



Healthcare Regulation in the UAE

Introduction

Healthcare is among the priority sectors identified by the UAE government and, as a result, the UAE healthcare industry has displayed extraordinary growth and significant progress in the past few years. The government's focus on healthcare is aimed not only to diversify the oil-reliant economy but also to develop unprecedented healthcare infrastructure to ensure that adequate services are provided in the Emirates.

Healthcare is regulated at both the Federal and Emirate level. Federal level legislation dates back to the 1970s and 1980s and there are pending legislative reform initiatives in order to facilitate the development of the healthcare industry. There are also two healthcare free zones in Dubai, Dubai Healthcare City and Dubai Biotechnology and Research Park, which have their own regulatory bodies.

Principle Regulatory Authorities

Public healthcare services are administered by different regulatory authorities in the United Arab Emirates. The Ministry of Health (Ministry), the Health Authority-Abu Dhabi (HAAD), the Dubai Health Authority (DHA), and the recently formed Emirates Health Authority (EHA) are the main authorities.

Ministry of Health (the Ministry) and Emirates Health Authority (EHA)

The UAE Ministry of Health (the Ministry) was established pursuant to Federal Law No. 1 of 1972 to, among other things, license companies and individuals providing healthcare services, build and manage health facilities and regulate various areas of healthcare, including the practice of medicine, dentistry, nursing, pharmaceuticals and laboratories. According to Cabinet Resolution No. 10 of 2008, the Ministry is to provide UAE citizens with healthcare, prepare health, preventive and training programs, organize the practicing of healthcare professions and establish, manage and supervise health facilities.

The Ministry administers a number of federal healthcare laws, including (i) Federal Law No. 5 of 1984 (regulating the licensing and registration of physicians, pharmacists and other healthcare specialists within both public and private healthcare establishments); (ii) Federal Law No. 7 of 1975 and Federal Law No. 2 of 1996 (defining the specific requirements for establishment and licensing of public and private medical laboratories, clinics and hospitals in the UAE); and (iii) Federal Law No. 4 of 1983 (governing pharmaceutical professions and establishments and the import, manufacture and distribution of pharmaceutical products).

Until 2009, the Ministry oversaw the Northern Emirates healthcare system (the Northern Emirates include Ras Al Khaimah, Ajman, Umm al Quwain, Sharjah and Fujairah). Federal Law No. 13 of 2009 established the Emirates Health Authority, which has similar regulatory functions and initiatives as HAAD and DHA (described below).

The Health Authority Abu Dhabi (HAAD)

In 2001, the Abu Dhabi government established GAHS, the General Authority of Health Services, with a mandate to oversee all public healthcare institutions in the Emirate of Abu Dhabi. In 2007, GAHS was split into two organizations, HAAD (Health Authority of Abu Dhabi), the regulatory body of healthcare in Abu Dhabi, and SEHA (Abu Dhabi Health Services Company), the operator of public healthcare assets.

HAAD was established as a public authority with financial and administrative independence pursuant to Abu Dhabi Law No. 1 of 2007. According to Law No. 1, HAAD's mandate is to provide the highest levels of medical and health insurance services and to develop the health sector and related policies in Abu Dhabi. HAAD is also responsible for, among other things, monitoring and regulating the healthcare industry in Abu Dhabi, and overseeing the process to upgrade the hospitals and clinics in the Emirate of Abu Dhabi in accordance with accredited international standards. In accordance with its mandate, HAAD has developed a number of policies addressing health service regulatory issues. The policies set forth authorisation, licensing and operational regulatory and compliance requirements for facilities, clinicians, health insurance and other health services. According to its website, HAAD is currently undertaking a comprehensive review of all HAAD Policies and Standards with the aim of producing consolidated manuals that will simplify this process.

