

High-level event on IDDA III



CONCEPT NOTE

**Strengthening Africa's Pharmaceutical Industry
– learning the lessons from COVID19**



1. BACKGROUND

The United Nations General Assembly (UNGA) adopted resolution A/RES/70/293 proclaiming the period 2016-2025 as the Third Industrial Development Decade for Africa (IDDA III) in July 2016. The proclamation was made based on the recognition that it is through sustainable industrialization that the continent will be able to have meaningful development. At the same time, the proclamation served to show that the international community is ready to enhance its partnership with African stakeholders for benefits that would go beyond the continent. It further called for the strengthening of public-private partnerships and enhanced international co-operation, including North-South, South-South and triangular, in order to expedite Africa's industrialization through the implementation of the IDDA III. Since the passing of the resolution, three high-level events on IDDA III have been held in the margins of the 71st, 72nd and 73rd UNGA in 2017, 2018 and 2019 respectively. The event this year will be the fourth.

2. THEME OF THE HIGH-LEVEL EVENT

The theme for this event is **“Strengthening Africa’s Pharmaceutical Industry – learning the lessons from COVID19”**. The pandemic has highlighted Africa’s vulnerability due to its reliance on imports for much of its vaccines, medicines and other health product needs. This high-level event will focus on the public health benefits that a stronger pharmaceutical industry in Africa can bring and the contribution it can make to economic development. The event will deliberate on key challenges that need to be overcome to strengthen health industries. The outcomes will contribute to the elaboration of a common vision and encourage renewed, coordinated multi-stakeholder efforts across all sectors to realize Africa’s objectives of greater self-sufficiency in essential medical products. The pharmaceutical industry is a priority sector under IDDA III and is included in continental frameworks and initiatives such as Agenda 2063 and the African Union’s Pharmaceutical Manufacturing Plan for Africa (PMPA) and its related business plan, and the Accelerated Industrial Development for Africa (AIDA).

Furthermore, as Africa started trading under the African Continental Free Trade Area in January 2021, it is pertinent to boost local pharmaceutical production and strongly encourage the procurement of medical products from Africa-based companies. There is a need, therefore, to bring coherence between health, industrial development, and trade policies in the pharmaceutical sector. Equally important, the relevance of boosting Africa’s pharma industry increases as we take into consideration the current preparation for the African Union Summit on Industrialization and Economic Diversification scheduled in November 2021 in Niger.

COVID 19 - a two track pandemic

The world is still in the throes of the COVID19 pandemic and Africa has not been spared. According to WHO, as of 9 September, 2021, African countries had reported 7,957,407 COVID19 cases and 138,480 deaths. The pandemic is having a devastating impact across many countries in Africa not least through compounding the heavy burden of disease that the continent already bears. Healthcare systems are struggling under the additional demands and disruption to global supply chains has further compromised availability of essential medical products. The development of vaccines against COVID19 in a remarkably short time provides a possible means to end the pandemic and reduce the impact of the disease. However, constrained manufacturing capacity for these products has seen global demand outstrip supply and led to substantial inequities in access between the Global North and the Global South. Delayed access to these innovative products is causing countless avoidable deaths in Africa.

There have been unprecedented efforts to address COVID19 vaccine availability in Africa. The African Union and its Member States have come together through initiatives such as the African Vaccine Acquisition Trust to secure vaccine doses for the continent. COVAX and its manufacturing and supply task force have worked tirelessly to increase capacity and secure doses for countries across the developing world. Despite these and other initiatives (such as the WHO-backed vaccine hub for Africa), vaccination rates in Africa remain in the low single digits, at the same time as the developed world is contemplating rolling out booster shots.

COVID19 is not the only pandemic affecting the continent as HIV, TB and malaria continue to plague many countries. Medicines can treat these and many other health priorities in Africa, but access is often inadequate and is compounded by the scourge of sub-standard and counterfeit products. International initiatives such as the Global Fund and PEPFAR support substantial procurement of medicines for priority diseases, and many initiatives seek to increase availability of products for a broad array of health issues such as sexual and reproductive health. However, access to a broad range of safe, effective, affordable, quality essential medical products in Africa continues to be limited.

