



The Vacci-Nation Hub

# TRANSFORMING STRATEGY INTO SUCCESS



# Index



### EXPERT DIALOGUE AT THE AMCHAM





EVMA- WHO COLLABORATIVE WORKSHOP





### **EVMA RCCN**

EGYPT 'S CO-HOSTING OF BIOMANFACTURING NETWORKS IN NORTH AFRICA



EVMA STRENGTHENING STRATEGIC COLLABORATION







EVMA -MPP COLLABORATION











EVMA & EUROPEAN COMMISSION ENGAGEMENT





EVMA- AVMI ALIGNMENT









**Dr.Hisham Stait**UPA chairman

# EMPOWERING VACCINE PRODUCTION: A VISION FOR EGYPT'S HEALTH FUTURE

In the dynamic landscape of healthcare and biomanufacturing, the importance of local capacity and innovation cannot be overstated.

As the Chairman of the Unified Procurement Authority (UPA), I am proud to highlight our commitment to enhancing Egypt's vaccine manufacturing capabilities through strategic initiatives.

Prime Minister Decision 719/2024 has empowered the Egyptian Authority of Unified Procurement and Medical Technology Management (UPA) to take the initiative to put Egypt's national strategy for vaccine localization into action. This strategy was thoughtfully formulated with two key arms: the Egyptian Vaccine Manufacturers Alliance (EVMA) and the Economic Participation Contracts. Together, these components are essential in advancing 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 EVMA, and with the honor of being awarded, in partnership with Morocco, the co-hosting of the secretariat for the North Africa region of the EVMA Regional Capacity and capabilities Network (RCCN), we stand at the threshold of a new era in healthcare for Egypt.

The EVMA RCCN plays a crucial role in enhancing both national and regional capabilities by facilitating the sharing of experiences and infrastructure across various sectors. By fostering collaboration among academic institutions, research and development entities, and manufacturers, the EVMA RCCN creates a comprehensive ecosystem that encourages innovation and knowledge transfer. This synergy not only strengthens Egypt's position in the biopharmaceutical landscape but also promotes a unified approach to tackling health challenges across the region. Through shared resources and expertise, the RCCN empowers stakeholders to optimize vaccine production, improve public health outcomes, and ensure a resilient healthcare infrastructure that meets the needs of all communities.

This allows us to leverage Egypt's powerful infrastructure to serve the entire continent. 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.

As we embark on this transformative journey, I invite all stakeholders to engage with us in building a resilient health sector that addresses the needs of all Egyptians. Together, we can create a healthier future for our nation.





**Dr. Ali Al-Ghamrawy**Head of the Egyptian Drug
Authority (EDA)

### EGYPTIAN DRUG AUTHORITY (EDA) AND VACCINE MANUFACTURING LOCALIZATION

In line with H.E. President Abdel Fattah El-Sisi directives to localize vaccines manufacturing, the Egyptian Drug Authority (EDA) is committed to protecting the national health security with strong leadership support.

The Egyptian Drug Authority (EDA) plays a key role in the Egyptian Vaccine Manufacturers Alliance (EVMA) to strengthen local vaccine production, reduce import dependence, and support economic growth.

The Egyptian Drug Authority (EDA) is a Leading National Regulatory authority (NRA) and Egypt, represented by EDA, achieved WHO GBT Maturity Level 3 for vaccine manufacturing (producing) in March 2022, becoming the first country in the Middle East and Africa to reach this milestone. This ensures compliance with global safety, efficacy, and quality standards, positioning Egypt as a continental hub for vaccine expertise transfer.

### **Capacity Building and Technical Support:**

EDA enhances local vaccine manufacturing by training professionals, collaborating with international experts, and organizing tailored programs on:

- Vaccines' quality, safety & efficacy.
- GXP principles in biopharmaceuticals manufacturing.
- Preclinical and Clinical Trials Oversight.
- Risk based lot release policies.

As an AUDA-NEPAD-designated Regional Center for Regulatory Excellence (RCORE), EDA conducted 6 international training programs for 37 trainees from East Africa and Ghana, supporting regional vaccine manufacturing capacity.

### **Collaboration with Stakeholders and Strategic Planning:**

EDA works with national health entities, vaccine manufacturers, and global organizations to ensure sustainable vaccine production.

It contributes to Egypt's long-term vaccine production strategy, including mandatory vaccines, aligning with health security objectives.

#### **Incentives for Local Manufacturers: -Locally: Internationally:**

- 1. Fast-track vaccine registration & priority review.
- 2. Technical support and scientific guidance at all development stages.
- 3. Issuance of internationally aligned guidelines to facilitate vaccine exports.
- 4. Workshops and training on licensing procedures, good manufacturing practices (GMP), and regulatory requirements.
- Accelerated inspection processes and licensing approvals.

- Supporting vaccine exports through agreements & partnerships with regulatory bodies.
- 2. Encouraging global partnerships for knowledge exchange & technology transfer.
- Assisting companies in obtaining WHO PQ & international accreditations.

Through these initiatives, EDA is positioning Egypt as a regional leader in vaccine manufacturing, ensuring self-sufficiency, economic growth, and broader African health security.





**Dr. Amr kandeel**Deputy Minister of Health
and Population

# EGYPT'S ACHIEVEMENTS "VACCINATION"

Since 1984, the Ministry of Health and Population has implemented a robust vaccination program with national strategic plans aimed at achieving over 95% vaccination coverage for all children in Egypt, both Egyptian and non-Egyptian, at all administrative levels.

Egypt has implemented a policy of maintaining a strategic stockpile of vaccines sufficient to meet the nation's needs for a minimum of six months to prevent any shortages in the supply of vaccines.

The vaccine supply system in Egypt is characterized by a robust cold chain that effectively manages the storage and transportation of vaccines from the point of arrival to distribution across all governorates. Cold chain equipment is regularly upgraded and renewed to ensure the efficiency of the cold chain at all levels.

