AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

1st Consultative Workshop on the Development of a Compendium of Good Policies and Practices

Workshop Report

28 - 30 June 2022 | Nairobi Kenya

Good Pharma Policy and Practices Framework

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List of Abbreviations

AfCFTA	African Continental Free Trade Area
API	Active Pharmaceutical Ingredient
AUDA	African Union Development Agency
COMESA	Common Market for Eastern and Southern Africa
EAC	East African Community
EAHRC	East African Health Research Commission
ECOWAS	Economic Community of West African States
EML	Essential Medicines List
FAPMA	Federation of African Pharmaceutical Manufacturers Associations
FEAPM	Federation of East African Pharmaceutical Manufacturers Associations
GMP	Good Manufacturing Practices
HPT	Health Products and Technologies
NEPAD	New Partnership for Africa's Development
NRAs	National Regulatory Agencies
PMPA	Pharmaceutical Manufacturing Plan for Africa
PPPFA	Preferential Procurement Policy Procurement Act
RECs	Regional Economic Communities
SADC	Southern African Development Community
SAGMA	Southern African Generic Medicines Association
WAPMA	West African Pharmaceutical Manufacturers Association
WHO	World Health Organization

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Introduction

In order to achieve the goals of the African Union (AU) Pharmaceutical Manufacturing Plan for Africa (PMPA), AUDA-NEPAD remains committed to playing its role in supporting Member States and regional economic communities (RECs) to engage in the implementation of initiatives aimed at

a. Enhancing coherence across relevant policies and implementing sector specific projects,
b. Building requisite human resources and skills in the area of health and biopharmaceutical industry,
c. Accelerating access to technology transfer,
d. Improving access to affordable, sustainable and predictable capital,
e. Strengthening and harmonising regulatory systems across RECs/continent,
f. Fostering strategic partnerships and collaboration,
g. Enhancing market data collection systems and market access including through the Africa Continental Free Trade Area (AfCFTA).

This report summarizes the proceedings and outcomes of the 1st consultative workshop on the development of a compendium of Good Pharma Policy and Practices in Africa hosted by the African Union Development Agency (AUDA-NEPAD). The workshop was held on the 28th and 29th of June 2022 at Sommerset Westview, Nairobi, Kenya.

Participants included policymakers and pharma experts from 8 AU Member states and from 5 AU regions, i.e., North (Tunisia and Algeria), South (South Africa and Zimbabwe), Central (Tchad), West (Cote D'Ivoire), and East (Kenya and Ethiopia). Other participants included representatives from 2 RECs (EAC and COMESA) while private sector was represented by the Federation of African Pharmaceutical Manufacturers Association (FAPMA), West African Pharmaceutical Manufacturers Association (WAPMA), Federation of East African Pharmaceutical Manufacturers (FEAPM) and Southern African Generic Manufacturers Association (SAGMA). In addition, as workshop facilitators there were experts from PATH, Pitch World Fast and Kenya Health Federation to facilitate and compile content for the compendium as well as other workshop documents.

Workshop Specific Objectives and Deliverables

The objectives of this first stakeholders' consultative meeting included:

a. Introducing and seeking stakeholders' inputs and buy-in of AUDA's proposed PMPA governance framework to facilitate effective coordination of all activities aimed at supporting local pharmaceutical production in Africa.

b. Deliberating on presentations by Member States (MS) and RECs on existing national/regional pharmaceutical policies, strategies, and initiatives with the goal of identifying best practices to include as content for the compendium of good pharma policies and practices.

c. Assessing and defining what constitutes good national and regional pharma policies, & practices.

d. Identifying gaps/challenges & opportunities in the current national policies/strategies/action plans and initiatives and practical approaches to address them.

e. Compiling the * list of sound policies and practices for inclusion into a continental compendium.

f. Providing a platform for networking among local pharmaceutical production stakeholders.

Workshop Outputs

a. Revised PMPA Governance framework.

b. A Draft list of good pharma policies and practices as content for the compendium.

c. Roadmap for next steps toward finalization and operationalization of the draft of the PMPA Governance framework & the Compendium of good pharma policies and practices for Africa.

Workshop Summary

AUDA-NEPAD representative after opening remarks set the scene for the workshop deliberations by highlighting the importance of an enabling policy environment for the growth of the African pharmaceutical manufacturing sector and thus the need to develop a compendium of such policies and practices. Furthermore, recognizing the good work delivered through a plethora of LPP initiatives currently underway in Africa, AUDA-NEPAD in accordance with its mandate to act as Africa's interface with development partners and to undertake full range of resource mobilization for the implementation of AU's continental and regional priorities presented the proposed PMPA governance framework.

All eight (8) Member States (Algeria, Chad, Cote d'Ivoire, Ethiopia, Kenya, South Africa, Tunisia and Zimbabwe), two (2) RECs (EAC represented by EAHRC, and COMESA) , and four (4) pharmaceutical manufacturers associations (FAPMA, FEAPM, WAPMA & SAGMA) presented for

discussion in plenary their current policies, strategies/action plans/initiatives for LPP from which the workshop identified gaps, opportunities and good policies and practices to form content for the compendium.

