PROPOSAL TO ASSESS THE READINESS OF AFRICAN PHARMA MANUFACTURERS TO PRODUCE ESSENTIAL MEDICINES

AUDA - NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

AFRICAN LEADERS MALARIA ALLIANCE

ALMA

Africa Pharma Platform

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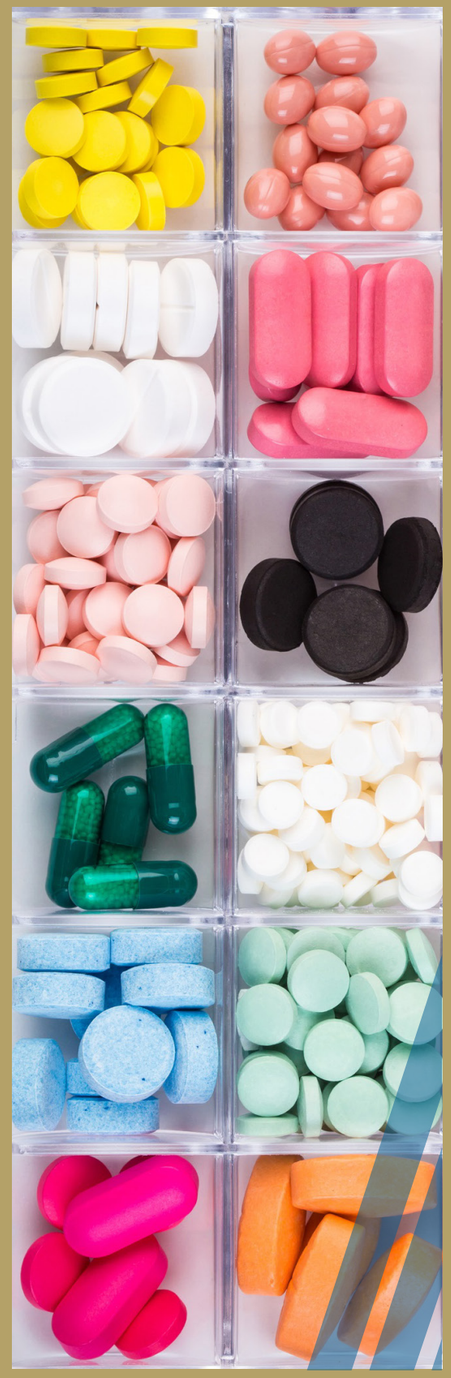

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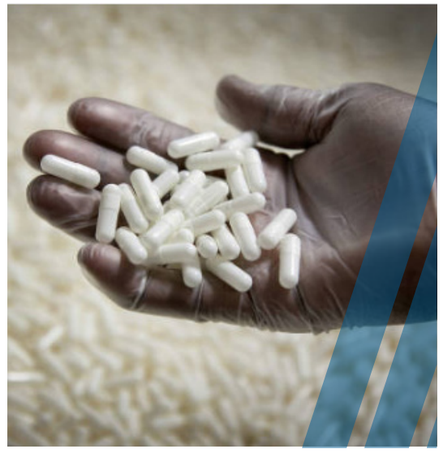
INTRODUCTION

The African Pharma Platform (APP), was conceived in 2018 to implement the Pharmaceutical Manufacturing Plan for Africa (PMPA) under the leadership of the African Union Development Agency (AUDA-NEPAD) and its consortium of partners which incorporates all relevant continental institutions, development partners, UN agencies and AUC Member States.