Egypt's immunization program boasts a remarkable track record of success, including:

- Polio eradication: The World Health Organization (WHO) declared Egypt polio-free in 2006, with the last case reported in 2004. WHO continues to monitor and reaffirm Egypt's polio-free status annually.
- Reduction of neonatal tetanus: in 2007.
- Elimination of measles and rubella: Achieved in 2022
- Control of Hepatitis B: In December 2024, Egypt reduced the prevalence of hepatitis B virus (HBV) among children under five to 0.1%, becoming the first country in both the Eastern Mediterranean region and the African continent to achieve the regional target for elimination of hepatitis B.





# EGYPT NATIONAL STRATEGY FOR VACCINE MANUFACTURING LOCALIZATION





VIEW EGYPT NATIONAL STRATEGY WWW.EVMA-EGYPT.ORG



### **VISION AND OBJECTIVE**

### **VISION**

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

### **OBJECTIVE**

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

### STRATEGY PILLARS

# LONG-TERM CONTRACTS

Ensure the purchase of vaccines locally through extended contracts to encourage manufacturing and investment.

### AFRICAN MARKETS ACCESS

Support efforts to export Egyptian vaccines in collaboration with the African Union.

# ALLIANCE OF LOCAL MANUFACTURERS

Establish a platform for cooperation among local companies to avoid unhealthy competition.

# ECONOMIC PARTNERSHIP AGREEMENTS

Involve companies in achieving national economic goals such as technology transfer, capacity building, and supporting scientific research.

### FINANCIAL INCENTIVES

Provide tax exemptions and support new investments.

# TECHNICAL AND REGULATORY SUPPORT

Offer government assistance to facilitate the registration and accreditation of vaccines

### **EXPECTED OUTCOMES**

- Increase local production to meet national needs.
- Enhance exports to African countries.

- Reduce spending on vaccine imports.
- Improve the quality of local production and increase its global competitiveness.



# **EVMA LAUNCH**





# Can We Bridge the Gap Between Strategy and Reality?

### **KEY PARTNERS**

### **Technology Transfer Providers**



































### **Local Manufacturers**













### **Governmental Partners**











**International Organizations** 









### **KICKOFF PLAN**





# Transforming Strategy into Success



# EXPERT DIALOGUE SESSION AT THE AMERICAN CHAMBER OF COMMERCE



# Discussion on the Proposed Economic Participation Program to Promote the Localization of Medical Industries

As part of efforts to support the medical industries sector in Egypt, a high-level dialogue session was held yesterday, Wednesday, December 18, at the American Chamber of Commerce. This session brought together elite representatives from both the government and private sectors, with participation from the Unified Procurement Authority, the Egyptian Drug Authority, heads of Egyptian and global vaccine manufacturing companies, and prominent experts from the International Finance Corporation (IFC) and the African Export-Import Bank (Afreximbank).



The session aimed to discuss the proposed "Economic Participation" program, which is set to launch soon. This program focuses on enhancing the localization of medical industries, particularly vaccine manufacturing, as a strategic step to achieve self-sufficiency, enhance national health security, and drive economic development through investment in vital sectors.

### PROGRAM OBJECTIVES AND BACKGROUND



The "Economic Participation" program is a strategic initiative that seeks to expand cooperation between the public and private sectors by establishing new mechanisms for implementing projects that enhance local production of essential medical products promoting the private sector's in achieving the state's participation economic and strategic goals. The program aims to create an attractive and integrated environment capable investment providing the necessary incentives for localization, technology enhancing productive efficiency, reducing reliance on imports, and ensuring the achievement of the state's sustainable development goals.

Vaccine manufacturing is at the forefront of the targeted industries within this program, given its pivotal role in achieving health security, especially after the challenges faced by the world during the COVID-19 pandemic. The speakers during the session, moderated by Dr. Yousri Nawar, Vice President of the Chamber, emphasized the importance of building an integrated vaccine production system in Egypt that meets local needs while opening up avenues for export to regional and African markets.



# WIDE PARTICIPATION FROM LOCAL AND INTERNATIONAL EXPERTS





The session included representatives from leading Egyptian and international private sector companies involved in vaccine manufacturing, including members of the Egyptian Vaccine Manufacturers Alliance, such as Vacsera, BGP, VBC, Gennecs, EVA Pharma and GyptoPharma. Additionally, experts from global companies like Sanofi, Pfizer, and General Electric provided practical insights into the challenges and opportunities associated with localizing this industry in Egypt. Experts from the IFC and Afreximbank also made valuable contributions regarding financing frameworks and investment solutions that could help ensure the program's success.





### **MAIN DISCUSSIONS**

The session featured a presentation by Dr. Hisham Badr, Vice President of the Unified Procurement Authority, and legal expert Mohamed Abdel Jawad, about the proposed "Economic Participation Program." This was followed by extensive discussions on:



### Regulatory Mechanisms of the Program:

The necessary legislative and regulatory framework to activate economic participation contracts was reviewed to ensure contract clarity and transparency.



### Role of the Private Sector:

Participants stressed the importance of the private sector's involvement as a key partner in implementing the program, providing investment incentives to attract capital and advanced technology.



### Financing and the Role of International Institutions:

Experts from IFC and Afreximbank pointed out the need for flexible and innovative financing solutions to support startups and SMEs, as well as enhancing regional partnerships to expand the target market, while also considering leading international experiences, such as Brazil's in this context.



#### Challenges and Opportunities:

Participants discussed the main challenges facing the localization of medical industries, such as the lack of advanced technology, the need to build qualified human resources, and how to overcome these challenges through international and regional cooperation.

### **KEY CONTRIBUTIONS**



Dr. Hisham Badr, Vice President of the Unified Procurement Authority, confirmed dialogue the authority's during the commitment to providing an appropriate regulatory environment to support the proposed program. He noted that the proposed "Economic Participation" program aims to serve the interests of all parties and enhance transparency and effectiveness. He indicated that the program represents a transformation in the traditional supply and procurement system that aligns with the vision of the new republic.

He also pointed out the Egyptian state's interest in this file, exemplified by the follow-up from Dr. Khaled Abdel Ghaffar, Deputy Prime Minister for Human Development, on the national strategy to localize vaccine manufacturing, which was launched last November, along with its executive arm, the Egyptian Vaccine Manufacturers Alliance (EVMA), and its legislative arm, the proposed "Economic Participation Program." He requested regular updates on the tangible steps being taken to implement the strategy.