Workshop opening Remarks

Dr. Janet Byaruhanga, Senior Program Officer, Health, AUDA-NEPAD, thanked all participants for accepting AUDA-NEPAD's invitation to the consultative workshop on developing a compendium of good pharma policies and practices. She started by highlighting the key achievements and ongoing activities underway toward implementing the PMPA since its adoption by African Union Heads of State and Government in 2007. Dr. Byaruhanga presented the objectives of the 2-days workshop, which were to 1) deliberate on a proposed framework for effective coordination of all PMPA efforts (at National, Regional, and continental) to strengthen Africa's capability and (2) identify current national and regional good pharmaceutical policies and practices to be included in a draft compendium to inform decision and policy making by AU member states and Regional economic communities interested in developing a robust pharmaceutical manufacturing ecosystem capable of sustainably supplying much needed essential medical products of good quality at an affordable cost.

In her opening remarks, ***Ms. Rosemarie Muganda, Regional Advocacy Director, PATH***, highlighted the support that PATH provides to AUDA–NEPAD in convening similar engagements. She emphasized the importance of manufacturing and the need to rely on the skills and expertise we have in the continent to boost and move forward the local manufacturing agenda.

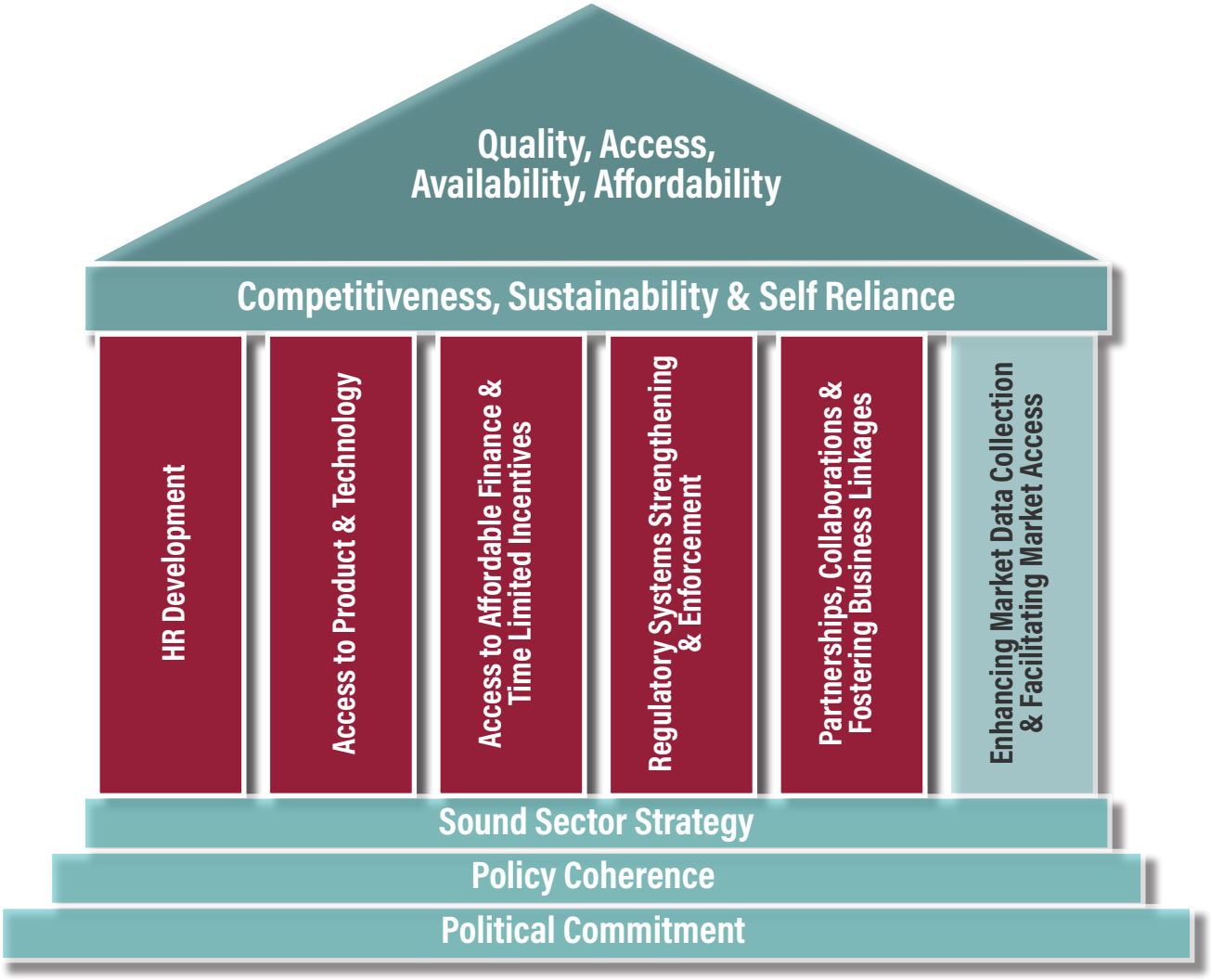
In his welcome statement, ***Dr. Macharia, Team Lead, Local pharmaceutical manufacturing, Ministry of Health of Kenya*** framed the African population landscape and emphasized the high disease burden Africa continues to bear and the limited local production level that has come to light over the past two years, only producing 30% of the products needed. He highlighted the COVID-19 experience in Africa and its impact on access to medical products especially in Low- and Middle-Income Countries (LMIC) and the export barriers on medical countermeasures such as that observed in India, which had to meet its needs before exporting outside its borders. Dr. Macharia highlighted the need for addressing local manufacturing in a coordinated rather than a competitive manner. 'A high level of centralization and organization will prevent resource wastage.' He declared the workshop officially open and wished all participants fruitful deliberations.