The platform is mandated, amongst other things, to implement initiatives that will ensure the African pharmaceutical ecosystem can promote sustainable access to essential medicines and improve health outcomes for all Africans. In order to facilitate improved efficiency in the implementation of projects and initiatives, AUDA-NEPAD appointed DFS Africa as its private sector implementation partner. The partnership between AUDA-NEPAD and DFS Africa has enabled the APP to advance initiatives that supports the following:

1. Enhancement of local manufacturing of pharmaceutical products in Africa
2. Improve opportunities for access to essential medicines for all Africans
3. Facilitate projects that support technology transfer in the pharmaceutical sector
4. Develop initiatives and projects that improves capacity development in Africa's pharmaceutical sector
5. Convening of thought leadership discussions with principal stakeholders to accelerate best practices and regulatory alignment in Africa's pharmaceutical sector

Since the commencement of the collaboration between AUDA-NEPAD and DFS Africa in 2018, the APP has built strong relationships with principal actors in the global pharmaceutical ecosystem. The platform has grown its influence through partnerships with aligned interest in developing the African pharmaceutical sector and ensuring Africans have access to essential medicines.



The PMPA implementation initiatives by the APP has received the support of the African Union Commission (AUC), African Governments, UN Agencies, Development Finance Institutions, Private sector investors and local pharmaceutical companies.

PROBLEM STATEMENT

The COVID-19 pandemic has made it clear that local pharmaceutical manufacturing should be treated as a national and continental security issue.

In response to the pandemic, the 'Pharmacy of the Developing World', India, banned the exportation of all the priority medicines that Africans desperately need. China, European countries including Russia, have also now formally prohibited the exportation of many medical technologies and priority medicines to Africa; hence in the age of the pandemic, nationalist tendencies will make nations look after their own people before they think of helping or doing business with Africa. This is the reason why Africa must galvanise her industrial capacity to produce critical pharmaceutical and medical Supplies.

This makes the issue of self-sufficiency a case of national security and less an economic discussion alone and summarises the problem that this research is aiming to fix.

CONTEXT OF THE RESEARCH

This is a research to assess the readiness of African pharma manufacturers to produce medicines on the WHO Essential Medicines List (EML) at scale, while adhering to global standards and best practices.

The output of the research will identify amongst other things a path for local manufacturers in Africa to increase their contribution to the supply of essential medicines procured on the continent from less than 10% in 2021 to 40% by 2030.

The premise of our research is that global suppliers of the WHO Essential Medicines List (EML) change from time to time for most African countries because of increasing cost of procuring EML products versus other competing demands of the government (GDP/Capital); hence governments and private procurers are constantly searching for suppliers offering affordable prices and at the same time ensuring falsified drugs are prohibited from their territory.

Furthermore, essential medicines procured across Africa reach the desired destinations on the continent as expensive medicines. According to the Centre for Global Development, ''low-income African countries 'pay 30 times more' for drugs and in countries such as Zambia, Senegal and Tunisia, everyday drugs like paracetamol can cost up to 30 times more than in the UK and USA".

This research aims to resolve the challenges posed by the two

premises stated above by articulating a clear path to significant increase in supply of essential medicines in Africa driven by pharma manufacturers local to the continent, while incorporating global standards and best practices from the fundamentals.

We see this research as an extension of the PMPA mandate, which is to increase local manufacturing capacity, invest in the pharma value chain and increase regulatory harmonisation as a precursor to market integration.

OBJECTIVES OF THE RESEARCH

The objective of this research is to analyse the key aspects of the local manufacturing of pharmaceutical products in Africa and identify the critical actions required to develop and grow the ecosystem. Below are the research objectives:

1. Produce a comprehensive list of local pharmaceutical companies across the African continent;
2. Produce a comprehensive list of priority medical products and supplies across the continent;
3. Identify the percentage of the essential medicines list that can be manufactured on the continent.
4. Analyse the capacity of the companies along therapeutic solutions and stage of manufacture, creating appropriate data points to ensure proper classifications;
5. Highlight categories of competencies within the ecosystem;
6. Infographic on Africa's Pharmaceutical industry showing:
    a. Market Size US $ (revenue in the past 5years)
    b. Sector Composition (top segments by US $ e.g., anti-diabetics, anti-hypertensives, analgesics etc over the last 5 years)
    c. Government initiatives facilitating growth
7. Recommend strategies to improve the percentage of locally manufactured medicines in the continental essential medicines list.
8. Recommend implementation strategies across the following areas:
    a. Regulatory Harmonisation
    b. Technology transfer
    c. Capacity development
    d. Access to financing
    e. Access to markets

f. Improved Mechanisms for procurement and supply chain for the distribution of the needed supplies;

