

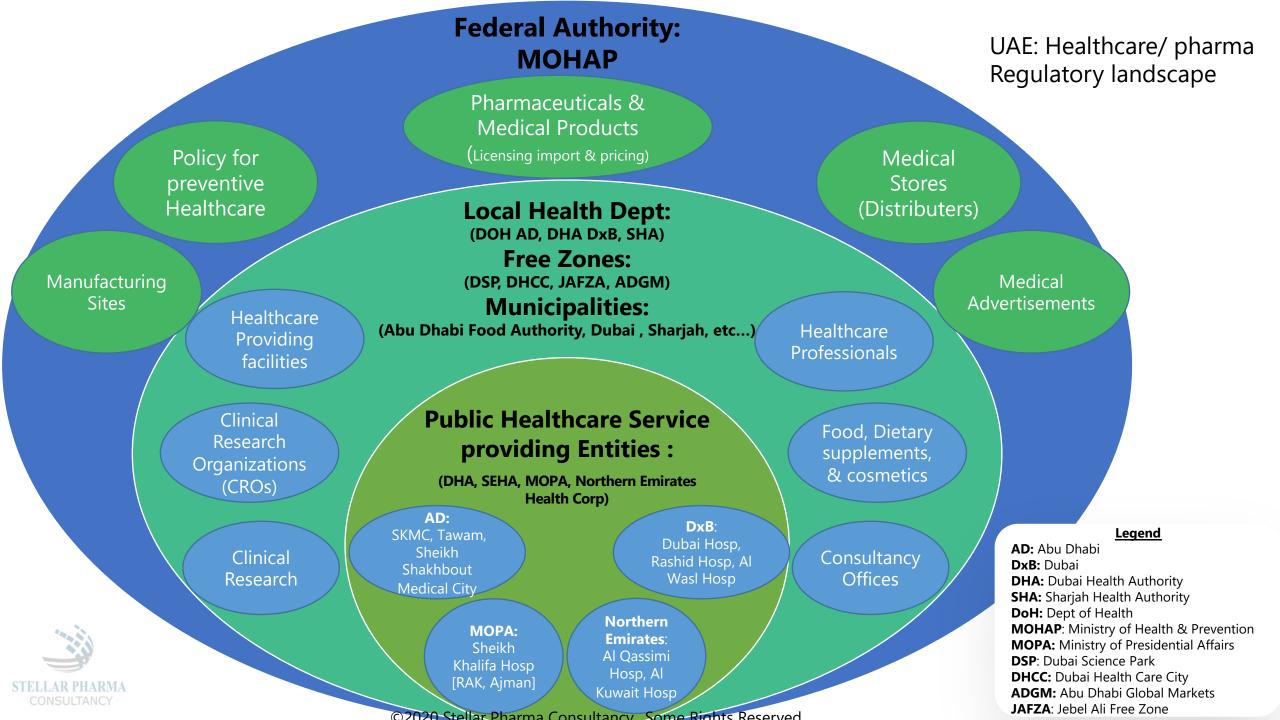
UAE Healthcare - Pharma Landscape

Exploring the landscape, business environment & key players within the healthcare /Pharma sector in the United Arab Emirates

Contact info:

Nadia.Younis@stellarpharmaconsult.com

www.stellarpharmaconsult.com





Product Registration NDA Submission Manufacturing Sites Pricing MAH (0-3 months) Registration (6-18 months) (6-9 months) (3-6 months) File Review & Product Testing File Review Legalized Documents Approval Letter [Submit • Module 2-5 as per GCC • Evaluation (Efficacy + Appeal → Accept Price) SMF guidelines [Stability for · Obtain Price Certificate from • Inquiries may arise from Safetyl Zone 4] 6-month data with Stability [GCC requirements] relevant committee MOH a commitment to submit Quality Control Lab · Proceed to market product Approval letter the 12 months upon [Requirements + Reagents] • UAE doesn't do site · Products that aren't Exemption from localized inspection as it only therapeutic do not get priced approval eCTD Publishing artworks if product has a approves sites approved by (ex. Dietary supplements • Schedule Submission limited or hospital only reference countries (ex: which don't include Vitamin D GCC, SFDA) or Iron etc...)