PMPA Objectives and Governance Framework

Presented By Dr. Janet Byaruhanga, Head, Health Unit AUDA-NEPAD

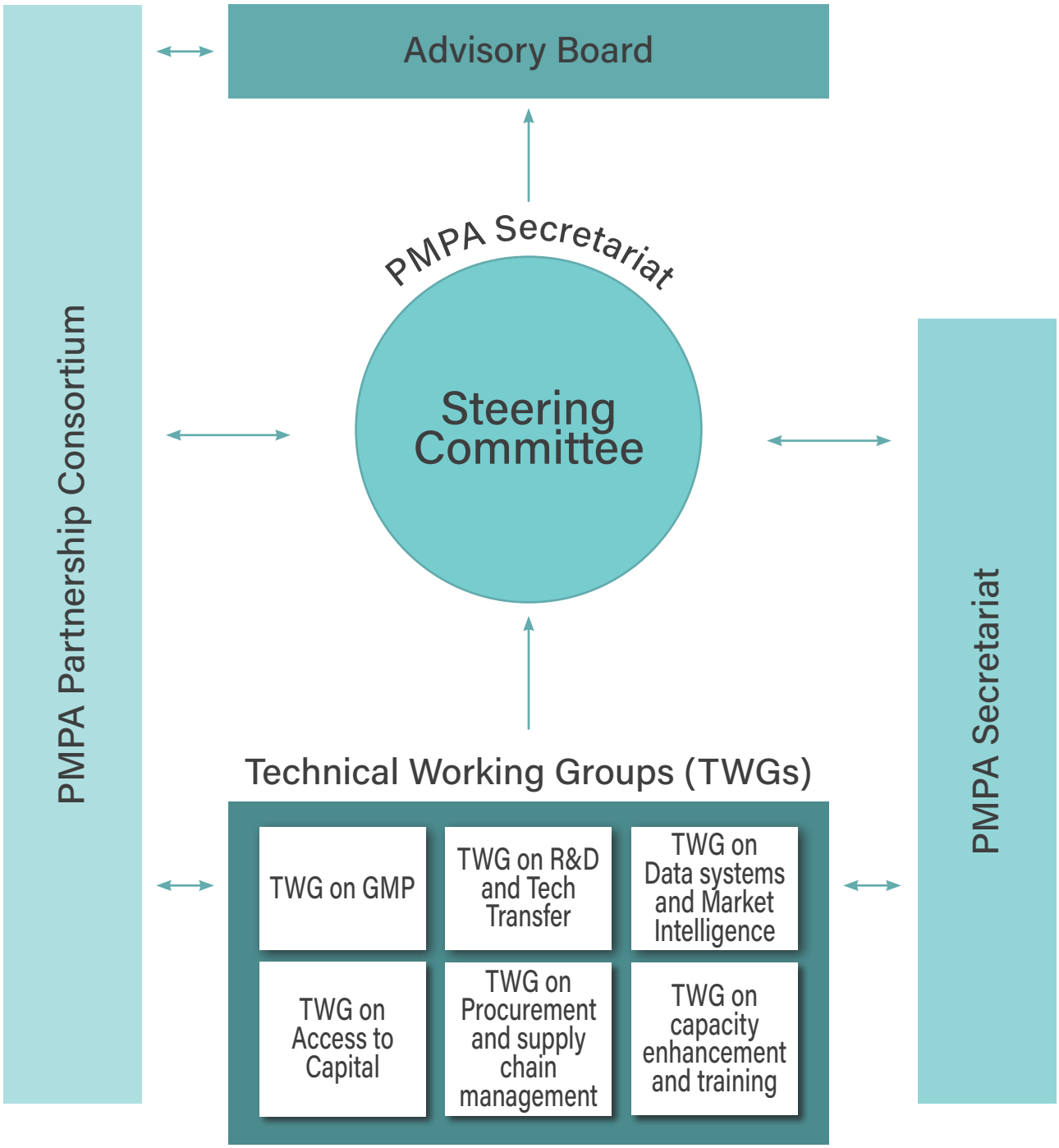
The success of the African pharma industry is founded on political commitment, policy coherence within the different ministries and countries, and sound sector strategies. An enabling environment can be created to promote self-reliance, sustainability, and provision of quality, accessible, available and affordable medicines

Some of the pillars to creating an enabling environment include:



PMPA aims to create industry competitiveness, sustainability, and self-reliance by producing high-quality, accessible, available, and affordable medicines. The PMPA is also tasked with harmonizing the policy framework to ensure that policies are in sync with the local pharmaceutical needs. While there have been notable achievements like the formation of the AMA, AfCFTA- anchored Local Pharmaceuticals Production initiative, the Africa Medical Supply Platform, Home Grown Solutions Accelerator, and 5 Africa Pharma Conference initiatives, the workshop would facilitate the suggestion of other initiatives within the countries and regions to promote harmonization.