Abu Dhabi Health Services Company (SEHA)

Abu Dhabi Amiri Decree No. 10 of 2007 established SEHA as an Abu Dhabi public joint stock company owned by the Abu Dhabi government. According to Decree No. 10, SEHA owns and manages, either directly or indirectly, public health facilities and is expected to implement the policies, projects and strategies approved by HAAD to develop the healthcare industry in the Emirate of Abu Dhabi. SEHA's website states that it owns and operates 12 hospital facilities, 2,644 licensed beds, and more than 40 Ambulatory and Primary Healthcare Clinics. According to its website, SEHA is currently collaborating with a number of healthcare groups, including the following:

- Johns Hopkins Medical for the management and operations of Tawam Hospital in Al Ain, Al Rahba Hospital located 40 km outside of Abu Dhabi and Corniche Maternity Hospital in Abu Dhabi;
- Cleveland Clinic to manage Sheikh Khalifa Medical City (SKMC), a network of healthcare facilities in Abu Dhabi consisting of Sheikh Khalifa Hospital, a Behavior Sciences Pavilion and the Abu Dhabi Rehabilitation Center, in addition to more than 12 specialized outpatient clinics and nine primary healthcare centers around the city of Abu Dhabi;
- Bangkok-based Bumrungrad International Limited (BIL) to manage Al Mafraq Hospital; and
- Vienna Medical University and VAMED for the management of the central hospital in Al-Ain.

Dubai Health Authority (DHA)

DHA was created in June 2007, pursuant to Law No. 13 issued by His Highness Sheikh Mohammed bin Rashid Al Maktoum, the Ruler of Dubai. As the strategic health authority for the Emirate of Dubai, DHA's principle objectives include healthcare planning and promotion of healthcare investment in Dubai, improving healthcare quality through information systems and standards, regulating healthcare services in Dubai, developing a comprehensive healthcare insurance and funding policy, public health promotion, developing medical education and research, and owning and operating Dubai government healthcare facilities.

DHA is authorized to regulate all healthcare services in Dubai, including those in free zones. Healthcare facilities and professionals in Dubai must be licensed by DHA. The principle facilities license categories are hospital and day surgical centers, ambulatory

care facilities, diagnostic centers, complementary and alternative medicine centers, pharmaceutical facilities and other facilities. Facilities are subject to inspection by the Health Regulation Department of DHA for purposes of ensuring compliance with local and federal laws and regulations.

DHA owns and operates a network of medical facilities including hospitals (Al Wasl, Dubai and Rashid), and primary health care and speciality centres (e.g. the Dubai Diabetes Center) spread throughout the Emirate of Dubai.

Center for Healthcare Planning & Quality, Dubai Healthcare City (DHC)

DHC is a free zone launched in late 2002. DHC comprises two “communities”: the Medical Community and the Wellness Community. The Medical Community focuses on clinical services for disease treatment and prevention and comprises two hospitals and medical, dental, nursing facilities and associated health schools. The Wellness Community houses outpatient clinics, spa resorts, and other providers of wellness services.

The Center for Healthcare Planning and Quality (CPQ) was established jointly with Harvard Medical International as an independent regulatory body responsible for implementing standards for healthcare delivery and patient care within DHC pursuant to various rules, policies, standards and guidelines that are intended to comport with international best practice. CPQ has a registration and licensing department that also deals with registration and commercial licensing of entities and branches doing business within the free zone. CPQ is responsible for licensing, enforcement and inspection of DHC-based entities and professionals.

UAE Regulation of Pharmaceuticals and Medical Devices

Pharmaceuticals

While there are a few domestic producers of pharmaceutical products, the UAE pharmaceutical market is dominated by foreign multinationals. Basic legal requirements governing the import, manufacture and distribution of pharmaceutical products are set forth under Federal Law No. 4 of 1983. (Law No. 4 refers to medicines and pharmaceutical compounds, although the following description generally refers to both as pharmaceutical products.) Law No. 4 prohibits anyone from engaging in the “pharmaceutical profession” without a license. The “pharmaceutical profession” is defined as the “preparation, composition, separation, manufacturing, packaging, selling or distribution of any medicine or pharmaceutical preparation for the prevention or cure of illnesses in human beings or animals”. Law No. 4 also prohibits, among other things, opening up a pharmacy, a “medical store”, or a pharmaceutical factory without a license. License applicants for a pharmacy or a medical store must be UAE nationals. A “medical store” is defined as an establishment within the UAE the business purpose of which is the import, storage and wholesale distribution of medicine.