9. Recommend continental / regional frameworks to fast-track approval of the clinical development, manufacture, market and distribution of needed medical products

SCOPE OF RESEARCH

The scope of this research is to analyse sixty Pharma manufacturing companies across the four regions of Africa. The research will leverage existing studies into Pharma manufacturing in Africa and African manufacturers' readiness for manufacturing essential medicines. The research will focus on the gaps that previous research works did not cover but is crucial to the growth and scalability of the sector as we push for an Africa that manufactures its own essential medicines.

This research will analyse the capacity, technology requirements and financing needs of the sixty organisations that have been identified for this study. Ultimately this research will chart a course that links addition supply of essential medicines as a result of increase in local manufacturing to the market opportunities and demand availability across the continent.

The research will help partners and stakeholders of PMPA to better understand the scale and the critical steps to undertake in order for Africa to grow its capacity of local production which is under 10% consumption to about 60% consumption.

The recommendations for this research work will focus on implementable solutions and it will cover the following areas:

1. How do we achieve improved capacity for local production of pharmaceutical products?
2. What are the gaps to be filled and the stakeholders responsible for implementing changes?
3. What is required for the development of efficient Supply chain and Procurement processes?
4. The role of Patient capital investments.
5. How to solve the Capacity development concerns?
6. What is required for sustained API production in Africa?
7. How do we ensure access to market for additional supply of medicines?
8. How do we guarantee global standards as production increases?

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Below is the initial analysis on the regions of operation, size, capacity of production and annual revenue of the sixty local manufactures that would be assessed in this research.

List of African pharmaceutical companies that will be covered in this research

Region	Country	Name	Capacity of Production / No of Products (approx)	Revenue (US $ Millions)	Number of Employees
North Africa	Egypt	Hikma	not available	97	
North Africa	Egypt	Medical Union Pharma	188	166	
North Africa	Egypt	Multiapex Pharma	not available	74	
North Africa	Egypt	Pharco Pharmaceuticals	200	193	
North Africa	Egypt	Sedico	180	88	
East Africa	Ethiopia	ADDIS PHARMACEUTICAL FACTORY PLC	100	107	
East Africa	Ethiopia	FAWES pharmaceuticals plc			
East Africa	Kenya	Beta Healthcare, Int Limited	Not available	88	
East Africa	Kenya	Biodeal Laboratories Limited	Not available	42.96	
East Africa	Kenya	Cosmos Limited	300	53.69	
East Africa	Kenya	Dawa Limited	190	23.7	
East Africa	Kenya	Ely's Chemical Industries Limited	100	7.3	
East Africa	Kenya	GlaxoSmithKline (GSK)			
East Africa	Kenya	Macs Pharmaceuticals Ltd	62	5.64	
East Africa	Kenya	Nerix Pharma Limited			
East Africa	Kenya	Regal Pharmaceuticals Limited	70	7	
East Africa	Kenya	Universal Corporation Limited	100	21.7	
North Africa	Morocco	Bottu Pharmaceuticals	300	56	
North Africa	Morocco	Cooper	100	62	

