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POSITION PAPER ON THE ESTABLISHMENT OF A FUND FOR THE DEVELOPMENT OF THE AFRICAN PHARMACEUTICAL MANUFACTURING SECTOR

ABBREVIATIONS AND ACRONYMS

AfDB	African Development Bank
Afreximbank	African Export-Import Bank
AIDA	Accelerated Industrial Development of Africa
AMRH	African Medicines Regulatory Harmonisation Programme
AU	African Union
AUC	African Union Commission
CHAI	Clinton Health Access Initiative
FAP-D	Fund for African Pharmaceutical sector Development
FAPMA	Federation of African Pharmaceutical Manufacturers Associations
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit: German Federal Enterprise for International Cooperation
GMP	Good Manufacturing Practices
IFAD	International Fund for Agricultural Development (IFAD)
NEPAD	New Economic Partnership for Africa's Development
PMPA	Pharmaceutical Manufacturing Plan for Africa
PMPA-BP	Pharmaceutical Manufacturing Plan for Africa-Business Plan
RECs	Regional Economic Communities
STISA	Science ,Technology and Innovation Strategy for Africa
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNECA	United Nations Economic Commission for Africa
UNIDO	United Nations Industrial Development Organisation
USP	United States Pharmacopeial Convention

EXECUTIVE SUMMARY

In recognition of the critical importance of the pharmaceutical manufacturing sector to Africa's health and sustainable development, the Heads of State and Government (Abuja, 2005) mandated formulation of the Pharmaceutical Manufacturing Plan for Africa (PMPA) and subsequently approved the business plan (PMPA-BP) for its implementation (Addis Ababa, 2012). The vision of PMPA is to strengthen Africa's ability to produce high quality, affordable medicines that will contribute to improved health outcomes and the realization of direct and indirect economic benefits.

While progress has been made in implementing aspects of the plan, critical components, such as attainment of international standards of Good Manufacturing Practices (GMP) and building of the requisite capacity in the industry are lagging behind.

This is because, as identified in the PMPA-BP, these mandates require, among other things, the physical modification of most existing manufacturing facilities, construction of new structures, procurement, installation and qualification of GMP-compliant equipment and building of human capital in technology and innovation. These activities are capital intensive and require long-term low-cost financing, which currently falls outside the scope of most facilities of the African banking and financial systems. The full and timely implementation of PMPA is therefore at risk of failure.

This jeopardizes the success of the PMPA and the numerous benefits expected, including access to medicines, technological advancement, harnessing of the demographic dividend through training of the youth in science and technology, job creation and poverty alleviation. Furthermore, it leaves Africa still incapable of self-sufficiently responding to health emergencies, such as HIV and Ebola epidemics, in a timely manner. The current situation therefore poses an existential security threat and should not be allowed to persist.

This proposal calls for the establishment of the Fund for African Pharmaceutical Development (FAP-D) to address the critical issue of access to capital by the industry and enable full and successful implementation of the PMPA. FAP-D will provide affordable financing for activities geared toward attainment of GMP, capacity building and enabling growth of the African pharmaceutical sector. The fund will also provide technical advisory services, oversee efficient use of financing, support partnerships and collaborations to enable private sector engagement in the development of herbal and traditional medicines, thereby seeking solutions through African innovation.

Precedence for the success of such funding mechanisms in the development of an indigenous pharmaceutical sector was set by India which, after mandating its fledgling industry to attain international standards, established a dedicated fund to transition the sector into the 4th leading pharmaceutical industry in the world. Another example is the International Fund for Agricultural Development, established by the UN, which has

been successfully used for the development of that critical sector as an approach to rural development and poverty alleviation.

It is proposed that Member States take all necessary measures to approve the establishment of FAP-D as a matter of urgency and call for its expeditious funding from multiple sources including Member State contributions, private donors, development partners and foundations. The value of a robust and sustainable pharmaceutical sector cannot be overemphasized. Deriving the benefits of a fully implemented PMPA must therefore not be delayed any further.