The PMPA will consist of a Governing board, a Steering Committee, Technical Working Groups, a PMPA Secretariat, and the PMPA Partnership Consortium, as illustrated in Figure 3.


Advisory Board
PMPA Secretariat
Steering Committee
PMPA Partnership Consortium
PMPA Secretariat
Technical Working Groups (TWGs)
TWG on GMP
TWG on R&D and Tech Transfer
TWG on Data systems and Market Intelligence
TWG on Access to Capital
TWG on Procurement and supply chain management
TWG on capacity enhancement and training

National Policy / Strategy / Initiative For Local Pharmaceutical Production (LPP)

Algeria

*Presented by **Dr. Reda Kessal**, Director of the Strategic Intelligence, Ministry of Pharmaceutical Industry, Algeria*

Algeria is the largest pharmaceutical market in North Africa and is emerging as the center of pharmaceutical production in Africa. 75% of locally produced products are generic drugs. In 2020, through a presidential declaration on a new pharmaceutical industry policy framework, the Algerian Government established the Ministry of Pharmaceutical Industry (MOPI)) to help boost the Algeria's pharmaceutical industry and implement a coherent industrial policy for the sector. The National Agency for Pharmaceutical Products (ANPP) created in 2014, which entered in function in 2018, became an institution under the authority of MOPI in 2020 to ensure a better governance of the pharmaceutical products. Since their inception and building on the work done by the Ministry of Health of Algeria, both organizations have made significant progress in steering the success of the Algerian pharma manufacturing landscape and accelerating the outcomes.

Pharmaceutical products in the Algeria pharma market are classified into four categories including 1) Strictly imported products in instances where there's no capacity for local manufacture; 2) Local products which are produced locally and for which importation is not allowed as the local needs are met; 3) Mixed products which may be imported to bridge the gap not covered by local manufacturing, and 4) Export products which are sold to foreign markets once the local needs are sufficiently met.

The Algerian Ministry strives towards producing quality, efficient products in line with international standards, facilitating exports to global North countries, including America, Europe and Russia. Some of the measures taken by the Algerian Government to protect the local pharma market in Algeria include:

i. Import restriction when local needs are met by local manufacturers
ii. Imports of pharmaceutical products subject to investment in the country within 2 years
iii. A 51%: 49% rule requires multinationals to get a local partner who holds the 51% shares.
iv. Price control & renegotiation of imported drugs during the registration renewal process according to the international prices.
v. Registration of similar medical products to control monopolies and lower the prices.

vi. An observatory at the ministry to monitor drug availability and conduct needs assessments.

vii. Partnership with China for the introduction of raw materials manufacture locally in Algeria (in progress)

The establishment of an entire ministry concentrated on pharma products indicates the willingness and vision of the leaders to progress pharmaceutical investments.

Côte d'Ivoire

Presented by ***Professor Mahama Ouattara,*** a Professor of Medicinal Chemistry and the Deputy Director of the Directorate of Pharmaceutical Activity, Ministry of Health, Côte d'Ivoire

Local pharmaceutical production in Côte d'Ivoire meets only 6% of the country's needs, with 94% met through imports. There is no locally manufactured medical equipment. The market is primarily private sector based with limited public sector participation.

While the pharma market in Cote d' Ivoire is largely unexploited, there are several impeding factors, including:

i. Multiple actors are involved in the pharmaceutical sector's policies, strategies, and regulations, making it very difficult to get authorization. Multiplicity of actors in the pharmaceutical sector: Lack of leadership and scattered actions

ii. Absence of proper product nomenclature.

iii. Preference for imported products even when local alternatives are available.

iv. High numbers of fake and substandard drugs in the markets. Lack of an effective strategy for pharmaceutical market surveillance

v. Lack of research and development.

vi. Lack of human resources – Numbers and qualifications.

The Government has instituted measures to support the existing local industries, including long-term contracts supply as an incentive for local manufacturing, tax exemptions on local pharmaceutical products, and to establish 20 essential medicines that cater for 80% of the needs and promote their local production (MED20/80) – the government Regulate the import of MED20/80: only gap and non-locally manufactured products whould be imported & Automatic suspension of the registration of locally manufactured MED20/80 as soon as local production fully supply the market. To capitalize on the untapped potential in the Cote d'Ivoire pharmaceutical industry, efforts to combat counterfeited medicines and build human resource capacity will be pertinent. In addition, advancing R&D by setting up research centers will promote local manufacturing. Political will, a robust regulatory framework, and a harmonized pharmaceutical market will be pivotal in achieving this.

