

Redefining Regional Pharma

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PAPER

The UAE's pharma landscape

The number of factories in the UAE has expanded rapidly, from 4 in 2010 to 23 in 2021

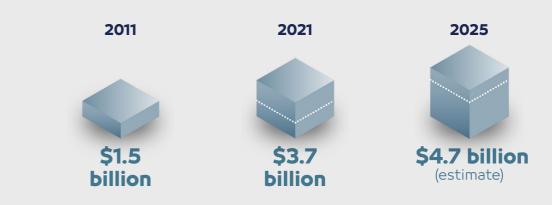






With this expansion, there are now more than 2,500 medicines produced in the UAE

Local market value



UAE pharmaceutical market

As a sustainable investor, we developed this ADQ FWD paper to examine key opportunities and investments for enhancing regional pharmaceutical capacity to ensure access to affordable, quality medication while advancing innovative treatments.

Jaap Kalkman Group Chief Investment Officer, ADQ

FOREWORD

The United Arab Emirates has made impressive inroads to redefine regional pharma.

The global pharmaceutical industry is increasingly realizing the value of a more agile and resilient supply chain model, which facilitates rapid response to changing market forces and mitigates the effect of cataclysmic events.

With a track record of substantial infrastructure investments, unprecedented legal reforms, and robust regulations, the UAE has become a regional hub for the pharmaceutical industry over the past decade and created an environment conducive to sustainable growth.

The nation will continue accelerating a resilient regional pharmaceutical ecosystem and ensure seamless access to affordable medications and innovative treatments.

The future of pharma is upon us.









2020





\$2.7 billion



FOREWORD

SECTION ONE

The UAE's decade of steady growth

To reshape pharmaceutical supply chains, it is important to decrease reliance on imports, eliminate single-source dependencies, and focus on local value creation.

The UAE's plans to localize the pharmaceutical industry were set in motion over a decade ago, with the sector identified as instrumental for the nation's diversification plans.

Cost of drugs in the UAE vs other GCC nations

The UAE's Ministry of Health and Prevention (MoHAP) intends to continue its 'Reduction in Medicine Prices' initiative until UAE drug pricing becomes the lowest in the Gulf.

Through a series of initiatives, the UAE has made significant strides to ease patients' financial burden and unlock access to modern drugs at affordable prices. It is testament to the resilience of the UAE pharmaceutical market that, despite price reductions, growth has remained strong and steady.

The drug development process

The time and cost to develop generic drugs is significantly lower than that required for innovative or originator drugs.

On average, originator drugs require over 13 years of development time whereas generics take between two to five years from development to market. The development costs of both originator and generic drugs are reflected in their market pricing.

The UAE has implemented generic substitution policies since 2018, resulting in more than 6,000 high-quality, affordable generic drugs that cost around 60% less than branded medicines.

Originator drugs

Development phases	Discovery	Lead compound optimization
Average development cost for originator drugs	\$1.3 billion –	overall costs increase
Average development duration for originator drugs	1-2 years	
Primary goals per phase	 Identify the cause of a disease at molecular level Explore potential mitigation methods by narrowing down proteins ('targets') that could potentially impact disease outcomes Conduct high throughput screening of compounds, then screen against non-targets 	 Synthesize compound library to identify lead and backup compounds Implement mechanism, safety, Pharmacokinetics (PK) and Pharmacodynamics testing (PD)
		Generic drug

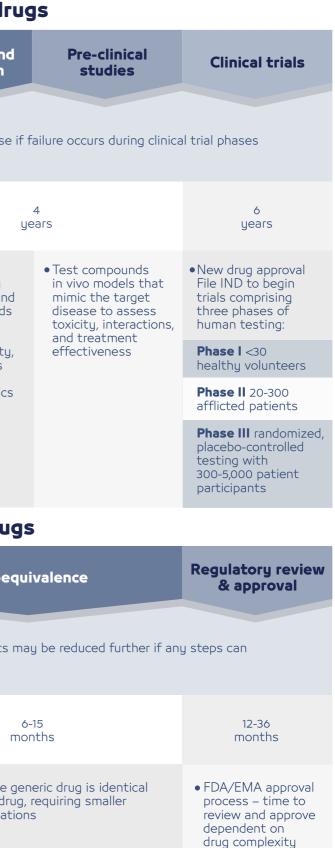
Development phases	Product Development	Bioed
Average development cost for generic drugs		n – timeline and costs i nted simultaneously
Average development duration for generic drugs	4-6 months	Г
Primary goals per phase	 Reverse engineering of existing drugs 	 Tests to prove g to originator dru testing population



From building public-private partnerships, incentivizing

pharmaceutical companies and opening up market access for innovative and novel medicines, we are realizing the UAE's vision to be a leading pharmaceutical hub for the region and beyond.