1. BACKGROUND

Development of the African pharmaceutical manufacturing sector is vital to sustainable development. In view of this, several commitments, strategies and declarations have been advanced and instituted to support its growth.

These include but are not limited to the following:

- The Pharmaceutical Manufacturing Plan for Africa and its business plan:
  At the AU Assembly IV (December 2005, Abuja, Nigeria) the Heads of State and Government resolved to take all necessary measures to produce quality drugs in Africa and requested the AUC, within the framework of NEPAD, to lead the development of the Pharmaceutical Manufacturing Plan for Africa (PMPA). Consequently in 2012, the Heads of State and Government endorsed the PMPA-BP as a package of solutions to the challenges confronting the African pharmaceutical manufacturing sector.

- Accelerated Industrial Development for Africa:
  During the 19th Conference of the African Ministers of Industry (March 2011 Algiers, Algeria) the Ministers recognized the potential role of the pharmaceutical sector in the overall industrial growth of Africa and recommended the integration of the PMPA into the plan of action for Accelerated Industrial Development of Africa (AIDA). The conference identified the pharmaceutical manufacturing sector and thus PMPA as a priority area for AIDA.

Other declarations whose success depends on a robust African pharmaceutical manufacturing sector include the Call for Accelerated Action towards Universal Access to HIV and AIDS, Tuberculosis and Malaria Services in Africa (Special Summit of the AU on HIV and AIDS, Tuberculosis and Malaria, May 2006, Abuja, Nigeria), the Decade of African Traditional Medicine 2000-2010 (AU Assembly V, July 2001, Lusaka, Zambia), the Renewed Decade of African Traditional Medicine 2011-2020 (Conference of African Ministers of Health, April 2011, Windhoek, Namibia), the AU Roadmap for Shared Responsibility and Global Solidarity for HIV, AIDS, TB and Malaria (AU Summit, Addis Ababa, 2012), and the Catalytic Framework to End AIDS, TB and Eliminate Malaria in Africa by 2030 (27th AU Summit, July 2016, Kigali, Rwanda).

The pharmaceutical sector is a knowledge-based and innovation-driven industry that requires advanced training in science and engineering, as well as specialized training in pharmaceutical sciences and technology. Growth of the sector is therefore in line with Agenda 2063 aspiration 1 of AU Agenda 2063 which envisions economic transformation and inclusive growth of the continent (24th Ordinary Session of the AU Assembly, January 2015, Addis Ababa, Ethiopia). To drive the desired economic transformation, Heads of State and Government instituted a call to action to actively promote science, technology, research and innovation so as to build the requisite human capital.

Furthermore with Africa undergoing a youthful demographic transition, the AU Agenda 2063 recognizes Science, Technology and Innovation as multi-functional

tools to enable the continent harness dividends from this transition. A fully supported and growing African pharmaceutical sector stands as a key enabler.

In view of the above, the Science, Technology and Innovation Strategy for Africa initiative (STISA-2024) was established to ensure an incremental (10 year) implementation of the agenda. STISA-2024 seeks to move Africa into an innovation-led, knowledge-based economy, with 'Prevention and Control of Disease' as one of its six priority areas. To this end, STISA-2024 has adopted a synergistic relationship with both the PMPA and AIDA.

Progress and Constraints in the Implementation of the PMPA

While significant progress has been made toward implementation of the PMPA, such as the African Medicines Regulatory Harmonization initiative, the adoption of the Business Plan (PMPA-BP) for the Implementation of the PMPA (19th Ordinary Session of the AU Assembly, July 2012, Addis Ababa, Ethiopia) and the endorsement of the proposal to establish the African Medicines Agency (1st Meeting of African Ministers of Health, Jointly Convened by WHO and AU, April 2014, Luanda, Angola), the growth of the industry itself remains stunted.

The following are key areas of deficiency:

- Majority of African pharmaceutical manufacturing facilities are not fully compliant with international standards of Good Manufacturing Practices (GMP). This is primarily because most facilities require structural modifications, new construction, installation of GMP-compliant equipment and further human capacity development.

