VACCINE PROCUREMENT
Pratictioners Network (VPPN)

Q&A SERIES

Manufacturing immunisation supplies locally

DISCUSSION WITH

EGYPT

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VACCINE PROCUREMENT
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Q&A SERIES

1. Why did you decide to localise vaccine manufacturing? What were the objectives and the scope of the initiative? And how did the government provide support?
2. How was the localisation initiative implemented in your country? What were the key steps in the process, and the timeline for each step?
3. What were the cost estimates/ financial requirements for each step in the process? How has the government provided financial support for local manufacturing? And what was the nature of this support?
4. Which policy levers and key stakeholders have been considered and engaged to support local manufacturing?
5. What support has the government provided for navigating technical and regulatory requirements, i.e. technology transfer, quality assurance, etc.?
6. What challenges have you faced during the process and what lessons learnt have you drawn?
7. What is the one key piece of advice you would share with other governments looking to embark on this process?

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1

Why did you decide to localise vaccine manufacturing? What were the objectives and the scope of the initiative? And how did the government provide support?

Dr. Mostafa Ghorab

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The decision to localise vaccine manufacturing in Egypt was driven by the need to enhance national health security, reduce reliance on imported vaccines, and improve the overall public health infrastructure.

The objectives include achieving self-sufficiency in essential vaccines, ensuring timely access during health crises, and positioning Egypt as a regional hub for vaccine export.

The government has supported this initiative through presidential directives, the establishment of the Egyptian Vaccine Manufacturers Alliance (EVMA), and the issuance of Executive Decree No. 719/2024 to implement the national strategy for vaccines manufacturing localisation.*

* To have a full picture of Egypt's strategy for localisation, please click here:
National Strategy - EVMA Egypt

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Due to the deterioration of South Africa's vaccine production infrastructure before and in the late '90s, it became necessary to leverage external expertise in this critical area. To address this need, the NDoH entered a strategic equity partnership with the Biovac Consortium (Pty) Ltd, a private company composed of private shareholders in 2003. As part of this partnership, the State retained a sufficient equity stake, namely 47.5% held by the NDoH, while the Biovac Consortium held a controlling stake in Biovac Institute (BI). Notably, the NDoH's shareholding was later transferred to the Department of Science and Technology.

This public-private partnership (PPP) was designed to support vaccine research and development, local manufacturing, and supply chain management. Biovac supplied 450M doses since its inception in 2003, facilitating uninterrupted vaccine supply and avoiding vaccine shortages. Biovac is also developing its ability to supply the broader African market with vaccines and other biologicals to ensure Africa has the capacity to respond to the next health emergency.*

* To read the full answer, please go to slide 14.

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2

How was the localisation initiative implemented in your country? What were the key steps in the process, and the timeline for each step?

Dr. Mostafa Ghorab

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The localisation initiative was implemented through several key steps:

- **Political Will :** Establishing a committee for the pharmaceutical national localization strategy with Decree issuance and then executing Decree No. 719/2024 to formalise the national strategy for vaccine manufacturing localization.
- **Stakeholder Engagement:** Engaging local manufacturers, government bodies, and international organisations to create a collaborative environment.
- **Implementation Framework:** Developing a regulatory framework for long-term contracts and financial incentives.

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- In 2003, the NDoH signed a **PPP agreement** with the Biovac Consortium to establish the Biovac Institute. It became the sole supplier of all public sector vaccines through international procurement and local production, and controlled the tender, procurement, and distribution process.
- The **manufacturing facility** was completed in 2012, and a **technology transfer (TT)** agreement was finalized with Sanofi for fill finish of acellular hexavalent vaccine.
- In 2020, South Africa transitioned vaccine procurement and distribution from Biovac to a **competitive tender process** managed by the NDoH. Currently, tenders are awarded based on a preference point system that considers price, Broad-Based Black Economic Empowerment scores, past performance, and local manufacturing.
- In 2021, **local manufacturing of Hexaxim and Prevnar 13** was in place but PCV 13 ceased in 2023.
- As of 2024, South Africa procures vaccines for the EPI as follows: 3 from Biovac, 3 from Cipla, 2 from GSK, and 1 from Sanofi, with Biovac being the only local manufacturer in the current procurement cycle.*

* To read the full answer, please go to slides 15 & 16.

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3

What were the cost estimates/ financial requirements for each step in the process? How has the government provided financial support for local manufacturing? And what was the nature of this support?

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EGYPT

While specific financial estimates were not detailed, the strategy emphasises the need for significant investments in vaccine manufacturing infrastructure. The government has provided financial support through:

- **Direct Investment:** Committing funds for the establishment of manufacturing facilities which will be through PPP models with the top multinational companies to ensure technology transfers in Egypt.
- **Financial Incentives:** Offering tax exemptions and subsidies to encourage local production; ensuring long-term contracts to provide financial security for manufacturers; and giving a “golden license” to investors to facilitate their process.

