

The AFRICAN DEVELOPMENT BANK GROUP

PHARMACEUTICAL INDUSTRY INVESTMENT CLINICS

A new collaborative approach in business development

Cairo
OCTOBER 2023
Concept Note

AFDB'S PHARMACEUTICAL ACTION PLAN AND BUSINESS DEVELOPMENT

The AfDB developed the 2030 Continental Pharmaceutical and Vaccine Manufacturing Vision and Action Plan, which guide its strategic interventions for the next 10 years under a strategic pillar and 4 enablers.

Strategic pillar: Increase the maturity of the industry by supporting the development of local production capacities

Enabler 1: Enable regional logistic integration to foster intra-African trade and the creation of trade hubs, Enabler 2: Help the implementation of quality industry standards for the African continent,

Enabler 3: Seed the creation of R&D capacities focusing on Africa specific diseases and needs.

Enabler 4: Pave the way for increased vaccines manufacturing on the continent

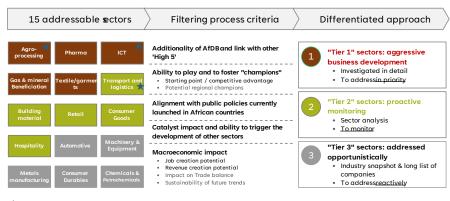
An overall envelope of \$111 billion would be needed for investments from all active players, through to 2030. \$11 billion of this would be dedicated to the development of the pharmaceutical industry, while the lion's share - \$100 billion is required for infrastructure development, to enable regional logistic integration.

AfDB is considering investing up to \$3.1 billion through to 2030 in support of the vision. AfDB is seeking to mobilize approximately \$100 million per year to finance the development of the pharmaceutical industry directly and allocating about a further \$200 million annually to support infrastructure development.

AfDB is following key principles to the prioritization of its pharmaceutical interventions. (i) Channel its support mostly through the development of the private sector. (ii) Leverage its comparative advantage in developing African infrastructure to support transformative projects in the pharmaceutical sector. (iii) Capitalize on its institutional capacities to foster a robust policy dialogue. (iv) Be highly selective to maximize the value added by its resources by prioritizing projects and initiatives with high and cross-cutting impact potential. (v) Focus resources on unique and transformative projects and initiatives and avoid duplicating projects or initiatives already initiated by other financial or development institutions.

According to a well-established filtering criterion, such as Additionality of AfDB and link with other 'High 5'; Ability to play and to foster "champions"; Alignment with public policies currently launched in African countries; Catalyst impact and ability to trigger the development of other sectors; and macroeconomic impact, **the pharmaceutical industry sector is highly prioritized** as "Tier 1" sectors where business development is conducted in an aggressive manner and investigated in detail.





 $\bigstar \ \mathsf{Sectors} \ \mathsf{in} \ \mathsf{which} \ \mathsf{AfDB} \ \mathsf{will} \ \mathsf{have} \ \mathsf{a} \ \mathsf{systemic} \ \mathsf{approach} \ \mathsf{-including} \ \mathsf{through} \ \mathsf{sectoral} \ \mathsf{reform}.$

EGYPTIAN PHARMACEUTICAL PRIVATE SECTOR

Egypt is the largest producer and consumer of pharmaceuticals in the MENA region, holding a market value estimated at \$ 56.6 billion. It is a significant player in the global supply chains of pharmaceutical products recording exports of \$ 400 million signifying the strength and importance of the sector to the Egyptian economy. Currently, Egypt's pharmaceutical industry is import-dominated, with around 90% of the raw materials used in production being imported. From a micro-economic perspective, because the Pharmaceutical sector has a relatively high level of average complexity, Egypt has ample opportunities to upgrade its economic complexity through the pharmaceuticals sector

Egypt's pharmaceutical industry is a generic-driven market. Despite few state-of-the-art manufacturers, the industry has a low competitive advantage when it comes to quality and level of production, which is considered to be below the general standards required by the European and US markets. Egypt has been able to export a large number of pharmaceutical products; however, it has yet to develop comparative advantage in specific products.

Egyptian pharmaceutical products have huge market access opportunities. In addition to a dynamic local market of 109 Million consumers in Egypt, the country has access to approximately Two Billion consumers around the globe through Suez Canal economic zone as it benefits from several free trade agreements Egypt has signed with a number of countries and blocks namely The African Continental Free Trade Agreement (AfCFTA) - The General Agreement of Tariffs and Trade (GATT) - The General Agreement on Trade in Services (GATS) - The European Union-Egypt Free Trade Agreement (Association Agreement) - The Free Trade Agreement with EFTA States; Turkey_Egypt Free Trade Agreement The Greater Arab Free Trade Agreement - Agadir Free Trade Agreement signed between Egypt, Morocco, Tunisia and Jordan & The Mercosur Free Trade Agreement with Latin American countries. Egypt has been invited to join the BRICS commencing January 2024. Egyptian pharmaceutical products have huge market access opportunities.

Egypt's pharmaceutical industry is undergoing aggressive and positive change. Egypt is one of the four African countries alongside Ghana, Nigeria and Tanzania that have recently achieved Maturity Level 3 that enables the export of vaccines. The Egyptian Drug Authority (EDA) is proactively establishing bilateral and regional harmonization agreement, the most recent of which has been with Zimbabwe and South Africa, where the drug authorities agree to accept vaccines and drugs that are made in the other countries without registration and other limitations.

Following export and marketing strategies, Egyptian manufacturers have shown bold African investment strategies with several mergers and greenfield projects in neighboring countries.