In turn, Dr. Ayman El-Khatib, Vice President of the Egyptian Drug Authority, emphasized the importance of unifying efforts to ensure compliance with international standards in vaccine production, noting that supporting local industry is an essential part of the state's strategy to achieve self-sufficiency. Representatives from vaccine manufacturing companies within the EVMA stressed the need for a clear and sustainable vision for the program, ensuring the stability of investment policies. They also called for strong government support in the initial production stages, particularly regarding supply chain management and the necessary financing system to implement the proposed business model, as well as providing the required raw materials and technology.

Experts from the International Finance Corporation (IFC) praised the innovative vision and pivotal role of the program in creating a promising investment environment and confirmed their readiness to provide technical and financial support to develop the infrastructure of medical industries in Egypt. Experts from Afreximbank noted that the program represents a strategic opportunity to expand regional cooperation in the medical industries and enhance exports to African markets.











### PRACTICAL RECOMMENDATIONS

# The session concluded with several practical recommendations to help achieve the program's goals, including:

- 1 Establishing a Clear Framework: Defining roles and responsibilities among government and private entities, ensuring contract transparency and monitoring their execution.
- 2 Enhancing Investment Incentives: Through offering tax and customs facilities, and supporting companies in obtaining advanced technology.
- 3 Building Human Capacities: By launching specialized training programs to qualify national workforce for the medical industries sector.
- 4 Strengthening International Partnerships: Through cooperation with international and regional institutions to support financing and technology transfer.
- Continuous Communication: Among all parties involved to ensure alignment on the program's goals and mechanisms.



Participants concluded that the proposed "Economic Participation" program represents a pivotal step towards enhancing Egypt's position as a regional hub for medical industries, especially given the significant capabilities the country possesses, both in terms of its strategic geographic location and qualified human resources.

Moreover, attendees emphasized the importance of ongoing dialogue between the public and private sectors and experienced international institutions to ensure the program's success, reaffirming commitment to achieving sustainable development that benefits the national economy and society as a whole.





# EVMA-WHO COLLABORATIVE WORKSHOP





On January 14, 2025, a pivotal meeting took place at the WHO office, focusing on the collaboration between the Egyptian Vaccine Manufacturers Association (EVMA) and the World Health Organization (WHO). The session aimed to orient EVMA members regarding WHO's role in supporting local vaccine production, particularly in light of Egypt's national vaccine strategy

### **KEY ATTENDEES AND OBJECTIVES**

The meeting brought together a diverse group of experts, including representatives from WHO, various vaccine manufacturers, and technical advisors. The primary objective was to consolidate efforts in vaccine production and address the pressing needs of local manufacturers.

### **INSIGHTS AND DISCUSSIONS**

It was highlighted by WHO the significance of strategic planning and resource allocation in meeting regulatory requirements for vaccine production. He stressed WHO's ongoing collaboration with public sector entities such as Vacsera and the Ministry of Health, while also acknowledging the vital role of private companies like Biogeneric Pharma in fostering public-private partnerships. It was elaborated the achievements made during the COVID-19 pandemic, noting the successful collaboration that led to significant regulatory advancements. The meeting served as a platform to discuss the government's demand for vaccine production and the prequalification (PQ) of locally produced vaccines.



### COLLABORATIVE INITIATIVES

# Several key action points emerged from the discussions: Conduct Workshops on Prequalification Processes:

- WHO will spearhead initiatives to educate manufacturers on PQ requirements.
- Map Training Needs: EVMA will consolidate training needs in vaccine production and share them with WHO and EDA.
- **Regular Meetings with Manufacturers:** Ongoing dialogue will be established to monitor progress and address challenges faced by manufacturers.
- **Strengthen Regulatory Frameworks:** Collaborative efforts will focus on simplifying regulatory processes to expedite vaccine approvals.

### **FUTURE DIRECTIONS**

The meeting concluded with a commitment to hold regular follow-ups and training sessions tailored to the needs of Egyptian manufacturers. This collaborative approach aims to enhance local capabilities in vaccine production, ensuring that Egypt is well-equipped to meet both local and international health challenges.

As the EVMA and WHO continue their partnership, the foundation is being laid for a robust vaccine production ecosystem in Egypt, promising improved health outcomes for the population and greater resilience against future health crises.



Prequalification of Medical Products

IVDs, Medicines, Vaccines and Immunization Devices, Vector Control

EVMA

### **EVMA Unveils Strategic Actions and** Engagements at the 2nd Annual Vaccine and Other Health Products Manufacturing Forum









2nd Vaccine and Other Health **Products Manufacturing Forum for African Union Member States** 

> **FEBRUARY** 2025

CAIRO. **EGYPT** 



### **EVMA RCCN**



Egypt is poised to take a leading role in strengthening Africa's biomanufacturing capacity. During the 2<sup>nd</sup> Vaccine and Other Health Products Manufacturing Forum for African Union Member States, held from February 4th to 6th, 2025, the country hosted the official launch of the North Africa Regional Capability and Capacity Network (RCCN) for Biomanufacturing Talent Development. This significant event underscores Egypt's commitment to advancing health security and sustainable vaccine production across the continent.

The announcement follows the recent selection of the Egyptian Vaccine Manufacturing Alliance (EVMA )the Executive arm of the Egyptian Authority for Unified Procurement (UPA), to co-host the RCCN Secretariat.

Sharing this responsibility with the esteemed Institute Pasteur Morocco, EVMA RCCN will play a crucial role in fostering collaboration, knowledge sharing, and workforce development within the North African biomanufacturing sector.



### Egypt's Co-hosting of Biomanufacturing Networks in North Africa

The forum was attended by key figures in African health and industry, including Dr. Hisham Stait, Chairman of UPA; Dr. Hesham Badr, Vice Chairman of UPA; Dr. Rania Mohsen, UPA Project Management Director; and Dr. Mostafa Ghorab, UPA Business Development Director. Their presence highlights the high-level support for this initiative within the Egyptian government and the broader health community.

The RCCN aims to address critical needs in biomanufacturing talent development, fostering a skilled workforce capable of driving innovation and production in the region. This initiative comes at a crucial time, as Africa seeks to enhance its self-reliance in vaccine and essential medicine production.