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SECTION TWO

Unlocking the UAE's pharma growth opportunity

Recent global events have reinforced the need for robust supply chains and increased self-reliance.

Ensuring adequate investment in life sciences infrastructure, establishing synergies between the public and private sectors to drive joint ventures, and fostering an attractive pharmaceutical and life sciences landscape, will lay the groundwork for multinationals to develop and produce innovative medicines in the UAE.

The UAE has inherent advantages that can further scale its localization agenda:

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A gateway to the world

With over 3.6 billion people located within a 10-hour flight radius of Abu Dhabi, it is ideally situated as a hub for local, regional and global pharmaceutical industries.



An agile and efficient pharmaceutical regulatory framework

The nation's modernized pharmaceutical regulatory framework has agility built-in and is capable of fast-tracking production within a 24 to 48-hour timeframe from initial application.

A sophisticated pharmaceutical infrastructure



AD Ports Group's operations include the region's largest temperaturecontrolled warehouse facility.

Additionally, the Group became the first organization in the UAE to receive Good Distribution Practice accreditation, certifying that all required measures to safeguard product quality have been implemented along the pharmaceutical supply chain.



A regional hub for global pharmaceutical players

Attracting international pharmaceutical companies to establish and expand their footprint in the UAE is a priority.

Eleven pharmaceutical multinationals currently operate in the UAE, including Johnson & Johnson, AstraZeneca, Novartis, Roche, Pfizer, GSK and Sanofi.



The UAE has a global mindset and sets the pace for global competitiveness in the biopharma sector.

Mohamed Nasser General Manager Middle East & Africa (MEA) Amgen

Establishing an agile and responsive regulatory landscape

A robust regulatory regime underpinned by a modern legal framework is vital to establish the nation as a regional pharmaceutical hub.

Accordingly, the UAE is taking steps to streamline its regulatory processes to align with international standards, which will, in turn, attract more companies to set up R&D and manufacturing operations in the country.

January 2020

Law No. 8 of 2019 on Medical Products, Pharmacy Profession and **Pharmaceutical Establishments** establishes a supreme committee for clinical study ethics, tighter price controls on medical products, and increased sanctions.

September 2020

Ministerial Decree 321 of 2020 caps data exclusivity for eight years from when marketing approval is secured, with generic drug companies able to apply within the last two years of the data exclusivity period.

January 2021

Federal Decree Law No. 26 of 2020, effective from 2 January 2021 removes the requirement to have 51% share capital owned by majority UAE national shareholders or a company wholly owned by UAE nationals.

July 2021

The Ministerial Resolution on Tracking Pharmaceutical Products **Resolution** requires businesses to log local and imported product information in the UAE's highly advanced track-and-trace platform from production to consumption.

August 2021

To fast-track innovative and rare medicine approvals, MoHAP has advised international pharmaceutical companies to apply for marketing approval for their products in the UAE before permission is secured in the country of manufacture.

November 2021

Federal Law No. 11 of 2021 aligns UAE patent law with international patent legislation, including introducing a 12-month grace period to disclose inventions before filing and accelerated processes for urgent applications.



Madhukar Tanna Chief Executive Officer, Pharmax

The regulatory reforms introduced to date have played an important role in our development and growth. To boost exports, the next step is to collaborate and unify regulatory policies across the region.



PHARMA GROWTH OPPORTUNITY

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SECTION TWO: UNLOCKING THE UAE'

Driving localized manufacturing capabilities

UAE is laying robust foundations to build on its position as a leading regional pharmaceutical hub and global gateway.

By incentivizing drug partnerships and encouraging manufacturers to set up local operations, the UAE's position as a regional drug manufacturing hub is strengthened, and access to innovative medicines improved.

New and existing production investment opportunities

The Abu Dhabi Department of Economic Development (ADDED) has implemented the Basic Industries Project, representing a total investment of AED 286.4 million to define vital industrial investment areas in Abu Dhabi in collaboration with Abu Dhabi Investment Office (ADIO), the Department of Health – Abu Dhabi (DoH) and the Abu Dhabi Health Services Company (SEHA).

