Healthcare and Pharmaceutical Industries in Saudi Arabia

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This article addresses the most significant Saudi Arabian legal issues to be considered in connection with investment in the healthcare sector in the Kingdom of Saudi Arabia. Saudi Arabia is the largest economy in the Middle East and, while oil wealth has brought new opportunities, it has led to a growing incidence of lifestyle diseases such as diabetes and heart disease.¹ The Saudi Arabian government has established certain regulatory reforms to encourage private sector investment in the healthcare sector. This article provides an overview of the legal landscape of the Saudi Arabian healthcare sector. The first section covers the pharmaceutical sector, and the second section covers healthcare facilities. Throughout this article, we also discuss general corporate and other issues to be considered by foreign investors in Saudi Arabia. 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.

As a relevant background, one must also consider that Saudi Arabian law is founded on the Shari‘ah (Islamic law), largely consisting of the Holy Qur‘an and the Hadith (sayings or “traditions” of the prophet Mohammed). There are four principal schools of Islamic jurisprudence: Hanafi, Maliki, Hanbali and Shafi‘i, each of which has its own set of

interpretations on issues of commercial law, family law, etc. The Hanbali school is the principal branch of the Shari’ah followed in Saudi Arabia. While generally conservative and strict in its interpretations of the Qur’an and the Hadith, the Hanbali school provides for the freedom of contract between competent contracting parties. Indeed, a maxim of the Hanbali school is that a “contract is the law between the parties, except to the extent that the contract violates the Shari’ah.” Thus, a contract to sell wine or pork would be void ab initio, as the subject matter of the contract is prohibited by Islam. On the other hand, a contract to borrow money and repay it with interest three years later would be valid in part and void in part, with the obligation to repay the principal amount enforceable but the interest component stricken from the contract. In addition to this body of “God-made law” there is a body of man-made law in Saudi Arabia, consisting of rules, regulations, and decisions in the form of Royal Decrees, Council of Ministers’ Resolutions, Ministerial Decrees, etc. The decrees and regulations carry the weight of law, but can always be challenged if they contradict the Shari’ah, and the various governmental bodies are provided discretion in the interpretation of many of the stated regulations. Thus, investors must work closely with parties familiar with the Shari’ah and with governmental restrictions and ministries in Saudi Arabia when pursuing investment opportunities.

Pharmaceuticals

The Saudi Arabian pharmaceutical market is one of the largest in the Middle East. Saudi Arabia represents 65%, or $1.7 billion of the pharmaceutical market in the member countries of the Gulf Cooperation Council (GCC), which is currently valued at $2.7 billion per year. This section will discuss the regulatory framework governing Saudi Arabian pharmaceuticals, highlighting the heavily regulated price controls imposed by the Saudi Arabian government and the barriers to access that multinational pharmaceutical companies face.

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2 See Jim Phipps et al., Middle Eastern Law, 40 INT’L LAW, 597.
4 The GCC is comprised of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates.
As the largest consuming market in the GCC, more than 82% of the medicines utilized in Saudi Arabia are imported.\(^6\) Unlike other jurisdictions that prefer generics, patients in the GCC have favored branded products over generics, although generics constitute the majority of the drugs produced in the GCC. One study estimates the market share of generic medicines in Saudi Arabia is just 5.8% versus 50% in many European countries.\(^7\) Moreover, because most medicines can be purchased from a pharmacy in Saudi Arabia without a prescription, consumers can easily exercise their preference for branded medicines. There is also a belief that there is still tremendous opportunity with the introduction of insurance laws requiring health insurance for all companies in Saudi Arabia with more than fifty international employees. Moreover, Saudi Arabia permits manufacturing facilities to be 100% foreign owned and provides various low-cost loan programs and low cost power to encourage investment in this sector. As a relatively new member of the WTO, Saudi Arabia has improved its protection of intellectual property and continues to liberalize its economy as it wishes to diversify its economy from its dependence on oil. There are challenges, however, including strict price controls, limits on foreign ownership for distribution of pharmaceutical products produced outside of Saudi Arabia, and the extensive process to approve new products, which are discussed below.

**Saudi Arabia Pharmaceuticals Regulatory Regime**

*Registration of Pharmaceutical Companies is Now the Saudi Food and Drug Authority’s Responsibility*

The Ministry of Health (MOH) was historically the primary pharmaceutical regulatory authority in Saudi Arabia, which was responsible for registering all pharmaceutical companies. However, the Saudi Food and Drug Authority (SFDA), established in March 2003, took over this function in July 2009 pursuant to Royal Decree No. M/6 dated 25/1/1428 H (13/2/2007 G) and appears now to be responsible for licensing pharmaceutical products and manufacturing facilities. As the exact jurisdiction of the SFDA is still being developed, this article will largely refer to the historical authority that

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\(7\) Id.
was held by the MOH, and readers should seek guidance as to which authorities now rest with the SFDA. The registration process for pharmaceutical companies typically takes between six and eighteen months to complete, although approval time has been decreasing steadily (e.g., in 1999, the process typically took twenty months). Registrations must be renewed every five years. In 2004, more than 200 international pharmaceutical companies were registered with the MOH. The fee for a company to be registered as an importer has been SAR 1,000 ($268), but may be adjusted under the SFDA. As indicated above, however, more than 82% of pharmaceuticals are produced outside of Saudi Arabia, suggesting that numerous foreign companies have been successful in navigating the registration process.

*Registration of Pharmaceutical Products With the Saudi Arabian Ministry of Health*

The MOH historically was in charge of approving all pharmaceutical products prior to sale and distribution in Saudi Arabia, including drugs that have been approved by the U.S. Food and Drug Administration (FDA) or the European Medicine Evaluation Agency. Consistent with Royal Decree No. M/6, we understand SFDA will be taking over this function, although that has not yet occurred. Industry sources often express frustration over the delays caused by Saudi re-evaluation of products already approved abroad, which equates to approximately 50% of the total approval time for a new product. The MOH historically reviewed the application, supported by certificates and other documents duly legalized by a Saudi Arabian consulate in the applicant’s country, and analyzed the sample product to ensure that it corresponded to certain specifications modeled after the FDA’s Good Manufacturing Practice (GMP) guidelines. Standards for all products are formulated by the Saudi Standards, Metrology and Quality Organization, commonly referred to as the Saudi Arabian Standards Organization (SASO). The fee for the registration of a new product is SAR 200 ($54), one of the lowest in the region. According to the Rules Registering Pharmaceutical Companies and their Products, registering the companies is simply a ministerial process. However, the lengthy process is in registering the pharmaceutical products. The MOH requires

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8 *Rules Registering the Pharmaceutical Companies.* See also the Third Chapter of the Implementing Rules of the Pharmacists Profession Regulation and amended pursuant to Ministerial Decision No. 1214/20/M Dated 17/6/1409H.
complete details of the ingredients of the medicines used and information on appropriate storage. The MOH is also concerned with ensuring that information matches the labeling on the drugs and the accuracy of translations along with accuracy of samples reviewed by the MOH. The registration timeline varies widely depending on the completeness of the information provided to the authorities in Saudi Arabia and the current volume of pharmaceutical products being reviewed. In general, the process takes between six and eighteen months to complete.