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- At the establishment of the PPP, significant **government funding**, including the land and buildings that were historically owned, was provided to Biovac as well as **guaranteed procurement** through Biovac for the duration of the PPP. The Government has retained some equity stake in Biovac and the Industrial Development Corporation (IDC) of South Africa is also a shareholder in Afrigen. The Biovac Consortium provided capital that was used for the cold chain, labelling and quality control buildings.
- Between 2003 and 2020, costs were funded via **grants** ($5M - $10M), **loans** ($20M - $40M) and **PPP price premiums** (~$150M). As the PPP premium was limited to 10% of the vaccines purchase price, it covered not all of Biovac’s overheads. Biovac had to seek loans and grants for capital projects, TTs, working capital as well as for new, bigger and updated buildings.
- From 2020 until early 2024, the 3 manufacturers in South Africa have also raised ZAR 1.5B in **external funding** committed by donors and Development Finance Institutions (Aspen: ZAR 1.2B, Biovac: ZAR 190M, Afrigen: ZAR 55M).

4

Which policy levers and key stakeholders have been considered and engaged to support local manufacturing?

Dr. Mostafa Ghorab

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Key policy levers include:

- **Long-term Contracts:** Establishing a stable purchasing framework for vaccines.
- **Economic Partnership Agreements:** Engaging manufacturers in commitments that support local economic goals.

Stakeholders involved include: the Ministry of Health, the Egyptian Drug Authority, local manufacturers, international organizations, and the EVMA members (top 6 local vaccine manufacturing facilities) either from the public or private sector:

- Vacsera
- Biogeneric Pharma
- Vaccines and Biotechnology City
- Gennvax
- EVA Pharma
- Gypto Pharma

In advancing the EVMA initiative, several stakeholders have been engaged to bolster local production, including:

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Several policy levers and key stakeholders have been engaged:

- **Industrial Policy Action Plan (IPAP):** This policy aims to enhance local manufacturing capabilities, create jobs, and boost exports by supporting industrial development in the pharmaceutical sector.
- **Preferential Procurement:** The NDoH prioritises locally produced pharmaceutical products during tender evaluations, promoting domestic manufacturing and reducing reliance on imports.
- **Interdepartmental Collaboration:** The NDoH works closely with the Department of Trade, Industry, and Competition (DTIC), the Department of Science and Innovation (DSI), and the National Treasury. An interdepartmental committee has been established to review, discuss, and implement strategies that support local vaccine and pharmaceutical production.

4

Which policy levers and key stakeholders have been considered and engaged to support local manufacturing?

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- **Ministry of Industry and Trade:** Engaging this ministry is crucial for aligning manufacturing capabilities with industrial policies that support local production.
- **Ministry of Investment:** This ministry is involved in creating a favourable investment climate for local manufacturers, facilitating funding and resources.
- **Ministry of Finance:** Collaboration with this ministry is essential to secure financial support and incentives for local manufacturers.

By 2030, the total production capacity of Egypt's vaccine facilities is projected to reach approximately **380 million doses from 6 manufacturers, representing more than 20% of African vaccines manufacturers**, with WHO Prequalification (PQ) submissions planned for several key vaccines.*

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- **Technology and Innovation Support:** By fostering partnerships between government, industry, and research institutions, South Africa encourages technology transfer and innovation in pharmaceutical manufacturing.

The Government historically provided support through the PPP which ended in 2020. The revised policies being drafted need to support local manufacturing going forward.

* To read the full answer, please go to slide 17.

5

What support has the government provided for navigating technical and regulatory requirements, i.e. technology transfer, quality assurance, etc.?

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The Government has facilitated through:

- **Technical Support:** Providing assistance through regulatory bodies to navigate TT processes.
- **Quality Assurance:** Establishing a framework to ensure compliance with international quality standards and facilitating accreditation processes.
- **EVMA:** Key governmental initiative aimed at enhancing local vaccine production, with a unified vision for localisation in Egypt. This initiative is supported by several governmental stakeholders, each playing a vital role:
  - **Ministry of Health and Population:** As the primary policy maker, this ministry is responsible for assessing the needs for vaccines in national immunisation programmes, ensuring that local production aligns with public health goals.

