

EGYPT NATIONAL STRATEGY FOR VACCINE MANUFACTURING LOCALIZATION

2024-2030





Egypt

National Strategy for Vaccine Manufacturing Localization

His Excellency President ABDEL FATTAH EL-SISI



His Excellency Doctor MOSTAFA MADBOULY





Prof. Khalid Abdel-Ghaffar

Deputy Prime Minister for Human Development and Minister of Health and Population

Foreword

Egypt had a great history in pharmaceutical production, which has laid a strong foundation for our current endeavors. In the wake of the COVID-19 pandemic, it became evident that there was a pressing necessity for a genuine commitment and the real capability to produce vaccines, ensuring that we can be proactive in securing vaccines under any circumstances.

In 2022, His Excellency President Abd El- Fatah El-Sisi issued pivotal presidential directives aimed at deepening the localization of biopharmaceutical industries, particularly within the vaccine sector. During His Excellency's speech at the World Health Organization Conference on the sidelines of the European Union - African Union Summit in Brussels in 2022, his excellency emphasized the urgent need for enhanced vaccine production capabilities and ideal resources utilization not only for local production but also for the supply to our neighboring African countries in order to address any health crises and improve public health outcomes for Africa according to African union agenda 2063.

Following this vision, Prime Minister Dr. Mostafa Madbouly issued Executive Decree No. 719/2024, which necessitates the shaping of a national strategy for vaccine localization. This decree entrusts the Egyptian Authority of Unified Procurement and Medical Technology Management (UPA) with the responsibility of implementing this strategy, ensuring that we take concrete actions toward achieving our goals. One of the primary outcomes of this strategy is the establishment of the Egyptian Vaccine Manufacturers Alliance (EVMA) and the proposed concept of Economic Participation Agreement.

In a world increasingly challenged by health crises, the importance of robust vaccine production capabilities cannot be overstated. The EVMA stands as a strategic alliance for vaccine manufacturers, uniting key stakeholders in our shared mission to enhance vaccine accessibility and support public health initiatives across Africa.

As we embark on this journey, it is essential to recognize Egypt's commitment to not only meeting its own vaccine needs but also extending its resources to neighboring countries. This initiative reflects our dedication to fostering collaboration among local manufacturers, governmental bodies, and international organizations.

General Doctor Bahaa El-Din Zeidan: UPA Chairman

Egypt National Strategy for Vaccine Localization represents a transformative approach to enhancing our nation's biopharmaceutical sector, with significant implications for our public economy. In an era marked by global health uncertainties, the imperative for biopharmaceutical localization has never been clearer. This strategy is not merely an operational initiative; it is a cornerstone for economic empowerment, health security, and innovation.

Furthermore, strengthening our health security through localization cannot be overstated. Dependence on imported vaccines exposes us to risks that can compromise timely access to essential healthcare. By



developing our own production capacities, we enhance national health security, ensuring that our population is protected against infectious diseases without the delays associated with international supply chains.

As we look beyond our borders, the localization of biopharmaceutical production mainly vaccines also enhance Egypt's global competitiveness. By prioritizing local solutions, we position ourselves as key players in the international health market, opening avenues for collaboration and export opportunities that can further strengthen our economy.

Prime Minister Decree 719/2024 has empowered the Egyptian Authority of Unified Procurement and Medical Technology Management (UPA) to take the initiative to put Egypt national strategy for vaccine localization. Since its announcement in March 2024, UPA has made substantial strides in operationalizing our vision. Through engagement with diverse stakeholders, we are establishing a thriving biopharmaceutical ecosystem that will benefit both our economy and public health.

As we launch the Egyptian Vaccine Manufacturers Alliance (EVMA), we stand at the threshold of a new era in healthcare for Egypt. Together, we will leverage the potential of biopharmaceutical localization to drive economic growth, enhance public health, and solidify Egypt's position as a leader in vaccine production.

Let us embrace this opportunity to build a resilient and innovative healthcare sector that serves the needs of all Egyptians.

Thank you.

Dr. Ali Ghamrawy Chairman of the Egyptian Drug Authority (EDA)

It is a great pride and optimism to address you in this publication dedicated to the Egyptian Vaccine Manufacturing Alliance (EVMA). This alliance represents a significant step forward in our collective efforts and commitment to enhance vaccine production capabilities in Egypt and to ensure the health and safety of our population and beyond.

In the recent years, COVID-19 pandemic has shown us that a robust and responsive vaccine manufacturing infrastructure is highly required to secure the health of our population.



Through EVMA, we aim to create a synergistic environment that promotes capacity development, innovation, and knowledge sharing among manufacturers, regulatory authorities, academia, research institutions, regional and international partners.

I would like to express my gratitude to all members of EVMA for their commitment to this important initiative.

Dr. Amr Kandil Deputy Minister of Health and Population for Preventive Medicine and Primary Care

In light of the rising health challenges facing the world, the ability to locally manufacture vaccines has become one of the fundamental pillars of national health security. The localization of vaccine production represents a strategic step aimed at ensuring nations' capability to efficiently combat pandemics and infectious diseases, thereby contributing to the preservation of health stability.



Under the directives of His Excellency President Abdel Fattah El-Sisi to enhance the health of Egyptian citizens, the Egyptian state places great emphasis on the localization of vaccine production and the strengthening of the infrastructure of medical industries.

The establishment of the Egyptian Vaccine Manufacturers Alliance (EVMA) comes as part of the implementation of the national strategy for vaccine localization. This initiative represents a qualitative step forward, unifying the efforts of local manufacturers and fostering collaboration among them to ensure integration. This, in turn, contributes to the development of vaccine manufacturing, maximizes the utilization of national capabilities, and ensures the sustainability of local production.

The localization of vaccine manufacturing in Egypt stands as a strategic investment in public health and a guarantee for the sustainability of the healthcare system. It paves the way for Egypt to move steadily toward achieving self-sufficiency while reaffirming its commitment to its leading role in supporting health security both nationally and regionally.

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EXECUTIVE SUMMARY OF EGYPT NATIONAL STRATEGY FOR VACCINE MANUFACTURING LOCALIZATION

Introduction

The strategy aims to enhance local vaccine manufacturing to meet national needs and reduce reliance on imports, contributing to improved health and economic security. Vaccines play a vital role in disease prevention, reducing treatment costs, and boosting economic wellbeing.

Vision and Objective

Vision

Empower Egypt to locally manufacture essential vaccines to meet national needs and export the surplus to Africa.

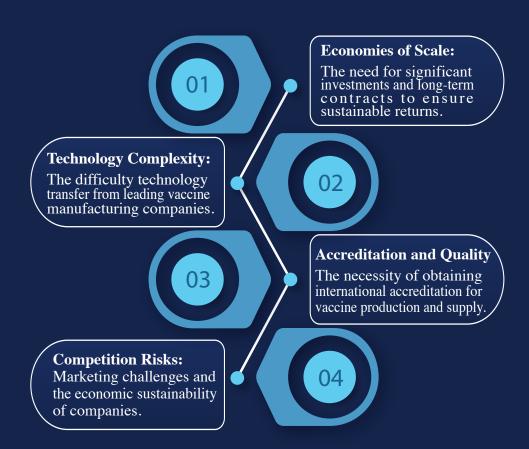


Objective

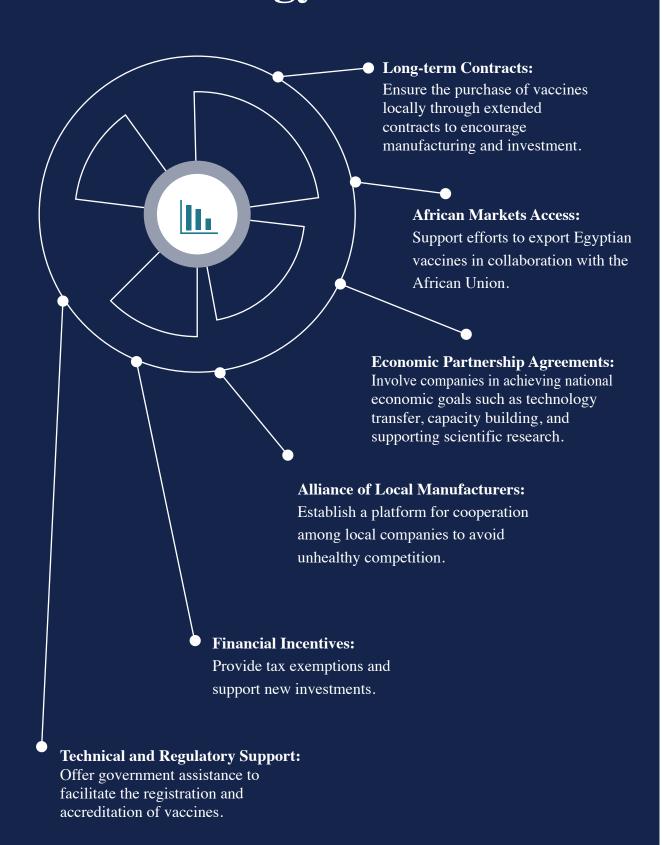
A chieve maximum self-sufficiency in essential vaccines while strengthening Egypt's position as a regional hub for vaccine export.

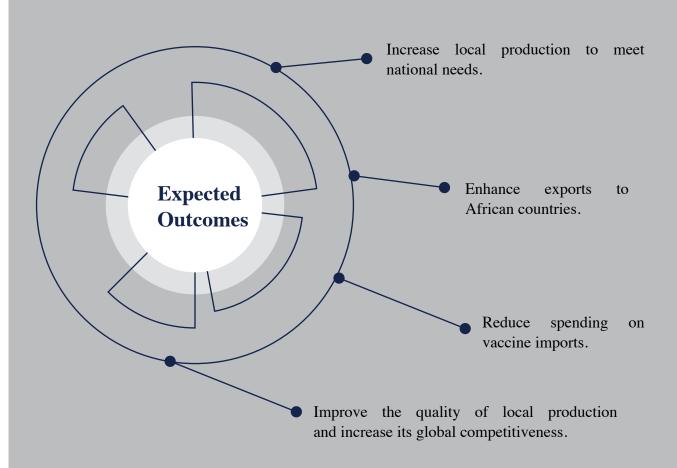


Key Challenges



Strategy Pillars







Executive Entities

A flexible structure that brings together the relevant ministries and representatives from the private sector to implement and follow up on the strategy.

Summary

The strategy represents an ambitious step towards achieving self-sufficiency in vaccine production and enhancing Egypt's role as a regional hub for this industry, with a focus on public-private partnership.

EGYPT NATIONAL STRATEGY FOR VACCINE MANUFACTURING LOCALIZATION

Outputs of the Vaccine Localization Committee The issue is addressed by Decree No. 719 of 2024







Introduction

Vaccines are of great importance in improving the health status of any community, as they are a key part of preventive medicine that proactively combats diseases. The expansion of the state's use of vaccines contributes to reducing the number of patients for targeted diseases, thereby improving the overall health of community members, which in turn benefits the economy by lowering treatment costs and the economic impact of illness on patient productivity, as well as enhancing individual well-being.

In this regard, the Arab Republic of Egypt places great importance on providing vaccines and managing several national vaccination programs. However, the country primarily relies on importing its vaccine needs from abroad. Despite significant developments in the pharmaceutical industry, vaccine production does not meet the desired level, even with various attempts through public or private investments.

Given the critical importance of providing and securing essential vaccines for the country, the esteemed Prime Minister has tasked a committee established by decree No. 3435 of 2022 with facilitating the establishment of factories for medical products, devices, and supplies to propose a national strategy for localizing vaccine production under decree No. 719 of 2024.

The committee formed a working group to study the matter and draft a proposal for the national strategy to localize vaccine production in the Arab Republic of Egypt.



Vision

The political leadership of the Arab Republic of Egypt has expressed its vision for localizing vaccine production in Egypt, with the desire to empower the country to produce essential vaccines to meet the National Egyptian needs as well as provide vaccines to African countries.

Objective



The strategy aims to realize the political vision by working to deepen the vaccine industry with the goal of achieving the highest possible degree of independence in the production of essential vaccines within the Arab Republic of Egypt, ensuring enough production to meet the national security needs for vaccines and allowing for the export of part of the production abroad, especially to African countries, enhancing Egypt's standing within the continent.

Data and Facts about the Vaccine Industry

Vaccine market size: (WHO global vaccine market report 2022: A shared understanding for equitable access to vaccines)

Global market:

The vaccine market size reached about \$141 billion in 2021, representing nearly 16 billion doses.

African market:

- It relies primarily on imported vaccines, as most African countries import 90% of their vaccines from abroad, indicating a pressing need to enhance local manufacturing capacity.
- About 30-60% of the total vaccine production by global companies is consumed in Africa.
- By 2025: 14 African countries will not be covered by the GAVI organization, with an estimated consumption of about 208 million doses in these countries.

Consumption size:

- 1.2 billion doses in 2022 rising to 1.8 billion doses by 2040
- \$1.4 billion in 2022 rising to \$4.5 billion by 2040 (not including COVID vaccine)
- Over 30 vaccine manufacturing projects have been announced across the continent

Major producing countries:

- China and India: Host about 31% of global manufacturers and have significant manufacturing capacity (SII- BIO E-CD BIO- Sinopharm –Walvax etc...)
- The United States and the European Union: Also play a key role in vaccine manufacturing, especially in terms of innovation and technology.



Egyptian vaccine market Vaccine Market Dynamics

Total Vaccine Market: 75 Million Doses This refers to the total vaccine doses needed for the country, possibly covering all age groups and types of vaccines.



I. Ministry of Health and Population - Covered Vaccine Expenses:

Expanded Program of Immunization (EPI):

The Ministry of Health and Population covers the vaccines for the Expanded Program on Immunization (EPI), a core immunization program in many countries. This program includes vaccines to prevent common childhood diseases, which are free of charge for the public.

EPI Include:

- Pentavalent Vaccine
- DTP (Diphtheria, Tetanus, Pertussis)
- DT (Diphtheria, Tetanus)
- MMR (Measles, Mumps, Rubella)
- OPV (Oral Polio Vaccine)
- IPV (Inactivated Polio Vaccine)
- Hepatitis B
- BCG

School Vaccinations:

Meningococcal Vaccine (AC) DT (Diphtheria, Tetanus)

03 National Initiatives:

Likely other vaccines or programs targeted at specific populations or disease outbreaks.

04 Non-EPI Vaccines (Government-Funded):

- Oral Cholera Vaccine
- Tetanus Toxoid
- Haemophilus Influenzae type B (HIB)
- Rabies Vaccine
- Yellow Fever Vaccine
- Menngioccocal vaccine ACWY

II. Out-of-Pocket Vaccines (Private Market)

These vaccines are typically not covered by the government or national health programs, and individuals may have to pay for them privately.

1. Pneumococcal Vaccines (PCV):

For prevention of pneumonia caused by pneumococcus bacteria.

2. Human Papillomavirus Vaccine (HPV):

Prevents certain types of HPV infections, which can cause cervical cancer.

3. ROTA Vaccine:

Prevents rotavirus infections, which can cause severe diarrhea in young children.

4. ACWY Meningococcal Vaccine:

Protects against multiple strains of meningococcal disease (A, C, W, and Y).

- 5. Hepatitis A Vaccine
- 6. Oral Cholera Vaccine.
- 7. Hexa Valent Vaccine



Local manufacturing capabilities

These local manufacturing facilities are crucial in meeting both domestic vaccine needs and enhancing global supply capabilities, especially for countries that aim to strengthen their vaccine manufacturing industries in response to health crises or long-term health goals.

VACSERA:

o Founded in 1881, VACSERA stands as one of the region's oldest and most reputable vaccine manufacturers, with a legacy spanning over a century in public health and vaccine production. Guided by a vision of leadership in the production, development, and marketing of biological preparations, serums, human and veterinary vaccines, and blood derivatives, VACSERA supports both local and regional healthcare markets. The company remains committed leveraging technological to advancements maintain global to competitiveness.

o With an annual production capacity of 405 million doses and a distribution capability of 200 million doses, VACSERA is equipped to meet both regional and local demands. The company has established eight technology transfer agreements to advance innovative vaccine and biopharmaceutical production.

o VACSERA's adherence to GMP standards and a comprehensive Quality Management System (QMS), including Pharmacovigilance (PV) measures, underscores its commitment to safety and quality.

GENNVAX:

o Gennvax project to build a greenfield vaccine manufacturing facility in order to provide essential vaccines for the Egyptian and African markets, as a first priority and then to other markets including the European Union

o Gennvax was granted the Golden License by the Egyptian Prime Minister's cabinet in July 2023, with the intention of providing support for the establishment of a scientific R&D center

GENNVAX State of the Art" Vaccine Manufacturing Facility aims To provide vaccines manufactured locally for Egypt & surrounding Markets, a Vaccine Manufacturing Plant will be built in several phases to cover:

Research and Product Development
Upstream Manufacture
Downstream Manufacture
Packaging
Quality Control

o Gennvax is meant to fulfil local and regional gaps for vaccines supplies, capacity of Gennvax production will reach 270 million Doses of vaccines covering the essential vaccines in different national immunization programs in Africa.

VBC:

- o VBC is a biopharmaceutical company dedicated to the discovery, development, and commercialization of vaccines and biotechnological products, with a primary emphasis on safeguarding against biological threats and emergency cases in Egypt, the Middle East, and Africa.
- o On an area of 45,000 m2 with an annual production capacity of 140M doses of Human vaccine and 5.5 M animal vaccine.
- o VBC has biosafety labs at both LEVEL 3 AND LEVEL 2, ensuring rigorous safety protocols for handling potentially hazardous materials. These specialized labs enable us to maintain high standards of safety while producing life-saving vaccines.