Region	Country	Name	Capacity of Production / No of Products (approx)	Revenue (US $ Millions)	Number of Employees
North Africa	Morocco	LAPROPHAN	400	150	
North Africa	Morocco	Pharma 5	400	100	
North Africa	Morocco	Sothema	300	32	
East Africa	Tanzania	Keko Pharma-ceutical Indus-tries Ltd	120	10.74	
East Africa	Tanzania	Zenufa Ltd	128	80	
East Africa	Uganda	Abacus Paren-tal Drugs Ltd	55	37.59	
East Africa	Uganda	CIPLA QUALI-TY CHEMICAL INDUSTRIES LIMITED	250	52	
East Africa	Uganda	"Kampala Pharmaceuti-cal Industries (1996) Ltd "	125	31	
East Africa	Uganda	Kwality Afro Asia	25	16.22	
East Africa	Uganda	Medipharm In-dustries (E.A.) Ltd			
East Africa	Uganda	RENE INDUS-TRIES LIMIT-ED	140	32.22	
Southern Africa	SA	Aspen	47	2600	10676
Southern Africa	SA	Adcock Ingram	16	477	2600
Southern Africa	SA	Activio Health	21	20.8	27
Southern Africa	SA	Alpha Pharm	16	85.16	740
Southern Africa	Mauritius	HealthActiv Mauritius	14	6	5.64
Southern Africa	Mauritius	Medi Systems Limited	11	6	
Southern Africa	Zambia	Missionpharma Zambia Limited	5	4	
Southern Africa	Zambia	Phillips Phar-maceuticals Zambia Limited	12	12	
Southern Africa	Mauritius	Techni Med Services Lim-ited	6	7	
Southern Africa	Mauritius	Unicorm MSJ Limited	16	7	
Southern Africa	SA	Avacare	70	48	244

Region	Country	Name	Capacity of Production / No of Products (approx)	Revenue (US $ Millions)	Number of Employees
Southern Africa	SA	Kiara Health	14	1.25	46
West African	Nigeria	FIDSON HEALTH CARE PLC	78	44	340
West African	Nigeria	EMZOR PHARM-IND-LTD	54	439	2118
West African	Nigeria	NEIMETH INTL PHARM. PLC	66	6	189
West African	Nigeria	BOND CHEM-ICAL INDUS-TRIES LTD	12	4	23
West African	Nigeria	BOLA PHAR-MACEUTI-CALS	13	6	33
West African	Nigeria	DRUGFIELD PHARM LTD	12	5	31
West African	Nigeria	PHARMA DEKO PLC	37	2	114
West African	Ghana	GEO MEDI-CINE LTD	43	7	63
West African	Ghana	Phyto-Riker Pharmaceuti-cals Limited	12	5	30
West African	Ghana	INTRAVE-NOUS INFU-SION PLC	12	5	27
West African	Ghana	PokuPharma Limited	67	6	27
West African	Ghana	ERNEST CHEMISTS LIMITED	76	100	453
West African	Ghana	MEDIS SENE-GAL	34	6.8	134
West African	Ghana	Sanbao (GH) Pharmaceuti-cals Limited	56	5	77
West African	Ghana	GR Industries Limited	45	5	78
West African	Ghana	KAMA PND. LTD ASPEN GROUP	56	38	5
West African	Ghana	DOPHARMA	12	45	6
West African	Ghana	DANNEX LTD	47	51	50

EXPECTED OUTPUT/OUTCOMES OF THE RESEARCH INCLUDES:

I. The research team will identify all the credible Pharmaceutical companies in Africa. The analysis work will separate the companies into the following categories::

   a. Local manufacturing companies;

   b. Distribution and packaging companies;

   c. Companies that can scale their production and what is required to scale i.e., financing, technology, corporate structure, access to markets, new formulation/production opportunities, GMP certification etc.

II. The research team will work with the management team of 60 local manufacturers in our database to gather critical research findings such as:

   a. What does it take to transform a local manufacturer to a regional supplier of essential medicines;

   b. How do you guarantee market access that leads to sustained improvements for these manufacturing companies;

   c. What type of corporate governance is required to make these companies bankable so they are able to access credit or funds for scalability;

III. The research will seek to understand how to improve the quality of medicines produced across Africa and ensure African products meets global requirements in terms of quality and certifications required;

IV. The research will identify the production capability of the continent and recommend solutions (technology, capacity and financing) required to scale production capabilities on the continent in the short, medium and long term;

V. The research will identify areas of the value chain where synergies and sustainable partnerships with global enterprises, industrial buyer and suppliers would make a difference to national and regional manufacturers;

VI. The research will curate solid intelligence on investing in the African pharmaceutical value chain, identifying the critical factors that should support private and public investors.