"This partnership marks a crucial step in strengthening Africa's capacity for vaccine and health product manufacturing,". "The RCCN will play a vital role in developing a skilled workforce, promoting innovation, and fostering regional collaboration to enhance public health outcomes. EVMA is honored to co-host the Secretariat and contribute to this transformative effort."

This initiative represents a significant step towards achieving the African Union's Agenda 2063 goals for health and well-being. By investing in biomanufacturing talent development, the RCCN will contribute to building a more resilient and self-sufficient health ecosystem in North Africa and across the continent.



### EVMA-Institute Pasteur Morocco Strategic Dialogue: Advancing Talent Development and Capacity Building in African Vaccine Manufacturing

### Introduction

On February 5, 2025, a pivotal meeting took place between the Unified Procurement Authority (UPA), the Institute Pasteur Morocco (IPM), and the Centers for Disease Control (CDC) during the sidelines of the 2<sup>nd</sup> Annual Conference for Vaccines and Biomanufacturing. Organized by GAVI, Africa CDC, RVMC, and UPA, this significant event gathered key stakeholders to discuss advancements in vaccine production and capacity building across Africa.

The meeting featured distinguished participants, including UPA's leadership: Dr. Hisham Stait, the UPA Chairman; Dr. Hesham Badr, UPA Vice Chairman; Dr. Fatma Mamish, Head of the General Administration of UPA Chairman's Office; Dr. Mostafa Ghorab, UPA Business Development Director; and Dr. Rania Mohsen, UPA Project Management Director. And from EVMA members Dr. Heba Wali (GM BGP).

From IPM, we were honored to have Prof. Abdurrahman Maaroufi, Director of Institute Pasteur Morocco, and Dr. Samir Ahid, Director of the Moroccan Agency for Medicines. Additionally, Chiluba Mwila from CDC and RCCN Project manager contributed valuable insights.











### **Key Discussions**



### Congratulatory Remarks on RCCN Award

meeting commenced with congratulations to both Egypt and Morocco for being awarded the North Africa Regional Capability Capacity Networks (RCCN) Biomanufacturing. This recognition highlights their commitment to enhancing vaccine manufacturing capabilities in the region.



### Collaboration for Capacity Building

A significant portion of the meeting focused on exploring ways to collaborate on training approximately 12,500 full-time equivalents (FTEs) across the continent over the next ten years. This initiative aims to build a skilled workforce to support biomanufacturing efforts in Africa.



# Recognition of EVMA and IPM's Achievements

It was noted that Egypt, through the EVMA and its capacity-building arm, EVMA RCCN, along with IPM, has been honored as the Northern RCCN from Africa CDC. The Egyptian proposal was selected among five out of 21 proposals, emphasizing its potential to enhance the capabilities of African talent.



### **Academic and Regulatory Support**

The discussions highlighted the collective effort of the EVMA RCCN network, which includes key academic institutions such as the Faculty of Pharmacy at Cairo University and Ain Shams University and Academy of scientific research and technology, as well as the Egyptian Drug Authority (EDA) and esteemed manufacturers like Vacsera, Gennvax, VBC, BGP, and EVA Pharma.



### Agreement on a Tripartite

A significant outcome of the meeting was the agreement to establish a tripartite Memorandum of Understanding (MOU) outlining the roles and responsibilities of UPA, IPM, and CDC. This MOU will serve as a roadmap to enhance the capabilities of African talents through a shared secretariat, ensuring coordinated efforts in capacity building and training initiatives.

### **Conclusion**

The UPA-IPM-CDC meeting marked a significant step toward strengthening vaccine manufacturing capabilities and capacity building in Africa. By leveraging the expertise of UPA, IPM, and CDC, the organizations aim to enhance the continent's self-sufficiency in vaccine production.



Biomanufacturing holds tremendous promise for Africa, addressing healthcare challenges, creating jobs, and driving economic growth. However, the urgent need for skilled talent remains a critical challenge in achieving the African Union's goal of producing 60% of its vaccines on the continent by 2040.

The outcomes of this meeting will contribute to ongoing efforts to improve public health in Africa, reinforcing the critical role of collaboration among manufacturers, regulators, and health organizations. Further engagement between UPA, IPM, and CDC will be vital in realizing these ambitious goals.



### EVMA STRENGTHENING STRATEGIC PARTNERSHIPS





# EVMA Strengthening Collaboration on mRNA Platform Development: Strategic Partnership Between BGP and Afrigen Biologics

### February 4, 2025

Under the auspices of the UPA, the Egyptian Vaccine Manufacturing Alliance (EVMA) is pleased to announce the signing of an addendum to their existing Memorandum of Understanding (MoU) Between BioGeneric Pharma, a leading Egyptian biopharmaceutical company and member of the Egyptian Vaccine Manufacturing Alliance (EVMA), and Afrigen Biologics, the South African mRNA hub, to significantly enhance their collaboration in mRNA platform technology development.

The signing took place during the 2<sup>nd</sup> Vaccine and Other Health Products Manufacturing Forum.

This momentous occasion was graced by the presence of distinguished leaders, including Dr. Hisham Stait, Chairman of the UPA; Dr. Hesham Badr, UPA Vice Chairman; Dr. Rania Mohsen, UPA Project Management Director; and Dr. Mostafa Ghorab, UPA Business Development Director.





This addendum marks a crucial step in addressing critical health challenges specific to Egypt and the Eastern Mediterranean region. The collaboration will focus on leveraging mRNA technology to develop innovative vaccines and therapeutics, with a particular emphasis on combating antimicrobial resistance and zoonotic diseases. This initiative will be conducted in close consultation with the World Health Organization (WHO) to ensure alignment with global health priorities.

BioGeneric Pharma is the only Egyptian member of the fifteen-member mRNA hub network. This enhanced partnership with Afrigen Biologics underscores BioGeneric Pharma's commitment to advancing biopharmaceutical innovation in Egypt and contributing to regional health security.