Essential medical products – proximity of production matters

The access to vaccines crisis and endemic supply shortages for essential medicines highlight the vulnerability of the continent due to its reliance on imports for many health products. For these and other medical products, proximity of production matters. Enhanced productive capacities

can accelerate access to innovative vaccines and medicines; enable greater regulatory oversight of products entering the market; and increase resilience to crises and spikes in global demand.

In total there are an estimated 600 manufacturers of essential medicines in Africa and 10 producers of vaccines, with vast majority of companies being active in the downstream manufacturing steps. Virtually all inputs for production of therapeutic medicines are imported and only three of the vaccine manufacturers have drug substance capabilities. The level of quality assurance varies significantly, posing a threat to public health and limiting the opportunities for growth from the substantial donor funded markets. The majority of companies operate in relatively limited therapeutic categories often due to the opacity of markets and the lack of reliable data on which to base decisions. The United Nations Economic Commission for Africa (UNECA) estimates that Africa imports about 94% of its pharmaceutical and medicinal needs from outside the continent at an annual cost of \$16 billion.

Strengthening health industries in Africa requires many interrelated challenges to be addressed and the power of the private sector to be leveraged. Investment needs to be mobilized, technology accessed, skills developed and policy frameworks that are supportive of industrial development implemented. Key pillars that need to be considered include:

- Investment:

To realise the objectives substantial investment is required to upgrade existing facilities, establish new capacity and develop new industries and capabilities across the value chains. The operating environment for the private sector needs to evolve to attract investment in the long-term, and facilitated access to affordable finance for the pharmaceutical sector would help to catalyse industrial development of the sector. Investment to the tune of many billions of dollars is required such that private sector capital needs to flow the sector through for example blended financing, public-private partnerships, domestic capital mobilization, and foreign direct investment. It is estimated that as part of a post pandemic recovery, FDI inflows to Africa could exceed the 2019 levels (USD 47 billion) and a conducive ecosystem would attract FDI in pharmaceutical sector also. It is important to note that access to long-term credit and working capital is limited in Africa due to the high cost of finance. While the cost of borrowing varies, the rate of interest is often in the range of 15- 25 % per annum in local currency and in some cases even higher. In the context of the PMPA, efforts are underway to implement the Fund for African Pharmaceutical sector Development (FAP-D). It is intended to support SMEs in the sector to access affordable capital.

- Market consolidation

Market opportunity is a key driver for industrial development. Fragmentation of Africa’s pharmaceutical market has limited the opportunities for sustainable, high-quality production to date. Progress towards consolidated regional markets has been made through the African Medicines Regulatory Harmonisation (AMRH) initiative and the establishment of the African Medicines Agency (AMA) will further enable this process. The advent of the AfCFTA in 2021 provides the opportunity for greater integration and free trade in a potential healthcare market of 1.3 billion people. Realizing the opportunities that these confer requires ongoing collaboration between AU member states, reduction/removal of tariff and non-tariff trade barriers, and enabling reliance mechanisms through strengthened regulatory systems. Furthermore, development of unified standards and certification is equally important. Promoting and scaling up of regional value and supply chains will further consolidate the African pharmaceutical market. Moreover, relevant data on market size, demand, and competition is critically important to track.
- Cost of production

African manufacturers suffer from several cost disadvantages including: higher unit costs associated with manufacturing, materials and machinery, finance and utility services. The small scale of most Sub Saharan African producers also tends to increase the unit costs of production. Unit labour costs in Africa are generally higher due to lower productivity and higher cost for hiring technically qualified people and experts from abroad. African manufacturers rely on imported sources for most of their requirements of active pharmaceutical ingredients, excipients, primary packaging materials, machinery and equipment. Import duties and value added tax on these materials and equipment increase the cost in many countries while imported medicines are often exempted from duties and taxes.
- Infrastructure and connectivity:

The unreliable, insufficient supply and high cost of electricity and water not only substantially increase operating costs in Africa, but also act as barriers against effective use of installed production capacity. The poor conditions of roads are also a major challenge, often causing long delays in clearing the imports of raw materials and delivery to manufacturers. There is often limited availability of land that is connected to utilities and suitable for pharmaceutical production across the continent.