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- **Demand offtake:** The exclusive 15-year supply agreement with the NDoH to procure and distribute EPI vaccines provided the necessary security to Biovac to focus on business expansion.
- **Access to technology:** Technology transfer partnerships with Sanofi for Hexaxim and with Pfizer for Prevnar13 and Comirnaty have enabled RSA to access critical vaccine manufacturing technologies.
- **Regulatory capability:** Attained capacity to regulate domestic vaccine production (WHO ML3 vaccine producing) for procurement by international organizations such as UNICEF.
- **Industrial and trade policy:** In addition to establishing IPAP, Industrial Development Corporation (IDC) and Technology Innovation Agency (TIA) have provided funding and support for infrastructure development and technology transfers.

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5

What support has the government provided for navigating technical and regulatory requirements, i.e. technology transfer, quality assurance, etc.?

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- **Unified Procurement Authority (UPA):** This body is tasked with ensuring a sustainable supply of vaccines. UPA plays a crucial role in procurement processes, supporting the EVMA's goals by ensuring that the necessary resources are available.
- **Egyptian Drug Authority (EDA):** EDA has achieved a significant milestone by becoming the first country in Africa to attain ML3 status for both medicines and vaccines regulation, as assessed by WHO's Global Benchmarking Tool. This regulatory body will have a crucial role in overseeing vaccine regulations, including the prequalification process, ensuring that locally produced vaccines meet international standards.

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- **Skilled Workforce:** RSA’s universities and technical colleges produce a steady stream of highly trained professionals in the fields of medicine, biotechnology, pharmacy, and related sciences. The Council for Scientific and Industrial Research (CSIR) has launched the African Biomanufacturing Workforce Training Programme to cover various aspects of vaccine production.

6

What challenges have you faced during the process and what lessons learnt have you drawn?

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Challenges include:

- **Complexity of Technology Transfer:** Difficulties in securing contracts with technology providers and ensuring successful transfer processes.
- **PQ Accreditation Hurdles.**
- **Collaboration between manufacturers:** Bringing together all manufacturers to collaborate on the EVMA initiative required convincing them that integration, rather than competition, would lead to a larger market size and ultimately higher returns on investment (ROI) for all involved.
- **Capabilities mapping process:** It was comprehensive and demanding, but critical for identifying strengths and gaps in the existing infrastructure.

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1. **Delays in meeting PPP objectives:**
   A major challenge was the slow establishment of a local vaccine manufacturing facility at Biovac. Although the PPP was signed in 2003, the first locally produced vaccines only became available in 2015. This prolonged timeline affected the expected benefits of local production, such as improved vaccine security and reduced dependency on imports.
2. **Vaccine pricing and market limitations:**
   - The long-term partnership with Biovac restricted the NDoH's ability to secure alternative pricing arrangements. Since Biovac relied on multinational vaccine manufacturers, the NDoH was subject to the prices Biovac could negotiate.
   - Many of Biovac's agreements with international vaccine suppliers included constraints that prevented the export of vaccines beyond South Africa. This restriction limited Biovac's ability to expand its market, achieve economies of scale, and become more competitive.

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What challenges have you faced during the process and what lessons learnt have you drawn?

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This thorough analysis helped in aligning the capabilities of various stakeholders with the objectives of the EVMA, namely ensuring that all manufacturers and governmental bodies are coordinated in their efforts.

Overall, these experiences highlighted the **importance of collaboration and strategic planning** in achieving the shared goals of vaccine localisation in Egypt.

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- Additionally, pricing negotiations were influenced by pre-existing global agreements between vaccine manufacturers and entities such as the PAHO. These agreements often set lower benchmark prices in other regions, making it difficult for South Africa to obtain similarly competitive pricing.

For Biovac, challenges include:

- **PPP timeline:** The PPP was initially a 4-year agreement, that was extended 3 times. Biovac could not show lenders and external funders a long-term revenue plan and therefore its capital raising efforts were limited. Hence some of the initiatives took longer than expected.
- **Initial limit to fill-finish:** Biovac had limited access to API/ Drug Substance technology, because they are highly protected by intellectual property and require significant volumes that a single market could not sustain. As a result, the potential for exports was limited, until now.*

* To read the full answer, please go to slide 18.

7

What is the one key piece of advice you would share with other governments looking to embark on this process?

Dr. Mostafa Ghorab

Dr. Rania Mohsen

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The key piece of advice is to foster **collaboration among all stakeholders** – government, private sector, and international organizations.

Establishing a **clear strategy** with defined roles and responsibilities, while ensuring ongoing communication and support, is essential for successful localisation of vaccine manufacturing.

We are keen on sharing our EVMA best practice and our business model and its role in putting all stakeholders at one table.

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A **whole-of-government approach** is essential for establishing a sustainable local vaccine manufacturing sector: relying solely on price premiums paid by the health department limits success and affordability. Collaboration across trade, industry, finance, and science sectors is crucial to ensure regulatory support, investment incentives, and infrastructure development.

