

INVESTING IN PRIVATE HEALTHCARE INSTITUTIONS AND PHARMACEUTICAL ESTABLISHMENTS IN SAUDI ARABIA.

Healthcare is one of the most promising sectors for investors in Saudi Arabia and is estimated to be growing at 5% per annum. This growth is being given renewed impetus by the Vision 2030 document, released in May 2016, which emphasizes the government's focus on building healthcare capabilities within the Kingdom. This briefing gives investors an overview of the current regulatory regime in Saudi Arabia.

Regulatory Framework

The principal legislation governing healthcare institutions in Saudi Arabia is the Private Health Institutions Law issued by Royal Decree No. M/40 dated 3/11/1423H (corresponding to 6 January 2003G) (the "**PHI Law**").

Pharmaceutical Establishments are governed by the Law of Pharmaceutical Establishments and Preparations issued by Royal Decree No. M/31 dated 1/6/1425H (corresponding to 18 July 2004) (the "**PE Law**"). The PE Law is considered at the end of this briefing.

The healthcare sector in Saudi Arabia is regulated by the Ministry of Health. The other key public body is the Saudi Food and Drug Authority ("**SFDA**") which grants licenses for pharmaceuticals and pharmaceutical manufacturing.

Foreign Ownership Restrictions

The PHI Law defines a "Private Health Institution" ("**PHI**") as a "health institution owned by the private sector and dedicated to providing health care, diagnostics, nursing services, medical laboratory tests, rehabilitation or convalescence services to patients". The PHI Law defines a number of different types of healthcare institutions, in particular, making the distinction between hospitals and other types of institutions, such as clinics, radiology centres, medical laboratories, one-day surgery centres, physiotherapy centres, optical stores, prosthetics centres and ambulance services. This distinction is important to foreign investors, because with the exception of hospitals, a PHI must be fully owned by a Saudi national.

"We are determined to optimize and better utilize the capacity of our hospitals and health care centres, and enhance the quality of our preventive and therapeutic health care services. The public sector will focus on promoting preventive care, on reducing infectious diseases and in encouraging citizens to make use of primary care as a first step....The public sector will focus on its planning, regulatory and supervisory roles in health care. We intend to provide our health care through public corporations both to enhance its quality and to prepare for the benefits of privatization in the longer term."

"Vision 2030"



There is a certain conflict between the PHI Law and the law under which Saudi Arabia acceded to the World Trade Organization Treaty (the "**WTO Law**"). The WTO Law provides that there should be no restriction on foreigners operating in both hospital services and "other human health services" save for the fact that the company must be formed between a foreign health company and a licensed Saudi medical professional. Notwithstanding this, at present the Ministry of Health will not grant licenses to companies with non-GCC shareholders.

In relation to GCC shareholders, again there is some ambiguity. The PHI Law only refers to Saudis, not GCC persons. However, the GCC Treaty affords equal treatment to all GCC citizens on a reciprocal basis. In practice, we understand that the Ministry of Health will issue licenses to companies with GCC shareholders on a case by case basis.

Additional Requirements

The PHI Law imposes a number of additional requirements on PHIs. In particular, PHIs must:

- have a fully dedicated Saudi medical supervisor or practitioner specialized in the relevant medical field (this requirement can be waived outside of the major cities);
- if a hospital, the hospital medical director must be a Saudi physician registered and classified by the Saudi Commission for Health Specialties;
- if a hospital, the administrative manager must be a qualified Saudi national;
- have a building that meets the requirements of the PHI Law (e.g. compliance with municipal regulations, disabled access etc);
- be equipped with an internal system to dispose of medical wastes, an infection control system and a health information system;
- have a contract with a waste disposal company certified by the Saudi Presidency of Meteorology and Environment to safely dispose of the medical waste; and

- have a modern system for information and have a location for the storage of patient files, which must be kept for five years.

Specific rules also apply depending on the type of PHI. A particularly extensive set of conditions apply to hospitals. For example, hospitals must have an emergency section, an outpatient clinic, a laboratory, a radiology department, a pharmacy, an operations theatre, an admission ward, an ICU department and a quarantine section. Each of these sections has its own regulatory requirements. In addition, special conditions apply to hospital administration and support services such as catering and laundry.

Hospitals must have not less than 30 beds in general hospitals, 20 beds in hospitals with two medical specialities and 10 beds in hospitals with one medical specialty.

Further special requirements apply to the other types of PHI, including medical laboratories, radiology centres, one-day surgery centres, and ambulance services.

Potential investors in PHIs in Saudi Arabia should ensure that enquiries are made of the target in relation to all these matters during the due diligence phase.

Licensing requirements

Licenses for PHIs are issued by the Ministry of Health. Licenses are issued for five years and can be renewed. Renewal applications should be submitted six months prior to expiry. License fees range from SAR 1,000 to SAR 15,000. The Ministry of Health has the power to inspect PHIs to ensure compliance with the PHI Law and other regulatory requirements. Licenses are deemed cancelled if the owner of the PHI fails to obtain the Ministry of Health's approval to transfer its title to another owner, change its activity or place of practice. However, merely taking a minority stake in a PHI will not normally require approval from the Ministry of Health, unless the license itself imposes specific conditions on the PHI in question.

All medical doctors, physicians, medical practitioners and pharmacists have to obtain a practising license from the Ministry of Health.

Penalties for breaches of the PHI Law or the licensing requirements include fines of up to SAR 300,000 and shutting the PHI down for up to six months.



Pharmaceutical Establishments

The PE Law defines "Pharmaceutical Establishments" widely. It not only includes dispensing pharmacies, but also factories preparing pharmaceuticals, pharmaceutical stores and the scientific offices of pharmaceutical companies.

Historically, all pharmaceutical establishments had to be licensed by the Ministry of Health. However, since 2009, the licensing of pharmaceutical establishments other than dispensing pharmacies is under the authority of the SFDA.

Ownership of dispensing pharmacies is restricted to Saudi nationals (although exemptions may be obtained if there are an insufficient number of pharmacists available or the pharmacy is in a remote area). Dispensing pharmacies in hospitals are included within the hospital license referred to above.

Pharmaceutical factories can be owned by foreigners provided they have a manufacturing license from the Saudi Arabian General Investment Authority. The technical manager must also be a Saudi pharmacist. Any pharmaceutical company with a factory registered in Saudi Arabia must have a scientific office, the office manager of which must also be a Saudi pharmacist.

Conclusion

It is clear that healthcare will remain an important sector in Saudi Arabia for some time to come. The Vision 2030 makes it clear that the strategic direction of the country is on increasing foreign investment in the Kingdom, as well as a general focus on healthcare. Accordingly, regulatory changes in this sector can be expected in the near future.

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