- Regulatory oversight:
 Strong regulatory oversight is required to protect patients from the scourge of sub-standard and falsified medicines, and in so doing ensure that the market for safe, effect quality assured medicines is not eroded. Close regulatory scrutiny of vaccine manufacturing is required and national regulatory medicines authorities must certify each lot before it is released. At present only two national medicines regulatory authorities in sub-Saharan Africa have reached WHO maturity level 3, the benchmark for satisfactory oversight. Hence, further investment in regulatory systems is required to protect public health, strengthen the business case for investment and to provide a basis for reliance mechanisms that can enable broad market access for manufacturers. Under the AMRH initiative implemented through regional economic communities (RECs) as well as the AU smart Safety Surveillance project national regulatory systems have registered improvement undertaking regulatory oversight. Further improvements are expected with the AMA kicking-off its operations in the near future.
- Human resource capacity and knowledge:
 Manufacturing of pharmaceutical and health care products requires highly skilled scientists, engineers, technicians etc. Africa's higher education system is evolving to meet these requirements and capabilities could be further enhanced through research and scientific collaboration with international partners. Expanded operations in Africa across research, development, production and distribution offer many opportunities for creating jobs and enhancing skills across the pharmaceutical value chain. This expansion of opportunities can be realized across public research institutes, contract research organisations, small and medium sized biotech/pharmaceutical companies and services providers for the pharmaceutical industry. AUDA-NEPAD is mobilizing support for the design and implementation of an online platform known as the Africa Pharma Learning Management system aimed at delivering online training for enhancing individual and institutional capacity on topical issues. The Africa Pharma Resource Data Base is another project AUDA-NEPAD is developing that is expected to provide digital platform for investors, academia, and all interested stakeholders to interact.
- New technology:
 New technology is driving the 4th industrial revolution and application of digital technologies can play a transformative role in the pharmaceutical industry. For example, it can increase market transparency, ensure consistent product quality, facilitate regulatory oversight and enable the virtual provision of services. mRNA technology holds great promise as a basis for new healthcare solutions not least to priority diseases in Africa. New approaches such as continuous manufacturing, improved process chemistry and modular

plant designs can enable Africa to leapfrog other domains and some manufacturers are already adopting these modern manufacturing processes. Hence an array of different technologies can be leveraged to open up new opportunities for healthcare industry development.

In addressing these and other issues, the context of the different industry sectors requires that approaches be tailored for vaccines, medicines and other health products. Recognizing this and other complexities, how can African institutions, member states and private sector work together to strengthen healthcare industries on the continent? What roles can the international community play in supporting and contributing to this vital undertaking?

COVID19 – A call to arms

The crisis has been a call to arms to redouble efforts to strengthen health industries in Africa and to work together to leverage the power of industrial development to contribute to improved public health. It has refocused efforts under established undertakings such as the PMPA and the AfCFTA anchored pharmaceutical initiative as well as REC and national level undertakings, and has prompted many new approaches.

In April 2021, the African Union and its Africa Centres for Disease Control (CDC) and Prevention launched the Partnerships for African Vaccine Manufacturing (PAVM) and established a target of the continent meeting 60% of its vaccine needs by 2040. Aligned to this, under the COVAX Manufacturing and Supply Task Force, WHO is working with a consortium of South African partners to establish the first mRNA vaccine technology transfer hub. A number of development finance institutions are providing investment for expanded vaccine manufacturing in selected countries. A number of bilateral deals by the international private sector are also on the rise. In March 2021, the European Union announced a €1bn Euro Team Europe initiative to support development of health industries in Africa. The manufacturing hub in Senegal is to produce vaccines against COVID-19 and other endemic diseases. With an estimated cost of \$200m, construction is expected to start later this year, with production volumes of 25m doses per month planned by the end of 2022.

As well as vaccine manufacturing, support is required to strengthen health care delivery, including COVID19 cases. AfroChampions, the African Academy of Sciences, the African Institute of Mathematical Sciences, the PanaBIOS Consortium, the African Organisation of Standards, Koldchain BioCordon and the United Nations Development Programme and several organs of the African Union have brought into life the 4D agenda. This is intended to take major pan-African and global development initiatives forward. For instance, the multi-stakeholder 4D agenda includes strengthening the Africa CDC's Trusted Travel and Trusted

Vaccines platforms. The COVID19 crisis has once again highlighted the importance of local production of essential health products, and the need to reshape Africa's approach to health care. How can established initiatives and new undertakings be supported to strengthen the fight against this pandemic and improve health security and access to health products in the longer-term?