VBC Strategic Capabilities:

- . R&D Pillar for Innovative Vaccines
- . Full Cycle Manufacturing (Starting from Seeds to Large-Scale Production)
- . 7 Different Filling Lines (PFS, Lyophilized Vials, Liquid Vials, Ampoules, Intranasal, Oral Tubes & Bottles)
- . Lab Animal Facility
- . International accreditation standards
- . WHO Prequalification Standards

Biogeneric Pharma

- o BioGeneric Pharma S.A.E. (BGP), is a new state-of-the-art biopharmaceutical facility, compliant with global standards (cGMP, FDA, EMA, WHO), specialized in the manufacturing of therapeutic recombinant proteins and vaccines.
- o Total production areas is 4000 m2 allocated to the production of biological products from seed vials to fill and finish of vials, cartridges and pre-filled syringes.
- o BGP has the capability to supply up to 800 million doses of vaccines annually, significantly contributing to Egypt's vaccination program of meeting 35% of Africa's vaccine requirements by 2030.
- BGP is nominated by WHO to be one of the WHO partners in receiving the technology transfer of the mRNA platform to manufacture vaccines and biosimilars since February 2022

GYPTO Pharma:

o Gypto Pharma's sprawling 180,000-square-meter campus includes fifteen advanced production areas equipped with the latest manufacturing technology, all designed to meet international quality and safety standards. With an annual capacity of up to 200 million units across diverse dosage forms.

o With an annual capacity of up to 200 million units across diverse dosage forms, Gypto Pharma is well-equipped to address Egypt's growing healthcare needs and contribute to the region's drug supply security.

o Its dedication to Good Manufacturing Practices (cGMP) and cutting-edge technology, such as advanced sterile production environments and automated quality control, reinforces Gypto Pharma's reputation as a trusted pharmaceutical provider

Milestones in Gypto Pharma's evolution include robust R&D systems, efficient laboratory operations, and a commitment to continuous human resource development. These foundational elements have positioned Gypto Pharma to support the national health sector while preparing for future export opportunities in the African, Arab, and CIS markets

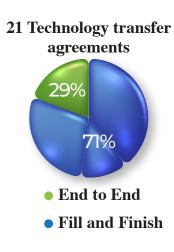
EVA Pharma

o EVA Pharma is dedicated to improving access to affordable, high-quality medicines around the world, focusing on three core pillars: innovation, development and sustainable access. The company leverages cutting-edge technology at two research centers bringing first-of its-kind capabilities to the Middle East and Africa including mRNA research and development from AI prediction to biological product.

o EVA Pharma has developed strong manufacturing capabilities starting with egg-based vaccine technologies in addition to fill-finish capabilities of 100 million fill-finish vials of vaccines.

EVA Pharma contributions focus on leveraging comprehensive research centers and extensive manufacturing capabilities to support the localization of vaccine innovation, development, and production. Through the deployment of mRNA strategic our Innovation Hub and large-scale production facilities capable of producing up to 90 million doses annually, we are pivotal in ensuring sustainable vaccine availability







THE CHALLENGES FACING THE LOCALIZATION OF VACCINE MANUFACTURING





The vaccine industry faces numerous challenges that significantly impact the economic return on investment in manufacturing, which limits companies' willingness to invest in this sector. The key challenges can be summarized as follows:

Economy of scale

Vaccine manufacturing is an economic activity that relies on economies of scale, requiring substantial investments that can only yield adequate returns through large-volume sales over a relatively long period. Given the nature of vaccine procurement contracts in most countries, which usually involve centralized state purchasing, the marketing and sales risks become one of the biggest obstacles to investment in the industry and hinder agreements related to technology transfer.

Technology transfer

Advanced stages of vaccine manufacturing are among the complex, high-tech industries, necessitating contracts with major firms that hold the technology for vaccine production to facilitate technology transfer at various stages of localizing the industry. Reaching the stage of contracting on this front represents one of the major hurdles due to the uncertainty surrounding the economic return for the technology provider, especially in light of market competition and insufficient sales security.

Accreditation and quality

Due to the technical complexity of vaccine manufacturing and the nature of its governmental contracts, manufacturers need to obtain accreditation from international bodies to ensure the quality of production and its acceptance in both local and global markets [WHO PQ].

High competition risks

While competition is crucial for the safety and stability of markets, the characteristics of the vaccine industry, as outlined above, and the market nature make investing in localizing the industry highly risky. Failure by companies to secure contracts for selling production after substantial investments in manufacturing could lead to enormous losses threatening the very existence of these companies. Furthermore, the entry of multiple firms into localizing the manufacturing of certain categories of vaccines inevitably leads to significant losses and wastage of available economic resources in the country.

THE EGYPTIAN STRATEGY FOR LOCALIZING VACCINE PRODUCTION





In light of the study on the vaccine industry and the analysis of the Egyptian market along with the challenges facing the industry as mentioned above, the national strategy for localizing vaccine production focuses on several axes aimed at addressing the industry's challenges and stimulating investment in localizing production from various stakeholders, as well as directing different government entities to play supportive roles that help mitigate the intensifying challenges and create a conducive environment to achieve the objectives of this strategy.

1- Long-term contracts:

The biggest challenge facing the industry is the certainty regarding the ability to achieve economies of scale and secure the sale of sufficient quantities to ensure a suitable return for the concerned parties, whether the local manufacturer or the technology transfer entity. This certainty can only be achieved by ensuring sales over long periods or through covering large markets (which we will discuss later in the axis of opening external markets). In light of the major reforms that Egypt has implemented in the field of government contracts related to medicines and medical supplies through the establishment of the Unified Procurement Authority, and given the nature of vaccines in terms of forecasting needs over long periods based on population growth predictions and available demographic information, the first and main axis of the strategy revolves around establishing a clear, transparent mechanism for the purchasing of vaccines through long-term contracts that align with the economics of the specific vaccine. Thus, the Unified Procurement Authority will issue long-term tenders aimed at localizing vaccine production and announce them in a timely manner, allowing companies interested in manufacturing and technology transfer companies to form alliances to bid and compete among themselves prior to manufacturing operations and technology transfer agreements, thus providing investors with a degree of certainty regarding the expected returns on investment. To achieve this axis, the Unified Procurement Authority will issue the regulatory framework for long-term contracts and establish clear mechanisms for implementation.

2- African markets Access:

In light of the vision and goal of this strategy, working to open African markets is considered one of the main pillars to encourage the localization of the vaccine industry in Egypt. Given the major challenges companies face in conducting commercial activities within Africa, the strategy aims to work on opening African markets.

3- The proposal of the Concept of Economic partnership contracts

The discussion about localizing vaccine production according to the vision outlined in this strategy is not primarily aimed at achieving a superficial level of industrial localization but rather seeks to deepen the industry and reach the highest possible levels from both a technical and economic standpoint for each type of vaccine. This is in light of the national dimension targeted in this strategy. Given the failure of many previous attempts to localize certain industries and the stalling of the localization process at the initial stages of manufacturing operations, we propose the third axis of this strategy be the concept of the economic partnership contracting.

The essence of economic partnership contracts is to go beyond the simple supply agreement for products and extend to impose commitments on contractors with the state, aimed at fulfilling certain obligations that benefit the contracting state's economy, regardless of how essential those obligations are for executing the contract. For instance, the contract may stipulate that the contractor must train a specific number of workers in certain skills or transfer technology and expertise to the Egyptian party in the agreement. In some cases, obligations may also include financial contributions such as establishing infrastructure for product storage or quality control.

Some countries have adopted an economic partnership policy in government contracts that exceed a certain value and have established a special body to negotiate with contractors on the specific commitments of the economic partnership. However, the approach taken in these countries has faced many objections from investors due to the controlling nature of the minimum investment value required, which is calculated as a percentage of the contract value. This leads to numerous complications for companies as they seek ways to meet this obligation, which may conflict with their investment plans.

Therefore, this strategy aims in this axis to adopt a flexible system for economic partnership contracts, enabling the Unified Purchasing Authority to set the state's targets regarding vaccine production and mechanisms for evaluating different targets, while allowing companies the freedom to include in their bids their commitment to achieving all or some of these targets. This will be taken into account when evaluating competing offers, with the possibility of negotiating with companies regarding these commitments through the Unified Purchasing Authority. Contracts will be established based on these commitments.

For example, commitments could include the technology transfer partner's promise to meet the needs of neighboring markets with products from the Egyptian factory, achieving a certain minimum level of exports. The gist of this aspect is to leverage the long-term unified purchasing power of the Egyptian state to encourage contractors with the state to achieve development targets.



4- Coordination among local manufacturers (The Egyptian Vaccine Manufacturers Alliance EVMA):

Given the current market situation and the challenges facing companies interested in manufacturing, and to avoid wasting resources by investing in the same vaccines beyond the needs of target markets, this aspect of the strategy focuses on establishing an alliance of local vaccine manufacturers, whether currently operating or in the future, to create a dialogue that helps reduce the negative impacts of unhealthy competition while complying with the principles of free competition under Egyptian law. The alliance also aims to provide a platform for cooperation, dialogue, and knowledge exchange that contributes to the overall advancement of the sector and helps the companies work together to optimally utilize available manufacturing capacities through collaboration in manufacturing areas.

5- Technical support:

Companies face many challenges related to inspection procedures for obtaining quality approvals from international bodies, where the state can assist through the relevant regulatory bodies by providing the necessary technical support.

6- Regulatory and oversight support:

To achieve the synergy of efforts from all stakeholders, the Egyptian Drug Authority, under this aspect, will establish the necessary capabilities to facilitate the procedures related to vaccine registration and other industry-related procedures, including regulatory procedures like permits and approvals, or oversight procedures using affiliated bodies and existing departments or creating specialized departments to ensure speed and ease in processes.

7- Financial incentives:

In light of the government's policy aimed at encouraging and stimulating industry in general while ensuring no negative impact on the state's tax revenues, we propose in this strategy to consider granting specific financial incentives, including some tax exemptions for the vaccine industry, as the targeted activities in localizing vaccine production are new industrial activities, and granting tax exemptions would not directly affect the current tax revenues of the state.

8- Private Sector Participation:

In light of the government's announced direction to empower the private sector and increase private investments, the strategy aims to encourage the private sector to invest in localizing vaccine production and fostering partnerships between the private and public sectors in this regard.

9- Encouraging International Vaccine Trade Activities and Regional and **International Distribution Centers:**

While the main goal of this strategy is to localize and deepen vaccine production in Egypt, focusing on trade is a key element in achieving this goal. Enabling technology transfer companies to expand their international trade through the Arab Republic of Egypt can influence future decisions related to localizing and deepening the industry. The strategy suggests forming a joint committee from the relevant parties, especially the Ministry of Finance, to examine the existing legal and financial systems for international trade operations conducted through Egypt in comparison to countries known for hosting regional and international distribution centers for pharmaceuticals like the Netherlands, the United Arab Emirates, and Singapore, so that Egypt can attract such activities.

Government Bodies Involved in Implementing the Strategy:

Successfully implementing this strategy requires collaborative efforts among various stakeholders. The roles of the Unified Procurement Authority are essential, as it oversees purchasing processes and is responsible for organizing and managing long-term contracts, while the Egyptian Drug Authority is in charge of the regulatory aspects such as approvals and licenses, as well as supervisory aspects including oversight, inspection, and accreditation. The Ministry of Health is responsible for determining national vaccine needs in terms of types and quantities, and the Ministry of Finance takes care of financial matters, whether it concerns studying and assessing financial incentives or securing and guaranteeing payments in the long-term purchasing process.





THE EGYPTIAN VACCINE MANUFACTURERS ALLIANCE EVMA

Executive Summary

Introduction

The Egyptian Vaccine Manufacturers Alliance was created under presidential directives to boost the localization of vaccine production in Egypt, based on a strategic vision aimed at achieving self-sufficiency and ensuring a continuous supply of vaccines both locally and internationally. This approach reflects the decision of the Prime Minister No. 719 for the year 2024 to prepare a unified strategy for the vaccine industry.

Definition of the Alliance

The "Egyptian Vaccine Manufacturers Alliance" is a strategic entity supervised by the Unified Procurement Authority, in coordination with the Ministry of Health and the Egyptian Drug Authority, along with international partners such as the World Health Organization (WHO) and the African Union. It

serves as the executive arm of the national strategy for vaccine localization in the Arab Republic of Egypt, aiming to develop a comprehensive plan to localize vaccines domestically and enhance their accessibility to markets, especially in Africa.

Strategic Objectives

Short-term goals (2025-2030)

- Localize 50% of vaccine production domestically.
- Technology transfer through 21 signed agreements.
- Obtain WHO PQ approval for four vaccines.

Medium-term goals (up to 2035)

- Localize 75% of vaccine production.
- Develop research partnerships to accelerate local production.
- Approve four additional vaccines from WHO.

Long-term goals (up to 2040)

- Achieve complete self-sufficiency at 100%.
- Grow exports by 50% and reach new markets.



Compliance of the Egyptian Vaccine Manufacturers Alliance with Free Competition Rules

As meetings among alliance members might be seen from an external perspective as a potential violation of the Competition Protection Law, the alliance is committed in all its activities to fully comply with all provisions and rules of competition protection as stipulated in the Competition Protection and Prohibition of Monopolistic Practices Law No. 3 for the year 2005, its executive regulations, and guidelines issued by the Competition Protection Authority.

Alliance Framework

- Enhance capabilities: Identify local capabilities and organize resources.
- Develop partnerships: Build collaborative relationships between manufacturers and international suppliers.
- Implement the strategic plan: Monitor the execution of

the national strategy according to a specified timeline.

• Capacity Building: Provide training programs to improve technical and administrative competencies.

STRATEGIC ROLE



1. National Capacity Building:

- Establishing a regional training center (EVMA-RCCN) to qualify Egyptian and African competencies in biomanufacturing.
- Enhancing Egypt's competitiveness as an accredited training hub for Africa.

2. Supporting International Accreditation:

Assisting companies in obtaining WHO PQ.

3. African Markets Access:

Developing effective strategies for entering the African market.

4. Enhancing Global Competitiveness:

Improving the quality of locally produced products and increasing exports.

5. Financial Support:

Securing grants and funding to achieve strategic goals and stimulate innovation.

Members and Partners

•6 Local Manufacturers:



Government entities:

The Egyptian Authority for Unified Procurement, medical supplies &the management of Technical Technology (UPA),

Egyptian Drug Authority,

Ministry of Health& population.







Alignment with **International organizations:**

In coordination with WHO Africa CDC **GAVI MPP**

others.

Expected Outcomes by 2040

- Achieving self-sufficiency in vaccines.
- Developing a comprehensive infrastructure for the industry.
- Strengthening Egypt's position as a regional hub for vaccine production and export.



The Vacci-Nation Hub

THE EGYPTIAN VACCINE MANUFACTURERS ALLIANCE (EVMA)

OUTPUTS OF THE VACCINE LOCALIZATION COMMITTEE

THE ISSUE WITH CABINET DECISION NO. 719 OF 2024

Intrduction

The formation of the "Egyptian Vaccine Manufacturers Alliance" comes in the context of presidential directives and efforts to localize vaccine production in Egypt, responding to a strategic vision aimed at boosting the country's capacity to produce safe and effective vaccines that meet local and international needs.

These directives were reinforced by the issuance of Prime Minister Decree No. 719 of 2024, which adds the responsibility for formulating a unified strategy for localizing vaccine production in Egypt to the Medical Industries Localization Committee.

Definition of the Egyptian Vaccine Manufacturers Alliance (EVMA):

The Egyptian Vaccine Manufacturers Alliance is a strategic coalition of vaccine manufacturers under the supervision of the Unified Procurement Authority, supported by the Ministry of Health and the Egyptian Drug Authority, in coordination with several international organizations such as the World Health Organization (WHO), the African

Union, and the Africa CDC, to establish a unified vision and implementation plan for the Egyptian state to localize vaccines and access regional markets, particularly the African market.



Goals

1. Building capacity:

- To increase the capacity of vaccine manufacturers in Egypt to produce and deliver high-quality, safe, and effective vaccines to meet local needs at competitive prices.
- To ensure self-sufficiency in vaccines and to be proactive in ensuring their timely availability, as well as obtaining vaccines during pandemics.
- 2. To align with African needs through coordination with the African Union's 2040 Initiative and the 2063 Agenda.

Members of the "Egyptian Vaccine Manufacturers Alliance (EVMA)":

Local vaccine manufacturers:

(VACSERA
Biogenerics Pharma
Vaccine & biotechnology
City VBC
GENNVAX
GYPTOPharma
EVA Pharma)

Supporting government entities represented:

Preventive Medicine Sector of the Ministry of Health and Population

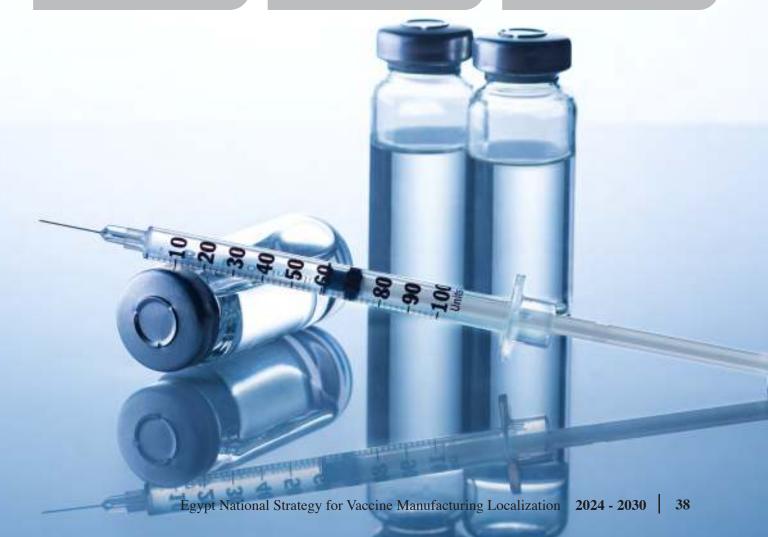
Egyptian Drug Authority

Unified Procurement Authority

Relevant global organizations

To receive the necessary support to achieve its goals of localizing this important industry and increasing its exports.