# Egyptian Vaccine Manufacturing Alliance – Advancing Health through Collaboration









# EVMA Strengthening Collaboration on mRNA Platform Development: Strategic Partnership Between EVA Pharma and Quantoom Biosciences and UNIZIMA for mRNA Production Platform

### February 4, 2025

- Under the auspices of the UPA, the Egyptian Vaccine Manufacturing Alliance (EVMA) is pleased to announce the signing of a Memorandum of Understanding (MoU) Between EVA Pharma Quantoom Biosciences and Unizima during the 2<sup>nd</sup> Vaccine and Other Health Products Manufacturing Forum.
- This momentous occasion was graced by the presence of distinguished leaders, including Dr. Hisham Stait, Chairman of the UPA; Dr. Hesham Badr, UPA Vice Chairman; Dr. Rania Mohsen, UPA Project Management Director; and Dr. Mostafa Ghorab, UPA Business Development Director
- As a proud member of EVMA, EVA Pharma aims to establish the first digital-to-biologics end-to-end mRNA production platform in Egypt.
- By harnessing the innovative technologies of DNA Script, Quantoom, and EVA Pharma, this partnership seeks to enhance mRNA production capabilities for both human and animal health.

### Key objectives of the MoU include:

- Developing a state-of-the-art nucleic acid R&D and manufacturing facility in Egypt.
- Integrating advanced mRNA synthesis and formulation technology.
- Ensuring compliance with the highest manufacturing standards.





This MoU marks a significant milestone in our collective efforts to strengthen Egypt's biotechnology sector and improve access to essential health products. We look forward to fruitful collaboration and will provide updates on our progress.

# Egyptian Vaccine Manufacturing Alliance – Advancing Health through Collaboration









### EVMA TAKES THE CENTER STAGE

DURING SESSIONS OF

The 2<sup>nd</sup> VACCINE AND OTHER HEALTH PRODUCTS MANUFACTURING FORUM





On February 5, 2025, the African 2<sup>nd</sup> Conference for Vaccines and Other Health Products Manufacturing Forum hosted a pivotal panel discussion titled "Egypt's Strategic Role in Pool Procurement and Vaccine Manufacturing." This session, held at the opulent Four Seasons Nile Plaza, gathered key stakeholders from the Egyptian government, vaccine manufacturers, and international organizations to explore Egypt's burgeoning potential as a leading vaccine manufacturing hub in Africa.

### **OBJECTIVES OF THE DISCUSSION**

The session aimed to address several critical objectives:

- Vaccine Manufacturing Localization: The panel examined Egypt's national strategy for localizing vaccine manufacturing, emphasizing the importance of self-sufficiency in healthcare.
- Role of the Egypt Vaccine Manufacturing Alliance (EVMA): Participants discussed how the EVMA
  is facilitating technology transfer and fostering partnerships, positioning Egypt as a gateway for
  African nations to enhance their healthcare procurement strategies.
- Infrastructure and Investment Opportunities: The discussion identified essential infrastructure enhancements and investment opportunities necessary to strengthen local production capabilities.
- Challenges and Success Stories: Panelists shared success stories while addressing the existing challenges within the vaccine manufacturing landscape.

### **OBJECTIVES OF THE DISCUSSION**

The session began with an introductory video from the EVMA, followed by engaging presentations and discussions led by prominent figures in the healthcare sector.



**Dr.Hisham Stait**UPA chairman

### Egypt vital role in Pool Procurement

Dr.Stait emphasized Egypt's vital role in pool procurement, positioning the country as a key collaborator for African nations. His insights focused on:

- Access to Medical Resources: Advocating for streamlined access to essential medical supplies, Dr.Stait highlighted Egypt's geographical advantages and existing infrastructure, aiming to enhance healthcare delivery across the continent.
- Regional Health Security: He stressed the importance of collaborative approaches among African nations to tackle common health challenges, citing successful case studies where joint procurement led to improved health outcomes.
- Investment in Local Manufacturing: Dr. Stait underscored the necessity of bolstering local manufacturing capabilities to mitigate dependence on imports, advocating for increased public and private investments in production infrastructure.
- International Partnerships: He pointed out the crucial role of collaborations with international organizations and vaccine manufacturers for technology transfer and capacity building.
- Vision for Unified Strategy: Dr. Stait presented a vision for a cohesive African vaccine strategy that leverages the strengths of various countries, aiming to harmonize regulatory frameworks and procurement strategies.





### Egypt Health Strategy 2024-2030

Dr. Kandil outlined Egypt's health strategy for 2024-2030, stressing the need for advancements in vaccine infrastructure. His keynote emphasized the urgency of aligning disease prevention policies with manufacturing initiatives to solidify Egypt's role as a vaccine manufacturing hub.



**Dr. Amr kandeel**Deputy Minister of Health and Population

Dr. Kandil provided an overview of the Ministry of Health and Population's (MOHP) plans through the Preventive Medicine Sector. He discussed several key initiatives:

• Strengthening Immunization Services: Dr. Kandil emphasized the MOHP's commitment to enhancing immunization services nationwide.

• Integration with Public Health Policies: He outlined how the immunization program is integrated with broader public health policies to create a cohesive approach to disease prevention.



**Dr. Hesham Badr** Vice Chairman of UPA

# Local power, Global impact: Egypt National strategy for vaccine manufacturing Localization in Egypt

- 1 Stakeholder Inclusion: Emphasizing the collaborative drafting of the strategy with manufacturers, regulators, and payers to ensure a comprehensive approach.
- 2 Diversification of Technology Sources: Highlighting agreements with various technology transfer providers worldwide to incorporate diverse technologies into local manufacturing.
- **3** Actionable Development: Ensuring that implementation pillars are ready and in place, particularly through the EVMA Economic Participation Agreement.
- Measurable and Manageable Systems: Establishing a robust monitoring and evaluation framework with KPIs and milestones to track progress effectively

# The Egyptian Drug Authority: Achieving Maturity Level 3 and Driving Vaccine Independence.

Dr. Asmaa Fouad, Head of central administration of biological and innovative products and clinical trials, she serves as a temporary advisor on the Experts Advisory Panel on Biological Standardisation with the WHO- ECBS and a member of Supreme Council for Clinical Research Ethics oversight in Egypt. Technical Advisory Group on Local Production & Technology Transfer with WHO.

Dr. Asmaa Fouad is EDA representative in ICH, She has been elected as IPRP vice chair of management committee.