Additional Information

- NDA: New drug application- only applicable for medical products classified as conventional medicines/Pharmaceutical Medical Devices
- Some Vitamins & Dietary Supplements are classified as conventional medicine.
- Some products fall under GSL (General Sale List) which is subject for registration but with less requirements than a regular NDA.
- In UAE, Dubai Municipality offers licensing services for dietary supplements that don't fall within the conventional medicines classification.
- Lab Testing takes place during first consignment

Ministry of Health & Prevention (MoHAP)





www.moh.gov.ae

- The federal regulatory authority in the U.A.E. for healthcare/ public health is the Ministry of Health and Prevention.
- The Ministry of Health and Prevention (MOHAP), formerly known as the Ministry of Health, oversees the implementation of Public Health policies on the federal level.
- MOHAP provides regulatory oversight in the northern emirates (through the medical district for each Northern **Emirate**)
- It also licenses and controls pharmaceutical products / medical products licensing and supply chains including the prices of medicinal products nationwide.
- While healthcare provision including licensing HCPs and HC service providing facilities in the northern emirates are regulated entirely by MOHAP, however certain emirates (Dubai & Abu Dhabi) or free zones also have their own Health Regulatory Departments.

Department of Health (DOH) Abu Dhabi





https://doh.gov.ae

formerly known as Health Authority – Abu Dhabi (HAAD), regulates the healthcare sector in Abu Dhabi ensures excellence in healthcare for the community by monitoring the health status of the population.

The Department of Health – Abu Dhabi (DOH-AD),

- It defines the strategy of the health system, and it monitors and analyzes both the health status of the population and the performance of the system
- The DOH shapes the regulatory framework for the health system, inspects against regulations, enforces standards, and encourages the adoption of world-class best practices and performance targets by all healthcare service providers in the Emirate.
- The DOH regulates the coverage & Benefits of Basic Insurance & Minimum Benefits for the Private Insurance.



Dubai Health Authority (DHA) Dubai





https://www.dha.gov.ae.

- The DHA is the main health authority in Dubai. DHA regulates all of Dubai's healthcare sector services through licensing healthcare facilities and professionals and inspecting health facilities.
- DHA also regulates the cost of healthcare in the emirate
- As per the Dubai Health Authority (DHA) Strategy 2016–2021, a government directive supports Dubai's aims to attract, retain, and develop the healthcare workforce, with a goal of providing access to world-class medical educational opportunities.
- DHA regulates Insurance minimum Benefits and coverage in Dubai



Sharjah Health Authority (SHA) Sharjah





http://www.sha.gov.ae/

- The Sharjah Health Authority newly established and works with the MOHAP- Sharjah Medical District to regulate Sharjah's Healthcare Sector.
- SHA's mission at present is to develop and manage Sharjah Healthcare City. It also manages the Sharjah Health Insurance Department (Insurance is not yet mandatory in Sharjah)
- The Sharjah Healthcare City (SHCC) will offer prospective investors i.e. individuals and companies across the globe an excellent investment opportunity in the field of healthcare and related fields under convenient free zone rules and regulations through single window service system





Free Zones-1



Dubai Science Park-(DSP)

- A science-focused business community, dedicated to supporting entrepreneurs, start-ups, SMEs, and MNEs
- It is responsible facilitating and supporting private sector companies who require specialized facilities for conducting research in the U.A.E.

Dubai Healthcare City Authority – Regulatory (DHCR)

- Regulates Dubai's healthcare free zone: Dubai Healthcare City (DHCC)
- It is responsible for the licensure of all healthcare professionals and healthcare operators in the free zone. It is also responsible for setting and maintaining international best practices in healthcare delivery and patient care within that zone
- http://dhcr.gov.ae.



https://dsp.ae

Free Zones-2 Abu Dhabi Global Markets (ADGM)



- Abu Dhabi Global Market is an award-winning international financial centre strategically located in the capital of the United Arab Emirates.
- ADGM's three independent authorities the Registration Authority (RA), the Financial Services Regulatory Authority (FSRA) and ADGM Courts - together ensure that its businessfriendly environment operates in line with international best practices, recognized by major financial centers worldwide
- ADGM and the Department of Health (DoH) have entered into an agreement of cooperation and delegation to establish a mutual strategic framework and collaboration between governmental entities. The agreement strives to enhance the position of Abu Dhabi as an economic centre in the areas of health, medical and pharmaceutical investments.

https://www.adgm.com





Healthcare financing in UAE: Key facts (1)

☐ The Nationals:

- ❖ Nationals (almost 16% of the total population) are eligible for universal Healthcare coverage. In UAE, the governmental healthcare services providing facilities (Ambulatory healthcare services, hospitals, preventive healthcare, etc) are meant to cover for Nationals healthcare needs.
- ❖ The local departments of health in Abu Dhabi (DoH-AD) & Dubai (DHA-DxB), the Ministry of Presidential Affairs (MOPA), along with the Northern Emirates Healthcare Corporation: all thrive to provide world class healthcare services to national patients through top notch governmental healthcare facilities and hospitals.
- ❖ Abu Dhabi and MOPA, tend to give the management of the prime government hospitals to world class healthcare institutions like Cleveland, Mayo clinic, Johns Hopkins etc.
- ❖ Abu Dhabi: Thiqa insurance scheme is provided to Nationals possessing the Abu Dhabi Passport or Nationals working for Abu Dhabi institutions: extremely generous coverage allowing patients to select their healthcare service provider even if it is from the private sector regardless of the costs.

☐ The rest of the population (Expats):

- Get their healthcare services from the private sector;
- ❖ 100% of residents in Dubai and Abu Dhabi have a sort of insurance that ranges between basic plans for the low-income residents (Laborers) up to very generous enhanced plans offered by employers to their executives



Healthcare financing in UAE: Key facts (2)

- ☐ Healthcare spending, if compared to advanced countries, has different characteristics mainly due to different demographics:
 - ❖ In the UAE (like other GCC countries) the population over 65 years which is far smaller in percentage when compared to the worldwide average.
 - ❖ The males are higher in percentage when compared to females (up to 70% are males)
 - ❖ The blue-collar workers make up 40% of the population
 - ❖ The Indian / Asian nationals make up to 60%-70% of the population.
- □ COVID 19 situation forced regulators to accept to go beyond the norm: telehealth and online pharma delivery became regulated for the first time since long in UAE.
- ☐ Healthcare cost control:
 - ❖ Insurance started to play a greater role in influencing the norms of healthcare providing to control for moral hazards and overutilization.
 - ❖ Abu Dhabi known for generosity in offering healthcare services started to put more restrictions on spending over pharmaceuticals encouraging generics and cost effectiveness.
 - ❖ Disease management is becoming a trend encouraged by insurance and local healthcare departments:
 - Research Based Pharma companies are trying hard to compensate for their higher cost products, bringing value beyond their products through establishing public private partnerships focused on disease awareness and management.



Special Considerations

- <u>Dietary supplements, (with ingredients below certain limits), food products including medical nutrition products</u> & cosmetics are regulated & controlled by:
 - Dubai Municipality
 - Abu Dhabi Food Authority (however AD accepts Dubai's Municipality control)
 - Local Emirates Municipalities (apart from Abu Dhabi)

However, borderline products, medicated cosmetics, pharmaceutical products need to be classified through a dedicated service provided by MOHAP (Ministry of Health & Prevention) to rule out the regulatory authority that the product should fall under its control.

- Ministry of Health & Prevention (MOHAP) controls:
 - Medicated cosmetics,
 - Vitamin D, Iron, Vitamin E, Calcium,
 - Herbal products with medical claims &
 - General Sale healthcare products with medical claims (GSL).
 - Pharmaceuticals with medical claims, drug products and medical devices.

All above type of products controlled by MOHAP should be:

- ✓ Registered (licensed) by MOHAP first before importation and trading.
- ✓ imported & distributed through a licensed medical store in UAE.
- ✓ Drug products & Therapeutic dietary supplements are subject for pricing by MOHAP.





Health Insurance UAE

Insurance overview

A mandatory health insurance exists in Abu Dhabi & Dubai.

The mandatory health Insurance since its inception had driven the demand for private facilities and attracted investments.

UAE Nationals

UAE nationals in UAE have universal coverage that covers 100% of their healthcare needs. Nationals obtains a healthcare card entitling them to get healthcare services at their respective emirates public sector, Abu Dhabi allows nationals to get services from Private sector reimburses the provided services. Nationals in the emirate of Abu Dhabi are covered at no cost through the "Thiqa" program. In Dubai is "Saada"

Employers

All employers are required to provide health insurance to their employees and their employees' dependents in Abu Dhabi & Dubai

Insurance Caps

Low-income expats have a basic plan but there are caps placed on their insurance policies

Abu Dhabi

mandatory health insurance for residents

Dubai

mandatory health insurance for residents

Sharjah

Gradual movement towards mandatory insurance

Ajman

does not have mandatory health insurance

Umm al Quwain

does not have mandatory hea Ith insurance

Ras Al Khaima

does not have mandatory hea Ith insurance

Fujairah

does not have mandatory hea Ith insurance