JOINT ACTION PLAN FOR AUDA-NEPAD AND AFRICAN LEADERS MALARIA ALLIANCE (ALMA) STRATEGIC COLLABORATION ON THE RESEARCH TO ASSESS THE READINESS OF AFRICAN PHARMA MANUFACTURERS TO PRODUCE MEDICINES:

Project Impact	Accessing the manufacturing capacity of local manufacturers in Africa to meet Africa's demand for Essential Medicines
Project Goals	The research will analyze sixty African pharmaceutical manufacturers and identify 100 pharma manufacturing companies that are qualified or at the cusp of qualification for the WHO GMP certification. The outcome of the research will focus on the following: • Ascertain what is required for companies at the cusp of GMP qualification to attain certification for the manufacturing of generic drugs. • Determine the percentage of products on the essential medicines list for African countries that is procured from African manufacturers. • Identify and map the capacity of each of the 100 pharma companies in this cohort to meet the demands for supplying products on the essential medicines list across Africa. • Ascertain what the pharma companies covered in the research requires to do in terms of capacity development, technology, financing and standards in order to be able to increase Africa's procurement of its essential medicines from African manufacturers to 60% by 2027.

Outputs / Targets	Performance Indicators	Means of Verification	Assumptions	Risks
OUTCOME 1: ***The governance of the research is successfully agreed between AUDA-NEPAD and ALMA. The research objectives are confirmed to contribute to the achievement of AU aspirations for development of the Pharmaceutical sector in Africa***				
1.1 The research governance program is agreed between AUDA-NEPAD and ALMA – **An Effective collaborative partnership commence**	Finalisation of MoU and JAP	Governance and reporting of research deliverables are agreed and shared between AUDA-NEPAD and ALMA	AUDA-NEPAD and ALMA has adequate resources to oversee the research	Delays in finalizing MOU

	Outputs / Targets	Performance Indicators	Means of Verification	Assumptions	Risks
1.2	The research objectives and activities are outlined and outsourced to a research organisation in the ecosystem – **AUDA-NEPAD and ALMA supports and oversees the research proceedings and agree deliverables**	Programme document developed and shared with potential funders	• Research Programme document is signed off • Resources mobilized for implementation	Research supporting PMPA remains a priority for the AU	Inability to secure funders Lack of resources
OUTCOME 2: ***Research management and dissemination of relevant research findings and knowledge that facilitates the uptake of best practices for sustainable pharmaceutical manufacturing in Africa***					
2.1	Data and information creation / collection / collation – **Targeted research and analysis for informed decision-making**	Analysis of information	Presentation of results	Data / information available	Info not accessible
2.2	Develop relevant knowledge products in different languages – **Accessible, relevant knowledge products developed**	Research findings packaged	Knowledge products	Adequate resources	Lack of resources
2.3	Dissemination and sharing of findings, lessons and best practices – **Knowledge products available and informing decision-making**	Knowledge products shared and used by stakeholders	Workshop / meeting reports	Knowledge products well targeted	Lack of political will
OUTCOME 3: ***Cooperative actions fostered between members of the Federation of African Pharmaceutical Manufacturers (FAPMA) and stakeholders who can contribute technology transfer, investment of funds and capacity development to enhance growth of the pharmaceutical manufacturing in Africa***					
3.1	Engagement with stakeholders, technology partners and financial institutions to agree on priority actions – **Priority actions agreed upon**	Engagement report	Priority actions identified	Stakeholder support and availability of resources	Poor response
3.2	Development of cooperative tools and mechanisms between manufacturers across the continent – **Cooperative mechanisms established**	Commitments to partnership	Partnership cooperation agreements	Resources available	Lack of willingness to cooperate