As part of the project, investment areas in the medical sector have been identified to drive local production and promote self-sufficiency.

Basic Industries Project's medical manufacturing investing areas



Operation 300bn: Driving the development of the local pharmaceuticals industry

Launched in March 2021 as part of Projects of the 50, Operation 300bn aims to stimulate the UAE's economy by raising the industrial sector's GDP contribution from AED 133 billion to AED 300 billion by 2031. Eleven vital industrial sectors have been identified, three of which have a direct impact on Pharmaceutical and Life Sciences:



Stimulating the growth of pharmaceuticals



Creating a conducive business environment



Supporting advanced manufacturing

Generics' formula for success

As cost containment is prioritized and local demand increases, generics are predicted to outperform patented drugs.

In Abu Dhabi, initiatives to drive the sector have included formal procedures for new drugs to be incorporated into the DoH formulary, and a regulation requiring pharmacists to dispense generics instead of branded medicines. Law No. 8 of 2019 requires patients preferring branded options to pay the difference in cost.



The main barrier to the uptake of generic medicines is patients preferring well-known brands. To expand the local pharmaceutical industry, we need the public to understand more about high-guality alternatives.

Dr Ali AlSayed Hussain

Untapped opportunity beckons with biosimilars

Biosimilars deliver similar results at 10-30% lower than the cost of the reference biopharmaceutical product that has previously been licensed.

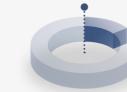
The adoption of biosimilars across the Middle East and Africa (MEA) region is relatively nascent. Progress is being made to establish a framework conducive to the production of biosimilars, and manufacturing incentives are fostering a positive environment. Following MoHAP's published pricing guidelines for biosimilars, prices of biosimilars fell by 34% in the UAE.



Biologics account for



15% (\$4.1 billion)



of the MEA of global pharmaceutical market pharmaceutical market

of the UAE pharmaceutical market



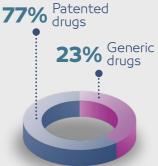
needed to manufacture these products.

Dr. Kiran Mazumdar-Shaw Executive Chairperson, Biocon

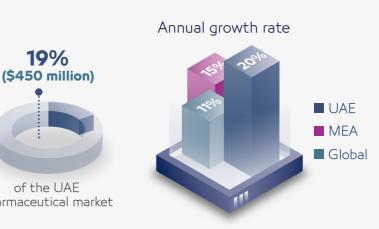


pharmaceutical market

UAE prescription drug market by 2030



Director of the Pharmacy Department, Dubai Health Department (DHA)



Biologics are very complex with specific manufacturing requirements. Longer-term, the UAE can emerge as a major player in this field due to its advanced technology capabilities and expertise in automation, which are both





Expedited clinical trials and localized vaccine production

Having expedited the first phase III clinical trial of an inactivated COVID-19 vaccine in the region, the UAE became the first nation in the Gulf to set up a coronavirus vaccine production facility in 2021.

The joint venture between Sinopharm CNBG and G42 Healthcare aims to produce up to 200 million Hayat-Vax doses annually at a purposebuilt plant in KIZAD Life Sciences Park.

Unlocking access to innovative medicines

The DoH is driving the development of several strategic partnerships and joint ventures to accelerate access to innovative medicines.



GROWTH OPPORTUNITY

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SECTION TWO: UNLOCKING

DoH and Roche announced that Casitivimab and Imdevimab medications will be made available across Abu Dhabi to treat mild to moderate COVID-19 symptoms.



DoH and GlaxoSmithKline (GSK) collaborated to secure COVID-19 treatment medication Sotrovimab through Rafed for use in the Emirate, making Abu Dhabi the first city in the world to receive the drug outside of clinical trials. Recently, both entities signed a Declaration of Collaboration to develop Real World Evidence (RWE) and capitalize on logistics related to innovative medicine.

Beyond the pandemic, DOH is driving further innovation through partnerships with global pharmaceutical companies to conduct clinical trials to explore new treatments for chronic conditions such as cancer. These included:



The signing of a Declaration of Collaboration between **DoH and AstraZeneca** to explore real-world evidence and conduct clinical trials through IROS in the UAE .