Strengthening Health industries in Africa –seizing the moment

Lessons learnt from COVID19, have provided an opportunity to revisit the local pharmaceutical production agenda. A stronger pharmaceutical industry in Africa can contribute to improved public health and economic development, and to society at large being better prepared for the next pandemic. This is a complex undertaking that will take time bearing in mind the key realities of Africa's pharma market. For example, the majority of Africa's pharmaceutical production is concentrated in a few countries and ten countries represent 70% of Africa's pharma market. Furthermore, large African pharma producers are owned, in full or in part, by foreign and multinational firms. Equally important, pharmaceutical manufacturing in Africa focusses on generics. In many African countries, generic drugs are rapidly gaining market share.

In recognition of the said complexities, moving forward will require collaboration and alignment at multiple levels over an extended period and for a framework in which different interests can be realized in delivering on the common good. Progress over the last decade has laid the foundations but how can the power of the market be harnessed to navigate the complexity? Although the TRIPS Agreement does contain several safeguards, known as the 'TRIPS flexibilities' , designed to ensure the protection of IP rights does not stifle competition or impede access to essential products, these safeguards have not been fully implemented or used in most African countries.

How can African countries resolve the tension between IP regimes and access to medicines and how can the use of public interest exceptions in international intellectual property law facilitate access to medicine? How can the varying needs of different health industry sectors be reflected? How can commitment be sustained over an extended time frame? How can we build back better, harness the full range of industrial development tools, and strengthen local production of health products in Africa to help address the profound inequities that have once again been so cruelly exposed?

3. LEAD ORGANIZING INSTITUTIONS

The high-level event is organized by the United Nations Industrial Development Organization (UNIDO) in cooperation with the African Union Commission (AUC), the United Nations

Economic Commission for Africa (UNECA), the African Development Bank (AfDB), the African Union Development Agency (AUDA-NEPAD), the United Nations Office of the Special Adviser on Africa (OSAA), AfroChampions Initiative and the African Export-Import Bank (Afreximbank).

4. OBJECTIVES:

The objectives of the event are to:

- a) Discuss and highlight tangible action areas, solutions and necessary policy measures to boost Africa's pharmaceutical industry.
- b) Explore innovative solutions for the systemic barriers hindering development of the continent's health industries.
- c) Discuss optimal approaches for mobilizing domestic and foreign investment for Africa's pharmaceutical sector.
- d) Highlight on-going initiatives to strengthen the sector and opportunities for new technologies to contribute to transformational change.
- e) Identify how current high-level focus can be translated into long term engagement.
- f) Deepen knowledge of policy makers on the current status and options for progressing Africa's pharma industry.
- g) Inform and guide efforts of relevant international and continental stakeholders to realize the envisaged common vision.
- h) Rally desired political momentum, partnerships and alliances towards an accelerated Africa- Pharmaceutical Industrialization drive.

5. FORMAT

The event will take place in a virtual format and will be comprised of various sessions including a high level session featuring selected African Heads of State and a technical panel discussion on "Strengthening Africa's pharmaceutical sector – the interface between public health and industrial development".

6. EXPECTED PARTICIPANTS

The event will be addressed by high level dignitaries from Africa and from the international community. It will bring together Africa's industrial development stakeholders including African Heads of State/Government, Ministers, the African Union Commission, UN agencies, African regional organizations and the private sector, financial institutions, donors, civil society and non-governmental organizations, academia and media.

7. OUTCOMES

- 1) A joint communique on industrial development of Africa's pharmaceutical sector;
- 2) High-level consensus on the need to expedite and support local production of pharmaceuticals and health industry in Africa;
- 3) Recommendations on key initiatives to advance Africa's pharmaceutical and health industries;
- 4) Mobilization of partnerships and resources in support of Africa's pharmaceutical industry agenda and;
- 5) Propose an effective monitoring and reporting framework to evaluate the progress in implementing the proposed policy actions.