Overview of Wholesale and Retail Markets

All pharmacies and drug stores in Saudi Arabia must be established in accordance with the Saudi Arabian Pharmaceutical Establishments and Synthetics Regulations. Under these regulations, only Saudi Arabian nationals are permitted to own pharmacies and pharmaceutical establishments. Thus, the wholesale and retail sector is closed to foreign pharmaceutical companies; however, foreign companies can build manufacturing facilities to produce approved products. We also understand that other GCC nationals may now invest in pharmacies in Saudi Arabia on a case-by-case basis. Because of the sensitivity of this sector, the MOH has not yet provided foreigners the ability to be involved in wholesale or other medicine distribution. Furthermore, the regulations set forth certain conditions that the pharmacy owner must satisfy, including: (1) being licensed by the MOH to practice as a pharmacist; (2) employing a Saudi national as manager; and (3) 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 not more than thirty. Currently, 100% foreign ownership is not permitted even if each individual pharmacy is managed by a Saudi national. However, a number of GCC-based pharmaceutical groups have increased their investments in pharmacies in Saudi Arabia recently. Dubai-based Abraaj Capital purchased a minority stake in Saudi Tadawi Healthcare Company, the largest pharmacy chain in Saudi Arabia and Ithmar Capital, also based in Dubai, invested in Pharma World Holdings, which distributes medicine and is expected to soon establish

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9 See Article 1 of the Rules Registering the Pharmaceutical Companies and Third Chapter of the Implementing Rules of the Pharmacists Profession Regulation.
operations in Saudi Arabia. Further, Planet Pharmacy, which is owned by GCC nationals, has also recently invested in pharmacies in Saudi Arabia.\footnote{Melissa Hancock, Healthcare \& Pharmaceuticals: States Turn to the Private Sector, MIDDLE EAST ECON. DIG., Vol. 53, Issue 33 (14-20 August 2009) at 30.}

Most foreign investors enter the Saudi Arabian market to sell their products, including pharmaceutical products, through joint ventures with local companies or by appointing local distributors. However, GCC regulations stipulate that producers in GCC member states undergo an accelerated process to acquire approval to export to Saudi Arabia. This effectively gives regional producers preferential treatment for entry into the Saudi market, particularly in the tendering system for public pharmaceutical drug purchases. Therefore, non-GCC companies generally think that the Saudi Arabian regulatory system favors local and other GCC-based manufacturers, who have a more efficient registration procedure. However, we note that it is possible for non-GCC foreign parties to establish a corporate entity in a GCC member state, and manufacture therein and obtain certain benefits for manufacturers in the GCC.

Free Trade Agreements

Free trade agreements (FTAs) are becoming increasingly important in ascertaining access to certain GCC markets. For instance, negotiations between the GCC and Japan over an FTA began in September 2006 and are ongoing. When finalized, this agreement could assist in developing Saudi Arabia’s non-oil industries, including pharmaceuticals, as Saudi Arabia is already Japan’s largest trading partner in the GCC region, accounting for 37.5% of total trade. In 2006, trade between the GCC and Japan was $112 billion, a 26% increase from 2005. Trade volume between the two partners is forecasted to double once the FTA is implemented.

According to official sources, the United States is looking into the possibility of signing a FTA with Saudi Arabia. The United States has a number of regional FTAs, most notably with Jordan, Bahrain, Morocco, and Israel, and a number of others are being negotiated. An FTA with the United States could allow U.S. companies much easier access to the Saudi market, and could allow greater production in Saudi Arabia for the United States and other foreign markets. While there are not export restrictions that would prevent production in Saudi Arabia for the U.S. market, a reduction in customs
duties would make it more cost competitive for such exports to the U.S. market. In addition, since branded products are preferred over generic products and almost all medicines manufactured in Saudi Arabia are generics, they would find a more receptive market for their products in the United States and elsewhere outside the GCC.

**Effect of Saudi Arabia’s Accession to the WTO on the Pharmaceuticals Industry**

In December 2005, Saudi Arabia became a member of the World Trade Organization (WTO). Prior to its accession, the country significantly reformed its trade regime by revising legislation in intellectual property protection, import licensing, customs valuation and fees, and standards and technical regulations.

Saudi Arabia has progressed by strengthening the protection of intellectual property rights and increasing private sector cooperation. The WTO membership requires Saudi Arabia to implement the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement without any transition period. Saudi Arabia is now TRIPS-compliant.\(^\text{11}\) Over the past six years, the following regulations have been implemented in Saudi Arabia:

1. Trademarks Regulations (August 2002);\(^\text{12}\)
2. Copyright Regulations (August 2003);\(^\text{13}\)
3. Patents Regulations (July 2004);\(^\text{14}\)
4. Borders Measures Regulations (July 2004);\(^\text{15}\) and
5. Rules for the Protection of Trade Secrets (including protection for undisclosed pharmaceutical data) (2005).\(^\text{16}\)

Full TRIPS compliance is expected to attract increased foreign investments in the sector and promote licensing manufacturing agreements between multinational proprietary drug producers and local manufacturers. This could subsequently reduce the country’s drug import bill and improve local access to new and advanced medicine. The Rules for the Protection of Trade Secrets is particularly important, as it includes a provision for

\(^{11}\) The local drug manufacturing industry requested a ten-year 'acclimatization period' in order to allow domestic firms to prepare for WTO accession, but this request was not accepted.

\(^{12}\) Trademarks Regulations issued pursuant to the Royal Decree No. M/21 dated 28/05/1423 H.

\(^{13}\) Copyright Regulations issued pursuant to the Royal Decree No. M/11 dated 19/05/1410 H.

\(^{14}\) Patents Regulations issued pursuant to the Royal Decree No. M/38 dated 10/06/1409 H.

\(^{15}\) Borders Measures Regulations issued pursuant to the Ministerial Decree No. 1277 dated 16/05/1425 H.