(Africa CDC, WHO, UNICEF, GAVI, MPP, CHAI, PATH)



Goals of the Egyptian Vaccine Manufacturers Alliance:

Short-term goals (2025-2030)

1- Localizing manufacturing stages:

- Achieve 50% localization of vaccine production by 2030, through various means including secondary packaging, filling and Finish, and starting the manufacturing process from antigens to make the product fully local.
- Activate technology transfer processes that reached 21 agreements by 2024 and implement them according to the proposed timelines.

2- Obtaining WHO PQ qualification for four vaccines for export:

- Achieve World Health Organization (WHO) approval for ten vaccines by 2030, which is a basic requirement for exporting to Africa and other countries.

Medium-term goals (up to 2035)

1- Localizing the vaccine industry:

- Achieve 75% localization of vaccine production by 2035, focusing on essential vaccines and developing the production process.
- Develop partnerships with local and international research centers to speed up localization and enhance the production process of vaccines starting from antigens rather than relying on secondary packaging and filling.

2- Obtaining WHO PQ qualification for four additional vaccines for export:

- Achieve WHO approval for four other vaccines by 2035, focusing on vaccines for endemic diseases in the African continent.

Long-term goals (up to 2040)

1- Localizing the vaccine industry in Egypt:

- Achieve 100% self-sufficiency in vaccine production by 2040.
- Develop a strong and integrated infrastructure for the vaccine industry that includes research and development, production, distribution, and export.

2- Expanding export scope:

Reach new markets in Africa and the Middle East, and increase Egyptian vaccine exports by 50% by 2040.





While the meetings of alliance members might be seen externally as a potential source of violations of competition protection laws, the alliance is dedicated to fully adhering to all provisions and rules of competition protection stipulated in the Competition Protection and Prohibition of Monopolistic Practices Law No. 3 of 2005, its executive regulations, and guidelines issued by the Competition Protection Authority.

In this regard, the alliance ensures that all its members commit during their meetings to, for example but not limited to, the following:

- Refrain from engaging in any discussions, disclosing, or entering into any agreements related to prices, discounts, terms of sale, product licensing, production plans, market shares or sales territories, or any restrictions on the timing or cost or volume of research, production, sales, or future plans, or anything that leads to the exchange of sensitive information that promotes unlawful coordination.
- Avoid any statements or behaviors that might restrict competition directly or indirectly, whether through explicit agreements or implied signals.
- Each member makes its business decisions independently, including pricing its products or services and choosing the markets in which to compete, without being influenced by any pressures or impacts from other members.
- Refrain from any form of coordination in bidding or entering tenders, including exchanging information about who will submit the bid, the amounts submitted, or any aspects related to the bidding process. Each bidding process should be based on genuine competition without any kind of coordination or unlawful understanding.
- Avoid any informal communications or correspondences among alliance members to sidestep discussions that could lead to anti-competitive behavior or enhance the likelihood of legal violations.
- Comply with all provisions of the Competition Protection Law, its executive regulations, and the guidelines issued by the Competition Protection Authority.
- The alliance also commits to keeping accurate and detailed records of all meetings and events, reflecting the topics discussed. These records should include minutes containing detailed information on attendance, issues raised, and decisions made.

Alliance Framework:

- 1. Identifying and enhancing the capabilities of vaccine manufacturers (an online model has been created to inventory local capabilities in terms of manufacturing capabilities, technology transfer agreements, vaccines produced, and those planned for production).
- 2. Acting as a bridge to strengthen partnerships among local manufacturers to optimize resource use.
- 3. Following the annual plan to activate contracts with technology transfer providers.
- **4. Creating a unified national strategic plan** for vaccine manufacturing to meet local and regional needs.
- **5. Closely supervising the implementation** of the national strategic plan for vaccine manufacturing according to a specific timeline agreed upon by all state bodies on Quarterly basis .



1. Developing skills and building national capacities (Capacity Building) for vaccine-producing companies.

- The field of vaccine manufacturing requires high technical competence that differs from other pharmaceutical industries, and the Egyptian market suffers from a lack of these competencies, making it essential to enhance qualified Egyptian capabilities in the vaccine manufacturing sector.
- The alliance's working group has already reached out to international supporting entities in the area of skill development and capacity enhancement, such as WHO, Africa CDC, and others, to provide free or discounted training programs for alliance members.
- The regional training center for enhancing biological manufacturing competencies EVMA -RCCN in North Africa:
- The Egyptian Alliance of Vaccine Manufacturers represents a unified Egyptian voice for vaccine manufacturing in all its aspects; therefore, when the Africa CDC announced its initiative to establish regional capacity-building centers to develop the

workforce in the biomanufacturing sector across the continent, the alliance was fully prepared for effective coordination and participation.

- This center is one of the initial fruits of the integration of Egyptian capabilities, whether academic and research (Cairo University and Ain Shams University's pharmacy faculties - Scientific Research Academy), manufacturing capabilities (VACSERA – Biogeneric Pharma – Vaccine & Biotechnology City VBC - Gennvax), and regulatory capabilities (Egyptian Drug Authority).

- The strategic role of the center:

- Locally: Enhancing Egyptian capabilities qualified for vaccine manufacturing, which aligns with one of the alliance's primary goals (Capacity Building).
- Regionally: Egypt is the country that hosts the accredited training center for the North African region, and the Egyptian training center will be one of the centers assigned to train African capabilities across the continent according to the Africa CDC initiative, taking into account that every African trainee trained at the center will be a source of foreign currency income.

2. Supporting manufacturing companies to obtain WHO PQ accreditation:

The alliance supports Egyptian vaccine manufacturers by coordinating with the World Health Organization and global support entities like PATH.

- 3. Formulating strategies for African Market Access.
- 4. Protecting local products and achieving global reach.

5. Providing financial support and enhancing capabilities:

Industry support: Securing necessary financial grants to support local vaccine production, contributing to enhancing regional competitiveness and stimulating innovation in this vital sector.

- Obtaining international accreditation (WHO PQ): Providing support to local factories to achieve the required certifications, ensuring the quality of products that allow for exporting local vaccines and strengthening the position of the Egyptian industry globally.



The Proposed Concept of Economic Partnership Contracts Program

Executive Summary of the Economic Partnership Contracts concept Guidelines



The Economic Partnership Contracts Program represents the legislative arm of the national strategy to localize vaccine manufacturing in Egypt. What's being proposed here is basically a vision that the Unified Procurement Authority will start working on as soon as the Egyptian vaccine manufacturers alliance is launched.

Objectives of the Economic Partnership Contracts Program

- **1. Maximizing the benefits of government procurement:** by localizing qualitative industries and services, enhancing local content, and supporting research and development.
- **2. Building vaccine industry capabilities:** by achieving sustainable economic development through technology and knowledge transfer.
- **3. Supporting local companies:** by increasing competitiveness and improving their capabilities for export and participation in global supply chains.
- **4. Developing human resources:** through training local staff and creating sustainable job opportunities.

Program Implementation Procedures

- Participation in the program:
- Contractors are required to submit a proposal outlining how they will achieve the economic development targets.
- Proposal evaluation:
- The Unified Procurement Authority is responsible for evaluating and discussing the proposals.
- Commitment implementation:
- Economic partnership contracts are signed concurrently with the main contracts.
- Implementation follow-up:
- Progress reports are submitted every 6 months, and performance is reviewed by the authority.



Eligible Activities

- 1. Technology transfer: including training, providing technical support, and transferring equipment.
- 2. Export development: achieving export revenues or improving the competitiveness of local products.
- 3. Research and development: supporting capital and operational expenditures for research activities.
- 4. Localizing industry: providing technical training and support to ensure the successful localization of industrial processes.

Monitoring and Evaluation

- The implementation of economic partnership contracts is monitored through periodic reports and field visits.
- Performance is evaluated based on the economic and social impact achieved.

In summary

Economic partnership contracts represent a strategic tool for achieving development goals by enhancing local industry, transferring technology, and developing human capabilities, while ensuring long-term economic benefits.

Concept of Economic Partnership Contracts Program in the Procurement Process:

The Unified Procurement Authority ("the Authority") manages and follows up on all procedures of the Economic Partnership Program related to vaccine manufacturing in coordination with government entities. Potential contractors submit a proposal for the economic partnership outlining areas of partnership in achieving the development goals mentioned below and the target investment value for each item, as well as the proposed method for fulfilling the economic partnership commitments. The partnership value is evaluated after studying and discussing the proposal with the contractor based on the investment calculation factors outlined in this document to determine the competitive advantages granted to the contractor in the tender or practice offered by the Unified Procurement Authority for long-term vaccine supply contracts in which the contractor participates.

Competition and Award

Preparing the Competition

Those wishing to participate in the Economic Partnership Program for vaccine manufacturing must submit a proposal for the economic partnership to benefit from competitive advantages.

Bidders will also be required to sign a commitment defining the obligations of the economic

Evaluating the Competition

Collecting the economic partnership proposals and referring them to the Authority

The authority evaluates the economic partnership proposal and will communicate with the bidder if necessary.

Signing the Contract

The winning applicant in the tender or practice must sign the economic partnership contract before or at

Implementation and Follow-up

The contractor implements the economic partnership activities in accordance with the economic partnership contract

Competition and Award

Preparing the Competition

Defining the obligations of the economic

Submitting a Proposal for the Implementation of the Main Stages of the Economic Partnership

Evaluating the Competition

The authority evaluates the economic partnership proposal and will communicate with the bidder if necessary.

Selecting the Bidder

Signing the Contract

The same time as signing the main contract.

Project Signing the Economic Partnership Contract

Implementation and Follow-up

The authority monitors the implementation of the economic partnership project and provides final approval for the obligations of the economic partnership.



Potential bidders must submit signed copies of the economic partnership proposal and commitments at the same time they present their main contract bid. The economic partnership proposal must include a plan for implementing the activities of the economic partnership. The economic partnership proposal serves as the foundation upon which the economic partnership contract is concluded.

The economic partnership proposal should detail the activities to be carried out and the associated timelines so that the content of the proposal can be evaluated. It may also include a risk assessment and any major dependencies that go beyond the framework of the economic partnership program, as well as any factors that intersect with other activities that need to be considered.

Economic Partnership Management:

Contractors work with the authority throughout the procurement process to develop the economic partnership proposal, sign the economic partnership contract, and monitor and evaluate progress in achieving the agreed-upon key stages.

Assessment of the Economic Partnership Proposal

- The proposed economic partnership offer must be submitted as part of the bid for the main contract and will be evaluated before the main contract is signed.
- The economic partnership proposal will be agreed upon after discussions between the contractor and the authority, and the final economic partnership proposal will be included in the economic partnership contract. Interim Report for the Economic Partnership Project:
- The contractor must submit an interim report to the authority every 6 months, including information on the status and performance of all economic partnership projects.
- The contractor is required to attend an annual meeting with the authority to discuss the progress made in implementing the economic partnership project.

Interim Report for the Economic Partnership Project:

- The contractor must submit an interim report to the authority every 6 months, including information on the status and performance of all economic partnership projects.
- The contractor is required to attend an annual meeting with the authority to discuss the progress made in implementing the economic partnership project.

Project Site Visit:

The authority reserves the right to follow up on the developments in executing economic partnership projects and to conduct performance reviews, and to visit the site whenever it sees fit. The purpose of the site visit is to verify the status of project implementation.

Economic Partnership Balance:

The table below summarizes the multiplier value of economic partnership activities and should be included in the economic partnership proposal.

Eligible Activities	How It's Calculated	Multiplier Value
Technology Transfer		
Documents and technical manuals directly related to the technology transferred to local beneficiaries.	The cost of the documents and manuals transferred at the contractor's expense to complete the process, and this activity should be part of the technology transfer offer provided by the contractor	0.5
Training for local beneficiaries directly related to using the transferred technology.	The expenses borne by the contractor to cover the training costs, excluding any travel expenses or daily allowances for trainees, which must be covered by the local beneficiary.	2
Local technical assistance for using the transferred technology.	The expenses incurred by the contractor to provide local assistance or technical support to the local beneficiary in the Arab Republic of Egypt.	1

Eligible Activities	How It's Calculated	Multiplier Value	
Technology Transfer			
Granting specific machines, equipment, or devices necessary for using the technology and not available in the Arab Republic of Egypt	The cost of machines, equipment, or devices and any additional expenses incurred by the contractor to transfer and deliver them to the local beneficiary	2	
Export sales resulting from the transferred technology.	Additional export revenues generated by the local beneficiary, directly related to the transferred technology due to the contractor's direct efforts during the economic partnership contract period.	3	
Export Development			
Exporting products.	Export revenues generated for local beneficiaries during the economic partnership contract period, directly associated with the economic partnership project and the contractor's efforts.	3	
Increasing the competitiveness of local beneficiaries by enhancing the profitability of local products, which can improve the position of local beneficiaries in global markets.	The cost savings achieved by local beneficiaries due to support from the contractor through achieving economies of scale during the economic partnership contract period.	3	
Research & Development			
Capital expenses for conducting research and development activities.	Any capital expenses incurred by the contractor for research and development activities included during the economic partnership contract period.	3	
Capital expenses for conducting research and development activities.	Any capital expenses incurred by the contractor for research and development activities included during the economic partnership contract period.	3	



Members of the **Egyptian Vaccine** Manufacturers Alliance (EVMA)



VACSERA

Dr. Sherif Shawky El Feel

Dr. Sherif Shawky El Feel, a distinguished leader with over four decades of experience in the pharmaceutical industry, currently serves as the Executive Managing Director of VACSERA. His career includes pivotal roles as Chairman and Managing Director of Acdima International, Upper Egypt Pharma, and Techno-Pharm. He has also served as CEO of October Pharma and Pharco IMPX Romania, overseeing and leading numerous initiatives across the Middle East, North Africa, and Europe.



Dr. Sherif earned a B.Sc. in Pharmacy from Alexandria University and an MBA in Marketing from the Arab Academy for Banking and Financial Sciences. He is also a Certified Board Member, reflecting his dedication to governance excellence and strategic direction in the healthcare sector.

Throughout his career, Dr. Sherif has consistently demonstrated expertise in pharmaceutical sales and marketing, corporate management, and strategic planning. His involvement in prestigious companies like Riyadh Pharma, SPIMACO, and Batterjee Pharma has been instrumental in expanding operations, fostering growth, and improving market share across various regions and sectors. Known for his depth of knowledge in managing teams, sales channels, marketing initiatives, and distribution networks, Dr. Sherif has a proven commitment to advancing healthcare solutions and broadening access to essential medicines. His dedication to professional development and innovation has made him a transformative figure in the pharmaceutical landscape, positioning him as a leader with both vision and the practical expertise necessary for VACSERA's mission.

Under Dr. Sherif El Feel's leadership, VACSERA has broadened its role as Egypt's central hub for vaccine manufacturing and distribution. By prioritizing local production and aligning closely with the Egyptian Vaccine Manufacturing Alliance (EVMA), Dr. Sherif has steered VACSERA toward a model of operational independence and quality assurance that meets both national needs and international standards. His approach has transformed VACSERA into a reliable partner in regional health security, marked by a commitment to producing vaccines that not only serve Egypt's population but also support broader efforts to improve access to high-quality vaccines across the Middle East and Africa.

Dr. Sherif El Feel emphasizes VACSERA's commitment to create a sustainable healthcare infrastructure that addresses both present and future needs. VACSERA's long-term investments in R&D, infrastructure, and workforce development reflect a forward-looking approach that aligns with Egypt's healthcare priorities, building a legacy of resilience to benefit future generations.

Through its involvement in EVMA, VACSERA continues to drive regional health advancements, securing Egypt's position as a leader in vaccine manufacturing and a model for sustainable public health. In its vision, VACSERA aspires not only to be a producer of vaccines but a leader in healthcare innovation and reliability, advancing the fight for public health security

Company Profile

Founded in 1881, VACSERA stands as one of the region's oldest and most reputable vaccine manufacturers, with a legacy spanning over a century in public health and vaccine production. Guided by a vision of leadership in the production, development, and marketing of biological preparations, serums, human and veterinary vaccines, and blood derivatives, VACSERA supports both local and regional healthcare markets. The company remains committed to leveraging technological advancements to maintain global competitiveness.

VACSERA's mission is to meet Egypt's demand for human and veterinary vaccines, biotechnological medicines, blood products, reagents, and medical supplies by enhancing production efficiency and ensuring employee rights. VACSERA is recognized as a strategic pillar in healthcare, Vacsera plays an integral role in Egypt's health infrastructure.

Operating under a robust structured corporate framework

VACSERA includes the following entities:

- •Egyptian Co. for Production of Vaccines, Sera & Drugs
- •Egyptian Co. for Blood Transfusion Services
- •Egyptian Company for Veterinary Drugs & Vaccines







With an annual production capacity of 405 million doses and a distribution capability of 200 million doses, VACSERA is equipped to meet both regional and local demands. The company has established several technology transfer agreements to advance innovative vaccine and biopharmaceutical production. VACSERA's adherence to GMP standards and a comprehensive Quality Management System (QMS), including Pharmacovigilance (PV) measures, underscores its commitment to safety and quality. VACSERA's diverse product portfolio contributes significantly to regional health security and self-sufficiency.













VACSERA's operations are anchored by an extensive network of specialized facilities across Egypt, each offering unique capabilities. The primary sites include Agouza Headquarters, the 6th of October Industrial Complex, and Helwan Facility, which together support VACSERA's public health mission on both local and regional levels..

Agouza Headquarters

Spanning 61,000 square meters, Agouza serves as VACSERA's central operationalheadquarter with specialized vaccine and biologic production facilities essential to Egypt's healthcare.