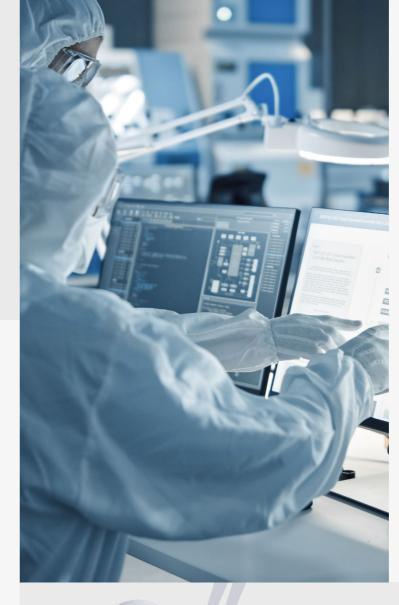
A partnership between **Abu Dhabi Stem Cells Centre (ADSCC) and Miltenyi Biotec** to conduct clinical trials on immunotherapies to fight bone marrow and blood cancers.



A partnership and collaborative-based approach in the pharmaceutical industry encourages multinational companies to introduce innovations at a much faster pace which ultimately stimulates investment.

Gizem Akalin

Vice President and General Manager, GlaxoSmithKline Gulf (GSK)





Investing in life sciences on a regional and global scale is critical to accelerate the UAE's self-sufficient pharmaceutical ecosystem that can manufacture cost-effective medicines and pharmaceutical goods.

Fahad Al Qassim Executive Director, Healthcare & Life Sciences, ADQ

Leading the charge on the region's pharma ecosystem

ADQ is investing in a healthcare and life sciences cluster that encompasses the entire value chain to ensure greater accessibility of healthcare and pharmaceutical products and supplies.

Recent investments in Acino, Amoun, Pharmax, and Biocon Biologics will enable greater self-reliance within the UAE, across the region and beyond.



Pharmax's state-of-the-art facility in the UAE has an annual production capacity of more than 250 million tablets and 85 million capsules.

One of only a few facilities in the UAE that has been approved by the European Union Good Manufacturing Practices (EU GMP), Pharmax received its first GMP approval from MoHAP in 2019.



Biocon Biologics develops and commercializes novel biologics, biosimilars, and complex generic APIs and formulations.

The company supports the development of the UAE's biosimilars sector, which is set to be a growth market as originator biologics' patents expire and demand for affordable medicines increases.

So far, five molecules from Biocon Biologics' biosimilars portfolio have been taken from lab to market, with three having been commercialized in developed markets.



The case for international coalitions

Establishing the new pharma corridor

By leveraging existing bilateral relationships, the UAE can build strategic coalitions with established international manufacturing hubs to accelerate its own growth as a world-class pharmaceutical hub.

Abu Dhabi is building an origin-to-destination pharmaceutical air corridor with Belgium. Once completed, it will be one of the world's leading end-to-end pharmaceutical supply chains and it will address pharmaceutical demand flows between the East and the West.

HOPE: A humanitarian response to the global pandemic

The UAE's robust healthcare system combined with efficient case finding of COVID-19, contact tracing and vigorous public health measures contributed to safeguarding the health of citizens and residents.

By leveraging its strategic location, world-class logistical capabilities and advancements in life sciences, the UAE made a vital contribution to global vaccine distribution and development.

Led by the DoH, the HOPE Consortium's complete supply chain solution transports, stores, handles, sources, and distributes the COVID-19 vaccines worldwide, with 18 billion vaccine doses delivered by the end of 2021.

DoH has oversight and quality assurance.

19,000 square meter

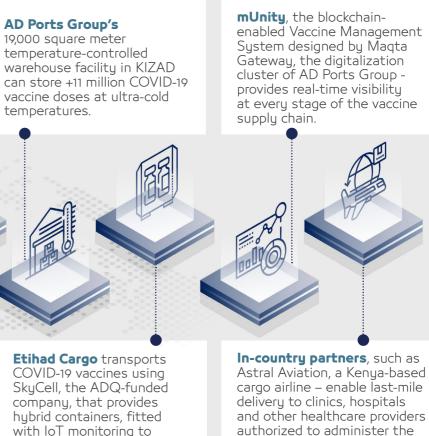
temperatures.



Rafed provides procurement

management services on

behalf of DoH.



with IoT monitoring to optimize temperatures.

Dr Asma Ibrahim Al Mannaei Executive Director of the Research and Innovation Centre. Department of Health Abu Dhabi (DoH)





Amoun Pharmaceutical Company, one of Egypt's leading manufacturers, distributors and exporters of branded pharmaceutical and animal health products, helps the UAE secure access to critical medicines at an affordable price. The company's expertise and proven track record will help to accelerate knowledge transfer to enhance local capabilities.