\(^{16}\) Rules for the Protection of Trade Secrets issued pursuant to the Ministerial Decree No. 319 dated 01/05/1426 H.
five-year data exclusivity. This guarantees, at least theoretically, that the test data submitted to obtain marketing approval for pharmaceutical products will be protected from unfair commercial use. Based on our discussions with foreign drug companies, we believe full TRIPS compliance will encourage more foreign companies to pursue production in Saudi Arabia. The recent protections may have encouraged France’s Sanofi-Aventis in April to enter into a memorandum of understanding to establish a base in one of Saudi Arabia’s newly established economic cities.\textsuperscript{17}

**GCC Patent Regulations**

Patent protections are normally filed with the GCC Patent Office, located on the premises of the GCC Secretariat General in Riyadh, Saudi Arabia. The GCC Patent Office started accessing applications in October 1998 pursuant to the GCC Patent Regulations\textsuperscript{18} and the Statute of the GCC Patent Office, and issued its first set of patent certificates in October 2002. These certificates provide the approved patents with the same level of protection that would have been afforded the patents if registered in each of the GCC member states. Each such patent is valid in each GCC member state on the same date the GCC Patent Office issues the patent, and no further processing of an application is required at the state level. This is similar to the European Union process, which has a similar process for central registration and the ability to obtain the same level of protection in each jurisdiction as a patent registered in that jurisdiction. While the first set of patents took approximately four years, we understand that the process is becoming more streamlined each year.

According to Article 2/1 of the GCC Patent Regulations, an invention is patentable if it: (1) is new, (2) involves an innovative development that is industrially applicable, and (3) does not violate the rules of Islamic law, public morality, or public order as applied in the GCC member states. Such an invention may consist of a new product, industrial process, or manufacturing method. Under Article 15 of the GCC Patent Regulations, an approved patent will be protected for twenty years from its filing date. The patent owner is required to actually use the patented invention in the GCC within three years from the date the patent is granted. The Board of Directors of the GCC

\textsuperscript{17} See Bains supra note 6 at 27.

\textsuperscript{18} GCC Patent Regulation approved by the GCC in the thirteenth session held in December 1992.
Patent Office may grant a “compulsory license” to a third party to use the patent if: (1) the patent owner fails to use the patented invention within the period prescribed for its use in the GCC; (2) the third party has attempted to obtain a license from the patent owner for a fair sum and over a reasonable period of time; and (3) provided that the patent owner is adequately compensated. A legal advisor at the GCC Patent Office has advised us previously that use of the patented invention in any of the six GCC countries is sufficient to avoid imposition of a compulsory license.

The GCC Patent Office registers almost all patents in Saudi Arabia because of the lack of patent examiners.

**Barriers to Market Access and Protection of Intellectual Property in Saudi Arabia**

Despite the recent improvements in some areas of Saudi Arabia’s intellectual property (IP) regulatory regime, the Office of the United States Trade Representative’s latest ‘Special 301’ Watch List for 2009 still includes Saudi Arabia as one of thirty-three U.S. trading partners on the lower-level Watch List. We understand from industry sources that the decision was because of the continuation of significant barriers to market access. However, according to various local press reports, Saudi Arabia continues to improve its efforts to protect IP.

The Shari’ah and various regulations promulgated in Saudi Arabia recognize that IP should be protected. The Shari’ah concept of property (mal) includes anything that exists, can be secured, and may be of benefit at a particular time of need. For example, air is an element that cannot be secured and thus cannot constitute property (mal). The usufruct of property is also considered mal under the Shari’ah. The relationship between an individual and property that is under his control to the exclusion of others constitutes ownership (milk) under the Shari’ah. A person may have physical possession of property (milk al-yad), the right to dispose of property (milk al-tassarif), or proprietary rights (milk al-raghabah). Intellectual property in the nature of copyright, trademark, patents, and trade secrets fall within the proprietary rights category (milk al-raghabah). These property rights are expressly recognized under Saudi Arabian law and are the subject of specific regulations that cover trademarks, copyrights, and patents, described above.
The concept of IP slightly differs under the Shari’ah as compared with the laws of Western jurisdictions. This has traditionally served as an impediment to those trying to enforce IP rights in Saudi Arabia, particularly with respect to obtaining monetary damages for infringement of those rights. In 1996, the Permanent Committee for Scientific Research and Fatwa, which was chaired by the late Sheikh Abdulaziz A. Bin Baz, the Grand Mufti in Saudi Arabia, issued a decree that condemned the copying of computer software if the owners of such software restricted the right to do so. The Grand Mufti issued another decree in 2000 to the effect that the Shari’ah forbids trading in counterfeit goods. These decrees significantly recognize IP rights as property rights (milk) under the Shari’ah in Saudi Arabia.

Additionally, Article 18 of the Basic Law\textsuperscript{19} provides that Saudi Arabia safeguard the freedom and ownership of private property. Under the Basic Law, private property may not be expropriated except in the public interest and then only upon payment of fair compensation. Article 5(5) of the Implementing Rules of the Foreign Investment Regulations\textsuperscript{20} also provides that it is prohibited to confiscate an investment in Saudi Arabia by a licensed foreign company wholly or partially without a court order or subjecting such investment to expropriation wholly or partially, except for the public interest and upon payment of fair compensation.

**Barriers to Market Access**

A number of barriers to market access by foreign investors exist in Saudi Arabia. Chief among them are price controls, registration requirements, tendering procedures, and certain aspects of agency/commercial law. Each of these barriers is discussed briefly below.

**Price Controls**

Historically, the MOH has strictly controlled the pricing system in Saudi Arabia. Pharmaceutical products can be sold only after their prices have been approved by the MOH, which endeavors to keep prices as low as possible. These controls are applicable to both the public and private sectors, thus pricing applies to both sectors. Using a price

\textsuperscript{19} Basic Regulations of Governance issued pursuant to the Royal Decree No. A/90 dated 23/08/1412 H (Basic Law). The Basic Law of Saudi Arabia serves as the “Constitution” of the Kingdom.

\textsuperscript{20} Implementing Rules of the Foreign Investment Regulations issued pursuant to the Resolution No. 2 dated 15/05/1421 H.
reference system, the pricing committee considers the manufacturers’ wholesale and retail prices in the “country of origin,” export (CIF) prices to Saudi Arabia, and CIF prices in thirty other countries (including other markets in the region where prices are relatively low, such as Algeria and Egypt). The committee fixes the lowest possible price for the product and controls any subsequent price increases. Generic drugs in Saudi Arabia are priced as follows: the first generic product on the market is priced at 70% of the price of the original product, and each next generic product is priced at 90% of the price of the previously introduced generic. The current margins for imported drugs were introduced in 2004 and were updated at the end of 2007. The revised price structure described in this paragraph took effect in February 2008.