- Installed capacities of most African pharmaceutical manufacturing plants, in terms of both volume and technology, are inadequate. This is a competitive disadvantage, as the industry cannot meet Africa's public health needs, leaving a deficit that is often filled by imported sub-standard medicines.

- The African pharmaceutical industry has limited capacity to tap into Africa's biodiversity, a source of novel chemical entities, as well as the continent's rich history of herbal and traditional medicines to produce quality-assured medicines of indigenous African-origin. This is because the industry has not as yet advanced to establish the requisite value chain of technologies, from primary drug discovery, through pharmaceutical and clinical development, to seamless integration into novel drug manufacturing and commercialization.

The relatively slow progress has a major root cause; lack of access to affordable funding for development of the industry.

FAP-D Proposal

This position paper is calling for the establishment of a dedicated financing mechanism to be known as the Fund for African Pharmaceutical Development (FAP-D). The goal of FAP-D is to finance the growth of Africa's pharmaceutical industry, as a critical imperative toward development of the pharmaceutical manufacturing sector in Africa, as stipulated by the PMPA and adopted by AIDA.

2. OBJECTIVES

The following are the proposed objectives of FAP-D:

a. Provide affordable financing for the African pharmaceutical industry primarily in the form of low interest loans:
Without adequate and robust funding, current plans and efforts to adopt international standards of GMP and to build capacity in pharmaceutical manufacturing in Africa are at risk of failure. Whereas other initiatives, such as the AMRH, have advanced to help address regulatory systems deficit in the pharmaceutical sector, no initiative has been advanced to address the lack of capital to enable pharmaceutical companies meet international standards of GMP and build the capacities needed to meet the needs of Africa sustainably. FAP-D will create an enabling environment for pharmaceutical companies to have access to capital.

b. Support development of African herbal and traditional medicines:
FAP-D will catalyze the establishment of the entire value chain, from drug discovery through development and commercialization, within the industry. This will include supporting involvement of the industry in the development and manufacture of quality-assured medicines from herbal and African traditional medicines.

c. Provide technical advisory services to the industry to assist them in making informed decisions on the sourcing of products and services:
The absence of established systems to support processes in the pharmaceutical industry makes it difficult for companies to get quality services. As a result, some resort to using consultants that are not properly vetted and obtain services that can be substandard. FAP-D will maximize the impact of access to capital by directing companies to vetted technical advisory services and facilitating access to enabling technologies worldwide.

d. Provide supervision support for effective funds utilization:
FAP-D will establish mechanisms to monitor and ensure successful use of funds so as to enable re-payment of loans. This will involve measures such as the establishment of a no-objection threshold for fund utilization and insistence on application of sound business principles to the use of funds.

3. BENEFITS

The benefits of FAP-D, as a means of ensuring the full implementation and sustainability of the PMPA, include the following:

a. Public health benefits
Production of affordable pharmaceuticals in Africa will help strengthen Africa's public health systems. A healthy population ensures a vibrant and productive workforce. Absenteeism from work as a result of illness lowers productivity and GDP in most parts of Africa. Availability of cost effective quality assured medicines will reduce disease burden and help improve quality of life. A vibrant and robust pharmaceutical industry on the continent will meet the challenges of

combatting infectious diseases as well as the emerging non-communicable diseases such as diabetes, cancer and hypertension.

The development of a robust pharmaceutical industry with stringent quality management systems will also create an avenue for the integration of traditional medicines into public health treatment guidelines and protocols. A mature industry will create opportunity to explore and develop African herbal and traditional medicines to their fullest potential toward finding African solutions to Africa's problems.

b. Scientific and technological development

The pharmaceutical industry is a knowledge-based sector and requires innovation and technology. Africa is positioned to take advantage of the PMPA to develop skills and expertise of the youth to meet the challenges of the industry. Through the youth, the continent can support and sustain innovation and technological breakthroughs to meet future disease challenges on the continent and beyond.

c. Economic and industrial development

With the youth increasingly making up a larger percentage of the African workforce, there is an urgency to create rewarding knowledge-driven jobs. A thriving pharmaceutical industry will create higher-wage jobs and harness this demographic dividend, thereby contributing to an increase in Africa's GDP.