Chad

Presented by ***Dr. Oksom J. Brice***, Doctor of Pharmacy, Chad

The pharmaceutical industry in Chad had been abandoned for a long time, with the country having only 50 qualified pharmacists in 2012. Along with the severe gap in the workforce, Chad is a landlocked country, making the transportation of drugs harder and subsequently increasing the final cost of pharmaceutical products. Pharmaceutical supply and regulatory systems were set up in 2012 to regulate the public and private sectors. The public pharmaceutical sector consists of 23 provincial supply pharmacies, 1672 pharma deports, and 139 hospital pharmacies. The private pharmaceutical sector is highly unregulated, creating loopholes for proliferation of substandard products. Notably, due to the limited numbers of qualified pharmacists, 381 pharma depots/stores are run by nurses, which has significantly hampered development of the pharmaceutical sector.

Currently, there are no policies or strategies targeting the pharmaceutical sector in Chad, but there is a goal at the ministry level to set up a quality control lab to address the public health threat posed by substandard and falsified medical products. There have been plans to set up industrial units and zones with a feasibility study already done in collaboration with the Italian Government. However, due to lack of financing, no work has been done towards the actualization of this project for the last ten years. According to Dr. Oksom, investing in the human resource capacity of Chad in the pharmaceutical sector is the first step to ensuring sustainability of the industry. The Public-private partnerships approach could be used to set up the industrial unit.

Tunisia

Presented by ***Myriam Khrouf***, Professor of Pharmacology at the Faculty of Pharmacy (University of Monastir) and Director of the Medical research direction at the Ministry of Health in Tunisia

The Tunisian pharma industry was established in the 1970s and had over 40 industries producing drugs, including radiopharmaceuticals and biosimilars. The pharmaceutical sector is a priority for the Government of Tunisia, with the country having ratified AMA. Within the Tunisian Health Policy, the National pharmaceutical policy aims to guarantee equitable patient access to quality, safe, and effective medicines, and medical devices. The policy also aims to ensure the national security of medicines through an effective and innovative local industry.

Tunisia's pharma market comprises 41 manufacturing plants with 141 agreements for manufacturing 16 different dosage forms. There are 15 fully generic companies of which six are entirely under license. The total investment is 1.4Mdnt ($460 million), with total revenues collected in 2020 from this investment totaling 1.2M dnt ($390 millions). The pharma sector in Tunisia employs 9000 people. Among the products produced are radiopharmaceuticals, vaccines, biologics, and other mainstream dosage forms. The Tunisia pharma industry covers 54% of the Tunisian market value. Tunisia exports to countries within Europe, including France, Malta, Italy, and Asian Countries like UAE, Iraq, and Lebanon. Tunisia also exports to over 15 African Countries, including Chad, Benin, Uganda, and Rwanda. Tunisian companies have invested in manufacturing plants in other African countries, including Algeria (Medis), Senegal (Medis), Ivory Coast (Teriak), and Cameroon (Teriak)

Since 2020, there have been significant efforts aimed at strengthening the local manufacturing capacity of Tunisia, including the establishment of the working group for the study and implementation of the vaccine manufacturing projects, one of the 6 countries chosen by WHO to produce COVID-19 mRNA vaccine, biotechnology, medical device & pharmaceutical industry considered as priority sector by the government , and the development of pharma reports, including the one on the development of strategies to support vaccine and pharmaceuticals production in Tunisia with the World Bank assistance.

Kenya

Presented by ***Dr. Gerald Macharia***, Team Lead local manufacturing, Ministry of Health, Kenya

Local Production in Kenya

Kenya is the hub of pharmaceutical manufacturing within the East African Community, with approximately KES 100 billion ($856 million) worth of annual pharmaceutical expenditure. This is almost 50% of the EAC market, estimated at US$ 2.1 Billion in 2017, and approximately 8% of the total annual expenditure in Sub-Saharan Africa. Kenya has 32 established local pharmaceutical companies, most of which manufacture non-sterile products such as tablets, capsules, syrups, suspensions, ointments, and creams with solid dosage forms and account for approximately 55% of the local products and sterile products account for 2.7%. Notably, only two companies have met the WHO GMP and NRAS certifications.

Local Production in Kenya includes 116 medical products and 82 non-pharmaceutical products, including syringes, surgical masks, disposable theatre capes, hospital linen, and PPES. Out of 764 products in the Kenya Essential Medicines List (KEML) 2019, only 118 (15 %) were found to be locally manufactured.

According to the Economic Survey Report of 2020, Kenya exports medical products worth KES 11.2 billion (0.112 billion USD) to countries in the COMESA region.

Policies that guide Healthcare in Kenya

The Kenyan Government focuses on the pharmaceutical industry with many policies and laws enacted to regulate the industry. Some of these include:

i. Constitution of Kenya, 2010, enshrines providing the highest quality of health to all Kenyans regardless of ethnic affiliations, religion, and social status.

ii. Vision 2030 envisages Kenya to be a globally competitive and prosperous nation with a high quality of life.

iii. Health Act 2017 establishes a national health system encompassing public and private institutions.

iv. The various essential lists of Essential Medicines List (EML), Essential Diagnostics list (EDL) and EML Guiding Policies

v. The health Policy 2014-2030 is geared toward ensuring the availability of effective, safe, and affordable HPTs

Through the Ministry of Industrialization and Enterprise Development, the Government of Kenya has developed the Preferential Procurement Master Roll No. 1 of 2022, which comprises products to be accorded preferential procurement in the public sector. This Master Roll comprises 128 Health Products and Technologies (HPTs), mainly pharmaceuticals and medical devices which 30% should be procured locally by public institutions through a government initiative dubbed "Buy Kenya - Build Kenya initiative".

