EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

Accessibility, Affordability, & Equitable Distribution for COVID-19 Vaccines & Therapeutics

September 2022

iPHEX GLOBAL REGULATORS CONCLAVE

pharmexcil

Azadi Ka Amrit Mahotsav

21 - 23 SEPTEMBER, 2022

IEML, KNOWLEDGE PARK II, GREATER NOIDA

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Content

1- About EDA

2- Functional Pillars to Accessibility

3- Market Enablers

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on 25 August 2019

Issuance of Law no. 151 of 2019

Establishment of

2

new bodies

EDA EGYPTIAN DRUG AUTHORITY

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U.P.A

They have acquired most of the specializations, and responsibilities of the Ministry of Health, regarding to pharmaceuticals and medical devices regulation.

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Functions

Product-based classification

- Human Pharmaceuticals
- Veterinary Medicines
- Herbal Medicines
- Biologicals & Innovative Products
- Cosmetics
- Pesticides & Disinfectants
- Medical Devices

- Registration
- Importation
- Licenses
- Pharmacovigilance
- Pricing
- Customs Release
- Inspection
- Availability & Drug Shortage
- Pharmacoeconomics
- Export
- Lab Analysis
- Promotional Materials

Function-based classification

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Organizational Structure

PPMA
Pharmaceutical Policies and Market Access

Drug Control

Bio-Inn
Biologicals & Innovators and Clinical Studies

9
Central Administrations

Operations

Pharmaceutical Products

45
General Administrations

Pharmaceutical Care

Medical Devices

109
Departments

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The Egyptian Pharmaceutical Market

1st

Growing Market
In MENA Region

17.9%

Average Annual Growth Rate

2nd

Market Size
In MENA

$6.3Bn

2021 Market Size

© SOURCE: STRATEGIC MARKET OVERVIEW – EGYPT BY IQVIA

The Egyptian Pharmaceutical Market

The growth forecast is expected to move the rank of Egypt in global pharma market rankings from 29 (2020) to 24 (2025)

IQVIA Pharma global market ranking
Rank by Value, (2015, 2020, 2025F)

Global Rankings

Country	Rank in 2015	Rank in 2020	Rank in 2025
KSA	16	▼ 17	▼ 19
Egypt	47	▲ 29	▲ 24
Algeria	45	▼ 48	◄► 48
UAE	38	▼ 46	▲ 45
Morocco	59	◄► 59	▲ 57
Lebanon	62	▼ 66	▼ 68
Kuwait	73	▲ 67	▲ 64
Tunisia	74	▲ 73	▼ 74
Jordan	79	▼ 80	▼ 82

© Source: IQVIA Market Prognosis

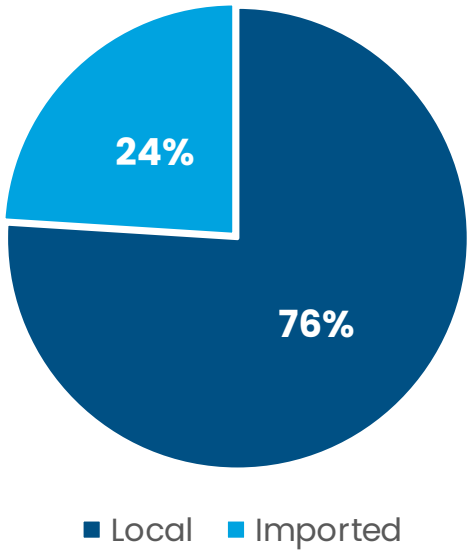
The Egyptian Pharmaceutical Market

Market Share of Local Products in 2021

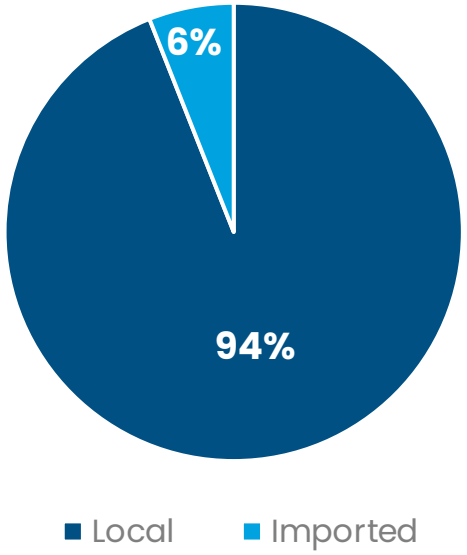
149
Billion EGP

4
Billion Unit

Egypt Pharma Market Sales (Value)
(2021), in Bn EGP



Egypt Pharma Market Sales (Volume)
(2021), in Bn EGP



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Development

- EDA's Reference Lab
- Molnupiravir

Authorization

- EUA
- Fast-Tracking Mechanisms

Local Production

- Therapeutics (e.g. Molnupiravir, Remdesivir, Favipiravir)
- Vaccines (e.g. Sinovac)

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EDA’s Reference Lab

Development

- In alignment with EDA’s vision to encourage **research and development** and in order to support interested industrial partners, EDA reference lab was established.