Dr. Asmaa discussed regulatory measures by the Egyptian Drug Authority to support local vaccine production, focusing on the impact of the ML3 initiative.



Dr. Asmaa Fouad



### **INTERNATIONAL ORGANIZATIONS INSIGHTS**

### Dr. Nema Abd, WHO Egypt country office representative:

Dr. Nema examined the WHO's collaborative efforts to enhance vaccine accessibility and strengthen local manufacturing capabilities and collaborative efforts is the WHO pursuing to enhance vaccine production capacity in Egypt and the surrounding region.



Dr. Nema Abd



Dr. Ike James

### Dr. Ike James, Technology Transfer Director, MPP:

Dr. Ike shared insights from the Medicines Patent Pool (MPP) on the global landscape of vaccine production and the critical role that technology transfer plays in attracting international investment to Egypt's vaccine sector.

### **VACCINES MANUFACTURERS AND EVMA MEMBERS' INSIGHTS**



Dr. Magdy El-Sayed, CEO, Vaccines and Biotechnology City (VBC)

Dr. Magdy provided insights into VBC's initiatives, stressing the importance of public-private partnerships for sustainable large-scale projects. He discussed strategies for enhancing access to the African vaccine market and the role of collaboration among stakeholders.



Dr. Nibal Dahaba, Gennecs Holding:

As the session moderator, Dr. Nibal presented the EVMA vision for vaccine localization and its alignment with national healthcare objectives.

Dr. Nibal Dahaba emphasizes Gennvax's robust manufacturing capabilities and its strategic technology transfer agreements as pivotal elements in advancing the localization of vaccine manufacturing in Egypt.



Dr. Heba Wali, General Manager, Biogeneric

Dr. Heba emphasized Biogeneric's initiatives in vaccine production and collaboration with the WHO and MPP for mRNA technology transfer, focusing on Egypt's potential as a manufacturing hub.



# Conclusion

and Future Recommendations

The session concluded with a summary of key insights and actionable steps to enhance Egypt's vaccine manufacturing capabilities. Recommendations included the formation of working groups and scheduling follow-up meetings to ensure ongoing dialogue and collaboration. As Egypt positions itself as a leading vaccine manufacturing hub in Africa, the insights shared during the session will undoubtedly contribute to the country's healthcare advancement and regional healthcare security. This collaborative approach is essential for driving innovation and ensuring equitable access to vaccines across the continent.





### EVMA Sharing Best Practices in Technology Transfer: Challenges and Capacity Building Sustainability



### Dr. Rania Mohsen Showcasing EVMA's Role in Technology Transfer and Capacity Building

During the 2<sup>nd</sup> Vaccine and Other Health Products Manufacturing Forum held in Cairo, Egypt, from February 4-6, 2025, Dr. Rania Mohsen, representing the Unified Procurement Authority (UPA), played a pivotal role in addressing critical issues in African vaccine manufacturing. Speaking on behalf of the Egyptian Vaccine Manufacturing Alliance (EVMA), she focused on two key topics: technology transfer challenges and the sustainability of capacity building within the sector.

### Addressing Technology Transfer Challenges

In her discussion on technology transfer, Dr. Rania noted the significant progress made during the forum, particularly the signing of nine Memoranda of Understanding (MOUs) and contracts between six local manufacturers and nine technology providers from six countries. These agreements will enable the development of 18 vaccines, aligning closely with the Expanded Program on Immunization (EPI) in Egypt.



### She emphasized:

- Fragmentation of Efforts: Despite the progress, the landscape remains fragmented, with various technology transfer agreements at different stages, highlighting the need for streamlined processes.
- Regulatory Hurdles: Navigating complex regulatory frameworks continues to be a challenge for local manufacturers. Dr. Rania advocated for support in meeting the stringent standards required for technology transfer approvals.
- Financial Constraints: Securing funding for these technology transfers remains a barrier, underscoring the need for better access to financial resources.





#### Advocating for Sustainable Capacity Building

Dr. Mohsen also underscored the importance of sustainable capacity building. She proudly announced that the EVMA's Regional Capacity and Capability Networking (RCCN) had been awarded the responsibility of co-hosting the secretariat for the northern region in collaboration with the Institute of Pasteur of Morocco.

#### This initiative aims to leverage various capabilities:

- Academic Resources: The EVMA will utilize academic strengths through partnerships with institutions like the Faculty of Pharmacy at Cairo University, Ain Shams University, and the Academy for Science and Research.
- Regulatory Expertise: The Egyptian Drug Authority will provide regulatory capabilities essential for ensuring compliance and quality in vaccine production.
- Manufacturing Strength: The alliance includes five manufacturers—VACSERA, Biogeneric Pharma, Vaccine and Biotechnology City, Gennvax, and EVA Pharma—contributing not only to national capabilities but also dedicating efforts to support the broader African region.

Dr. Rania emphasized that these capabilities are designed to raise the bar for vaccine manufacturing in Egypt while also establishing a strong foundation for collaboration across Africa.

### **Conclusion**

Dr. Rania Mohsen's contributions at the 2<sup>nd</sup> Vaccine and Other Health Products Manufacturing Forum were critical in addressing technology transfer and capacity building in African vaccine manufacturing. Her insights highlighted the strategic alliance represented by the EVMA and the collaborative efforts underway to enhance local manufacturing capabilities. As Africa strives for self-sufficiency in vaccine production, Dr. Rania's advocacy for sustainable practices and partnerships will play a vital role in shaping a healthier future for the continent.

# Panel discussion: African vaccine manufacturing supply landscape









Dr. Abebe Genetu Bayih PHAHM Coordinator





Philip
Dorell

Senior program
manager, Vaccine markets





Mohsen

Project Management
Department Director

Rania





Kris Howard Consultant





### EVMA-MPP COLLABORATION:

# Advancing Technology Transfer Initiatives to Enhance Vaccine Manufacturing Capacity and Accessibility in Africa



Under the auspices of the unified Procurement Authority UPA ,The Egyptian Vaccine Manufacturers Alliance (EVMA) is pleased to announce the successful side meeting held during the 2<sup>nd</sup> Vaccines and Other Health Products Manufacturing Forum of African Union Member States.