According to Dr. Gerald, while there has been progress, policy changes are required to advance the pharma industry in Kenya to improve self-reliance. Some proposed approaches include:

i. Establishment of special economic zones (pharmaceutical villages) where companies can share common facilities like testing laboratories and packaging materials

ii. Amendments to the Public Finance and Management Act to convert the HPT taxation regime from exempt to zero-rated status.

iii. Abolishment of the heavy taxes, fees, and levies imposed on API, pharmaceutical manufacturing equipment, packaging to encourage the upgrading of factories and new investments.

iv. Local manufacturing companies to be facilitated to diversify their product ranges to include essential HPT that are currently not manufactured locally.

Zimbabwe

Presented by ***Masimba Dube,*** a Zimbabwean Pharmacist and Health Economist. Masimba currently works in the Directorate of Pharmacy Services in the Ministry of Health and Child Care, ZImbabwe.

Overview of the Zimbabwe Pharmaceutical Industry
There are 13 Manufacturers with the capacity to produce, Oral Solid Dosage, oral liquids and external topical formulations, among them only 2 make parenteral solutions as well. There are 810 community pharmacies located mainly in major cities and Over 2500 public and private health facilities.

By 2020/21, the pharmaceutical Market Size was estimated at USD$ 367 million serving a total population of 14.6 million. Local production caters to only 10% of the pharmaceutical needs of Zimbabwe, with 90% of the medicines for local consumption imported mainly from India. Zimbabwe also relied heavily on donated medicines. Two companies in Zimbabwe export to countries within the SADC region, including South Africa, Botswana, Zambia, Namibia, and Lesotho.

Pharmaceutical Production Policies & Strategies
A Pharmaceutical Manufacturing Strategy (2021-2025) was rolled out in Zimbabwe and is anchored on six pillars, including Research and Development; Expedited registration processes; Export orientation; Compliance with Good Manufacturing Practices; and Government support

Fiscal Incentives instituted for the pharmaceutical industry include Exemption from import duty for raw materials, Exemption from import duty for equipment, Full export duty exemption, and Reduced product registration fees ($900 Vs. $2500 for international). Non-Fiscal Incentives are also in place to foster local production. Some of these include Expedited product registrations for local manufacturers (3-6months Vs. 18-24months for foreign companies), Preferential domestic tendering for locally manufactured medicines, 15% price preference for local manufacturers on the international tendering system, and the existence of a Legally protected/ restricted list of products from importation.

The Medicines Control Authority of Zimbabwe (MCAZ) has been on a facilitatory regulatory pathway since 2016. It seeks to support local production by assisting and guiding local companies to attain GMP. In this regard, MCAZ has developed several pieces of training on human resources capacitation of key GMP and registration issues such as Bioequivalence and Good Manufacturing Practices. MCAZ also holds technical sessions during which local industry players are introduced to current trends in the pharmaceutical industry. MCAZ has also developed the small business support unit, which supports the local industry by reviewing the schematics of new green field pharmaceutical industries and providing facilitative recommendations. This has resulted in establishing two GMP-approved facilities over the past two years.

Ethiopia

Presented by: ***Dr Sufyan Abdulber***, Pharmaceuticals and medical equipment advisor, Federal Ministry of Health, Ethiopia

Ethiopia is the second-most populous country in Africa, with a population of more than 110 million and growing by 2.3 million annually. It is also among the fastest-growing economies in the world, having grown by 9.4% from 2010 – 2020. Ethiopia follows a three-tier health system with more focus on primary-level healthcare.

Ethiopia pharmaceutical market

In 2015, the Ethiopian pharmaceutical market was estimated to be $450M, with an estimated value of $1.8Bn by 2025. The Ethiopian pharmaceutical market is highly dependent on imports which account for up to 90%.

Currently, 11 pharma manufacturers are operating in Ethiopia, but only 3 meet the local GMP requirements, and none are GMP certified internationally. Most of the local manufacturers in Ethiopia operate far below their installed capacity. The Government of Ethiopia rolled out the National Strategy and Plan of Action for pharmaceutical manufacturing in Ethiopia (2015 – 2025), which is founded on ten strategic Objectives, including the development of pharma hubs for cluster development, creating incentives for companies along the value chain and, Creation of a research and development platform among others.

Ethiopia boasts of the Kilinto Pharma Industrial Park (KPIP), dedicated to pharmaceuticals, vaccines, other biological products, and medical device manufacturers. It consists of 15 government-owned and ten privately owned pharmaceutical companies. The industrial park aims to provide one window service and host facilities like Banks, Logistics firms, R&D facilities, Training canters, Regulatory consultancies, calibration institutions/companies, etc. This park has been enabled by the institution of incentives including 255 price preference for locally produced products, Loss carry forward for up to 5 years, Personal income tax exemption, long-term employment visa work permit, 100% customs duty exemption on the importation of Raw materials/inputs, Capital goods/machinery, and spare parts.