We understand that the Pharmaceutical Research and Manufacturers of America (PhRMA) has voiced concern that price controls in Saudi Arabia act as a considerable barrier to market access for its members. In the past, the MOH reviewed prices charged by domestic drug producers every five years, compared with every four years for foreign importers. In government tenders, a preference is normally granted to local or GCC-based companies over multinationals, in the form of preferring local or GCC-based companies if the prices of such are not more than 10% higher than that offered by multinationals. Industry observers expect this bias to continue. PhRMA believes that government policy with regard to the lowering of drug prices is not adequately transparent. PhRMA has also criticized the Saudi Arabian government’s alleged policy of “dollarization,” whereby Euro import prices are converted into U.S. Dollars, based on an arbitrary exchange rate. PhRMA believes that this arbitrary exchange has led to losses of up to 20% for PhRMA member companies due to the difference in value between Euro and the U.S. Dollar. PhRMA has also noted that Saudi Arabia has increased the number of reference countries used for pricing pharmaceutical products, and that Saudi Arabia’s re-pricing criteria favor local producers over foreign importers. PhRMA argues that markets such as Egypt and Algeria are not comparable to Saudi Arabia in terms of living standards, drug consumption patterns, income levels, exchange rates, or regulatory requirements. It is also arguable that such violates Saudi Arabia’s commitments as a member of the WTO since December 2005.
GCC Regulatory Developments

The GCC is planning to consolidate its pharmaceutical regulations with the ultimate goal of harmonizing prices and creating a central registration procedure. In 1999, the Gulf General Committee for Drug Registration (GCC-DR) was established to unify the process for drug registration. However, the GCC-DR still runs concurrently with domestic regulatory bodies. Nevertheless, the GCC states already collectively purchase pharmaceuticals and vaccines through the Secretariat-General of Health (SGH Tender), which is further discussed below.

In July 2005, the health ministers from the six GCC member states, including Saudi Arabia, approved a mechanism for the unification of the price of pharmaceutical products in the private sector market of each member state. The unified drug-pricing mechanism must still be endorsed by the local authorities in each GCC member state. Industry observers believe that the proposed move is likely to lead to stricter pricing restrictions across the GCC member states.

Delay in the Registration of Foreign Pharmaceutical Companies and New Drugs

As discussed above, the MOH historically appeared to discriminate in favor of local or regional (GCC-based) companies by providing them with accelerated registration procedures. The MOH has been accused of delaying the registration of innovative drugs in the country by requesting laboratory analysis for potential new drugs, even if the FDA or European Medicine Evaluation Agency has already approved them. In 2003, approval times for new products averaged thirteen months. Although this is an improvement from 1999, when the average processing time was twenty months, the analysis stage of the approval process accounts for 50% or more of the total approval time.

Tendering Procedures

The Saudi Arabian government plays a prominent role in the purchase of pharmaceuticals, negotiating with the leading drug companies to buy large quantities of product and deciding upon the supply schedule. Prices are decided at the beginning of each year. The two principal buyers of pharmaceutical products in Saudi Arabia are the MOH (which will likely be replaced by the SFDA) and the SGH.
GCC member countries, including Saudi Arabia, practice 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. It has also enabled the consistent supply of specialty products that were previously unavailable in GCC countries due to high prices and low demand. The SGH Tender was valued at $665 million in 2006, according to official reports, an increase of $84.5 million over 2005 levels. The largest percentage of the SGH Tender (33%) was hospital supplies, with oral hygiene (28%) ranking second, followed by vaccines (15%). Further growth is forecast in future years, fueled by aging populations; a growing incidence of obesity, heart disease, diabetes, and similar health-related conditions; and rising spending power. However, GCC governments hope to move away from dependency on imports by developing GCC manufacturing capabilities, which currently account for production of less than 10% of drug consumption in the region.

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 GCC-DR. Saudi Arabia accounts for the largest share of the SGH Tender, followed by the United Arab Emirates.

**Commercial Agency Law in Saudi Arabia**

Unless the product is produced in Saudi Arabia, all foreign companies sell their products through distributors/agents in Saudi Arabia. Commercial agency and distribution activities are regulated in Saudi Arabia by the Commercial Agency Regulations and the Implementation Rules to the Commercial Agency Regulations (together, the Commercial Agency Regulations). The Commercial Agency Regulations broadly define a “commercial agency” to include anyone who enters into an agreement with a foreign principal to undertake commercial activities, whether as an agent or distributor or in any form of dealership or distribution, in exchange for profit, commission, or facilities of

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22 The Commercial Agencies Regulations issued pursuant to the Royal Decree No. M/11 dated 2002/1382 H., as amended by Royal Decree No. M/32 dated 10/08/1400 H.
23 The Implementing Rules to the Commercial Agencies Regulations issued pursuant to the Ministerial Decree No. 1897 dated 24/05/1401 H.
whatever nature. The Commercial Agency Regulations limit commercial agency activities to Saudi Arabian nationals and companies wholly owned by Saudi Arabian nationals.

As of January 2009, foreign investors are permitted to invest in retail or wholesale trade, including distribution of healthcare products but excluding medicines, as discussed above. This is a recent development required under Saudi Arabia’s WTO requirements, as traditionally foreigners had no choice but to sell products through distributors, as retail and wholesale trade was historically reserved for wholly owned Saudi companies. Foreign participation in the share capital of a company that conducts wholesale or retail activities is currently limited to 75% of the share capital, although such is still not available for distribution of medicines. Also, the minimum investment by the foreign partner is 20 million Saudi Arabian Riyals (approximately $5,333,333). Despite the foregoing, a foreign shareholder who invests in or sets up a manufacturing facility in Saudi Arabia is allowed to distribute the products produced by such facility inside or outside Saudi Arabia.

Generally, the Commercial Agency Regulations require registration of all commercial agencies in a special commercial agency register maintained by the Saudi Arabian Ministry of Commerce and Industry (MoCI) within three months of the effective date of a commercial agency agreement. Registration of an agreement under the Commercial Agency Regulations primarily benefits the Saudi Arabian agent, as it confirms that a commercial agency relationship has been created and allows the local party to qualify for certain statutory protections granted to registered commercial agents. The Commercial Agency Regulations provide that in the event of a dispute arising under the commercial agency agreement, no further agency may be registered with the MoCI unless the terminated agent provides his written consent to the new agency, or unless the foreign principal or the new agent provides a copy of the competent court decision evidencing the termination, expiration, or non-renewal of the old agency. The onus for registrations falls on the Saudi Arabian agent; failure to register the agreement is punishable by a fine against the Saudi Arabian agent (but not the foreign principal). However, parties commonly do not register their agency or distribution agreements. Failure to register a commercial agency agreement does not render it
unenforceable, although a non-registered agent may find it difficult to obtain orders from government agencies, as government agencies must purchase products from a registered agent whenever possible. This rule, however, is not universally or consistently applied in Saudi Arabia.