Several companies have an integral focus on R&D and the production of Drug Substance, and this will support the growth, sustainability and competitiveness of the Egyptian pharmaceutical industry.

However, challenges hindering the export of Egyptian pharmaceutical goods include: (i) the length of drug registration processes; (ii) fragmented representation of Egyptian pharmaceuticals companies and the absence of a united medical cluster in international tenders; (iii) scarcity of market intelligence; (iv) lack of possibilities for local sourcing of raw materials; and (v) limited export support in the context of high costs when it comes to internal transport and customs imposed on raw materials. In the case of Africa, there is limited accessibility and high transportation costs; lack of export guarantees; limited market exposure for local pharmaceutical companies; and the imposition of strict conditions by other countries in product registration.

Experience showed that financing the Egypt's Pharmaceutical industry has challenges to surmount and opportunities to leverage and build towards its **potential of becoming a regional/continental pharmaceutical hub**.

• The market is marred with volatility of local currency and underlying F/X risk linked to foreign currency deters companies from borrowing in F/X. The majority of the manufacturers are looking for local currency

funding as most of their operations are serving the local market. However, there is a growing interest in export-oriented projects for foreign currency revenues.

- Local banks remain liquid and synthetic loans (in their current form).
- Major private sector sponsors prefer to be partially financed through equity.
- Given the AfDB's minimum ticket of \$10 million, private sector companies are less interested to borrow from the Bank given the relatively smaller size of production lines expansions.
- Peers in the country seem to have focused on supporting sovereign projects, providing for lines of credit to local commercial Banks and providence of as low as EUR 1 million ticket sizes and a pricing alignment on commercial banks.

Under these conditions, the main opportunities seem to be for very large projects seeking funds in EUR or USD exclusively, and therefore export oriented. There is a potential here for AfDB's lending to be competitive, as it may align in parallel co-financing with Commercial banks. In addition, the Bank may provide high level advisory on market access in Africa and finance technical assistance for preparation of "bankable" projects.

PHARMACEUTICAL INVESTMENT CLINICS

The pharmaceutical investment team is working closely with local partners in undertaking **innovative business** development and identifying strategic regional champions. Projects will be identified efficiently through a collaborative approach with the Egyptian African Businessmen Association (EABA) and the National Bank of Egypt and with the participation of the Islamic Development Bank, and other funders and stakeholders to fast-track the development of a strong pipeline of bankable projects.

How the PIC is prepared and run

Before the PIC: The team invites companies to answer online forms with the following criteria. Invitations will be sent to companies that meet all 11 readiness criteria.

- 1. Availability of 3 years audited financial statements
- 2. Agreement to sign non-disclosure agreement with the Bank
- 3. Size of project larger or equal USD 30 million
- 4. Borrowing currency is the USD or Euro
- 5. Availability of feasibility study or any initial market studies
- 6. Financing interest by DFI, commercial bank or other major financial partner
- 7. Product line of molecules high in demand in major markets
- **8.** Existing facility with expansion plans
- 9. Greenfield facility and investment in an African country
- 10. Identified cost of Tech Transfer in F&F
- 11. WHO Pre-qualification in case of DS

Based on the readiness of the documentation, the project sponsor will be asked to share the following ahead of the PIC:

- Copy of the **annual financial reports** (last 3 years) of the equity sponsors.
- The signed **pre-selection form** that meets the 11-criterion set above.
- Project Information Form or a **brief Project Evaluation Note** in line with the Bank's PEN template.
- Bankable **feasibility study** and financial model.
- Signed non-disclosure agreement in accordance with the Bank's template.

During the PIC: The project sponsor will deliver a presentation of the investment memorandum that will cover the following aspects of the project:

- Background information on the opportunity and description of the project sector, location, component, an
 executive summary of the proposed transaction, project rationale, key info on the sponsor and the
 following factors.
- Legal structure of the project company (borrower) including shareholding structure.
- Equity Sponsor– Name of the equity sponsors, their profile and track record/ relevant experience.
- Proposed financing structure.
- Investment highlights: key attractions of the project. Eg strength and experience of the management, strong demand for the product, competitive advantage over other manufacturers, barriers to entry/first mover advantage (if applicable), strength of financial model, off-take and revenue streams, etc.
- Implementation plan with indicative timelines.
- Risk mitigation: i) Funding risk (equity & debt); ii) Construction risk; iii) Market risk; iv) Operation risk (operator); v) Forex risk; Supply & Maintenance of assets risks:
- Development impacts.
- Contact person details.

In addition, the PICs will bring together a full transaction team to explore the bankability of the project including with core investment teams from AfDB and local commercial banks, pharmaceutical project sponsors, and financial advisors. Through a thorough selection process, the project sponsors will be identified and matched with the appropriate extended team. Members of the PICs:

- Core investment teams from the Bank's and the project sponsor to address finance and co-finance structure of the project.
- Technical pharmaceutical experts will ascertain production, capacity, and technology issues.
- Representatives from the Egyptian Drug Authority outline the intra-African export possibilities, market access and regulations.
- In cases of manufacturing through F&F, international technical partners will discuss existing or potential technology transfer agreements. In case of DS manufacturing, respective regulatory agency (e.g. WHO) will be involved.
- Infrastructure teams will address infrastructure, logistics, distribution, and trade facilitation gaps.

After the presentation, PIC teams will engage in constructive discussions to investigate project's eligibility and bankability to potentially win the financial backing from the Banks. A draft Project Evaluation Note will be prepared as a result of the discussion.