Notable facilities include:

Building 60: A dedicated site for sterile filling of lyophilized and liquid vaccines with a production capacity of 100 million doses annually, supporting high-demand vaccines such as COVID-19, Penta Vaccine, DTP (Diphtheria, Tetanus, Pertussis), DT (Diphtheria, Tetanus), Hepatitis B, and TT (Tetanus Toxoid). Building 60 is a cornerstone of VACSERA's vaccine production, addressing a substantial share of Egypt's immunization needs.





Building 1: This facility has a capacity of 3 million doses per year. It specializes in life-saving products such as anti-scorpion, anti-snake, and anti-viper serums, as well as various tetanus (anti-tetanic) serums in doses of 1,500 and 30,000 units, crucial for treating venomous bites and stings in emergency healthcare.



Building 2: Known as the biotechnology products plant, this facility also produces 3 million doses per year, manufacturing essential biotechnological products, including insulin and rabies vaccines



BCG-T Production Area: Specializes in producing the Bacillus Calmette-Guérin Tumor (BCG T) therapeutic used for urinary bladder cancer treatment.



Additional facilities under upgrading at Agouza headquarters

which include bulk antigen production facilities form upstream for Diphtheria-Pertussis (DP) and Tetanus Toxoid (TT), handling strains of diphtheria, tetanus, pertussis, cholera and typhoid and staffed by highly skilled workforce. Agouza site includes robust Quality Control (QC) laboratories to ensure product quality overseeing and release. Agouza site also serves as the main vaccination center, supported by an additional network of 23 vaccination centers across Egypt to serve the public.



Significantly, Agouza houses two WHO-designated regional reference laboratories: The Flu Reference Lab and the Polio Regional Reference Lab, essential for Egypt's contributions to global disease monitoring and containment











The 6th of October Industrial Complex

Covering 95,000 square meters, VACSERA's 6th of October Industrial Complex is designed to meet the high-output demands essential for national and regional vaccine distribution.

KEY FACILITIES WITHIN THE COMPLEX INCLUDE:

•Human Vaccine Filling Facility: With an annual capacity of 300 million doses, this facility focuses on producing critical vaccines, enabling VACSERA to meet large-scale immunization needs.



•Avian Flu Vaccine Production & Filling Facility: Dedicated to avian flu vaccine production, this facility has a capacity of 800 million doses per year, guarding against potential zoonotic outbreaks that could affect both animal and human health.



•Central Cold Storage Building: Spanning 3,200 square meters with a storage capacity of 150 million doses, this fully automated cold chain facility ensures vaccines are kept at precise temperatures, preserving their quality for distribution. This facility is comparable to top international logistics centers worldwide. The warehouse is equipped with 3 shipping docks for automatic loading and unloading of products, equipped with insulated doors to prevent any temperature leakage, and to improve communication between refrigerated trucks, loading and unloading products, and increasing efficiency.

The warehouse is designed and implemented according to the (WHO) World Health Organization Code of Good Storage Rules (GSP) and the Egyptian Medicine Authority as follows:

- Each cooling room is controlled through a dual cooling system (one system for use and the other For backup).
- The warehouse is equipped with 24-hour temperature monitoring alarm systems.
- The warehouse is equipped with electronic monitoring systems (46 cameras)
- The warehouse is equipped with alarm system to denote any deviation.
- The warehouse is equipped with an automatic warehouse management system using the WCS system, linked to the WMS system, "a system for managing inventory and goods in and out of ware houses automatically," and equipped with 6 AGV robots.





Quality Control Laboratories:

The complex houses eight central laboratories that uphold international safety and efficacy standards for all products.



Auto-Disabled Syringe Production Facility:

This facility is a joint venture between Vacsera and Scope (Emirati Company) to produce auto-disabled syringes, which prevent needle reuse and enhance the safety of vaccination programs





Brown field for Future Expansion:

The complex includes a building for future projects and an expansion, demonstrating VACSERA's commitment to adapt and grow in response to Egypt's healthcare needs.

•Free space for future expansion:

Vacsera plans to construct a Biosafety Level 3 (BSL-3) laboratory in cooperation with the Egyptian Ministry Of Health in its free extension space. This advanced lab will play a crucial role in enhancing Egypt's readiness for future pandemics by allowing safe research on high-risk pathogens, accelerating vaccine development, and supporting public health security. Equipped to handle dangerous airborne diseases, the BSL-3 lab will enable rapid outbreak response and help Egypt achieve greater self-sufficiency in infectious disease management, positioning VACSERA as a leader in regional health security and pandemic preparedness.

The 6th of October Industrial Complex exemplifies VACSERA's focus on scalability, allowing the company to support national immunization initiatives and exports to neighboring regions.



Egypt National Strategy for Vaccine Manufacturing Localization 2024 - 2030



Helwan Site

Located in Helwan, this site is integral to VACSERA's network, specializing in immunobiological products derived from animal sources. The Helwan farm and facilities focus on producing vital anti-venoms and antitoxins.

KEY FEATURES INCLUDE

•Horse Stable and Plasma Separation Unit:

This area is essential for plasma extraction used for various serums and immunobiological products.

•Toxicology Unit:

Supporting the development of antitoxins for venomous bites and stings, this unit plays a crucial role in emergency healthcare issues.

•Animal House (Laboratory and Reptiles):

Housing venomous animals like snakes, vipers, and scorpions and laboratory animals as for ex. rabbits, mice---etc.

•Specialized Venom Extraction and Antidote Production:

For safe handling and processing of venomous animals, providing a primary source of anti-venoms in Egypt.







Key Milestones & Achievements

VACSERA's significant achievements during the last years include a landmark partnership with Sinovac to locally produce COVID-19 vaccine, making Egypt the first African nation to produce COVID-19 vaccine domestically. In a rapid 123-day timeline from project approval to technology transfer, VAC-SERA initiated large-scale COVID-19 vaccine production. Over 18 months, VACSERA produced 142 batches, totaling 45 million doses, which has positioned the organization as a benchmark in African vaccine production.

Recognized internationally, VACSERA received visits from Africa CDC in September 2021 and January 2023, underscoring its role in continental health security. The organization's centralized cold chain logistics facility was praised as it resembled to UNICEF's logistics hub in Copenhagen, ensures the safe storage and distribution of vaccines, reinforcing VACSERA's leadership in maintaining vaccine integrity.

Strategic Goals & Vision

Aligned with Egypt's national healthcare goals, VACSERA's strategic objectives focus on:

Enhanced Vaccine Accessibility

VACSERA supports Egypt's Expanded Program on Immunization (EPI), and covering the vaccination needs of school children, police, and military personnel. This reduces reliance on imported vaccines, strengthening self-sufficiency.

Supply Chain Resilience

To address global supply chain challenges, VACSERA is boosting production and diversifying supply channels to secure vaccine availability during international shortages.

Talent Development

By offering training in biotechnology and vaccine production, VACSERA cultivates a skilled workforce, forming a foundation for Egypt's biotech industry.

R&D for Innovation

Focused on advancing vaccine technology, VACSERA collaborates with research institutions to develop next-generation immunobiological products, supporting Egypt's goal to lead in regional biotechnology

Public Health Policy Alignment

VACSERA works closely with government and international organizations, ensuring that its GMP-certified processes meet national and international standards

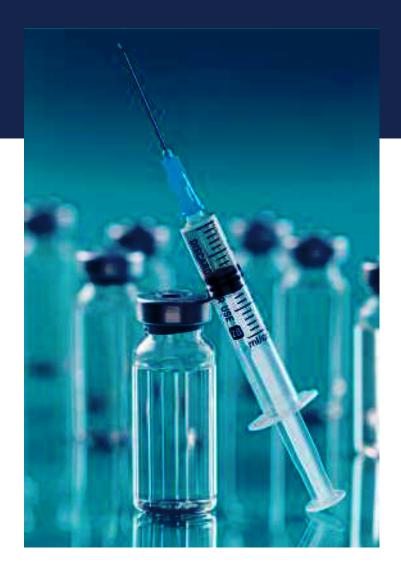
Technology Transfer

Technology transfer partnerships form the foundation of VACSERA's growth strategy, enabling the local production of critical vaccines and biological products. By collaborating with global leaders like Sinovac, Serum Institute of India, CD Bio, Walvax, Bilthoven, and Green Cross, VACSERA gains access to advanced manufacturing technologies and international best practices, which significantly strengthen its capabilities and impact.

Locally Produced Products:

VACSERA manufactures essential biological products and vaccines to support Egypt's healthcare system, including:

- •Anti-Tetanic Serum
- •Anti-Diphtheria Serum
- •Anti-Snake Venom (Liquid & Lyophilized)
- •Anti-Scorpion Venom (Liquid & Lyophilized)
- •Anti-Viper Venom (Liquid & Lyophilized)
- •COVID-19 Vaccine
- •BCG-T Vaccine
- •Bee Venom



Technology Transfer Products:

Through partnerships with international companies, VACSERA has expanded its production portfolio, now manufacturing an array of vaccines, including:

•Serum Institute of India (SII):

Penta Vaccine, Tetanus Toxoid (TT) Vaccine, Hepatitis B Vaccine (adult and pediatric), MMR Vaccine,

DTP Vaccine, and DT Vaccine

Five Years of Success and Over 70 Million Doses Supplied:

The partnership between VACSERA and SII has been instrumental in strengthening Egypt's vaccine production, with over 70 million doses produced since the collaboration began. This five-year partnership has reduced Egypt's dependency on imported vaccines, equipped local teams with vital manufacturing skills, and positioned Egypt as a key vaccine supplier to neighboring regions, exemplifying the potential of international collaboration in advancing local healthcare resilience and accessibility.

CD Bio: Rabies Vaccine

Walvax: Meningococcal AC Vaccine, Meningococcal ACWY Vaccine, Pneumococcal Polysaccharide Vaccine (PPSV 23)

Bilthoven:

Inactivated Poliovirus Vaccine (IPV)



Green Cross:

Tetra Flu Vaccine, Varicella Vaccine



Impact of Technology Transfer Partnerships

- •Adoption of International Standards: Technology transfer partnerships enable VACSERA to comply with rigorous international standards, including Good Manufacturing Practice (GMP) certification. This ensures all products meet global benchmarks for safety, efficacy, and quality, enhancing product competitiveness and reliability.
- •Enhanced Production Capabilities: The partnership with Sinovac enabled VACSERA to rapidly scale up COVID-19 vaccine production, achieving over 45 million doses across 142 batches within 18 months. This high-output production reflects VACSERA's success in technology transfer, underscoring its ability to meet large-scale demand.
- •Workforce Development: Technology transfer partnerships advance VACSERA's technical capabilities and enhance workforce skills. Through specialized training, employees acquire expertise in operating advanced equipment, implementing quality assurance protocols, and refining technical competencies.
- •Strategic Resilience and National Health Security: Leveraging international expertise, VACSERA has established a robust production framework, resilient against supply chain disruptions. This resilience aligns with Egypt's healthcare goals, ensuring a reliable supply of essential vaccines and biologics.

Role within the Egyptian Vaccine Manufacturing Alliance (EVMA)

As an EVMA member, VACSERA plays a pivotal role, combining its technical expertise, scalable infrastructure, and collaborative approach to build a resilient vaccine production ecosystem in Egypt. Its efforts directly align with EVMA's mission to transform Egypt into a regional leader in vaccine manufacturing while addressing critical health needs across Africa. Through these initiatives, VACSERA solidifies its role as a vital part of Egypt's healthcare framework and a key player in the broader African and Middle Eastern healthcare landscape.

1. Expanding Production Capacity

Advanced Infrastructure: Vacsera's capabilities beside the new facilities at 6th of October site, significantly enhance Egypt's vaccine production capacity. The new facility by itself can produce 300 million doses annually, addressing domestic needs and supporting exports across Africa. Logistics and Distribution: Its extensive logistical network ensures efficient vaccine delivery, contributing to EVMA's mission of making vaccines accessible throughout Egypt and the region.

2. Driving Technical Collaboration and Knowledge Exchange

VACSERA fosters a collaborative environment by sharing expertise and training in advanced vaccine production techniques. This exchange of knowledge improves operational standards across the alliance, enhancing the overall capacity of Egypt's healthcare sector.

3. Accelerating Vaccine Development

Speeding up Research: VACSERA coordinates with partnerships to support R&D to reduce vaccine development timelines.

Streamlining Production: By optimizing workflows, Vacsera ensures the rapid rollout of critical vaccines to address urgent health challenges in Egypt and the region.

4. Enhancing Vaccine Independence for Africa

Local Manufacturing: VACSERA reduces reliance on imported vaccines by producing vaccines and sera products locally, supporting EVMA's vision of self-sufficiency for Egypt and Africa Regional Focus: By targeting diseases prevalent in Africa, VACSERA contributes to improving public health outcomes across the continent

5. Strengthening Partnerships and Innovation

Global Collaborations: Partnerships with global organization as WHO and international pharmaceutical companies enable VACSERA to adopt cutting-edge technologies and meet global health standards.

Innovation in R&D: VACSERA's contributions to vaccine innovation within EVMA align with goal of addressing both current and emerging health challenges.

Conclusion

Looking forward, VACSERA is dedicated to expanding its leadership in Egypt's vaccine manufacturing industry, advancing national self-sufficiency and regional health security. With a continued emphasis on innovative technologies, enhanced production capabilities, and collaborative initiatives within the Egyptian Vaccine Manufacturing Alliance (EVMA), VACSERA is poised to make a lasting impact on public health across the Middle East and Africa.



GENNVAX

Dr. Nibal Dahaba

•Nibal Dahaba currently holds the position of Co-founder &General Manager Emerging Markets for Gennvax the first full production cycle vaccines facility in Egypt.



- •Over 20 years of solid experience in Marketing, Governmental Relations, Business development, market access, managing teams, commercial negotiation, Business excellence, Key country metrics follow up, Corporate Communication, PR, regulatory affairs &policy.
- •The exciting challenge of dealing with ambiguity and complexity of a constantly changing environment in emerging markets especially the key markets Africa, Egypt, Gulf & Levant were always her domain.
- •Coming from a continued multinational back ground Nibal was holding her most recent position as General manager Egypt & Africa for Sanofi Pastuer the Vaccines arm of Sanofi, prior to that she was holding the position of Corporate Head Middle East, Africa & Pakistan in AbbVie Pharmaceuticals where she was responsible for the spin off from Abbott & full launch of the new entity in 52 markets where Abbvie was the biotech arm of Abbott, setting the strategy and vision for dealing with all public markets and governments within the scope of more than 30 top revenue generating countries, doubling the top and bottom lines within 2 years of Abbvie's Launch in the region was quite a success story with the top selling drug in the world Humira.
- •Prior to that she was heading the governmental & public market section for Merck sharp and dome (MSD) regionally where she was responsible for launching their vaccines line within MEA in addition to all public market deals

- •She is the winner of a number of global awards like the emerging market award for diabetes control across the ME region , global IP award for IP protection and fighting infringement project in Egypt & Saudi , another top notch award was Middle East & Africa breakthrough award for increasing the vaccination coverage across 25 markets & developing their EPI national vaccination programs thus allowing more kids protection across the region , and finally the best marketing & public market access award which is one of the most prestigious marketing awards for the Hepatitis C campaign in Egypt which led to having Virus C eradication as a top governmental priority in Egypt and ending the waiting list queues for Virus C patients in an unprecedented achievement which the WHO & Lancet magazine have mentioned on all their publications.
- •In addition to her curricular activities Nibal have always been passionate about the public domain and she started serving that passion since 20 years ago, recently she was the Executive board consultant for Zewail City a top R&D institute inaugurated by the Nobel prize winner Dr Ahmed Zewail, in addition She is a permanent member and founder for a large number of eminent NGOs and councils that works basically on elevating the standard of living for the unprivileged population covering multi scopes as health, education, unemployment and many others. 57357, national youth council, national women council, national human rights council, US embassy in Cairo exchange alumni NGO are a few examples.
- •Nibal is a Cairo university faculty of pharmacy graduate and holds her post graduate diploma from George Washington University in DC



Company Profile



Setting up a state-of-the-art Vaccines manufacturing facility in Egypt –Which's one of the biggest vaccine facilities in Africa with Full production cycle & First R&D Hub in the region with total solar energy

Gennvax Location in Suez Canal Industrial Zone



Gennvax Budget & QMS:

The manufacturing site is being built in compliance with the highest regulatory standards to ensure smooth and issue free product and manufacturing site registration in the world's markets Project is well recognized locally and globally with full investment 150 million USD including around 60 million USD for WHO prequalification and aiming for vaccines exportation to the whole region with Quality Management System designed to define and manage all activities with regulatory requirements and compliance with relevant industry standards.

