

## 2013 Update: Healthcare Regulation in the United Arab Emirates

**The healthcare industry continues to develop in the UAE with new world class projects and more elaborated policies and regulations.**

### Introduction

This Client Alert updates a [previous Latham publication](#) with new information to help companies navigate changes to regulatory bodies and understand healthcare policies with which they will need to comply. Though the regulatory landscape has not changed dramatically, notable recent developments, include clearer efforts from the federal government to integrate the Northern Emirates in the healthcare growth trend, the issuance of a new set of policies and manuals in Abu Dhabi, and certain legal and regulatory updates in Dubai.

### Background

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 at diversifying the oil-reliant economy but also at developing 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.

### Principal Regulatory Authorities

Public healthcare services are administered by different regulatory authorities in the United Arab Emirates. The Ministry of Health, Health Authority-Abu Dhabi (HAAD), the Dubai Health Authority (DHA) and the Emirates Health Authority (EHA) are the main authorities. Despite the government's efforts at modernizing the healthcare system by creating new authorities and issuing new regulations in the last decade, the division of powers and authorities among the various regulatory entities (between the Federal and Emirates levels and between different entities at each level) remains unclear in certain areas. Some overlaps exist between the different authorities, in particular, in relation to licensing as well as to the monitoring and control of medical institutions.

## **Ministry of Health and Emirates Health Authority**

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 practice 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).

The Ministry oversees the Northern Emirates healthcare system (the Northern Emirates include Ras Al Khaimah, Ajman, Umm al Quwain, Sharjah and Fujairah). Some of the Northern Emirates recently started establishing new healthcare institutions or reforming existing ones. Sharjah, for example, established the Sharjah Health Authority by Sharjah Amiri Decree No. 12 of 2010. The Ministry, however, still invests substantial efforts to improve the level of healthcare services in the Northern Emirates. The projects announced by the Ministry in 2012 were mainly in these Emirates.

Federal Law No. 13 of 2009 established the Emirates Health Authority (EHA), which has similar regulatory functions and initiatives as HAAD and DHA (described below). One of EHA's main objectives is to encourage cooperation between the federal and local health authorities and between such authorities and the private sector. EHA is based in the Northern Emirate of Sharjah.

## **The Health Authority – Abu Dhabi (HAAD)**

In 2001, the Abu Dhabi government established the General Authority of Health Services (GAHS) with a mandate to oversee all public healthcare institutions in the Emirate of Abu Dhabi. In 2007, GAHS was split into two organizations, Health Authority - Abu Dhabi (HAAD), the regulatory body of healthcare in Abu Dhabi, and Abu Dhabi Health Services Company (SEHA), 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 authorization, licensing and operational regulatory and compliance requirements for facilities, clinicians, health insurance and other health services.

In December 2012, HAAD released a new set of policy manuals seen as the “foundation stone” for the regulation of the healthcare system in Abu Dhabi. All entities operating in the healthcare sector in Abu Dhabi are required to comply with the new set of policies and regulations which aim to enhance quality control, transparency, good governance and access to healthcare. The new policies and regulations also aim to enhance coordination between the major stakeholders (regulator, healthcare providers, healthcare professionals, patients and insurance companies) and to define the division of roles, responsibilities and accountabilities between them. In addition, in its announcement of the new policy manuals, HAAD stated that the promotion of private investment opportunities is one of HAAD’s strategic priorities. The announcement added that the new policies and regulations will greatly contribute to achieving this priority.

## **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 several hospital facilities and a large number of ambulatory and primary healthcare centers. 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; 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 main health authority for the Emirate of Dubai, DHA’s principal 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.

The Dubai Executive Council issued Decision No. 32 of 2012 setting out a new licensing and disciplinary framework for healthcare professionals. Decision No. 32 established a permanent commission under the

name of Medical Practice Commission which proposes and revises the rules, conditions and criteria for the practice of health-related professions in the Emirate. The new commission is affiliated with the DHA and will have licensing and disciplinary powers which it exercises in coordination with DHA. Article 2 of the Decision explicitly excludes Dubai Healthcare City (described below) from its scope.

DHA owns and operates a network of medical facilities including hospitals (e.g. Latifa Hospital, Dubai Hospital and Rashid Hospital), and primary health care and specialty centers (e.g. the Dubai Diabetes Center) spread throughout the Emirate of Dubai.

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

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.

Law No. 9 of 2011 established the Dubai Healthcare City Authority (DHCA) which oversees DHC and implements its objectives. DHCA shall establish and manage DHC’s infrastructure and administrative framework. It shall be responsible, among other things, for the development of medical and paramedical colleges and universities, research centers, specialized medical and health related facilities, clinics, pharmaceutical companies, medical devices companies, hotels and other related facilities. DHCA may also establish and license hospitals, medical institutions and companies, and shall have a monitoring and inspection role in relation to such institutions.

The Center for Healthcare Planning and Quality (CPQ) was established 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.

## **UAE Regulation of Pharmaceuticals and Medical Devices**

### **Pharmaceuticals**

There are a few domestic producers of pharmaceutical products and 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, "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 the Ministry's guidelines, 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 International Medical Device Regulators Forum, 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 percent tax-free environment and 100 percent 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 recently announced that it registered a year-on-year increase of 50 percent in the number of new commercial licenses issued, taking the total number of companies based in the free zone in 2012 to 126. The last two years also saw the establishment of the first pharmaceutical manufacturing facility in DuBiotech and the opening of the first industrial biotech laboratory.

## **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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