Under the Implementation Rules, a commercial agency can be deregistered when the Saudi Arabian agent ceases to do business, or when the commercial agency’s term expires and has not been renewed or extended. Furthermore, the relevant implementation rules provide that the MoCI may strike the agency from the register within one month of verification of the facts requiring “crossing off” of the commercial agency, with notice to be given to both parties by registered mail. In practice, however, the MoCI does not unilaterally deregister such agencies, and in the event that the Saudi Arabian agent objects to the administrative cancellation of the commercial agency, the agent may lodge an appeal with the MoCI. If either party objects to the decision of the MoCI, such party may bring a suit against the MoCI at the competent court.

Since 1992, the MoCI has implemented a specific procedure for resolving commercial agency disputes. This procedure calls for the foreign principal and its Saudi Arabian agent to mediate their dispute before a special committee consisting of the deputy minister of Commerce and Industry for Technical Affairs, the secretary general of the Riyadh Chamber of Commerce & Industry, and the secretary general of the Jeddah Chamber of Commerce and Industry. In recent years, a separate committee at each Chamber of Commerce and Industry has undertaken this mediation in Saudi Arabia. Such mediation is not mandatory, and any recommendations made by the mediators in respect of parties that consent to the mediation procedure may not be imposed upon either party against its will.

Healthcare Facilities

Saudi Arabia’s population growth rate is the highest in the GCC. Public spending in Saudi Arabia on healthcare currently is almost 11% of the national budget, making it second only to education in terms of percentage of government spending. In addition, there has been a tremendous increase in the demand for healthcare services and

\[24\text{ See Hancock }supra\text{ note 10 at 30.}\]

\[25\text{ Id.}\]
medical awareness among Saudi Arabian citizens. Traditionally, patients in the GCC were often sent overseas for treatment, but this is becoming increasingly unsustainable. Demand for hospital beds in Saudi Arabia is predicted to increase dramatically. These factors have encouraged the Saudi Arabian government to support investment in the healthcare sector and to attract national and foreign entrepreneurs to invest in this field. In its 2009 budget, Saudi Arabia allocated $14 billion to its healthcare and social services sector, including the cost of building eighty-six hospitals with a total of 11,750 beds.26

The Saudi Arabian government has recently improved the regulatory framework for the insurance sector, including healthcare insurance, by introducing new laws that make it mandatory for companies (i.e., employers/sponsors) to provide health insurance coverage for their Saudi and expatriate employees and their spouses and children if they live in Saudi Arabia.27 This reform is also expected to increase the expenditure on and demand of Saudi Arabian residents for healthcare services.

While Saudi Arabia hopes to encourage more Saudi Arabian nationals to work in the healthcare sector, the reality is that approximately 80% of physicians are foreigners, as well as almost all nurses.28 Similar to other GCC jurisdictions, Saudi Arabia continues to invest in educational facilities and in the training of doctors abroad to reduce dependency on foreign doctors and other healthcare professionals.

At present, foreign investors are permitted to invest only in hospitals, but not in other health sectors (including local management thereof). Therefore, this section will focus on investment in hospitals in Saudi Arabia, as opposed to other types of healthcare facilities, such as clinics or same-day surgery facilities. We note, however, that it is widely expected that foreign ownership of hospitals and other healthcare facilities will be permitted in the various economic cities that are being established in Saudi Arabia that will likely be regulated only by the Saudi Arabian General Investment Authority (SAGIA) and not include MOH oversight.

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28 See Bains supra note 26 at 25.
Regulatory Regime of Private Healthcare Sector in Saudi Arabia

Overview of the Regulatory Framework Governing the Private Healthcare Sector in Saudi Arabia

The regulatory framework of the healthcare sector in Saudi Arabia is primarily contained in the (1) Private Healthcare Institutions Regulations\(^\text{29}\) and the Implementing Rules\(^\text{30}\) (Regulations), (2) Hospitals Regulations,\(^\text{31}\) and (3) Health Regulations and their Implementing Rules.\(^\text{32}\) Other regulations that are relevant to the offering of healthcare services are the Protective Healthcare Measures of Communicable Diseases Regulations\(^\text{33}\) and the Healthcare Profession Practice Regulations, which regulate the qualifications, obligations, ethics, civil, and criminal liability of healthcare practitioners.\(^\text{34}\)

Private healthcare institutions are also required to comply with the circulars and directives issued by the MOH and the General Directorate of Healthcare Affairs. In addition to the above, foreign investors, if setting up a presence in Saudi Arabia, are specifically subject to the Foreign Investment Regulations,\(^\text{35}\) Labor Regulations, and the Companies Regulations in relation to operational and corporate matters of their investment vehicles.\(^\text{36}\)

Private Healthcare Institutions

Privately owned healthcare institutions, which offer treatment, diagnostic, laboratory, rehabilitation, and nursing services (Private Healthcare Institutions), are classified under the Regulations as one of the following:

(1) hospitals that are equipped to diagnose, treat, and admit patients on inpatient basis;
(2) general health centers prepared to diagnose and treat patients that offer at least three medical specializations;

\(^{29}\) The Private Healthcare Institutions Regulations issued pursuant to the Royal Decree no. M/40 dated 3/11/1423 H.
\(^{30}\) The Implementing Rules of the Private Healthcare Institutions Regulations issued pursuant to the Ministerial Decision no. 12/1/45787 dated 16/4/1424 H.
\(^{31}\) The Hospitals Regulations issued pursuant to the Royal Decree no. 57/1/10 dated 30/7/1354 H.
\(^{32}\) The Health Regulations and its Implementing Rules issued pursuant to the Royal Decree no. M/11 dated 23/3/1423 H.
\(^{33}\) The Protective Healthcare Measures of Communicable Diseases Regulations issued pursuant to the Royal Decree no. M/1 dated 5/1/1380 H.
\(^{34}\) The Healthcare Profession Practice Regulations issued pursuant to the Royal Decree no. M/59 dated 4/11/1426 H.
\(^{35}\) Foreign Investment Regulations issued pursuant to the Royal Decree no. M/1 dated 5/1/1421 H.
\(^{36}\) Labor Regulations issued pursuant to the Royal Decree No. M/5 dated 23/8/1426 H.
(3) specialized healthcare centers that focus on one medical specialty or more;
(4) physician office (clinics) prepared for treatment and diagnosis of patients;
(5) radiology centers for diagnostic imaging and radiology treatment;
(6) medical laboratories;
(7) same-day surgical facilities (i.e., ambulatory surgery centers) that are licensed to
admit patients for minor and medium surgeries, provided that patients are discharged
on the same day of admission;
(8) supporting medical services facilities that provide complementary medical and
technical services and include: physical therapy centers, vision, nutrition centers,
artificial limbs, or any other facilities that are classified as a supporting medical facility
by the MOH; and
(9) 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.37