The Gennvax QMS covers all the company activities that may impact product quality and regulatory compliance

The QMS consists of 3 activities

- Company Policies
- •Quality Standards for Product Development, GMP and GDP
- •Engineering Standards Facilities, Equipment, Utilities and IT Systems

The Gennvax QMS will comply with the QMS models from the FDA, EMA and ICH Q10 and is determined by Managerial Responsibility

Gennvax QMS Governance and Oversight

- 1.Audits
- 2. Customer Feedback
- 3. Complaint and ADE Management
- 4. Tracking of Key Performance Indicators
- 5. Reporting to the Quality Council and Senior Management

The Gennvax Quality Management System (QMS) has been designed to define and manage all activities in the Gennvax organization that could impact product quality or compliance with regulatory requirements and compliance with relevant industry standards like

Regulatory Bodies

- 1.EDA (Egyptian Drug Authorities)
- 2.WHO (World Health Organization)
- 3.EMA (European Medicine Agency)









Industry Standards

PDA (Parenteral Drug Association) - ISPE- ICH

Gennvax Manufacturing Site will have fully equipped QC Laboratories for the analysis and qualification of vaccines. These will include:

- •Microbiology for contamination prevention and control, environmental and utility system monitoring and sterility, mycoplasma and bioburden testing
- •Analytical testing for vaccine qualification, starting and intermediate materials and product analyses
- •Packaging Article analysis



Gennvax Vision "State of the Art" Vaccine Manufacturing Facility





Gennyax Vision

"State of the Art" Vaccine Manufacturing Facility

To provide vaccines manufactured locally for Egypt & surrounding Markets, a Vaccine Manufacturing Plant will be built in several phases to cover:

- •Research and Product Development
- •Upstream Manufacture
- •Downstream Manufacture
- Packaging
- Quality Control

Gennvax project to build a greenfield vaccine manufacturing facility in order to provide essential vaccines for the Egyptian and African markets, as a first priority and then to other markets including the European Union

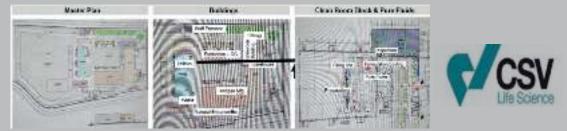
Gennyax Local and Global Recognition:

Presented the detailed Project Infront of the Egyptian Prime Minister who gave direct recommendations for all Egyptian authorities to facilitate and accelerate all requested milestones to finalize Gennvax the soonest and guaranteed the Golden licence for the only Healthcare & Vaccine Manufacturing facility in

Gennvax was granted the Golden License by the Egyptian Prime Minister's cabinet in July 2023, with the intention of providing support for the establishment of a scientific R&D center

Gennyax Construction

Signed the contract with the Italian contractor, CSV, is an Italian company operating in the fields of pharmaceutical validation, engineering and construction starting the construction during Q3 2023 after receiving EDA approval on conceptual design in Q1 2023, The facility will be constructed in the Suez Canal Economic Zone, over an area of 49,048 sqm in agreement with SIDC.



Gennyax Team:

An experienced team with extensive knowledge in the field has been exclusively selected to manage establishing the vaccine manufacturing facility

Gennvax Equipment:

Gennvax successfully purchased highest quality and innovative technology equipment Inspection Machines - Filling line - Packaging line from the most eminent European supplies and Finalizing MEP Equipment form European suppliers

- •Packaging line Marchesini (Italian Company)
- •Filling line Syntegon (German Company)
- •Inspection Machines Korber (German Company)
- •Washers and Autoclaves Belimed (Switzerland)
- •Water station & Patriations (From Italian Company)





Gennyax Value Proposition & Production Capacity

Gennyax is meant to fulfil local and regional gaps for vaccines supplies, capacity of Gennyax production will reach 270 million Doses of vaccines covering the essential vaccines in different national immunization programs in Africa

Gennvax R&D Hub in Africa

As Gennvax is a greenfield vaccine facility aiming to have a unique R&D Hub to assure implementing full technology transfer process with global vaccines suppliers to be able to conduct full production cycle in Egypt and cater the whole continent with essential vaccines and be ready for any pandemics affecting African Countries

Gennvax Academy:

Aiming to provide training and work experience to all operational staff working in the manufacture, distribution and control of vaccines.

Gennvax will recruit talented and experienced people for key positions. New joiners will benefit

from in-house training. Training will include:

Induction to Gennvax

GMPs

Basic manufacturing techniques

QC and QA Requirements

On the job training

Exterior Courses to improve Knowledge and Understanding via Gennvax Academy

Gennvax Academy Roles:

- •Identify talent at College and University level, assists them through their studies and prepares them for entry to Gennvax
- •Ensures training in the fundamentals of vaccine manufacturing and control as well as the requirements of Regulatory Agencies GMPs, GDPs, and Post Marketing Surveillance
- •Propose in-depth training through exterior courses and Regulatory Agencies
 Trainings will be Provided in Accordance and/or Partnership with ISPE PDA- EMA- WHO







Gennvax Supplier Selection Process and Certification Programs

All suppliers are vetted and approved by Gennvax through a comprehensive certification program, including

- •Identification of suitable suppliers
- •Auditing
- Quality Technical Agreements
- Approved Supplier List

Key Suppliers includes Vaccine Supplies (Intermediate Product and technology) - Starting Materials, Components and Packaging Articles & Services by Providers

Gennyax and Climate:

Addressing the sustainable development goals through its operations Including

- •The impacts of climate change, in alignment with Carbon Neutral Environment of COP27 through
- •Leading Green Vaccine Facility in the world with solar panels
- •Enhancing research, technology & knowledge transfer
- •Enhancing Adaptive Capacity & Resilience to Climate Change



Technology Transfer





13-Valent pneumococcal Conjugate Vaccine

•Minhai Biotechnology, officially known as Beijing Minhai Biotechnology Co., Ltd., is a significant player in China's vaccine industry. Founded in 2004, Minhai specializes in the research, development, and production of vaccines. The company focuses on creating safe, stable, and affordable vaccines aimed at increasing global immunization coverage and reducing the incidence of infectious diseases

•Minhai has developed various vaccines, including its 13-valent pneumococcal conjugate vaccine (PCV) and COVID-19 vaccine (KCONVAC). The 13-valent PCV is notable for its use of a dual-carrier system, which aims to reduce immunosuppression, making it a key innovation compared to single-carrier vaccines. This vaccine was the product of 16 years of research and development and is marketed globally, including partnerships in Southeast Asia and other emerging markets.

Minhai's parent company, Shenzhen Kangtai Biological Products



Mr. Miao Xiang

Mr. Miao Xiang,he is the Group President of Shenzhen Kangtai Biological Products Co., Ltd. (Bio-Kangtai). He served as Vice President, Chief Financial Officer, and Secretary of the Board. he is a Certified Public Accountant in China. Currently, Mr. Miao serves as the vice president of China Association of Vaccines.

Mr. Miao believes that it is an honorable mission to safeguard human health. Many leading R&D laboratories have been established by BioKangtai, including "Shenzhen New Vaccine Engineering Laboratory", "Guangdong Therapeutic HepB Vaccine Engineering Laboratory", "The Key Laboratory of Beijing for New Technology of Conjugate Vaccine" and "Beijing New Vaccine Engineering Laboratory". Moreover, the well-structured, multi-layered Vaccine Development Pipelines have been established by BioKangtai.



AJ Vaccines is a Danish-based company that specializes in the development, production, and global distribution of vaccines. It was formed after the acquisition of the Statens Serum Institut's

(SSI) vaccine the company focuses on vaccines that prevent life-threatening diseases, such as polio, tetanus, diphtheria, and whooping cough.

AJ Vaccines is particularly known for its involvement in the production of Inactivated Polio Vaccine (IPV) Salk, which plays a critical role in global polio eradication efforts. Some key points about AJ Vaccines' contribution to the polio file are:

AJ Vaccines is one of the key global manufacturers of IPV, which is part of the World Health Organization (WHO)'s Polio Endgame Strategy. The IPV is essential in transitioning from the Oral Polio Vaccine (OPV) to a more controlled approach to eradicating polio, reducing the risk of vaccine-derived polio strains.

collaborates with international health organizations such as UNICEF and WHO to ensure a stable and reliable supply of polio vaccines. Its IPV is widely used in immunization programs across various countries, as part of its global health initiatives, AJ Vaccines is honored to align with Egypt's Vision 2030 and Africa's Vision 2040 in fostering sustainable healthcare solutions for the continent. Recognizing the pivotal moment as many African nations transition beyond GAVI support, we are dedicated to collaborating with governments and regional stakeholders to strengthen healthcare systems, ensure vaccine accessibility, and enhance local capacity. By joining forces, we aim to contribute to a resilient and self-sufficient Africa, fully prepared to meet the health needs of its people while driving progress toward the ambitious goals of these transformative visions.

Works with global health stakeholders, including governments, non-governmental organizations (NGOs), and multilateral institutions to scale up polio immunization campaigns, particularly in low-and middle-income countries.



CEO at AJ Vaccines
KEY FOCUS AREAS:
Product portfolios
Business development
Partner/alliance management

Role within the Egyptian Vaccine Manufacturing Alliance (EVMA)

The Role of Gennvax in Shaping the Future of Vaccine Manufacturing in Egypt

As a pioneer in the Egyptian healthcare landscape, Gennvax is proud to be at the forefront of driving innovation and excellence in vaccine manufacturing. Our commitment is rooted in ensuring Egypt's self-sufficiency in vaccines and contributing to global health security.

Technology Transfer: A Pillar of Progress

Gennvax firmly believes in the power of collaboration and knowledge sharing. Through robust partnerships with leading global vaccines suppliers, we are driving comprehensive technology transfer initiatives that enable the seamless localization of vaccine production. This ensures that Egypt remains at the cutting edge of vaccine manufacturing, while adhering to the highest international standards for quality and safety.

Greenfield Facility: Building for the Future

Our state-of-the-art greenfield vaccine facility is a testament to our forward-looking vision. Strategically designed with cutting-edge technologies, this facility is equipped to produce a diverse portfolio of vaccines, meeting both local and regional needs. The design prioritizes efficiency, scalability, and sustainability, reflecting our commitment to minimizing environmental impact while maximizing output.

An Expert Team Leading the Mission

At the heart of Gennvax's success is our dedicated team of experts. Our workforce brings together world-class scientists, engineers, and technicians with extensive experience in vaccine research and manufacturing. Their expertise enables us to tackle the most complex challenges in vaccine development and production, ensuring that we deliver on our promise of high-quality vaccines for all.

Driving the Future Together

Gennvax envisions a future where Egypt plays a central role in the global vaccine ecosystem. By focusing on innovation, collaboration, and sustainability, we aim to lead the charge in making life-saving vaccines accessible to everyone. Together with our allies in the Egyptian vaccine manufacturing sector, we are building a healthier, safer future for generations to come.

We at Gennvax are honored to join hands with our esteemed peers at this pivotal meeting. Let us chart a collective path toward a resilient and self-reliant vaccine industry in Egypt

Conclusion

As a conclusion Gennvax vision for the future is to expand vaccine accessibility, advancing Egypt's self-sufficiency in health security, and driving technological innovation in the vaccine sector through a state of art vaccines facility that will act as a hub for local and international market

With a full cooperation with all EVMA Members the WHO Roadmap can be achieved to satisfy the need for vaccines in African countries at 2024 by around 60% coming from 99% imported in the current status



VBC

Dr. Magdy Mahmoud El-Sayed

Positions:

- •CEO of Vaccines and Biotechnology City (VBC)
- •Chairman of Middle East Vaccines for Animal Vaccines (MEVAC)
- •Board Member of UVAC for Human Vaccines (UVAC)
- •Shareholder in United BioMed Pharma/Vet. (United BioMed)
- •Partner in UBM for Pharma -Egypt and UBM for Biological -Dubai
- •Shareholder in EgyHolland for cleaners and disinfectant

Biography:

Magdy Elsayed is a Professor of Infectious Diseases at the Faculty of Veterinary Medicine, Cairo University, He has over 35 years of experience working for numerous global corporations, including Pfizer, MSD, and Boehringer Ingelheim

He is the CEO, founder, and shareholder of Vaccines and Biotechnology City (VBC), a private-public partnership between MEVAC/UVAC and the National Services Project Organization (NSPO). VBC is focused on the vaccines industry and works to protect humans and animals from emerging diseases while also promoting self-sufficiency in the Middle East and Africa.

The Middle East for Vaccines Company (MEVAC), an Egyptian / American / Arab company that manufactures animal health vaccines and exports to over 40 countries, is one of the biggest healthcare exporting companies in Egypt and a member of the Egyptian Medical Industries Export Council. He also serves as its chairman, founder, and shareholder.

Dr. Magdy founded UVAC For Human Vaccines and serves as a shareholder.

He founded and shareholder at UBM for Pharma & Veterinary Products, which represents over seven foreign businesses in the Middle East and Egypt. Dr. Magdy El-Sayed established a facility in 2019 to produce products for human health range of pharmaceuticals, cosmetics, and plant medicines.

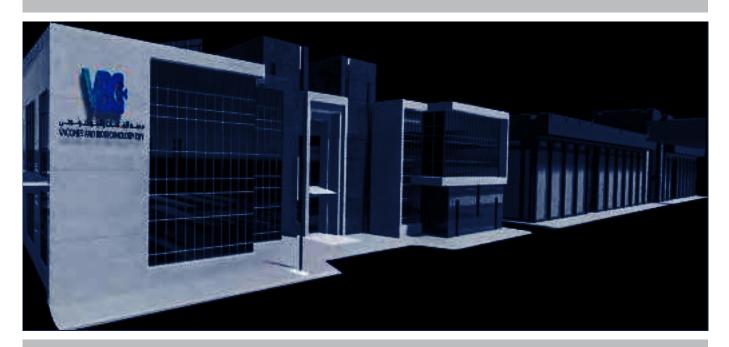
Additionally, he has a great experience producing different types of vaccines like classical inactivated & Live vaccines and successful in leading a special R&D team of Egyptian and international scientists to develop Recombinant and mRNA vaccines. Adhering to the EVMA's goal of localizing the vaccines industry in Egypt, with a commitment to One Health for Humans, Animals, and the Environment, targeting MEA to have equitable and sustainable access to vaccinations.



Company Profile

VBC is a biopharmaceutical company dedicated to the discovery, development, and commercialization of vaccines and biotechnological products, with a primary emphasis on safeguarding against biological threats and emergency cases in Egypt, the Middle East, and Africa.

Through our diverse portfolio, we keep people and animals healthy by providing safe, reliable, and effective vaccines. Supported by robust research and a team of experts who are dedicated to advancing preventive healthcare. We prioritize initiatives that elevate community health standards and contribute to enhancing the overall quality of life. By focusing on prevention, we aim to reduce the burden of diseases and promote healthier populations.



Founding Story

VBC is founded on the belief that manufacturing biological medicines, like vaccines, is crucial for the future of healthcare.

We recognize the need to localize vaccine production in Egypt, the Middle East, and Africa. Moreover, the global COVID-19 pandemic has shown how important it is to have the capability to develop and produce vaccines locally.



Project Idea

On 23 December 2021, PRESIDENT ABDEL FATTAH AL-SISI - THE PRESIDENT OF Arab

Republic of Egypt issued his directives to immediately start the establishment of Vaccines and Biotechnology City in Egypt within the framework of the country strategy to:

Localize the human and veterinary vaccines industry

Bridge the gap between domestic production and importation and work to reach self-sufficiency for

- human & Vet. Vaccines in Egypt, Middle East & Africa
- Protect Egypt, Africa and Middle East from Biological Threats.

With over 14 years of solid experience in vaccines production from MEVAC/UVAC and technology

• transfer from reputable international companies and research institutes, the Egyptian/American private company (MEVAC/UVAC) along with the National Services Project Organization (NSPO) established VBC as strategic project for national security against biological threats & localizing the vaccines industry.



MEVAC (TT Partner in VBC) is one of the biggest healthcare exporting companies in Egypt and a member of the Egyptian Medical Industries Export Council





On December 12, 2022, the Egyptian Prime Minister Dr. Mostafa Madbouly witnessed Vaccine and Biotechnology City progress and followed up the project's implementation







On December 4, 2022, the Egyptian Prime Minister Dr. Mostafa Madbouly granted the Golden License to Vaccines and Biotechnology City as the first human and veterinary vaccines manufacturer in Egypt receiving it







Vision

To localize and lead vaccines industry & other biopharmaceutical products in Egypt, Africa & Middle East

Mission

For self-sufficiency of vaccines and other biological products in Egypt, Middle East and Africa by establishing a sustainable industry with world-class quality. To offer affordable, safe and effective healthcare solutions to combat infections.

Goals & Objectives

National security

To fully protect the region from biological threats.

Equity

Providing the needs of Egypt and Africa from specialized vaccines and achieving equitable distribution.

Vaccines industry localization

The ability in vaccines industry reaching self-sufficiency.

Saving foreign currencies

Increase in exports and reduce imports.

VBC is a Best Fit for Unmet Needs

- We believe in One Health with Equity and Sustainability for Human, Animals and Environment
- As African Manufacturer we can Offer the highly needed vaccines for Egypt, Africa and Middle east with affordable cost
- VBC aims to be African Hub to avoid Shortage of Essential Vaccines and match the African Union Objective to produce 60% of Vaccines Locally by 2040
- High Potential to Focus on Neglected Tropical Diseases of Particular interest for Egypt, Africa & Middle East

VBC Project Outlines

115,000 square meters for production of Human & Animal Vaccines and biotechnological products Located at 98 Cairo Ismailia Desert Road, The intersection of Cairo Ismailia Road and Sarabium Road





Target in Figures

- CONTROL 8 Human diseases
- CONTROL 30 Animal diseases
- PROTECT 70 Countries
- EMPLOY 1500 Employees

Vaccines Categories at VBC

- Essential Human Vaccines for Extended / National Immunization Program
- Veterinary Vaccines (Poultry, Equine, Ruminant, Pet & Fish)
- Emergency Vaccines in cases of epidemics

Production Volumes



Strategic Capabilities

R&D Pillar for Innovative Vaccines

Full Cycle Manufacturing (Starting from Seeds to Large-Scale Production)

7 Different Filling Lines (PFS, Lyophilized Vials, Liquid Vials, Ampoules, Intranasal, Oral Tubes &Bottles)

Lab Animal Facility

Biosafety Level 3 & Level 2 QC Labs

International accreditation standards

WHO Prequalification Standards

Qualified Biosafety Labs

VBC has biosafety labs at both LEVEL 3 AND LEVEL 2, ensuring rigorous safety protocols for handling potentially hazardous materials. These specialized labs enable us to maintain high standards of safety while producing life-saving vaccines.

QUALITY SYSTEM

An integrated system module is created to ensure the implementation of all relevant international standards and national legislation:

- QUALITY STANDARDS: EDA, WHO, EMA & FDA.
- BIOSAFETY &BIOSECURITY: CDC, WHO & NIH.
- ENGINEERING STANDARDS: ISPE, ANSI, ISO, EN, ASHRE & PMBOOK.
- HSE STANDARDS: EPA & OSHA.
- DIGITALIZATION: SMART CITY.
- SUSTAINABILITY: LESS CO2 EMISSIONS

Utilizing real-time data capture, analysis and trends are identified, and data integrity is ensured through the implementation of intelligent solutions.

