (iqamas) in Saudi Arabia are permitted to acquire a residential property for their personal accommodation upon the approval of the Saudi Arabian Ministry of Interior.

ix Barriers to market access

There are a number of barriers to market access by foreign investors in the healthcare and pharmaceutical sector in Saudi Arabia. Chief among them are the following:

- a* Price controls: Pharmaceutical products can be sold only after their prices have been approved and undergone registration requirements. Such, however, also applies to 100 per cent Saudi-owned entities.
- b* Tendering procedures: The two principal buyers of pharmaceutical products in Saudi Arabia are the SFDA and the General Directorate of Healthcare Affairs (SGH). GCC member countries, including Saudi Arabia, practise collective purchasing of pharmaceuticals, vaccines and other healthcare products through the SGH tender – this process allows GCC countries to buy in bulk and benefit from significant cost savings from multinational drug-makers. Companies that wish to participate in the SGH tender must have already registered products in at least three GCC member states or be directly registered with the Gulf General Committee for Drug Registration.
- c* Certain aspects of agency and commercial law: Unless a product is produced in Saudi Arabia, all foreign companies must sell their products through licensed distributors or agents in Saudi Arabia.

x TCR

We are aware the MoH is permitted to waive in part or in whole its restriction on ownership and provision of services. If the MoH believes an area of healthcare is underserved, it can award a government contract. The foreign entity can then obtain a temporary commercial registration (TCR). For example, because of the high rates of diabetes and need for dialysis care, the MoH awarded substantial contracts separately to DaVita and Diaverum. Both entities have 100 per cent foreign-owned TCR branches to provides dialysis care to MoH patients. We also understand another foreign company was permitted to establish a laboratory in partnership with the Saudi Arabian National Guard by establishing a TCR.

VII COMMISSIONING AND PROCUREMENT

The MoH and 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 CBAHI. Pharmaceutical companies are also required to obtain licences from MoH and the MoCI.

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 specialised 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 the safety measures of radiation and other necessary measures for the radiation departments in the hospital; (2) its compliance with the specifications and standards; and (3) the availability of protection measures from radiation and measures for early detection of radiation leakage. Upon completion of the construction work, the relevant MoH committee will inspect the hospital buildings and preparations work and issue an inspection report within two weeks from 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.

VIII 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. Investcorp recently invested in Al Borg Laboratories based in Jeddah and a number of hospitals, dental clinics, etc., are expanding through raising new funds or through IPOs.

Furthermore, Saudi Arabia has been looking to increase foreign investment in large hospitals. There are also a number of privatisations occurring in this sector. Saudi Arabian Airlines is currently entertaining bids to privatise its medical centre and create a new medical centre to serve its employees and the general public.

IX CONCLUSIONS

Saudi Arabia is currently liberalising its regulations to encourage more foreign participation in the healthcare sector in Saudi Arabia. There continues to be tremendous opportunity for investment in this sector. We expect such to further accelerate, with the expected announcement of medical centres and hospitals that the government hopes to partially or wholly privatise.

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Nabil is ranked in Band 1 for his work on investment funds in the Middle East by *Chambers Global* 2014–2017 and Band 2 for his corporate work in the Middle East by *Chambers Global* 2017, in addition to being highly ranked for his corporate work in the UAE. He is also recognised as a Leading Individual for his corporate work in Saudi Arabia by *The Legal 500: Europe, Middle East & Africa* 2017.

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