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.38 Its medical staff, including doctors and
pharmacists,39 must be properly licensed by the MOH and the General Directorate of
Health Affairs in accordance with the Healthcare Profession Practice Regulations,40
including any regulations or circulars published by the Saudi Commission for Health
Specialties, which is the regulatory body responsible for licensing doctors.41

Hospitals, unlike other Private Healthcare Institutions, are mainly required under the
Regulations to be prepared with necessary medical equipment, a laboratory, radiology

See the Implementing Rules of the Private Healthcare Institutions Regulations, supra note 30, art. 1.
See the Implementing Rules of the Private Healthcare Institutions Regulations, supra note 30, art. 3.
Visiting doctors are required to be approved by the General Directorate of Health Affairs, and hospitals
are required to provide a banking guarantee of 150,000 Saudi Riyal (equivalent of $40,000) valid for one
year from the date of approval. See the Implementing Rules of the Private Healthcare Institutions
Regulations, supra note 30, art. 8.
See the Implementing Rules of the Private Healthcare Institutions Regulations, supra note 30, art. 3, 8;
see also the Healthcare Profession Practice Regulations, supra note 34.
The requirements of the Saudi Commission for Health Specialties are available at http://scfhs.org.sa/.
unit, emergency units, outpatient clinics, and a surgery unit. The premises must be compliant with the specifications set out by the MOH and other relevant authorities in the area where a hospital is to be constructed.\(^\text{42}\) For example, the hospital must be equipped with an internal pharmacy operated in accordance with requirements set out in the Regulations pertaining to pharmaceutical practice.\(^\text{43}\) Further, hospitals must have an internal medical library and offer subscriptions with scientific periodicals relevant to the hospital’s specializations.\(^\text{44}\) Under the Regulations, the minimum numbers of beds in hospitals are: (1) thirty beds for general hospitals; (2) twenty beds for hospitals with two specializations; and (3) ten beds in hospitals with one specialization.\(^\text{45}\) The Regulations further set out the requirements and arrangements in relation to the emergency unit, surgery units, in-patient units, intensive care units, quarantine unit, medical records, and other supporting units such as catering and laundry.\(^\text{46}\)

**Investment in the Private Healthcare Sector by Foreign Entities**

*Foreign Investment in the Healthcare Sector of Saudi Arabia*

Non-Saudi GCC nationals are permitted to conduct healthcare services in Saudi Arabia. As per the WTO Schedule of Commitments, Saudi Arabia has not set any restrictions on hospital service or other human health services. Saudi Arabia liberalized foreign investment in all economic sectors, except for the activities excluded by the Supreme Economic Council, which maintains a list of excluded activities that are not open for foreign investment (Negative List). Healthcare activities are not listed on the Negative List, with the exception of services provided by “midwives, nurses, physical therapy and quasi-doctor services.” Notwithstanding the WTO obligations of Saudi Arabia and the official Negative List, the MOH has not provided licenses to foreign parties wishing to invest in most healthcare sectors.

In addition, as a member of the GCC, Saudi Arabia gives preferential treatment in general to GCC nationals in several aspects, including conducting economic activities in Saudi Arabia. GCC nationals are afforded almost identical rights to Saudi Arabian


\(^{43}\) See the Implementing Rules of the Private Healthcare Institutions Regulations, *supra* note 30, art. 11.

\(^{44}\) See the Implementing Rules of the Private Healthcare Institutions Regulations, *supra* note 30, art. 27.

\(^{45}\) See the Implementing Rules of the Private Healthcare Institutions Regulations, *supra* note 30, art. 9.

\(^{46}\) See the Implementing Rules of the Private Healthcare Institutions Regulations, *supra* note 30, art. 11.
nationals, other than the right to own land in the holy cities of Mecca and Medina, and the right to qualify for low-cost financing of healthcare centers afforded to Saudi Arabian nationals or companies wholly owned by Saudi Arabian nationals.

Despite the foregoing, the Regulations have not been amended according to the international commitments of Saudi Arabia, and the Regulations continue to require that Private Health Institutions shall be wholly owned by Saudi nationals except for hospitals. However, the Regulations provide for the possibility of “non-Saudi ownership of private hospital, clinics centers and one-day surgery facility,” in remote (rural) areas stipulated by the following: (a) to be located in remote areas decided by the Minster in the light of the severe needs and scarcity in the specialties required to be licensed; (b) the specialized non-Saudi shall obtain the approval of the investment authorities; (c) obtain a license for one facility only and (d) the non-Saudi practitioner, the owner of the healthcare facility, shall supervise the facility on a full-time basis.” The MOH has taken the position that foreigners, including GCC nationals, are permitted to set up hospitals in major cities (Riyadh, Jeddah, Dammam, Al Khobar, Makkah, and Al Madina), if the hospitals have no fewer than 150 beds, and in remote and rural areas, if the hospitals have no fewer than forty beds. Therefore, investment in other types of healthcare facilities such as one-day surgical facilities and clinical centers are not open for non-Saudi investors at present, but the MOH may grant, on exceptional basis, an approval for a foreigner to set up a single clinic in a remote area.

Management and Staffing Rules

The nationalization labor requirements are strict in Saudi Arabia, as the government has endeavored to decrease unemployment in the country. In general, the private sector in Saudi Arabia is required to comply with nationalization requirements as declared by the MOL from time to time. The current nationalization requirement for the private sector, including hospitals, is to employ Saudi Arabian nationals equivalent to at least 15% of the workforce for companies employing more than fifty people, and 10% if the company employs fewer than fifty people. In addition, the MOL creates a list that reserves certain

47 A non-Saudi physician practicing in a one-day surgery facility is required to be a consultant holding a valid professional license and insurance against malpractice valid for at least six months after termination of engagement as a consultant to the facility. The valid professional license is often primarily based on the degree and credentials of such physician obtained outside of Saudi Arabia, and such credentials shall be reviewed by the MOH.
positions for Saudi nationals (e.g., security guards, receptionists, etc), which is frequently amended from time to time.