	Outputs / Targets	Performance Indicators	Means of Verification	Assumptions	Risks
3.3	Advocacy and awareness – **Increased awareness of opportunities in pharma manufacturing**	Increased commitment to development of the sector	Commitment statements, Resources committed	Resources available	Lack of interest
OUTCOME 4: ***Responsible private sector partnerships and targeted investment to stimulate sustainable pharma manufacturing in Africa.***					
4.1	Assessment of structural gaps in pharma companies, opportunities to scale and the identification of options for investment – **Identification of investment options and partnerships for growth**	Analysis Report	Presentation of the finding	Pharma companies are interested in growth and they commit resources to growth	Optimism bias
4.2	Investor road show – **Share information about pharma companies that have participated in the research with interested financial institutions**	Criteria outlined for investment	Number of financial institutions participating	Stakeholder support and availability of resources	Lack of resources
4.3	Investment facilitation – **Matching of pharma companies and investments**	Investment facilitation is successfully orchestrated	Number of investment commitments	Availability of investors and resources	Lack of political will

PROJECT WORK PLAN AND BUDGET

Activity	Cost Component	Cost Components	Total Budget
OUTCOME 1: ***The governance of the research is successfully agreed between AUDA-NEPAD and ALMA. The research objectives are confirmed to contribute to the achievement of AU aspirations for development of the Pharmaceutical sector in Africa***			
1.1 Develop a costed collaborative project outline with targeted actions and responsibilities to access the manufacturing capacity of local manufacturers in Africa	• Partnership Agreement finalisation • Project Plan Development • Assessment of potential investors/ funders • Development of project - criteria and project proposals	10 days	USD
1.2 Draft a programme document and lobby for mobilisation of resources	Document drafting, Information dissemination and advocacy	10 days	USD
1.3 Implementation of joint collaborative project activities to analyse sixty African pharmaceutical manufacturers and identify 100 pharma manufacturing companies that are qualified or at the cusp of qualification for the WHO GMP certification.			
Budget Outcome 1			**USD**
Outcome 2: ***Research management and dissemination of relevant research findings and knowledge that facilitates the uptake of best practices for sustainable pharmaceutical manufacturing in Africa***			
2.1 Data and information creation / collection / collation	Desk Analysis, Research	25 days x 800 USD	20,000.00 USD
2.2 Development relevant research outcomes	Document design, production and printing, development of web platform, video development	75 days x 800 USD	60,000.00 USD
2.3 Translation (French, Arabic, Portuguese, English + any African language)	Translations services	3 x 3 days x 3 translators x 800 USD	21,600.00 USD
2.4 Dissemination and sharing of findings, lessons and best practices	Webinars, workshops, training sessions, publishing of research findings	3 x 3 days x 800 USD	10,000.00 USD
Budget Outcome 2			**USD**
Outcome 3: ***Cooperative actions fostered between members of the Federation of African Pharmaceutical Manufacturers (FAPMA) and stakeholders who can contribute technology transfer, investment of funds and capacity development to enhance growth of the pharmaceutical manufacturing in Africa***			
3.1 Engagement with stakeholders, technology partners and financial institutions to agree on priority actions	Communication, webinars, training workshops, company restructuring, market analysis, partnership facilitation, recommendation of APIs, tech support	150 x 3 days x 400,00 USD	180,000.00 USD
3.2 Development of cooperative tools and mechanisms	Communication, workshops, meetings	40 x 3 days x 400,00 USD	48,000.00 USD
3.3 Advocacy and awareness	Webinars, workshops, publishing of , research findings, visits, communication		16,000.00 USD
Budget Outcome 3			**USD**
OUTCOME 4: ***Responsible private sector partnerships and targeted investment to stimulate sustainable pharma manufacturing in Africa.***			
4.1 Assessment of structural gaps in pharma companies, opportunities to scale and the identification of options for investment	Consultant Packaging and Investment plans	25 days x 800 USD	20,000.00 USD
4.2 Investor road show	Submissions, due diligence and assessments	5 x 5 days x 800 USD	20,000.00 USD
4.3 Investment facilitation	Partnership Agreement • Project Plan finalisation • Deal implementation		14,400.00 USD
Final Budget			**410,000 USD**

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