- The laboratory encompasses several specialized laboratories in which many different studies are conducted; For example: toxicological studies, evaluation of biosimilars, pharmaceutical raw materials, nutritional supplements, and IVDs.

- For COVID therapeutics, the reference lab supported locally developing **Molnupiravir**.

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Development | **Authorization** | Local Production

- EDA's Reference Lab
- Molnupiravir

- **EUA**
- **Fast-Tracking Mechanisms**

- Therapeutics (e.g. Molnupiravir, Remdesivir, Favipiravir)

- Vaccines (e.g. Sinovac)

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Combating Covid-19 pandemic:

Authorization

- EDA has provided the **necessary** support to many companies to ensure the **availability** of medical products used in the treatment protocol of Covid-19 infections

A strategic safety stock

EUA
Emergency Use Authorization

Monitor Supply & Demand

fast-track
Registration mechanisms

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Result

Pharmaceutical products
registered with
EUA

Vaccines registered with
EUA

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Development

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Combating Covid-19 pandemic:

Local Production

- **Egypt is the first country in the Middle East to locally manufacture "Remdesivir and favipiravir" with a very low financial cost compared to global averages representing only 10-20% of the average global price.**

Exporting To 27 Countries

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Egypt’s Drug Authority grants VACSERA-Sinovac vaccine the emergency use license

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The Pharmaceutical City - Gypto Pharma:

GYPTO PHARMA

on 1st April 2021

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International Accreditation

- National Regulatory Authorities
- Industrial Partners and Products

Regional Initiatives

Global Procurement Mechanisms

- Alliances & Partnerships

Generic Licensing

- Therapeutics: Remdesivir
- Vaccines: Sinovac

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International Accreditation

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International Accreditations

- **WHO ML 3 /vaccine scope**
  March 2022

- **ICH OBSERVER**
  November 2021

- **ICCR OBSERVER**
  October 2021

- **ICMRA Associate Member**
  March 2022

- **IPRP MEMBER**

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MATURITY LEVEL 3

VACCINE SCOPE

LOCALLY PRODUCED & IMPORTED

March 2022

Formal BM against WHO Global Benchmarking Tool (GBT)

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International Accreditations

World Health Organization

World Health Organization

List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3)[1] and maturity level 4 (ML4)[2] (as benchmarked against WHO Global Benchmarking Tool (GBT)

(in alphabetical order) - As of April 2022

Country	Regulatory authority	Maturity Level (ML)	Scope of products	Year of announcement
Egypt	Egyptian Drug Authority (EDA)	ML3	1. Vaccines (producing)	2022
Ghana	Food and Drugs Authority (FDA)	ML3	1. Medicines 2. Vaccines (non producing)	2020
India	Central Drugs Standard Control Organisation (CDSCO)	ML3	1. Vaccines (producing)	2017
Indonesia	National Agency of Drug and Food Control (BADAN POM)	ML3	1. Vaccines (producing)	2019
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)	ML3	1. Medicines 2. Vaccines (non producing)	2022
Serbia	Medicines and Medical Devices Agency (ALIMS)	ML3	1. Vaccines (producing)	2019

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Export Support Initiative

Encourage & Support Egyptian Pharmaceutical Companies to get International Accreditation

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World Health Organization

Health Topics | Countries | Newsroom | Emergencies

Home / News / WHO announces first technology recipients of mRNA vaccine hub with strong support from African and European partners

WHO announces first technology recipients of mRNA vaccine hub with strong support from African and European partners

18 February 2022 | News release | Geneva/Brussels | Reading time: 3 min (850 words)

Egypt, Kenya, Nigeria, Senegal, South Africa and Tunisia to establish mRNA vaccine production

At the European Union - African Union summit in Brussels today WHO Director-General, Dr Tedros Adhanom Ghebreyesus, announced the first six countries that will receive the technology needed to produce mRNA vaccines on the African continent. Egypt, Kenya, Nigeria, Senegal, South Africa and Tunisia all applied and have been selected as recipients.

African Union | AFRICA CDC Centres for Disease Control and Prevention Safeguarding Africa's Health | Afrigen Biologics & Vaccines An Avacare Health & IDC Company

BIOVAC | saMRC advancinglife | medicines patent pool | World Health Organization

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