Law No. 4 prohibits the import of pharmaceutical products except by licensed medical stores, and prohibits the distribution of imported pharmaceutical products unless they have been registered with the Ministry of Health. Law No. 4 requires each medical company that plans to market its products in the UAE to register with the Ministry. The law contains various labeling requirements, and provides for the establishment of a committee within the Ministry to oversee registration of medicine and pharmaceutical companies and determine the pricing of medicines.

Law No. 4 does not prescribe a registration procedure, although various procedures and information requirements are set forth on the Ministry’s website. Registration requirements vary based on the classification of the pharmaceutical product. Classification is determined by the classification committee of the Ministry, based on information submitted by the registration applicant.

UAE Cabinet Resolution No. 7 of 2007 prohibits the advertising or promotion of medical products without a prior license issued by the Ministry. Licenses contain a number of conditions, including among others requirements for "correct and balanced " statements, the absence of harm to third party products, the absence of exaggerations or misleading statements, and the absence of prejudice to customs or Islamic values.

Medical Devices

Medical devices are also regulated by the Ministry. According to guidelines on the Ministry's website, medical device manufacturers must register with the Ministry before they can market their products in the UAE. Companies who wish to export their products into the UAE must do so via a local representative or distributor who has a licensed medical store. Medical devices are categorized under Class I, Class II a, Class II b, Class III and active implantable devices. The appointed local representative or distributor must submit a medical device registration application form to the Ministry's Drug Control Department. If the application is approved, a registration number is given, which is valid for five years. A registration number can be revoked (i) if the applicant requests it or (ii) upon failure to meet the following standards based on assessment or monitoring: (A) the devices are unsafe and/or harmful; (B) the quality of the devices is substandard; or (C) the devices differ from the approved label (including if the brand name used is the property of and owned by another legal entity). According to the Ministry, the approval process takes between eight to twelve weeks after the application is submitted.

According to Ministry guidelines, classification, requirements and evaluation of devices follow international standards, mainly those of the Global Harmonization Task Force for Medical Devices, the US Food and Drug Administration and the EU Medical Device Directive 93/42/EEC, the EU In Vitro Diagnostic Device Directive (IVDD) 98/79/EC and the EU Active Implantable Medical Device Directive (AIMDD) 90/385/EEC. The guidelines provide for a simplified registration process for devices that have received approval from recognized regulatory agencies, such as those in Europe, the US, Australia, Canada or Japan.

As with pharmaceuticals, the medical device market is dominated by foreign multinationals.

Biotech

The UAE has undertaken some early stage initiatives into biotechnology. Dubai Biotechnology and Research Park (DuBiotech) is a Dubai free zone that was officially launched in 2005 as part of Dubai's 2010 vision to establish a knowledge-based economy. As a free zone, DuBiotech aims to provide benefits such as a streamlined registration process and regulatory regime, a 100% tax-free environment and 100% foreign ownership. According to its website, DuBiotech targets the following business segments: Therapeutics, Diagnostic and Analysis, Agricultural, Forestry, Horticulture, Food, Environment, Specialty Supplies, Equipment, Life Science Consultancy, and Life Science and Biomedical Associations. DuBiotech has a department of Regulatory & Science Affairs that assists companies in complying with federal and local laws, and develops and implements codes of practice.

DuBiotech is not the only biotech initiative in the UAE. In November 2009, an announcement was made that Abu Dhabi government-owned Emirates Biochemical and Pharmaceutical Company had entered into an agreement with two Korean biomedical firms to set up the first biotechnology plant in the Middle East for the production of drugs to treat diabetes mellitus, nephrological diseases and tumors.

Other Considerations for Foreign Entrants

Foreign entities wishing to enter the UAE healthcare market must consider a number of other factors relating to doing business in the country, such as corporate, regulatory, employment, intellectual property, tax and dispute resolution matters. For a brief review of these types of issues, please see our guide entitled "Doing Business in the United Arab Emirates."

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