South Africa

Presented by ***Gillian Christians***, the Deputy Director in the Pharmaceuticals and Medical Devices Directorate, South Africa

South Africa is currently the largest pharmaceutical market in Sub-Saharan Africa, with the total pharmaceutical expenditure estimated at $4.1 billion in 2019 and $3.6 billion in 2020. It has a health expenditure of 525 US$ per capita.

South Africa producers have as a varied capacity for solids, liquids, ampoules, effervescent tables and sachets, injectable, etc. across 25 registered formulators and in multiple forms API (human & animal), Vaccines (human & animal), Liquids, Creams, Ointments, Tablets (anti-microbial, anti-pyretics, etc), Capsules, Granules/Powders, Injectable (anesthetics, corticosteroids, etc.), Steriles (ampoules, dental cartridges, drops, LVPs, SVPs), radiopharmaceutical. The local needs are met by local production.

Policies and Strategies: The preferential procurement policy (PPPFA) empowers the designation of specific industries for local procurement by organs if the state supports industrialization. A single exit pricing strategy is instituted through the National Health Department, and the local manufacturers get a 15% price preference. The sector's challenges include a lack of specific pharma funding, delays in the regulatory process, limited R&D, and electricity supply shortages.

South Africa has pushed to Develop and enhance local manufacturing capacity and capabilities. (Local Content Regulations came into effect on 7 December 2011 through the 2011 PPPFA), the goal being to Increase localization and uptake of local products within public and private sector & increase export potential among others. Industrial policy interventions included the Industrial Policy Actions Plans (IPAP) and the National Industrial Participation Program (NIPP), linked to public procurement, which aims to promote development of domestic manufacture capacity. In terms of the Re-Imagined Industrial Strategy, a Masterplan for Medical Health products is currently under development to strengthen the medical devices sector as the first phase. It aims to create an enabling environment and support mechanisms to increase localization and innovation, public and private procurement, and competitiveness to increase participation in export markets. The pending Procurement Bill will aim to further leverage public procurement of locally manufactured products, in all spheres of government. The Manufacture Support program, an incentive program developed in 2019, targeted at the pharmaceutical industry has not been approved to date.

Presentation of Rec/Regional Policy/Strategy/ Initiative for LPP

East African Health Research Commission (EAHRC)

Presented by: ***Mr Fabian Mashauri.***

East African Health Research Commission was operationalized in 2015 as the principal advisory institution to the EAC on health matters. The EAC rolled out the 1st EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC -RPMPOA) 2012 – 2016, whose key achievements included establishing the manufacturers' regional associations and training over 300 technical personnel on pharmacovigilance, clinical trials, GMP, and dossier evaluation. Challenges in implementing the (EAC -RPMPOA) 2012 – 2016 included lack of awareness of WTO TRIPS flexibilities, unavailability of data on the regional pharma market

In 2017, the 2nd EAC -RPMPOA (2017 – 2027) was launched with four critical targets, including:

i. Decreasing dependency on pharmaceutical imports from outside EAC from more than 70% to less than 50%.

ii. Supporting the expansion of the product portfolio of EAC firms to cater to more than 90% of disease conditions.

iii. Ensuring at least 50% of purchases by EAC national medicines procurement agencies are sourced from EAC pharmaceutical manufacturers.

iv. Having at least five (5) companies to produce more advanced pharmaceutical formulations such as delayed-release formulations, small volume injectables, and double-layered tablets, among others.

Common Market for Eastern and Southern Africa (COMESA)

Presented by: ***Ms Esther Mwimba***, Senior Private sector development officer, Industry & Agriculture Division, COMESA

The COMESA Industrial Strategy (2017-2026) prioritizes the pharmaceutical sector for industrial development in the COMESA region. In 2020, the region imported

pharmaceuticals worth USD 5.6 billion and exported USD 457 million, with intra-regional trade being USD 178 million.

COMESA conducted market research to identify and analyze supply and demand gaps in the pharmaceutical market. A key finding was that imports into the region are significantly higher than the inter-regional trade causing local manufacturers to lose out on the imports. Currently, COMESA is working on a 4-year project (2023 -2026) supported by the AfDB dubbed "COMESA Support Towards Regional Pharmaceutical Sector Development in the Region – Public Goods Window" This project is aimed at promoting the institutionalization and domestication of the PMPA and the African Medicines Regulatory Harmonization Program.

Regional Pharmaceutical Manufacturers' Perspectives on Good Pharma Policies and Practices

Federation of African Pharmaceutical Manufacturers Association (FAPMA)

Presented by ***Emmanuel Mujuru***, Chairman of Federation of African Pharmaceutical Manufacturers Associations (FAPMA)

The vision of PMPA is to develop a competitive and enduring pharma industry in Africa responsive to the continent's needs for safe, affordable, and productive medicines. The mission of FAPMA is to facilitate regional manufacturing collaboration to enhance opportunities for self-sufficiency through advocacy and partnerships.

The work and mission of FAPMA are founded on the heavy burden of tropical diseases, infectious diseases, and neglected tropical diseases. Despite this heavy disease burden, local pharmaceuticals account for only 25% – 30% of the supplies in the African market. The African pharmaceutical market size is estimated at 45 billion USD.