Additionally, governments should negotiate agreements that allow **pricing flexibility** and regional market access, avoiding constraints that limit exports and competitiveness. Addressing these factors from the outset will enhance long-term viability and self-sufficiency in vaccine production.

For Biovac, the Government's support is key in establishing a new sector. Opting for other mechanisms than price premiums, such as **20-year agreements** with advance market commitment/ guarantees, would also allow to raise capital sustainably.

Annexes

1

Why did you decide to localise vaccine manufacturing? What were the objectives and the scope of the initiative? And how did the government provide support?

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The National Department of Health (NDoH) actively supports the local manufacturing of vaccines and other pharmaceutical products to strengthen South Africa's healthcare security and resilience in the face of global supply chain disruptions. By fostering local production, the country can reduce dependence on international suppliers, ensuring a stable and reliable supply of essential medicines and vaccines.

Additionally, local manufacturing promotes technology transfer, and the development of new, innovative pharmaceutical products tailored to the specific health needs of the population. This approach not only enhances the country's scientific and technological capabilities but also stimulates economic growth by attracting investment, creating skilled jobs, and fostering a robust pharmaceutical sector. Furthermore, a strong local manufacturing industry contributes to regional and continental self-sufficiency, aligning with broader public health objectives, including equitable access to life-saving medicines.

2

How was the localisation initiative implemented in your country? What were the key steps in the process, and the timeline for each step?

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- The **original PPP agreement** included a Supply Agreement through which the NdoH outsourced the procurement, central-level storage, and distribution of vaccines to 9 provincial vaccine storage depots. Biovac charged the NDoH both the purchase cost of vaccines and a price premium, while assuming full responsibility for procurement, distribution, and capital investment in research and development necessary for establishing vaccine manufacturing capabilities.
- As Biovac inherited dilapidated facilities, it had to independently **source funds** (loans and grants), **create a supply network** and **build technology transfers from scratch**. Since the business model couldn't attract the appropriate funding, Biovac started with the reverse integration strategy with the following activities whilst supplying vaccines to the NDoH and provinces.
- In 2005, it built **labelling inspections and cold chain facilities**, whilst raining the appropriate funding. It also embarked on a Haemophilus influenza b (Hib) vaccine development that it aimed to incorporate into a whole cell combination vaccine.

2

How was the localisation initiative implemented in your country? What were the key steps in the process, and the timeline for each step?

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It had to abandon this project as the NDoH opted for acellular pertussis combination in 2008. This technology was however out licensed to other companies in Indonesia, Thailand and Japan.

- In 2007, it built a **new quality control laboratory** and in 2008, it managed to raise the required funding through loans and started the **construction of sterile filling facilities**.
- In 2015, it secured a **second TT with Pfizer.** To date, Biovac has completed 3 TTs, each taking a shorter time period, leveraging platform, capabilities and increased experience. The first took 7 years (Sanofi), the second 5 years (Pfizer) and the third 2 years (Pfizer). This timeline is still expected to shorten. The TT for the Pfizer-BioNTech COVID-19 vaccine was completed in approximately 2 years.
- Since 2022, Biovac has been developing an **oral cholera vaccine** that will be the first locally developed, end-to-end manufactured product, that it will aim to supply to UN agencies.
- Since 2024, it has entered **new TTs for IPV and Meningitis vaccine** that it will aim to supply to UN agencies.

4

Which policy levers and key stakeholders have been considered and engaged to support local manufacturing?

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In addition to internal stakeholders, we are actively engaging with **external partners**, including various technical and funding organisations, such as WHO, African Union, Africa CDC, World Bank, IFC, MPP, EU and others. These collaborations are aimed at ensuring the long-term sustainability of the EVMA initiative. By leveraging the expertise and resources from these organisations, we can strengthen our approach to local manufacturing and enhance the capacity for vaccine production in Egypt.

6

What challenges have you faced during the process and what lessons learnt have you drawn?

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- **Limited R&D funding:** The Government's R&D budget could not sustain vaccine R&D. As technology is limited for API/ Drug Substance, the only other way to build such end-to-end capacity is to develop vaccines locally. It was impossible for Biovac to dedicate R&D funding and build the required infrastructure through the PPP premium.
- **Limited payoff:** Despite a lengthy process to locally manufacture PCV13, Biovac lost the procurement tender to Cipla's imported PCV10, due to compliance and pricing issues, resulting in a limited payoff for its extensive efforts. What is required is higher volume throughput through facilities to reduce costs through economies of scale. For local manufacturers reliant on domestic markets, it is not possible to be competitive. Since the pandemic, significant advancements in the ecosystem have allowed Biovac to sign 4 TTs for export markets, one of which is an end-to-end Oral Cholera development project. Consequently, Biovac will be able to compete with incumbent, high-volume, lower-cost suppliers in the longer term.

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