Currently, over 70% of medicines are imported into Africa and local manufacturing meets only 30% of the needs on the continent. This heavy dependence on imports will be reduced as a result of a growing pharmaceutical sector and the consequent benefits from import substitution realized. This will also contribute to the diversification of the African economy and improve the continent's global competitiveness.

In addition, the bulk of funds provided by development partners and donors to procure medicines for Africa often goes to Indian and Chinese companies because these have attained the requisite GMP compliance. Increasing the number of GMP compliant facilities in Africa will therefore go a long way in enabling access to donor markets, thus improving opportunities for achieving the economies of scale and the overall growth of the domestic industry - a goal of the PMPA.

d. National security

Lack of access to technology and know-how to develop medicines to meet critical needs, especially in times of epidemics like Ebola and Zika, puts the continent at major security risk. This is especially important as an epidemic of any other highly contagious disease, such as Dengue or Lassa fever, poses a looming threat to the continent. Lack of access to critical and timely interventions during health emergencies is an existential threat and a national security concern that will be mitigated by a vibrant pharmaceutical industry.

Additionally, as envisioned by the PMPA, Africa will be in a position to take advantage of initiatives such as the Medicines Patent Pool and TRIPS flexibilities to manufacture generic versions of innovator medicines. Today,

Africa is not taking advantage of such initiatives because of a weak pharmaceutical sector.

e. Wealth creation

The pharmaceutical industry is supported by a number of auxiliary and allied industries. These industries include those providing services for equipment installation, maintenance, tooling, qualification and calibration. In addition, allied industries, including manufacture of raw and packaging material, as well as fabrication of manufacturing equipment will emerge and grow as the pharmaceutical industry grows, leading to multiple job creation beyond the pharmaceutical industry itself. This will provide an exponential contribution to technological growth, poverty reduction and GDP growth.

4. FEASIBILITY

India is an excellent case history in successful use of public sector funding to develop and grow the pharmaceutical industry. India's share of the global market is growing at 10% a year compared to overall worldwide sector growth of 7% a year. Pharmaceutical manufacturing started in India in 1950, about the same period as in Africa. The Indian industry has however grown to become the fourth largest pharmaceutical sector in the world, with an annual export growth of 30%.

While a number of incentives were instituted earlier to develop the industry, the dramatic growth that has brought it thus far, started with the establishment of a dedicated fund to finance upgrade of technology. This followed the institution of Schedule M, a regulatory mandate to achieve international standards of GMP in India by 2005. The Credit Linked Capital Subsidy Scheme that was established to support the mandate still enables small and medium sized pharmaceutical companies to access low interest rate government funds for plant upgrading, product promotion and marketing. Under a subsequent scheme, Agenda 2020, aimed at making India the world leader in end-to-end pharmaceutical manufacturing by 2020, the Indian government has established a public private partnership scheme that allows 50% of funding, needed by the industry, to come from the public sector. The tremendous success derived from these dedicated funding schemes has recently led to the announcement by the Indian Department of Pharmaceuticals that a venture capital fund of USD149 million is being created to support start-ups of research in pharmaceuticals and biotechnology.

The UN's International Fund for Agricultural Development (IFAD) is an example of a multilateral fund set up for the development of a vital sector. Since its establishment in 1977, IFAD has provided low-cost loans and grants for successful private sector agricultural development projects aimed at curbing food insecurity through eradication of rural poverty. IFAD provides supervision and implementation support to its funded projects to ensure success.

These successful programs serve as models and provide examples for the feasibility of the establishment of FAP-D and its potential to enable a successful and sustainable implementation of the PMPA.