This meeting brought together and UPA Chairman Dr. Hisham Stait and Vice Chairman Dr. Hesham Badr , Dr. Rania Mohsen Project management Director and Dr. Mostafa Ghorab Business development director and EVMA members with key representatives from the Medicines Patent Pool (MPP) to discuss crucial collaborations aimed at enhancing vaccine manufacturing capabilities in Africa.

Dr.Charles Gore, Executive Director of MPP, along with other MPP representatives, engaged with EVMA members, including Dr. Magdy El Sayed (CEO of Vaccine and Biotechnology City), Dr. Nibal Dahaba (Gennvax CEO), Dr. Amr Mamdouh GYPTO Pharma CEO ,Dr. Mohamed Rabie, Biogeneric Pharma CEO, Dr. Heba Wali, Biogeneric Pharma GM , Dr. Heba Ali, VACSERA.





MPP shared insights on its strategic initiatives focused on increasing access to bio therapeutics and vaccines in low- and middle-income countries (LMICs) through voluntary licensing and technology transfer.

The collaboration between MPP, WHO, and Biogeneric Pharmaceutical (BGP) on mRNA technology transfer was highlighted, showcasing the empowerment of LMICs to produce their own vaccines.

### **Next steps:**

- The potential Memorandum of Understanding (MOU) between MPP and the Unified Procurement Authority (UPA) was discussed to formalize cooperative efforts in vaccine manufacturing.
- 2. MPP received multiple expressions of interest from EVMA members to collaborate, reflecting a strong commitment to partnership in enhancing vaccine production and distribution.

This meeting underscores the vital role of collaboration in building a robust vaccine manufacturing landscape in Africa.

UPA looks forward to continuing discussions and partnerships with MPP, EVMA members, to ensure equitable access to vaccines for all.



### **Strengthening Health Security:**

### **EVMA AND IFC**



### To Boost Vaccine Production and Health Product Innovation

**On February 4, 2025,** The unified procurement authority UPA and the Egyptian Vaccine Manufacturers Alliance (EVMA) hosted a significant side meeting during the 2<sup>nd</sup> Vaccines and Other Health Products Manufacturing Forum, bringing together key representatives from the International Finance Corporation (IFC) and (UPA) to discuss collaborative opportunities in vaccine manufacturing across the continent.

The meeting featured distinguished attendees, Headed by Dr. Hisham Stait UPA Chairman, Dr. Hesham Badr and Dr. Amr Gad UPA Vice Chairmans as well as, Dr. Rania Mohsen UPA Project Mangement Director, and Dr. Mostafa Ghorab UPA Business development Director and from IFC side, Mr. Farid Fezouna, Mr. Raza Miraz, and Mrs. Zaynep Kantur Ozenici.







A significant portion of the meeting explored potential cooperation opportunities between the IFC and UPA, particularly through the engagement of EVMA members, identifying synergies and collaborative projects to bolster vaccine production and distribution across the continent. UPA also foresaw several opportunities not just in vaccine manufacturing, but also in the localization of various medical products, such as blood bags.



empowering local manufacturers.

#### **Next steps:**

The meeting concluded with the agreement to prepare a list of forecasted projects that may require funding from the IFC. This side meeting marked a crucial step in fostering collaboration within the African vaccine manufacturing sector, with EVMA committed to facilitating discussions that can enhance production capabilities and improve health outcomes across Africa.



# EUROPEAN COMMISSION ENGAGEMENT:

# Strengthening Collaborative Efforts for Health Security and Vaccine Accessibility in Egypt



**On February 5, 2025**, The Unified Procurement Authority (UPA) and its executive arm, the Egyptian Vaccine Manufacturers Alliance (EVMA), hosted a pivotal side meeting during the 2<sup>nd</sup> Vaccines and Other Health Products Manufacturing Forum. This gathering brought together key representatives from the European Commission and UPA to explore collaborative opportunities in the healthcare and pharmaceutical sectors, particularly in vaccine production.

The meeting featured distinguished attendees, including Dr. Hisham Stait, UPA Chairman, Dr. Hesham Badr, along with Dr. Mostafa Ghorab, UPA Business Development Director and Dr. Rania Mohsen, UPA Project Management Director.

From the European Commission, we were honored to have Alice Peslin, Team Leader of the Human Development and Inclusive Growth Cooperation Section, and Iva Stemanova, Program Manager. Additionally, Mona Maarouf, Pharmaceutical Coordinator at the WHO Egypt Country Office, contributed valuable insights in addition to all EVMA members from the manufactures.





The agenda facilitated meaningful discussions, beginning with introductions that underscored a shared commitment to advancing healthcare in Africa. Alice Peslin highlighted the European Commission's support for the healthcare and pharmaceutical sectors, emphasizing the critical role of vaccines in achieving health security. She praised the importance of all stakeholders in Egypt coming together as one voice at the same table to address these challenges.

A significant portion of the meeting focused on collaboration opportunities between Egypt and the European Commission, particularly in enhancing vaccine production capabilities. The attendees discussed the importance of aligning efforts to ensure that Egypt can effectively respond to the healthcare needs of its population while contributing to regional health security.

The collaboration between Egypt and the European Commission was recognized as a model for success, showcasing how joint efforts can lead to impactful solutions in healthcare. The meeting concluded with a commitment to fostering ongoing dialogue and cooperation, ensuring that the collective vision for improved health outcomes becomes a reality.

This side meeting marked a crucial step in strengthening ties between Egypt and the European Commission, with EVMA dedicated to promoting discussions that enhance vaccine production and overall health security across the continent.



# EVMA-AVMI COLLABORATION:



# **Boosting Vaccine Manufacturing Capabilities for Regional Self-Sufficiency in Africa**





On February 5, 2025, The Unified Procurement Authority (UPA) and its executive arm, the Egyptian Vaccine Manufacturers Alliance (EVMA), hosted a pivotal side meeting during the 2<sup>nd</sup> Vaccines and Other Health Products Manufacturing Forum. This gathering brought together key representatives from the African Vaccine Manufacturing Initiative (AVMI) and UPA to explore collaborative opportunities in the healthcare and pharmaceutical sectors, particularly in vaccine production.