WE MAINTAIN QUALITY ACROSS:

- Every vial
- Every syringe
- Every dose
- Every life Touched by our products

THE VACCINES AND BIOTECHNOLOGY CITY IS BEING IMPLEMENTED AS A SMART CITY TO

- Promote sustainability
- Enhance efficiency
- Foster innovation
- Improve quality of life
- Combat climate change

Access Strategy



VBC is present in more than 15 MEA countries through its partners KEMIN & MEVAC & Planning to expand in additional 11 countries to capture 10% of Vaccines Business in Africa by 2030

Our Global Team

United in Diversity (7 Nationalities from 5 Continents)

Training Academy building up New Generation of Experts

VBC Center of Excellence is fully equipped with Experts, Materials and Tools to achieve its goals





To provide a healthy environment for employees and trainees, VBC has established modern accommodation building with wide and well- organized green landscaping areas.



VBC's training Academy is an integral part of its mission to advance the progress of the biopharma industry in the region which delivered from:

- 1- VBC state-of-the-art facility, that is designed to equip participants with real-life skills that align with the highest industry standards. VBC Training Academy includes more than five training halls with various capacities, from 20 to 250 PAX
- 2-Great Field experiences that provides industry leading on-demand courses on key aspects of biopharma manufacturing.

Furthermore, we are committed to providing scientific research and innovative development in collaboration with Egyptian expertise and an international team, fostering cultural and scientific exchange, contributing to technology transfer, and developing local skills. Additionally, we work closely to offer various initiatives to engage and promote future generations in building a better future through educational, training, and volunteering programs.

As a leading organization in the field, we are delighted to have a vaccine manufacturing training and research academy in the Middel East and Africa. Which offers:

- Continuous education programs to keep knowledge updated.
- Integration of the latest technology into learning.
- Immersive learning experience to cultivate skills.
- Pioneering the future of vaccines manufacturing in the region.
- Leading innovation, excellence, and self-reliance within the industry.
- -Strong infrastructure, comfortable environment and professional Trainers that help achieving the effectiveness of training programs objectives

Role within the Egyptian Vaccine Manufacturing Alliance (EVMA)

VBC began working with internal and external organizations under the umbrella of EVMA in order to expedite the deadlines for technology transfer and the localization of the vaccines industry		
With the goal of expanding filling capabilities and logistics, VBC will create twinning initiatives with other EVMA members.		
We are grouped together for number of reasons; At VBC, we can serve as a hub for accessing the Middle East and Africa and to serve as a toll manufacturing facility for others.		
Given that R&D was always the missing component for Vaccines to Africa in the last decades. We are having a global team of scientists and experts in vaccines R&D and will use our center of excellence to train and exchange experience with other EVMA members		
In line with EVMA objectives, VBC aims to play a significant role in National Immunization Programs VBC will be ready to protect MEA region against any emergency diseases threats		

Technology Transfer

Through VBC International Board members and their global partners we have our solid plan of Technology Transfer for Vaccines Development, Manufacturing and Commercialization through our own network of distribution within Africa & Middle East.

VBC is committed to aligning with international standards and following GMP Guidelines At phase 1, We are focusing on TT of high priority vaccines for Egypt, Africa & Middle East: Pneumococcal Conjugate Vaccine PCV13, Hepatitis B, Measles, Rubella & Rota Vaccines

Conclusion

We noticed that recently The UN announced - Coincidentally that there is a focus on One Health Initiative as an integrated, unifying approach to balance and optimize the health of people, animals and ecosystems.

One thing we can do is to make sure the world sees this approach together with the support of EVMA Partners. We are coming with a view beyond supplying vaccines only. Because it was always historically focused on supply and access to vaccines. But now we are talking about Full Cycle Development, Vaccine Formulation and fill & finish, we are talking about several manufacturing processes

Currently the hot topic in MEA is primarily about localizing vaccine industry, that's a theme that everybody's using because of challenges related to access, affordability and unmet medical needs in this region. It's becoming a national security issue, so we are in shape as **EVMA** members

No single entity can do industry localization alone, so we call for partnership with global organizations like WHO, UNICEF, Africa CDC & GAVI, we need the support of the governments and authorities like EDA & UPA to materialize these objectives

I hope that VBC is voice for the wave starting to move in the right direction, we are calling on all stakeholders, governments, private sector & civil society for their commitment to make the choice to invest in health. Please join us



BIOGENERIC PHARMA S.A.E

Prof. Dr. Mohamed Sayed

Prof. Mohamed Sayed is an accomplished Executive and Research Scientist with over two decades of expertise in cellular and molecular biology. With a strong foundation in recombinant DNA, Vaccines and mRNA technology, Prof. Sayed has applied his skills extensively to both ex vivo and in vivo models of malignant diseases in humans and animals. As the CEO and Co-Founder of Biogeneric Pharma SAE in Egypt and Biogeneric Pharma R&D LLC in the USA, he has spearheaded innovative research



initiatives. Additionally, he serves as Chief Scientific Officer at Amoytop Biotech in China and has contributed to the scientific community as a Professor and Oncologist at Memorial Sloan Kettering Cancer Center. Prof. Sayed's academic and professional journey is distinguished by numerous publications, honors, and a profound commitment to advancing cancer research and therapeutics.

"I am honoured to lead a company positioned at the forefront of the global biopharmaceutical field. At BioGeneric Pharma S.A.E., our shared vision and steadfast dedication have propelled us to become a leader in the development, production, and marketing of therapeutic recombinant antibodies, proteins, and vaccines, setting a new standard of excellence in the industry.

With a deep commitment to elevating Egypt's healthcare landscape, I am focused on advancing local vaccine production through BioGeneric Pharma S.A.E. Our active role within the Egyptian Vaccine Manufacturing Alliance (EVMA) embodies our mission to strengthen Egypt's capacity for essential vaccine production, supporting increased access to critical treatments and a more robust, self-sufficient healthcare system."

Company Profile



BioGeneric Pharma S.A.E 10th of Ramadan Industrial Zone

1. Business and product profile in BGP:

BioGeneric Pharma S.A.E. (BGP), is a new state-of-the-art biopharmaceutical facility specialized in the manufacturing of therapeutic recombinant proteins and vaccines. The facility is located in the 10th of Ramadan industrial city with all advanced technologies and sophisticated equipment.

Biogeneric Pharma S.A.E Edge Capabilities;

Capacity to Support Vaccination Programs: BGP has the capability to supply up to 800 million doses of vaccines annually, significantly contributing to Egypt's vaccination program of meeting 35% of Africa's vaccine requirements by 2030.

Advanced Storage Facilities: BGP boasts state-of-the-art warehouses with multiple temperature-controlled environments, including:

- 25–15 °C
- 2–8 °C
- -20 °C

Cutting-Edge Manufacturing Technologies:

- Single-Use Dual Chromatography/TFF Systems: Ensuring high efficiency and quality in production.
- Robotic Formulation and Filling Lines: A versatile, integrated solution for vials, cartridges, and pre-filled syringes, provided by Syntegon®.
- Single-Use Formulation Tanks: Supplied by trusted industry leaders Merck® and PALL®.
- •Automated Vial Filling Line: A dedicated and fully automated vial production line powered by Syntegon® technology.
- •Comprehensive Quality Control Infrastructure: Centralized QC labs equipped to uphold the highest standards of Bio therapeutic vaccine quality and safety.

2. Brief History of The Organization:

BGP's main principal activities are the development, production and marketing of genetically engineered biosimilar proteins and vaccines.

The plant has been designed and constructed /equipped to comply with the International Standards of current Good Manufacturing Practices (cGMP) in compliance with US FDA, EMA and WHO requirements for the manufacturing of sterile biopharmaceutical products and vaccines.

BGP is built on an experienced team of experts from various areas of biotechnology and quality capable of facing any challenges that may occur within the fast-growing biotech field.

BGP is among the few Rabies Vaccine suppliers in Egypt, and in October 2024, in collaboration with the Egyptian Authority for Unified Procurement (UPA), the first delivery of our Rabies Vaccine Inactivated (Freeze-Dried) - RabiVax-S was made to the Ministry of Health & Population (MOHP) Stores.

BGP is nominated by WHO to be one of the WHO partners in receiving the technology transfer of the mRNA platform to manufacture vaccines and biosimilars since February 2022 (https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/recipients-of-mrnatechnology-from-the-who-mrna-technology-transfer-hub).

BGP Success Partners









































BGP plant consists of two main floors (besides the mezzanine floors for gowning and offices):

Ground floor is dedicated for qualified warehouses, inspection, labelling, secondary packaging and utilities.

- The warehouse occupies an area of 1,550 m2 (around 1750 pallet location) with several separate cold rooms to store temperature sensitive materials and finished products requiring controlled temperatures. Monitoring of temperature is through "Continuous monitoring system".
- Inspection, labelling and packaging areas are equipped with an automatic visual inspection machine & 2ry packaging line with track & trace system supplied by Syntegon®. Equipment are qualified and used for packaging vials, syringes & cartridges with a capacity of around 100 cartoon/minute.





• Water treatment station, which is located in the ground floor, supplied from Pharmatech, is qualified for producing purified water, water for injection and clean steam following United States and European pharmacopeia requirements.

Purified water generation unit is of capacity 2 m³/hr and storage tank is 6000 L.

WFI is produced by distillation of PW with capacity of 1 m3/hr. WFI storage tank is 4000 L.

The Pharmatech Distillation Unit is designed for the production of pure steam with capacity of 500 kg/hr suitable for steam autoclaving and SIP-sterilization.

First floor is dedicated for labs, bioproduction areas for production of drug substances of multiple biopharmaceutical products and vaccines and 2 separate formulation and filling lines.

Total production areas is 4000 m2 allocated to the production of biological products from seed vials to fill and finish of vials, cartridges and pre-filled syringes.



Figure 4: Water treatment station

• Bioproduction areas

Contains the manufacture of biologically active materials on an area of 1,500 square meters, including bioreactors, purification and concentration systems using the latest single-use technology, and including other related service areas such as cell culture and media/buffer preparation areas.

The area is also equipped with the latest bioreactors that apply the single-use technology, with a capacity ranging from 25 to 2000 liters. An additional area has been designated to accommodate mRNA technology in cooperation with the World Health Organization (WHO).



STR2000L Bioreactor

- The formulation and filling areas is composed of 2 qualified production lines:
- 1. The first production area contains a robotic open active RABS filling production line constructed on 850 m2 producing the final products in three types of containers (vials cartridges pre-filled syringes).

Pre-formulation, formulation, filtration and filling by using single use technology, supplied by Syntegon® and single use formulation tanks supplied by Merck® & PALL® starting from 10 L to 1500 L which enables the facility to produce multiple products without the risk of cross contamination between different products. Purging and filling in presence of qualified Nitrogen is available.



Robotic 3 in 1 open Active RABS single use filling line

Container	Working Capacity/Hour	Annual Maximum Capacity
Pre-filled Syringe	7,536	30,144,000
Cartridge	5,472	21,888,000
6R Vial	4,032	16,128,000
20R Vial	2,120	8,480,000
50R Vial	1,120	4,480,000

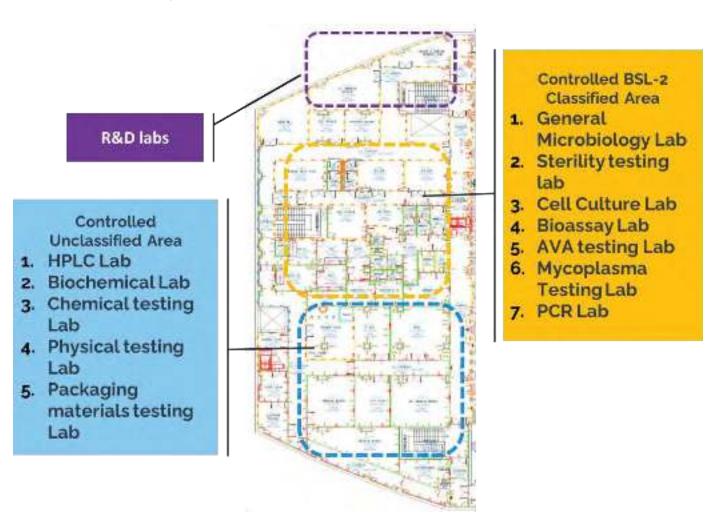
- 2. The second production area contains an open active RABS automatic preparation and filling production line constructed on 650 m2 producing the final products in vials with different sizes.
- o Pre-formulation, formulation, filtration and filling with 300 L and 600 L pre- formulation tanks and 600L sterile receiving tank supplied by Syntegon®. Formulation and filling in presence of qualified Nitrogen is available.



o Production capacity is as follow:

Container	Working Capacity/Hour	Annual Maximum Capacity
2R Vial	19,200	76,800,000
6R Vial	16,000	64,000,000
10R Vial	13,824	55,296,000
20R Vial	8,208	32,832,000
50R Vial	3,072	12,288,000

Quality control labs occupy 830 m2 separated from the production area. QC labs are divided into 2 categories:



Layout for R&D and QC labs

The labs are well designed and qualified where separate air handling units were provided for biological, microbiology testing areas with regular supply of appropriate quality of water for cleaning, testing purpose & supported with wherever considered necessary such as airlocks, pass boxes & biological safety cabinet



Layout for R&D laboratories accommodating mRNA technology

QC labs are well equipped with latest analytical instruments, devices and equipment which have been appropriately qualified and calibrated for their intended use to fulfil the QC testing requirements.

All lab activities are connected and managed by electronic LIMS, where the data integrity and audit trails are ensured according to CFR- 21 Part 11

BGP QC is capable of supporting various application in biopharmaceutics including but not limited to:

- o Monoclonal Antibodies, Insulin & Other Recombinant Proteins
- o Cell and Gene Therapeutics
- o Vaccines
- o Excipients & Adjuvants



Stability chambers

It can perform qualitatively assessing or quantitatively measuring the presence or amount or the functional activity of a target entity (the analyte) which can be a drug or biochemical substance or organic sample using different

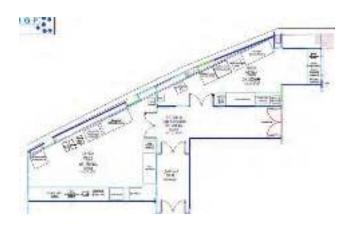
techniques:

- o Physicochemical assay techniques
- o Immunoassays techniques
- o Microbiological assays techniques
- o Bioassay techniques



HPLC in Separation lab

Separate R&D labs for accommodation of mRNA technology in co-operation with WHO are designated in collaboration with international institutes and universities for pandemic preparedness utilizing mRNA platform and in development of new candidate vaccines



3. BioGeneric Pharma S.A.E. (BGP) Integrated Management System Policy:

The policy is signed and approved by BGP's top management who in turn ensures that this policy is declared, communicated to and understood by all BGP's employees.

The following is BGP's policy:

BioGeneric Pharma S.A.E (BGP) as an international, new state of the art biopharmaceutical corporate firmly commits to operate Integrated Management System in accordance with the requirements of ISO9001:2015,

ISO14001:2015, ISO45001:2018, ISO27001:2022 PAS 99: 2012, international standards of cGMP in compliance with US FDA, EMA, WHO requireme

nts, Egyptian Drug Authority, contractual requirements, applicable regulations and other requirements.

BGP is considered to be a world class biopharmaceutical

BioGeneric Plearus S.A.E.
Integrated Management System Policy

Sys-P104

Audience Plearus 3.A.E (807) as a relevance of the set implementation concerns from process of the set implementation of the set in the set implementation of the set implementatio

production facility with different production lines that operates under global regulatory, quality and safety standards guaranteeing information security, products quality accompanied by an environment-friendly production and testing system and providing a safe workplace.

BGP's aim is to develop, manufacture, analyse and market biopharmaceutical products and vaccines in a consistent

affordable price all the way through products' life cycle, focusing on continual improvement through BGPs strategic direction, objectives and programs appropriate to the nature and scale of risks and aspects and ensuring customer satisfaction, security of information, preservation of the environment; avoiding pollution, injury and ill health and complying with laws, regulations and other requirements.

BGP is built on an experienced team of experts from various areas of biotechnology and quality capable of facing any challenges that may occur within the fast-growing biotech field.

BGP believes in the diverse contributions of employees and provides extra ordinary value to the customers, community, shareholders and other relevant interested parties.

The security of data and information of the organization is BGP's priority, and BGP is committed to safeguard and maintain it.

4. Scope of BGP's Integrated Quality Management System:

BGP applies one framework to manage all quality, safety and information security activities via implementing Integrated Management System (IMS) in accordance with the requirements of ISO9001:2015, ISO14001:2015, ISO45001:2018, ISO27001:2022, PAS 2012:99, EDA, EU, FDA

cGMP regulations, guidelines and requirements.

The scope of BioGeneric Pharma includes development, manufacturing, quality control, marketing and sales of therapeutic proteins and vaccines in the form of finished products.

BGP is certified from BSI in accordance with the requirements of ISO9001:2015, ISO14001:2015, ISO45001:2018 and ISO27001:2022.











BGP's certifications from BSI for ISO9001:2015, ISO14001:2015, ISO45001:2018 and ISO27001:2022

Meeting Healthcare Needs Through Accessibility and Supply Chain Resilience:

- BGP, located in the 10th of Ramadan Industrial state-of-the-art equipped with a manufacturing facility designed to meet international standards (cGMP, ISO). This facility positions BGP to serve Egypt and the surrounding region with high-quality biopharmaceuticals and vaccines.
- The company has strategically aligned itself to act as a local supplier to improve Egypt's healthcare accessibility, aiming to become a regional logistics and manufacturing hub due to Egypt's strategic location. This goal includes exporting products to meet regional demand, further strengthening the supply chain across Africa, the Middle East, and Asia.
- BGP's manufacturing approach incorporates cutting-edge single-use technologies in its bioreactors, minimizing contamination risks and ensuring consistent production quality. The use of advanced equipment, such as automated inspection and packaging systems, supports scalability and resilience in response to supply chain disruptions.