A hospital is required to recruit a certain number of resident doctors, specialists, consultants, pharmacists, technicians, nurses, and medical staff, based on its size.\textsuperscript{48} The Regulations require that hospitals appoint a locally qualified doctor who is a Saudi Arabian national as a medical manager for the hospital, except for hospitals located in rural and remote areas. Furthermore, hospitals and clinics are required to appoint a qualified Saudi national as an administrative manager and a qualified Saudi pharmacist as a manager or deputy manager of the hospital’s pharmacy. In general, foreign companies that wish to provide management services must do so from outside Saudi Arabia, and payments owed to the foreign company are subject to withholding taxes that could be as high as 20% of amounts owed for provision of management from outside Saudi Arabia. We believe, however, since management is not prohibited under the Negative List, it is likely that such may be approved to be conducted in Saudi Arabia by foreign companies on a case-by-case basis.

\textit{Licensing Formalities}

The registration process and procedural steps for obtaining a sector-specific regulatory license to set up a hospital in Saudi Arabia can be divided into three key steps: (1) obtaining MOH’s preliminary approval; (2) obtaining MoCI’s approval; and (3) obtaining final approval from the General Directorate of Health Affairs. These three steps are further set out below. Pharmaceutical companies are also required to obtain licenses from MOH and the MoCI.

\textit{Obtaining MOH’s Preliminary Approval}

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

\textsuperscript{48} See the Implementing Rules of the Private Healthcare Institutions Regulations, \textit{supra} note 30, art. 10.
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.

Obtaining MoCI’s Approval

After successfully obtaining the MOH’s initial approval, a legal vehicle 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. If the corporate entity is going to be partially or wholly owned by non-GCC investors, a foreign investment license must also be obtained from the SAGIA.

The two most common forms of companies in Saudi Arabia are limited liability companies (LLCs) and joint-stock companies (JSCs). Establishing a JSC takes longer than establishing a LLC and is subject to additional requirements under the relevant regulations. In addition, the minimum number of shareholders of a JSC is five, while the minimum number of shareholders of a LLC is two. In terms of advantages, under the Saudi Arabian Companies Regulations, a JSC is permitted to issue tradable shares. Therefore, the JSC may be an appropriate corporate vehicle for investors who wish to offer part of the company’s share capital to other potential investors to raise additional funds through public or private placement or to pledge such shares to a lender as part of a financing.

The relevant authorities require various documents from the prospective shareholders, including the constitutive documents of each corporate shareholder; necessary approvals and powers of attorney from each shareholder approving the incorporation of the entity; information about the proposed managers of the entity; evidence of deposit of

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49 Most documents will be required to be in proper legalized form (up through the Saudi Arabian embassy or consulate in the country in which document is originated) and translated into Arabic by a translator licensed in Saudi Arabia. The documents must also be authenticated by the Saudi Ministry of Foreign Affairs in Riyadh and, for powers of attorney, by the Saudi Ministry of Justice.

50 The Companies Regulations Issued pursuant to Royal Decree No. M/6 dated 22/3/1385 H.

51 Unlike, for example, a LLC in which the shareholders’ investment is represented by interests that can only be transferred among the existing partners or new partners subject to certain restrictions and cannot be offered to public through private or public placement.

52 Unlike LLCs, JSCs may issue share certificates. We therefore expect that lenders will prefer to lend to JSC borrowers and take a pledge of such shares.
the required share capital in a local bank;⁵³ and lease of premises for the entity. SAGIA will also likely request foreign investors to submit their annual financial reports for the past two years (except for companies publicly listed in a reputable capital market outside Saudi Arabia) and may further request evidence of the expertise of the foreign shareholders.⁵⁴

After obtaining the commercial registration from MoCI and the investment license from SAGIA (if required), Saudi Arabian companies must register with the Department of Zakat and Income Tax (DZIT), as the company’s income will be subject to a tax (zakat). In general, the net income of non-GCC foreigners is subject to a 20% tax, while GCC and Saudi shareholders pay a tax of 2.5% of the value of the company’s assets. Dividends that leave the country are also subject to a 5% withholding tax, and payments to third parties outside Saudi Arabia may also subject to a withholding tax of 5% to 20%.

The company must also register with the General Organization for Social Insurance (GOSI). Saudi Arabian companies are required to participate in the social insurance scheme offered by GOSI for Saudi employees. Employers are required to pay 9% of the monthly compensation of each Saudi employee to GOSI, and deduct approximately 9% of the compensation for GOSI, which is the employee’s responsibility. Further, a fixed payment of 2% of each employee’s compensation (including non-Saudi employees) must be paid to GOSI for insurance against occupational hazards.

**Final Approval**

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(s). 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

⁵³ Many LLCs are capitalized at only SAR 500,000 (approximately $133,333) but the minimum capital will depend on the discretion of the MoCI and MOH.
⁵⁴ Most documents will be required to be in proper legalized form (through the Saudi Arabian embassy or consulate in the country in which document is originated) and translated into Arabic by a translator licensed in Saudi Arabia. The documents must also be authenticated by the Saudi Ministry of Foreign Affairs in Riyadh and, for powers of attorney, by the Ministry of Justice.
municipality, and the Civil Defense. A technical study must be submitted to the Civil Defense 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 Defense, and specialized in safety and fire protection. The Civil Defense 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 specialized licensed entity for the safe disposal of medical waste, and obtain a report from a specialized 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 MOL 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 licenses and approvals for professionals hired in Saudi Arabia. The license issued by the MOH are valid for five years and cost SAR 5,000 to 15,000 ($1,333-$4,000), based on the number of beds.

Ownership of Real Estate by Non-Saudi Investors

Owners of healthcare facilities are often interested in owning the underlying land but must be cognizant of certain limitations under local regulations. A non-Saudi entity may not own real estate in Saudi Arabia before it establishes a commercial presence in Saudi Arabia. The ownership rules applicable to GCC nationals are regulated in Saudi Arabia by The Ownership of Real Estate by GCC Nationals Regulations. Non-GCC

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55 Construction must be in compliance with the technical specifications set out by The Ministry of Municipalities and Rural Affairs (MOMRA).
56 Site and construction specifications must also be in compliance with the Resolution No. 12/1/W/15/DF dated 8/8/1425 H published by the Civil Defense Council in respect of Hospitals Safety and Fire Protection Regulations.
57 The Regulations of the Ownership of Real Estate by GCC Nationals issued pursuant to the Royal Decree No. M/55 dated 17/5/1415 and amended by the Royal Decree No. M/8 dated 15/12/1422.
nationals’ ownership is regulated by the Regulation on the Ownership and Investment of Real Estate by Non-Saudis.\textsuperscript{58}

In general, non-Saudi nationals or corporate entities that are licensed to conduct professional or commercial activities in Saudi Arabia are permitted to own property in Saudi Arabia, subject to the following requirements:

1. The property is designated for the licensed economic activities;
2. The zoning of the intended land matches the type of property in which such entity is permitted to invest (e.g., a company licensed to invest in industrial property cannot purchase land zoned as agricultural);
3. The owner may not dispose of the property unless the company discontinues its business or changes its location;
4. The size of the property must be suitable for the objects of the company; and
5. The total value of the land and the project must be SAR 30 million (approximately $8,000,000) or more.