5. PROPOSED MODEL

The following features constitute the model proposed for FAP-D:

- It will be set up as a financing entity, designed to grow and be self-sustaining. The levels of interest and other forms of profit must remain low and only at levels that sustain and maintain the fund.
- It will be preferably hosted within existing structures, such as an established pan-African financial institution, with overarching governance arrangements.
- A specific governance system, incorporating appropriate stakeholder representation and interests will be set up to guide its activities. The governance will also include establishment of operational modalities and financing criteria for the fund. Such a semi-independent governance arrangement would ensure that procedures are established to enable a nimble management of FAP-D funds, separate from normal host operations and meeting industry needs in a timely manner.
- Funding for FAP-D will be derived from any combination of the following stakeholder groups and sources:
  - AU member states
  - Development partners
  - Donor agencies
  - Private sector
  - Foundations
  - Special levies
- Utilization of funds will be limited to activities outlined in the PMPA-BP, such as GMP improvements, access to technology, support of partnerships and collaborations, product planning, process/efficiency improvements and working capital that can be demonstrated to support the growth and sustainability of the beneficiaries' operations.

6. IMPLICATIONS

The establishment of FAP-D could have legal, institutional and financial implications as outlined below.

a. Potential legal implications

FAP-D could be established as a treaty based organ thereby committing all member states to contribute toward its funding. It could also be established as a non-treaty based assembly decision, contribution to which shall be optional for member states. The decision may however be advised by the fact that an established and growing industry inures to the benefit of the entire continent and hence all member states.

b. Potential institutional implications

This proposal recommends that an existing pan-African institution with established financial management system host FAP-D. Examples of such institutions are the African Development Bank and the African Export-Import Bank. A process will have to be instituted to identify the appropriate match

among all African financial institutions. If this is found to be untenable, then a new institution, under AU mandates, may have to be established.

c. Potential financial implications

The recommended financial launch objective for FAP-D is USD 60 million. This is based on estimates to support ten projects at launch to upgrade manufacturing facilities, establish processes, provide working capital and develop human capital. Member states could contribute between USD 0.5 million to 10 million as appropriate. This level of funding and number of beneficiaries will constitute an impactful launch.

7. ROLE AND RESPONSIBILITIES OF AU MEMBER STATES

The following are the recommendations:

- That member states adopt and ratify the establishment of FAP-D in an assembly decision and concomitantly approve the establishment of a governance board for the fund.
- That an initial call to member states and partners for seed funds to launch FAP-D be made soon after adoption.

8. PARTNERS AND STAKEHOLDERS

The establishment of FAP-D is proposed as a means to catalyze the implementation of the Abuja declaration, in which the Heads of State and Government resolved to take all necessary measures to produce quality drugs in Africa and requested the AUC, within the framework of NEPAD, to lead the development of PMPA. The AU therefore owns FAP-D. The fund is therefore responsible for ensuring that its operations meet the purposes of the PMPA.

In this regard, it is envisioned that the AU, within the framework of NEPAD, will continue to lead in its implementation. While it is recognized that this may be an incomplete list, potential stakeholders are identified in Table 1.

Table 1. Potential stakeholders in the implementation of FAP-D

Stakeholder		**Role/Interest**
1.	African Development Bank	Pan-African financial institution, a potential host for FAP-D
2.	African Union Commission	Lead implementer and custodian of the PMPA
3.	African Export-Import Bank	Pan-African financial institution, a potential host for FAP-D
4.	CHAI	Funding treatment for HIV/AIDS - Potential donor

Stakeholder		Role/Interest
5.	FAPMA	Continental organization representing pharmaceutical manufacturers: funding targets and delivery of objectives of the PMPA
6.	Gates Foundation	Potential donor supporting collaborative inclusive partnerships
7.	GIZ	Partner in sustainable development, providing technical support to African pharmaceutical manufacturers
8.	Global Fund	International health financing organization – potential donor
9.	NEPAD Agency	Lead implementer and coordination of African regional regulatory harmonisation program
10.	RECs	Currently working with NEPAD to implement the AMRH under the PMPA
11.	UNAIDS	Promoting manufacturing of antiretroviral drugs in Africa
12.	UNECA	Partner for economic development of Africa
13.11.	UNIDO	Partner forindustrial development
14.12.	USP	Pharmaceutical quality standard setting organization. Conception of FAP-D to help complete objective of ensuring quality of medicines in Africa
15.	WHO	Word Health Organisation, global mandate for Norms and standards setting