Self-Reliance in Production and National Healthcare Strategy Support:

- To bolster self-reliance, BGP has adopted a comprehensive Integrated management system (IMS) certified under cGMP and ISO standards, covering quality, environmental, and safety management (ISO 9001:2015, ISO 14001:2015, ISO 45001:2018, and ISO 27001:2022). This aligns with Egyptian, US, EMA, and WHO regulations, ensuring stability and quality consistency.
- The facility employs sophisticated production lines capable of handling multiple product types, including vials, Pre-filled syringes, and cartridges. BGP uses advanced robotic filling systems to produce millions

- of units annually, ensuring a stable and continuous supply of biopharmaceuticals that meet local and regional demands.
- Workforce development is a core aspect of BGP's strategy to sustain self-reliance. The company actively invests in training programs for local talent to build a skilled workforce in biotechnology and pharmaceutical manufacturing. This commitment includes training in mRNA technology and other advanced biomanufacturing techniques in collaboration with WHO.

Creating a Strong R&D Environment for Innovation:

- BGP's R&D labs focus on advancing mRNA technology for vaccines and therapies, making it one of WHO's mRNA technology transfer hubs. This facility enables BGP to explore the development of mRNA-based vaccines, including those for COVID-19 and other emerging diseases.
- BGP emphasizes continual innovation through its dedicated R&D labs, equipped with state-of-the-art tools to support extensive research and testing in

mRNA technology and biosimilar development. This research focus extends to new areas such as cancer therapeutics and gene editing.

• The company's partnerships with WHO and leading global institutions strengthen its R&D capabilities, allowing BGP to share data, optimize manufacturing processes, and conduct efficient clinical trials, which accelerate the development of next-generation vaccines and therapies.

Strategic Partnerships and Alignment with Public Health Policies:

- BGP collaborates closely with governmental health agencies and international organizations, including WHO and the Medicines Patent Pool (MPP), to ensure that its production and product offerings align with Egypt's public health policies and global standards.
- These partnerships enable BGP to access global expertise, allowing it to contribute significantly to pandemic preparedness and public health initiatives in Egypt and the broader region. BGP's role as a WHO-designated mRNA technology hub reflects its alignment with international health strategies and standards, underscoring its commitment to enhancing healthcare resilience in low- and middle-income countries.
- By participating in WHO's technology transfer programs, BGP has positioned itself as a strategic player in advancing Egypt's biopharmaceutical infrastructure, contributing to Egypt's healthcare self-sufficiency and resilience against global health crises.



BGP's certifications from BSI for ISO9001:2015, ISO14001:2015, ISO45001:2018 and ISO27001:2022

Meeting Healthcare Needs Through Accessibility and Supply Chain Resilience:

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Technology Transfer

• BGP & Technology Transfer

BGP is one of the WHO partners in the technology transfer programme for the mRNA platform, where BGP will receive a well characterised mRNA platform, including manufacturing and testing processes starting from plasmid manufacture till fill and finish.

The technology transfer process will start off with COVID-19 as a proof of concept and this platform can then be used for manufacture of other vaccines and proteins with minimum non clinical and clinical trials to be requested from regulatory authorities for registration and use.

To support the research and development of vaccines using mRNA technology, BGP has partnered with Sheffield University in England for the design and development of the expression construct of selected candidate vaccines.

BGP is recognised by the Africa CDC to be one of the 9 commercial vaccine facilities installed and aiming to provide 35% of the continent's vaccine demand by 2030.

Another technology transfer project that is ongoing at BGP is the production and testing of Filgrastim with Chinese company Amoytop. The company is listed in the stock markets and is one of the shareholders in BGP. Filgrastim is now in the registration phase, and its stability studies are ongoing to confirm the successful technology transfer process between both sites.

Also, technology transfer of Inactivated Polio Vaccine with WHO prequalified Chinese company Sinopharm was started, and registration was successfully done for the first phase in the technology transfer agreement.

Additionally, technology transfer is initiated with WHO prequalified Indian company Serum Institute for

Inactivated Rabies vaccine, and first consignment was successfully delivered to UPA. Technology transfer phases are ongoing.

Other technology transfer projects are in the pipeline from European Vaccine manufacturers, which will be announced soon.

• Advanced technologies and its implementation

mRNA platform is the most recent and advanced technology available up to date worldwide for the manufacture of vaccines and biotherapeutic proteins. Unlike other biological platforms, which are product specific and time-consuming in all stages, mRNA is shorter in manufacturing and registration timelines, which impact product availability in the market, or in case of pandemics, and efficiently makes use of resources.

For other technology transfer partnerships previously mentioned, BGP's vision is to work with WHO prequalified partners for vaccines and/or EMA/FDA approved manufacturers this to make sure of the quality of the product and to assure a successful technology transfer process throughout all stages.

Benefits of technology transfer agreements:

• Empowerment of the government through readiness of an efficient platform that can meet local and African needs of vaccines in case of any pandemic and not to wait for developed countries to satisfy their needs then start looking for the needs of LMICs

- Meeting local needs through local manufacturing of already needed vaccines, thus saving hard currency for other strategic needs and creating job opportunities for youth
- Being up to date with the latest technologies and requirements by sharing best practices with other qualified/certified partners, thus raising and enhancing quality and expertise of the team and the system overall.
- Egypt to be identified in the continent as a high-quality supplier for vaccines and biotherapeutics, thus raising the country's economic state, importance, and creating high social morale.

• Technology Transfer and long term results

As previously mentioned, technology transfer encourages best practice sharing between both companies and fulfilment of identified gaps, thus raising knowledge and capabilities for both companies.

WHO initiative for the technology transfer of the mRNA platform is a highly notable partnerships as it places Egypt in the forefront of being a key player for the African region in case of an outbreak presence of any pandemics.

Amoytop



Li Sun

Li Sun is the Chairman and Chief Executive Officer of Xiamen Amoytop Biotech Co., Ltd., a leading Chinese biopharmaceutical company specializing in the research, development, and production of recombinant protein drugs. He has held the position of CEO since April 2013,30.

Mr. Sun's academic background includes a graduate degree from the Chinese Academy of Sciences and an undergraduate degree from Fudan University.

Under his leadership, Amoytop Biotech has achieved significant milestones, including the development and approval of Pegbing (Mipeginterferon alfa-2b) in 2016, the world's first 40kD Y-shaped PEG-modified interferon alfa-2b injection, which has been instrumental in advancing hepatitis treatment.

In 2020, the company was listed on the Shanghai Stock Exchange's STAR Market, marking a significant achievement in its growth trajectory.

Sinopharm



Liu Yong

Liu Yong is the President and Executive Director of Sinopharm Group Co., Ltd., a leading Chinese pharmaceutical company, since November 2017. He holds a Bachelor's degree in Business Administration of Pharmaceutical Enterprises from China Pharmaceutical University, a Master's in Business Administration from Fudan University, and a PhD in Social and Administrative Pharmacy from China Pharmaceutical University.

With over 27 years of experience in the pharmaceutical industry and more than 24 years in leadership roles, Liu Yong has held various positions, including General Manager at Sinopharm subsidiaries and Vice President of Sinopharm Group. He is a certified chief pharmacist and practicing pharmacist.

Role within the Egyptian Vaccine Manufacturing Alliance (EVMA)

Leadership in Vaccine Production:

- BGP's state-of-the-art facility, compliant with global standards (cGMP, FDA, EMA, WHO), positions it as a production leader within EVMA. With its high-capacity bioreactors and advanced production lines, BGP can produce vaccines at scale, directly supporting EVMA's objectives of enhancing local vaccine availability and reducing reliance on imports.
- BGP's production infrastructure includes advanced single-use production line, allowing flexibility and efficiency in vaccine production, with capabilities ranging from 25 to 2000 liters. This capacity positions BGP as a leader in EVMA's mission to strengthen vaccine production infrastructure Setting Standards and Optimizing Processes Across EVMA:
- Through BGP's adherence to rigorous quality standards and cGMP & ISO-certified Integrated Management System (IMS), the company sets a high benchmark for operational excellence. This standardization benefits EVMA by creating a model that other Alliance members can follow, promoting quality consistency and efficiency across the vaccine manufacturing landscape in Egypt.
- BGP's capabilities in advanced single-use bioprocessing technology and automated filling lines offer EVMA members a scalable production model that balances flexibility with high output, enhancing the Alliance's overall capacity to produce quality-assured vaccines.

Knowledge Sharing and Capacity Building:

- As a WHO mRNA technology transfer hub, BGP serves as an anchor for knowledge dissemination within EVMA. BGP provides training and technical assistance in advanced manufacturing techniques, mRNA technology, and quality control, ensuring that EVMA members are equipped with the latest skills and methodologies for efficient vaccine production.
- BGP's role in capacity building helps EVMA cultivate a skilled workforce ready to manage modern vaccine technologies. By sharing expertise in regulatory requirements, process optimization, and technical best practices, BGP accelerates the learning curve for other EVMA members, fostering a self-reliant, highly competent vaccine manufacturing network.

Collaboration and Harmonization within EVMA:

• BGP's collaborations with WHO, Medicines Patent Pool (MPP), and other global health organizations reinforce EVMA's goal to harmonize production standards across members. By aligning with international best practices, BGP provides EVMA with the framework needed to unify quality benchmarks, which enhances the credibility and global competitiveness of Egypt's vaccine industry.

Through joint efforts in clinical trials, quality assurance, and data analysis, BGP enables EVMA to streamline approval processes and fast-track new vaccine introductions. This collaborative approach is crucial for addressing urgent health challenges, ensuring that vaccines reach the Egyptian population and the wider region efficiently.

Tech Transfer Partners and CEOs:

WHO



Dr. Tedros Adhanom Ghebreyesus, born on March 1965, 3, in Asmara

Dr. Tedros Adhanom Ghebreyesus is an Ethiopian public health expert and diplomat, serving as the Director-General of the World Health Organization (WHO) since 2017, reappointed for a second term in 2022. He holds a PhD in Community Health and a Master's in Infectious Disease Immunology.

As Ethiopia's Minister of Health (2012–2005), he led health system reforms, reduced child and maternal mortality, and expanded health coverage with 40,000 health workers. Later, as Minister of Foreign Affairs (2016–2012), he contributed to global initiatives like the Sustainable Development Goals.

At WHO, Dr. Tedros focuses on universal health coverage, emergency preparedness, and equitable access to healthcare, playing a pivotal role during the COVID-19 pandemic.





Dr. Tedros Adhanom, director general of WHO accompanied by his excellency Egyptian Minister of Health visit to BGP facility in October 2022

Conclusion

BioGeneric Pharma (BGP) aligns with Egypt's Vision 2030 by driving the localization of vaccine production, which is essential for achieving self-sufficiency and reducing dependence on imports. Through its state-of-the-art manufacturing facility and role as a WHO mRNA technology transfer hub, BGP not only bolsters domestic production capabilities but also facilitates knowledge transfer within EVMA, fostering a skilled workforce prepared for sustainable vaccine manufacturing. This alignment with Vision 2030 helps establish Egypt as a regional leader in healthcare resilience, ensuring a secure, accessible vaccine supply for the nation and the surrounding region.



GYPTO

Dr. Amr Mamdouh

Amr Mamdouh has been the Chairman & CEO of Gypto Pharma since September 2020, leading one of Egypt's largest and most advanced pharmaceutical hubs. With state-of-the-art manufacturing facilities, Gypto Pharma is dedicated to providing high-quality, affordable medications and positioning itself as a regional hub for international partnerships, technology transfer, and exports to Africa and the Middle East.



Before joining Gypto Pharma, Amr served as Chairman & Vice President of GlaxoSmithKline (GSK) Egypt & North Africa, overseeing GSK's top-ranking operations in Egypt, Algeria, Tunisia, Morocco, and the Near East (Iraq, Lebanon, and Jordan). During his tenure, he managed a robust portfolio across classic, innovative, and vaccine brands, achieving an annual sales turnover of approximately USD 435 million. Previously, Amr held the role of Vice President of Marketing for the Middle East & Africa, based in

London. In this capacity, he directed commercial operations across 30 regional markets, generating an annual sales turnover of nearly USD 1 billion. His work emphasized marketing strategies, sales excellence, and business development across diverse markets.

Amr has extensive experience in the pharmaceutical industry, gained over more than 30 years across diverse markets and cultures within the Middle East and Africa. His career includes both operational and regional roles at GlaxoSmithKline and Johnson & Johnson. With a strong track record in general management, strategic marketing, and new product development, Amr has worked in multiple countries, including Egypt, Saudi Arabia, the UK, UAE, and Belgium. This depth of experience has enabled him to adapt to varied business environments and drive success across international markets.

Amr holds a Bachelor's degree in Pharmaceutical Sciences and has completed numerous executive management, marketing, and leadership programs. His extensive industry experience and commitment to

Company Profile

Strategic Vision and Leadership of Gypto Pharma's CEO

The vision of Egypt's political leadership was to establish the Egyptian Drug City (Gypto Pharma) as a fundamental pillar in drug manufacturing and health security. Gypto Pharma's strategy, therefore, revolves around the idea that it is not merely a company, but rather an integrated city devoted to drug production—embodying the Egyptian Drug City (Gypto Pharma) vision in full.

Commissioned by the political leadership and inaugurated by His Excellency President Abdel Fattah El-Sisi in April 2021, Gypto Pharma has since dedicated itself to leadership in development, efficiency, and quality. Every individual working within Gypto Pharma strives



to establish it as a key source of drug security for the nation.

At the helm of Gypto Pharma is CEO Dr. Amre Mamdouh, a visionary leader whose expertise in the pharmaceutical and biotech sectors has positioned Gypto Pharma as a cornerstone in Egypt's healthcare landscape. Dr. Mamdouh's strategic vision is driven by his ambition to align Gypto Pharma's goals with Egypt's national priorities. His mission extends beyond manufacturing; he is committed to achieving self-reliance in critical healthcare supplies, making affordable, high-quality medicines accessible to all Egyptians.

Firmly dedicated to advancing Egypt's healthcare ecosystem, Dr. Mamdouh aims to transform Gypto Pharma into a leading pharmaceutical hub that supports the nation's long-term health security. His focus on building strategic alliances with international pharmaceutical leaders reinforces Gypto Pharma's role in the Egyptian Vaccine Manufacturing Alliance (EVMA), while his initiatives emphasize technological innovation, excellence in manufacturing, and resilience in public health.

Dr. Mamdouh's broader ambition aligns with Egypt's goal of building a "New Republic" that prioritizes healthcare. He envisions Gypto Pharma as playing a central role in national initiatives such as the 100 Million Healthy Lives campaign, comprehensive health insurance expansion, and efforts to eradicate Hepatitis C. Under his leadership, Gypto Pharma is set to become a cornerstone of Egypt's healthcare transformation, ensuring that all Egyptians have access to safe, effective, and high-quality medicines.

Gypto Pharma is more than a production site; it stands as an integrated city for drug manufacturing, pivotal to Egypt's strategy to secure accessible, high-quality medicines for its citizens. This ambition reflects a deep commitment to the Egyptian people's right to healthcare, establishing Gypto Pharma as an essential element of the country's national health security.

Gypto Pharma's Comprehensive Manufacturing Capabilities

Gypto Pharma's sprawling 180,000-square-meter campus includes fifteen advanced production areas equipped with the latest manufacturing technology, all designed to meet international quality and safety standards. With an annual capacity of up to 200 million units across diverse dosage forms, Gypto Pharma is well-equipped to address Egypt's growing healthcare needs and contribute to the region's drug supply security. Its dedication to Good Manufacturing Practices (cGMP) and cutting-edge technology, such as advanced sterile production environments and automated quality control, reinforces Gypto Pharma's reputation as a trusted pharmaceutical provider.

Milestones in Gypto Pharma's evolution include robust R&D systems, efficient laboratory operations, and a commitment to continuous human resource development. These foundational elements have positioned Gypto Pharma to support the national health sector while preparing for future export opportunities in the African, Arab, and CIS markets.



Strategic Goals and Long-Term Vision

To fulfill its mission, Gypto Pharma has set four core objectives that guide its work:

- 1. Accessible and Affordable Medicines: Gypto Pharma aims to ensure that every Egyptian can access safe, effective, and affordable medications. This goal lies at the heart of its commitment to equitable healthcare.
- 2. Regional Hub for International Collaboration: As Egypt's leading pharmaceutical manufacturer, Gypto Pharma collaborates with global pharmaceutical companies, enhancing its production capabilities and expertise. These alliances enable Gypto Pharma to innovate and provide high-quality drugs that meet Egypt's healthcare needs.
- 3. Expanding Exports: With an ambitious production goal of 60 million packages by 2024 and 200 products by 2028, Gypto Pharma plans to extend its reach to multiple regions. This expansion supports Egypt's health security strategy while fostering economic growth through exports.
- 4. Specialized Drug Manufacturing: Gypto Pharma is focused on producing biologics, oncology drugs, and vaccines, which are essential for Egypt's healthcare needs. This specialization reduces dependency on imports and provides critical treatments for Egyptian patients.

Gypto Pharma's vision is supported by a robust R&D department that continuously drives product innovation and quality improvements. In addition, Gypto Pharma invests in workforce development through collaborations with Egyptian universities, offering training and mentorship to future healthcare professionals.

To ensure that medicines reach those who need them most, we have launched our marketing efforts as a first step, focusing on establishing an initial presence by addressing the health sector's needs within the state through the Unified Procurement Authority and the Armed Forces.

Technology Transfer

Tech Transfer:

Gypto Pharma's growth has been significantly advanced through strategic partnerships with prominent international pharmaceutical leaders, facilitating technology transfer and strengthening its manufacturing expertise. These alliances not only highlight Gypto Pharma's integral role in Egypt's healthcare ecosystem but also reinforce its commitment to upholding world-class manufacturing standards.