The meeting featured distinguished participants, including UPA's leadership: Dr. Hisham Stait, the UPA Chairman; Dr. Hisham Badr, the UPA Vice Chairman, Dr.Fatma Mamish Head of the Central Administration of UPA chairman's office. Dr. Mostafa Ghorab, the UPA Business Development Director and EVMA Project Manager; Dr. Rania Mohsen, the UPA Project Management Director and EVMA Project Manager; and from the EVMA members: Dr. General Manager BGP and Dr. Nibal Dahaba, Co-Founder & General Manager of Emerging Markets at Gennecs Holding.

From AVMI, the attendees included Prof. William Ampofo, the Executive Director; and Dr. Simon Agwale, the Vice-Chair. Their collective expertise underscored the importance of the discussions that unfolded.

The meeting began with a comprehensive overview of AVMI's mission, aims, and current workplan, highlighting its commitment to boosting vaccine manufacturing capabilities in Africa. UPA presented its objectives, emphasizing its role in fostering collaboration among pharmaceutical manufacturers and stakeholders in the region.

A significant point of discussion was the representation of six manufacturers from Egypt within the EVMA framework. This presence underscores the growing capabilities of the Egyptian pharmaceutical sector and its potential to contribute to broader vaccine manufacturing efforts across Africa.



#### **Next steps:**

- The participants explored various collaboration avenues between EVMA and AVMI. The discussion centered on how EVMA's members could integrate into AVMI, enhancing their capabilities and expanding their reach.
- The potential for joint initiatives aimed at improving vaccine production processes and ensuring quality standards was identified as a critical pathway for collaboration.
- Another notable outcome of the meeting was the prospect of hosting AVMI's new headquarters in Egypt





This move could serve as a strategic advantage, benefiting local manufacturers and positioning Egypt as a central hub for vaccine manufacturing in Africa. The participants agreed to further investigate the feasibility and implications of such a decision.

The AVMI-UPA meeting marked a significant step towards strengthening vaccine manufacturing capabilities in Africa. By leveraging the expertise of EVMA's members and exploring collaborative opportunities, both organizations aim to enhance the continent's self-sufficiency in vaccine production. As discussions progress, the potential for hosting AVMI's headquarters in Egypt presents an exciting opportunity that could drive innovation and growth in the region's biomanufacturing landscape.

The outcomes of this meeting will contribute to ongoing efforts to improve public health in Africa, reinforcing the critical role of collaboration among manufacturers, regulators, and health organizations. Further engagement between AVMI and UPA will be essential in realizing these ambitious goals.







# THE PIONEERING APPLICATION OF ECONOMIC PARTICIPATION CONTRACTS IN VACCINE LOCALIZATION:

Sanofi to partner with BGP to localize its vaccine production in Egypt

### Introduction

On 18th February 2025, a pivotal meeting took place between the Egyptian authority of unified procurement (UPA) and Sanofi along BGP to discuss Sanofi-BGP mutual project for vaccine manufacturing localization. This significant event gathered key stakeholders to discuss the implementation of economic participation agreements and the localization of vaccine manufacturing in Egypt.

The meeting featured distinguished participants, including UPA's leadership: Dr. Hisham Stait, the UPA Chairman; Dr. Hisham Badr, the UPA Vice Chairman; Dr. Fatima Mamish, Head of the Central Administration of UPA Chairman Office; Dr. Mostafa Ghorab, the UPA Business Development Director; and Dr. Rania Mohsen, the UPA Project Management Director.



From BGP: Dr Mohamed Rabie CEO Biogeneric Pharma, Dr Heba Wali Biogeneric Pharma General Manager From Sanofi, Jean Philippe, Vaccine Head of Africa, Esin Osge, Africa Strategic Partnership Head, Magued Elsayed, Sanofi Africa Corporate Affairs Head, Ahmed Hegazy, Egypt Head of Vaccines, Ehab Sharawy, Public Affairs Manager, Sanofi Egypt, Mawel Sameh, Vaccine Medical Head, Sanofi Egypt



### **Key Discussions**

### 1 Overview of UPA and Sanofi's Collaborative Goals

The meeting began with a comprehensive overview of UPA's objectives and Sanofi's commitment to enhancing vaccine manufacturing capabilities in Egypt. Discussions highlighted the strategic importance of localizing vaccine production to ensure sustainable access to quality vaccines.

### 2 First Real Application of Economic Participation Agreements

A significant outcome of the meeting was the agreement to initiate the first real application of the economic participation contracts. This marks a foundational step in aligning local manufacturing capabilities with international standards, facilitating technology transfer and local workforce development.

### 3 Localization of Vaccines Project

The participants recognized the localization of vaccines as a critical project. This initiative aims to establish local production processes for key vaccines, addressing public health needs in Egypt and paving the way for broader regional supply.

### 4 Collaboration Opportunities for Implementation

Various collaboration avenues were explored to ensure the successful implementation of the localization project. Participants discussed joint initiatives, including training programs for local staff, technology transfer mechanisms, and enhancing quality assurance processes.

### 5 Next Steps and contracts signing

The meeting concluded with an agreement to conduct feasibility studies regarding the localization project, including timelines, resource allocation, and potential challenges. Future meetings will focus on refining the implementation strategy and securing necessary investments.









# UPCOMING KEY MILESTONES

### **UPCOMING KEY MILESTONES**

### MARCH 2025

### Cape Town

March 17-21

EVMA will participate in a mentorship training program in collaboration with Africa CDC and AMVI. This initiative aims to develop intern tutors from vaccine manufacturing companies to enhance awareness and build capabilities in vaccine manufacturing through a Training of Trainers (TOT) approach.

## Cape Town March 25-27

EVMA RCCN will engage in the Africa CDC's efforts to establish pilot vaccine manufacturing internship and biomanufacturing fellowship programs, aimed at supporting workforce development.

### APRIL 2025

3<sup>rd</sup> World Local Production Forum Abu Dhabi April 7-9 EVMA will take part in the 3rd World Local Production Forum, focusing on the theme "Advancing Local Production for Health Equity, Global Health Security, and Sustainable Development."

### World Immunization Week Preparations April 24-30

**EVMA** will prepare for World Immunization Week

























# The Vacci-Nation Hub

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