🆅 acino

Acino, a Swiss-based, global leader of novel pharmaceutical products with a diverse product portfolio and licenses across emerging markets, significantly expands ADQ's international footprint.

Acino and Pharmax are collaborating to license, manufacture and supply selected Acino products across the MENA region, in line with local demand.



Abu Dhabi continues to strengthen its position as a leading destination for advanced healthcare, as well as an incubator for innovation in life sciences and a regional hub for international cooperation and unification of world-class healthcare efforts.

vaccine.





SECTION THREE

The cornerstones of success

Critical components to ensure that the UAE pharmaceutical industry reaches its full potential include:

Drive collaboration among stakeholders

Bilateral relationships need to continue to be leveraged to foster investment in clinical research that addresses local and regional healthcare needs. By establishing cooperation between the public and private sectors and academia, public health programs and research can be more robust. Additionally, attracting FDI is vital to meet rising local demand.



Establish a robust life sciences R&D ecosystem

The UAE's knowledge-based economy will be instrumental for accelerating R&D and the production of novel and innovative medicines and vaccines. Progressive technologies, such as gene and cell therapies and genome editing, that help to address critical therapeutic areas have attracted investments globally.

Develop UAE-based biotech and life sciences parks

Biotech companies are essential for the research and development of novel medical breakthroughs that help sustain the pharmaceuticals industry.

KIZAD's Life Sciences Park, a purpose-built R&D hub for life sciences, biotechnology and vaccine production, is home to a number of leading companies. A new plant that will produce up to 200 million Hayat-Vax doses per year is under construction.



To encourage ecosystem growth, boost local R&D and facilitate access to the region, we need an enabling environment where unique patented branded products can be built and manufactured early in the cycle. To realize this, we need to continue strengthening patent protection.

Dream Samir Secretary General, PHRMAG



Increase the UAE's manufacturing capabilities

As the UAE's pharmaceutical sector covers only 5% of local consumption, there is opportunity for growth. Robust measures are in place to increase local manufacturing volumes through the Basic Industries Project and various incentives to decrease set up and operational costs. This will significantly increase production over the medium term.

Capture the use of cutting-edge technologies

Technological advances offer the potential for the UAE to reduce its reliance on importing medical equipment and products. For example, UAE universities are exploring the potential for 3D printing. Two Mechanical Engineering students from Khalifa University presented a lower limb prosthetic manufactured using 3D printing at Innovator 2020 in Abu Dhabi, which costs less than \$1,000 to print and can be produced in 48 hours.

Grow a highly skilled talent pool

The sheer complexity of pharmaceuticals elevates the importance of having a deep talent pool with diverse skillsets.

DoH recently announced a collaboration with Pfizer for a specialized training program to train up to 150 clinical researchers within two years. In addition, the UAE has launched a Projects of the 50 initiative that aims to bring 10,000 UAE Nationals into the medical field in the next five years via scholarships in various healthcare disciplines for qualifying candidates.

Steffen Saltofte Chief Executive Officer, Acino

It is our responsibility and duty to bring education and share knowledge across the regions we operate in, especially in areas where we are looking at things in a different way.



SECTION FOUR

Conclusion

Following a decade of work to establish an enabling environment conducive to local pharmaceutical growth, the UAE has become a model for localization and is poised to lead the region as a pharmaceutical manufacturing hub.

Key drivers to redefine the regional pharmaceutical industry



Harnessing disruptive technologies



Developing R&D and manufacturing hubs



Fostering local talent to expand capacity and capability



Driving stakeholder collaboration with an agile regulatory framework



Attracting FDI to further push the boundaries of innovation for the sector

Having established robust foundations for sustainable growth, the UAE's pharmaceutical industry is poised for a new era of evolution.

Defined by resilience and self-sufficiency, tomorrow's pharmaceutical landscape will safeguard the health of citizens and residents while facilitating a reliable pipeline of essential drug and medical products, redefining pharma for the region and beyond.





Redefining Regional Pharma

Check out our ADQ FWD papers at <u>fwd.adq.ae</u>

Find us on social media



Established in 2018, ADQ is an Abu Dhabi-based investment and holding company with a broad portfolio of major enterprises. Its investments span key sectors of the UAE's diversified economy including energy and utilities, food and agriculture, healthcare and life sciences, and mobility and logistics, among others. As a strategic partner of Abu Dhabi's government, ADQ is committed to accelerating the transformation of the emirate into a globally competitive and knowledge-based economy.





ADQofficial