Key Partnerships:

- Tech Transfer & Biotechnology: In collaboration with Roche in the field of oncology and Biological E in vaccines, Gypto Pharma is leveraging expertise to enhance drug and vaccine production capabilities. Beginning in February 2024, the partnership with Biological E includes the manufacturing of four essential vaccines: Pentavalent, Trivalent, Bivalent, and Tetanus toxoid. This alliance was later extended to produce the pneumococcal vaccine (PCV), addressing Egypt's immunization needs and aligning with the national healthcare objectives led by Egypt's leadership.
- Joint Venture (JV): Partnering with Otsuka, Gypto Pharma has established a joint venture that integrates innovative research and development to enhance product offerings and expand into new therapeutic areas.
- Joint Manufacturing: Through collaborative manufacturing agreements with Sanofi, Abbott, and Aspen, Gypto Pharma gains access to advanced production processes that ensure its products align with international quality standards.

These partnerships provide Gypto Pharma with state-of-the-art manufacturing technologies, ensuring the quality and efficacy of its products meet global benchmarks. The accompanying knowledge transfer is pivotal for developing local expertise, allowing Gypto Pharma to build and train a highly skilled workforce that will drive forward Egypt's pharmaceutical manufacturing sector and support its commitment to sustainable healthcare solutions.

Role within the Egyptian Vaccine Manufacturing Alliance (EVMA)

Role within the Egyptian Vaccine Manufacturing Alliance (EVMA)

Gypto Pharma is a key member of the Egyptian Vaccine Manufacturing Alliance (EVMA), a coalition committed to strengthening Egypt's vaccine manufacturing infrastructure. This alliance aligns with Egypt's goal to achieve vaccine self-sufficiency, reduce dependence on imports, and bolster health security. As an integral part of EVMA, Gypto Pharma contributes technical expertise, process standardization, and production scalability, ensuring that vaccines are available to meet national and regional health demands.

Within EVMA, Gypto Pharma focuses on harmonizing vaccine standards across Alliance members and sharing best practices. This collaborative approach not only supports Egypt's public health objectives but also enhances the regional healthcare framework, reinforcing Gypto Pharma's role as a trusted partner in vaccine accessibility and quality.

Conclusion

A Vision for the Future: A Self-Reliant, Health-Secure Egypt

Gypto Pharma is committed to ensuring Egypt's healthcare security, playing a pivotal role in the nation's journey toward self-sufficiency. Through ongoing collaboration with the Egyptian government, strategic international partnerships, and a relentless focus on innovation, Gypto Pharma is helping to build a resilient healthcare infrastructure capable of meeting Egypt's needs for years to come.

The Egyptian Drug City has successfully achieved a level of quality that qualifies it for export, and has already begun its journey to export products to several African, Arab, and CIS countries.

The Egyptian Drug City has also hosted a prominent exhibition for Egyptian medicines and products under the leadership of UNICEF, organized through the Unified Procurement Authority.

At the core of the Egyptian Drug City's vision is a deep commitment to human resources, attracting top talent to manage modern technology. The city provides training, continuous qualification, and an optimal working environment, including health insurance, reliable transportation for employees, and a variety of employee benefits.

Additionally, we have formed partnerships with Egyptian universities to create training protocols for outstanding students during the summer months, ensuring a pipeline of top-tier talent for future employment.

The Egyptian Drug City is steadily advancing to become a cornerstone of pharmaceutical security in Egypt, supplying safe, effective medications to Egyptian citizens. This success is driven by continuous support from the political leadership, demonstrating a steadfast commitment to the health and well-being of the Egyptian people.

As part of Egypt's national development strategy, the Egyptian Drug City (Gypto Pharma) is one of the country's key projects, reflecting Egypt's broader vision and its aspirations to be a leading force in all sectors. Its unique approach to development helps position Egypt among the ranks of advanced nations, playing a crucial role in shaping the new republic.

At Gypto Pharma, we are dedicated to providing the highest quality healthcare products that every Egyptian citizen deserves.

By working closely with our partners—doctors, pharmacists, and healthcare professionals—we strive to ensure that millions of patients can lead healthy, dignified lives.



EVA PHARMA

Dr. Riad Armanious

Riad is a serial entrepreneur that strives to empower the fight for health and well-being as a right. He heads the EVA group, which is one of the leading healthcare organizations in Africa and Middle East (AFME). Riad is an active member in the YPO (Young Presidents Association), YGL (Young Global Leaders), holds the



role of Vice-chairman in the Egyptian Industrial Chamber, the role of founder and former president of the Association of Graduates of Business Administration in Harvard and a member of the board in the Egyptian / Hungarian / Ethiopian / Bahraini & Emirati Business councils. Moreover, Riad is the founder of the "T20" foundation, a non- profit that focuses on utilizing the knowledge of highly educated youth to develop people and programs for social and economic improvement.

He gives special attention to biomedical research projects as he made a 21 million grant to be awarded to high-priority basic biomedical research projects with the potential for high scientific impact addressing new concepts and techniques to improve health in 3 fields: Multiple drug Resistance Bacteria, Immunotherapy in Cancer and NASH Non-alcoholic Steatohepatitis.

His experience includes Business Development, Marketing, Production, International Markets, and Project Management. Prior to his current position in Eva Pharma, Riad sets the company strategy, vision, and objectives to achieve the company's profitability.

Armanious's goal is to help patients and physicians across the Middle East and Africa. He wants to make sure that quality generics are accessible throughout this part of the world. He believes that the number of people without access is enormous, yet few companies are working to overcome the hurdles to reach and help these people. He sees the potentiality of making a strong impact in terms of improving access to affordable and high-quality medicine across Africa, and he sees a need to continue to invest with this goal in mind despite any political and economic turmoil."

Riad has a Bachelor of Pharmacy from Cairo University and an MBA degree from Harvard Business School.



As the CEO of EVA Pharma,

Riad Armanious leads the organization with a clear focus on advancing research and manufacturing in Egypt with intensified focus on innovative vaccine technology in recent years. Under his leadership, the company has set up the pioneering mRNA Innovation Hub, equipped to manage the complete development cycle of mRNA vaccines from early discovery till formulated vaccine product. This hub underscores EVA Pharma's commitment to empower sustainable accessibility to innovative healthcare solutions right from our region.

His vision has led EVA Pharma to expand its manufacturing processes to include both egg-based and cell culture-based vaccines with near future plans for bacterial fermentation-based vaccines technologies, significantly boosting local production capabilities. These developments are in direct response to the goals set by the Egyptian Vaccine Manufacturers Alliance (EVMA), aiming to cover a substantial part of Africa's vaccine requirements locally.

Armanious' work with EVMA highlights a commitment to not only enhancing vaccine availability in Egypt but also to fostering regional and African health autonomy by ensuring that local markets have timely access to essential vaccines.

Company Profile

Overview of the company's manufacturing capabilities, strategic goals

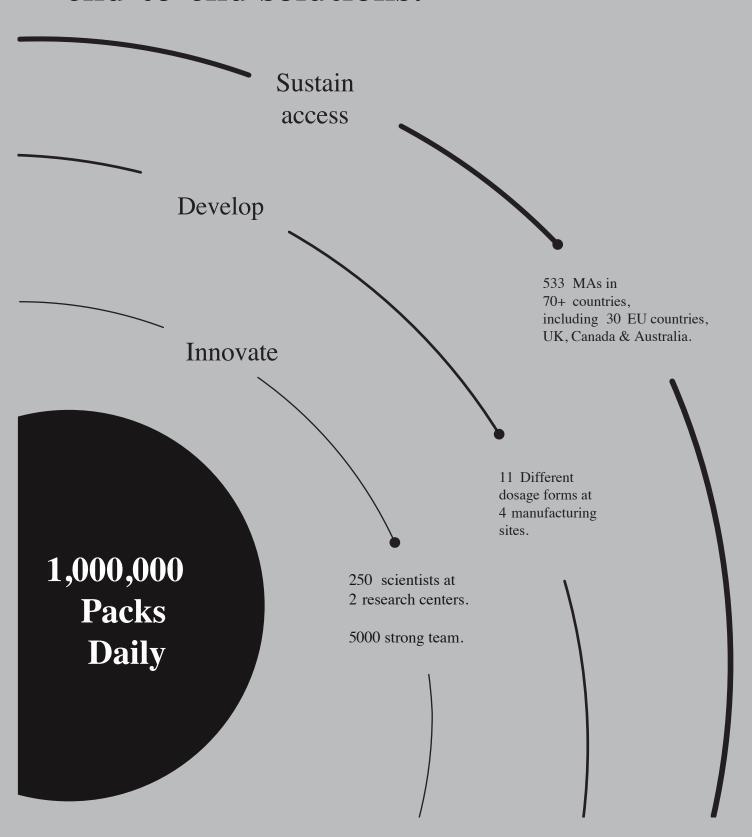
EVA Pharma is dedicated to improving access to affordable, high-quality medicines around the world, focusing on three core pillars: innovation, development and sustainable access. The company leverages cutting-edge technology at two research centers bringing first-ofits-kind capabilities to the Middle East and Africa including mRNA research and development from AI prediction to biological product.

EVA Pharma has developed strong manufacturing capabilities starting with egg-based vaccine technologies in addition to fill-finish capabilities of 100 million fill-finish vials of vaccines. EVAPHARMA currently has a special focus on avian influenza prevention in addition to developing diverse portfolio of vaccines which is projected to reach over 1.2 billion doses. Additionally, EVA Pharma is adopting new cell culture-based vaccine technology for highly infectious diseases with strategic direction to scale up production to around 15 million doses; Our Vaccine manufacturing strategy comes with establishing bacterial fermentation-based production capabilities expanding to new markets.

The company's strategic focus extends also to next-generation mRNA technology aiming to bring cutting-edge advancements to the vaccine industry, where EVA Pharma has notably focused on localizing innovation in recent years. The company has established an in-house R&D footprint and is introducing the first capabilities in Africa to focus on early discovery through its mRNA Innovation Hub which is fully equipped to handle the complete mRNA vaccine development lifecycle—from digital sequencing to final drug formulation. This includes antigen selection, protein engineering, mRNA construct design, innovative formulation and delivery systems and analytical method development, this state-of-the-art platform will enable the rapid development and production of vaccines for complex and emerging diseases

Our portfolio management target is to improve the standard of Health care in Egypt, the middle east and beyond. These investments highlight EVA Pharma's commitment to pioneering safe and innovative solutions in the vaccine industry providing opportunity to localize vaccine manufacturing in Africa and the middle east and providing solutions for combating pandemics

Patient-centered end-to-end solutions:



Quality

EVA Pharma's state-of-the-art manufacturing facilities are equipped with cutting-edge technology, are internationally recognized for innovation, and have been approved by multiple regulatory agencies.































Manufacturing Capabilities **Producing 1,000,000 packs daily.**

EVA Pharma 6th of October Manufacturing Complex

125,000 sqm - 206 million medicines / year

Allows upscaling of manufacturing capabilities to produce different dosage forms: tablets, capsules, sachets, soft gelatin, a dedicated area for cephalosporins, carbapenems and a dedicated sterile filling area for biologics. The complex hosts a biologics' facility for human and animal therapeutics and vaccines. API manufacturing & animal house are under construction.

Haram Complex

114 million medicines / year

Produces different dosage forms such as vials, ampoules, sachets, tubes, capsules, tablets, syrups, creams, inhalation, BFS, patches (hydrogel & transdermal) and ODF.



10th of Ramadan Facility

12,000 sqm – 5.2 million medicines / year First dedicated high-containment manufacturing site in the MENA region.



Limitless Naturals (6th of October)

3000 sqm - 26 million medicines / year Produces a diverse portfolio of 78 supplements, including vitamins, minerals, antioxidants, and herbal

minerals, antioxidants, and herbal products for both the domestic market and exports to over 13 countries worldwide.

Technology Transfer

A record of successful collaborations:

EgyVax- COVID-19 vaccine:

EVA Pharma worked on developing COVID-19 vaccine "EgyVax" with killed virus technology in collaboration with governmental institutes.

EVA Pharma finalized the preclinical studies on non-human primates "macaque monkeys" & preparation for entering phase 1 clinical studies.

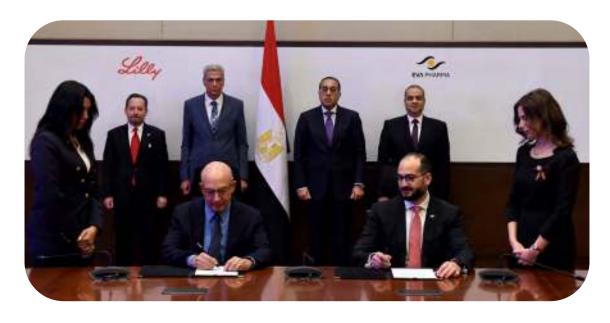
In March 2022, EVA Pharma announced the start of phase 1 clinical trials.



Metabolic health biologics:

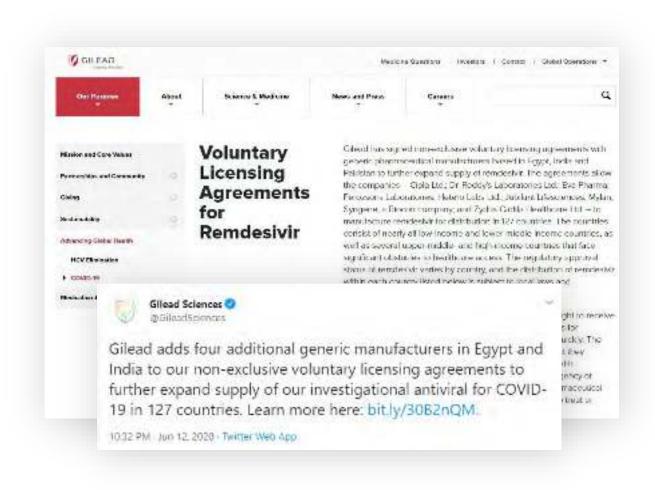
As part of Lilly's 30x30 initiative, Eli Lilly and EVA Pharma are collaborating to deliver a sustainable supply of human and analogue insulin to people living with type 1 and type 2 diabetes in low- to middle-income countries.

Eli Lilly is supplying API along with technical assistance, enabling EVA Pharma to manufacture and supply insulin to at least one million people in Africa.



Voluntary license agreement for Remdesivir:

Gilead Sciences has granted EVA Pharma a VL for Remdesivir in 127 countries (including our home markets) that enables the scaling-up of production, increasing COVID-19 patients' ability to access this life-saving treatment.



Localizing HIV treatment Lenacapavir:

EVA Pharma enter into agreement with Gilead allowing EVA Pharma to manufacture and supply generic lenacapavir in form of active pharmaceutical ingredient and finished pharmaceutical product. This agreement includes the technology transfer of know-how to make and use lenacapavir allowing for sustainable accessibility to lenacapavir in high-incidence, resource-limited countries through EVA Pharma's local manufacturing capabilities and strong foothold in Africa.



Localizing high potency medicine baricitinib:

EVA Pharma and Lilly have entered into an agreement to expand access to baricitinib to lowmiddle-income countries in Africa. Lilly has licensed baricitinib certain manufacturing know-how to enable EVA Pharma to manufacture and supply treatment for various immunological diseases including rheumatoid arthritis, alopecia areata, atopic dermatitis, and COVID-19.



Role within the Egyptian Vaccine Manufacturing Alliance (EVMA)

EVA Pharma role within the EVMA Alliance.

EVA Pharma is committed to empowering the Egyptian Vaccine Manufacturers Alliance (EVMA) by enhancing the entire vaccine value chain in Africa. Our contributions focus on leveraging our comprehensive research centers and extensive manufacturing capabilities to support the localization of vaccine innovation, development, and production. Through the strategic deployment of our mRNA Innovation Hub and large-scale production facilities capable of producing up to 90 million doses annually, we are pivotal in ensuring sustainable vaccine availability. Additionally, EVA

Pharma utilizes its pan- African on-ground presence as well as build on our expertise from supplying critical medicines across continent (Remdesivir, insulin among others) to ensure that these advancements benefit not just Egypt but the entire continent, aligning closely with EVMA's mission to achieve self-sufficiency in vaccine supply.



Innovation to sustainable access.



info@evapharma.com



Conclusion

It is essential to reaffirm the significance of the Egypt National Strategy for Vaccine Localization. This strategy represents a comprehensive approach to enhancing our nation's capacity for vaccine production, hoping that we are going to be well-equipped to meet both our domestic needs and those of our neighboring countries by 2040.

The establishment of the Egyptian Vaccine Manufacturers Alliance (EVMA) is a pivotal component of this strategy. By uniting key stakeholders—from local manufacturers to governmental bodies and international organizations—we are fostering a collaborative environment that prioritizes vaccine accessibility and innovation. The EVMA stands as a testament to our commitment to building a resilient healthcare ecosystem that can effectively respond to public health challenges.

Furthermore, the proposed concept Economic Participation Agreement is a vital step toward enhancing our pharmaceutical landscape. This agreement aims to create a conducive environment for investment and collaboration, ultimately driving forward our goals of localization and capacity building. By engaging in this partnership, we are not only investing in our healthcare infrastructure but also ensuring that our initiatives translate into tangible benefits for our society.

At the heart of these efforts lies our commitment to the health and well-being of the Egyptian child. By improving vaccine accessibility and strengthening preventive measures, we are taking significant strides toward enhancing overall public health in Egypt. Our focus on localization and collaboration reflects our dedication to safeguarding the futures of our children and ensuring that they grow up in a healthier, more secure environment.

In summary, the Egypt National Strategy for Vaccine Localization, supported by the EVMA and the proposed concept of Economic Participation Agreement, is a transformative initiative aimed at improving public health outcomes. Together, we are laying the groundwork for a healthier future for all Egyptians, particularly our children. Let us move forward with determination and unity to realize this vision and make a lasting impact on the health of our nation.