Property ownership by a company that is wholly or partially owned by non-Saudi nationals within the boundaries of the holy cities of Mecca and Medina is not permitted. Individual foreigners who hold residency permits (\textit{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.

\textbf{Government Funding}

In order to encourage investment in and development of the healthcare industry, the Saudi Arabian Ministry of Finance (MOF) has created a financing program (Lending Program) whereby a Saudi Arabian national or company (Applicant) may obtain an interest-free loan in order to construct and develop healthcare facilities in Saudi Arabia. At present, the funding will only be offered to Saudi nationals or companies wholly owned by Saudi nationals. The Lending Program provides funds to an Applicant for utilization in connection with the construction and development of a new hospital, clinic, or treatment center in Saudi Arabia. The MOF may also approve the allocation of funds to an Applicant for use in connection with an extension to an existing healthcare facility

\textsuperscript{58} The Regulation on the Ownership and Investment of Real Estate by Non-Saudi Nationals issued pursuant to the Royal Decree No. M/15 dated 17/4/1421 H.
(Extension) with certain conditions. The Extension must (1) be located adjacent to or on
the same plot of land as the existing healthcare facility to which it relates, and (2) must
involve a new specialty area non-existent in the existing healthcare facility that the MOH
agrees to be of “importance.” The amount loaned to an Applicant (whether in connection
with a healthcare facility or an Extension) cannot be greater than the lesser of SAR 50
million (approximately $13,333,333) or 50% of the cost of construction of buildings,
medical equipment, furnishings, and workers’ accommodation facilities in the healthcare
facility or Extension as estimated by the MOF. The loan amounts are disbursed
throughout the project’s term in accordance with the disbursement schedule and as
certain milestones are fulfilled. For example, the draw down on the portion designated
for buildings is disbursed only upon completion of 10% of the project. The installments
designated for medical equipment and furnishings will be disbursed only upon
completion of more than 60% of the construction works. As discussed above, it may be
possible to have a facility that is 100% Saudi-owned managed by a non-Saudi entity,
but such approval must be obtained on a case-by-case basis.

Each Applicant and healthcare facility or Extension under the Lending Program must be
approved by the MOF in its sole and absolute discretion. Each application is subject to
the following conditions:

(1) The Applicant must be a Saudi Arabian national or corporate person;
(2) The Applicant must commence project’s implementation within eight months from
the date of execution of the loan agreement between the Applicant and the MOF;
(3) The Applicant must guarantee the loan provided by the MOF by either a real estate
mortgage or bank guarantee in an amount equal to the full amount of the loan;
(4) The Applicant must repay the loan in sixteen equal installments, the first of which
shall be payable after four years from the loan agreement’s execution date;
(5) The Applicant must engage a Saudi Arabian engineering consultant office to
supervise the project’s implementation (solely or in association with a foreign
engineering office) and a Saudi Arabian accounting firm to audit the accounts of the
project; and
(6) The Applicant must use steel, cement, sanitary ware, aluminum, and furnishings
manufactured in Saudi Arabia.
The Application to receive financing through the Lending Program is quite extensive and should be submitted only upon the final design’s completion. In addition to an application form, each Applicant is required to submit detailed documentary evidence relating to the Applicant’s financial background and the project. For example, the Applicant must submit copies of the Applicant’s financial statements for the two years prior to the date of the application and a copy of the deed to the land on which the healthcare facility will be located. The Applicant must also demonstrate that it has satisfied all governmental licensing and regulatory requirements, including: receipt of a valid health license; receipt of any relevant municipality construction licenses and approvals relating to the project’s engineering plans from a licensed engineering office, the MOH, and any relevant municipalities; satisfaction of the relevant Saudization percentages; and receipt of a certificate from the social securities department confirming that the Applicant is an establishment that is registered and in good standing with the social securities department. In addition, the Applicant must submit: (1) copies of the technical and economic studies of the project; (2) the final engineering drawings and plans for the project; (3) lists of medical equipment and furnishings (including the price of each unit and the allocation of such items to the relevant sections and rooms in the facility); (4) the price offers submitted by the Applicant for medical equipment and furniture, and (5) the draft agreement to be entered into between the Applicant and the construction contractor of the project.

If approved for a loan, an Applicant may not apply for another government-supported loan from MOF for a healthcare facility or Extension in the same city until after the first MOF loan is paid back in full. An Applicant may apply for another government-supported loan from MOF for a healthcare facility or an Extension in another city if the Applicant can show at the time of the second application that the first healthcare facility or Extension for which approval was obtained is operational, and three annual installments of the loan on the first healthcare facility or Extension was paid by the Applicant on time and in full. If a second MOF loan is approved, another real estate mortgage or guarantee must be provided by the Applicant to the MOF equal to the amount of the second loan.
Conclusion

The Saudi Arabian government is expected to require the assistance of the private sector to participate in the development of healthcare services. The MOH and SAGIA are working together to reform and improve the healthcare sector’s regulatory framework. Saudi Arabian regulators are reportedly proposing to establish a new governmental entity separate from the MOH to increase public-private partnerships, and a new national fund will be established by MOF to finance healthcare services in addition to the current lending program described above.59 We also understand that the government is considering privatizing or outsourcing the management of 218 government-owned hospitals to raise the standard of treatment and meet market demands.60 In the last year, we have noticed a number of private equity groups increasing their investments in the healthcare sector in Saudi Arabia and expect this trend to continue. Various private equity groups report annual returns in the range of 30-40% on their investments in the healthcare sector in the GCC.61

Parties interested in investing in the healthcare sector in Saudi Arabia or elsewhere in the Middle East need to consider all potential issues, including: (1) local law restrictions (including limits on foreign ownership) and tax consequences; (2) protection of intellectual property; (3) government funding programs and finance available generally (and if any co-investors require financing be done in a Shari’ah-compliant manner62);

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61 See Hancock supra note 7 at 30.
and (4) co-investment opportunities with regional players. While some view legal services as an afterthought, an experienced law firm can play an active role in vetting local partners and structuring investments to comply with local regulations and improve tax efficiency.

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