High-profile initiatives like the Global Fund have increased funding for public health programs and consequently the demand for WHO - Prequalified pharmaceutical products, which are still very few in Africa.

Policy Issues in Africa
The greatest challenge for policymakers is the lack of policy elements that function as constructive steps to build on existing conditions and local institutional capacities.

Lack of policy harmonization, where health policies are often pitted against local industrial policies, results in local products being significantly expensive compared to products in the international market.

Human resources in the African Pharma market, including engineers, scientists, and skilled staff, impedes GMP attainment. The skill to produce complex formulations like vaccines, sterile products, and fixed-dose combinations is also lacking.

The pharmaceutical registration process in most African countries is cumbersome, expensive, and corrupt, limiting local and foreign investments.

Federation of East African Pharmaceutical Manufacturers (FEAPM)

Presented by ***Mr. Perviz Dhanani***, Director FEAPM and Managing Director, Universal Corporation Limited.

FEAPM is the Apex Association of Pharmaceutical Manufacturers within the East African Community (EAC). It was established in 2011 to foster the interests of EAC Pharmaceutical Manufacturers and promote Local Pharmaceutical Production within the East African Community.

Political will is the most critical factor in the success of the local pharma industry. Production in Africa is expensive, putting her in an unfair position with foreign industries, particularly India and China. During Covid, universal Corporation Limited, the only WHO prequalified industry in Kenya, supplied 19 countries with Cotrimoxazole which never ran out of stock. The tax policies need to be changed to lower production costs and consequently lower the final cost of medicines, harmonizing Africa's registration and regulatory framework. There is a deficit in human resources, which pushes industries to contract expatriates who charge exorbitant fees. It is therefore pertinent to adopt mechanisms to ensure industry can thrive.

Donors need to support local manufacturing by awarding tenders to local companies that meet the required GMP standards.

The local production of APIs is limited by the lack of guaranteed markets and the stringent regulations on the chemicals used.

South African Generic Medicines Association (SAGMA)

Presented by ***Gertrude Mothibe,*** Chair SAGMA.

SAGMA Represents generic manufacturers in the SADC region and includes associates with interest in the industry, industry associations, and pharmacy professional associations. The SAGMA region presents significant opportunities in pharma owing to the high prevalence of HIV, TB, and other non-communicable diseases.

Regulatory practice in SAGMA

The regulatory practice is stable and supportive. A harmonized regulatory body known as ZAZIBONA assesses essential medicines and drugs for priority diseases like HIV, TB, malaria, and reproductive health products in the SADC region. SADC pharmaceutical program was formed to improve self-sustainability by harmonizing standard treatment guidelines, promoting joint procurement of medicines, and developing competent human resources for the pharma industry.

SAGMA plays a key advocacy role in ZAZIBONA and an advisory role on AMRH, promoting regulatory harmonization. Despite the enabling factors, only 30% of the required pharma products are produced locally in the SAGMA region. Notably, through advocacy led by SAGMA, the petition to set up a regulatory body for pharma in Lesotho reached parliament on the 24th of June 2022.

West Africa Pharmaceutical Manufacturers Association (WAPMA)

Presented by Ms Lucia Addae-Ntiri, Executive Secretary, WAPMA

WAPMA aims to promote self-sufficiency through collaboration, policy harmonization, and the elimination of trade barriers. The west African pharma market consists of large, medium, and small-scale companies. In Ghana, for instance, there are 40 large pharmaceutical manufacturing companies. The smaller companies are not well regulated, creating loopholes for substandard medicines. WAPMA advocates for determining market needs before establishing companies to prevent regional product duplication. Investment opportunities in the West African pharma market include manufacturing vaccines, APIs, herbal medicines, packaging materials, support services, and bioequivalence studies. Affordable and long-term financing in the local currency is a significant limiting factor for the pharma industry.

The Ghanian Pharma industry is growing due to high political will and government support.

Group Work- Compendium of Good Pharma Policies & Practices & PMPA Governance Framework

The delegates were split into two groups for a deep dive on good pharma policies and the PMPA governance framework. Group 1 consisted of the delegates representing the member states and RECs while group 2 consisted of delegates from the Regional pharmaceutical associations and private sector federations.

Group Presentations On Good Pharma Policies and Practices

The following list outlines existing good pharma policies and practices that have been implemented in various countries and regions that could be incorporated in the Compendium of good policies and practices for pharma in Africa.

1. Development and implementation of national medicines/drug policies
2. Clear investment proclamations which specify priority areas and incentives for investors (Ethiopia, Côte d'Ivoire, SA)
3. Special Economic Zones for pharmaceutical companies with a clear basket of incentives
4. Development of Pharma Parks with all round amenities providing a "one-stop-shop" for pharma investors – (Ethiopia, Côte d'Ivoire, Senegal,)
5. Implementation of a customs union within RECs (EAC, ECOWAS, SACU)
6. Establishment of Biotech centers to support R&D in biologicals with incentive for producers such as land, tax exemptions – (Tunisia, South Africa)
7. Zero taxes on raw materials, equipment, (Côte d'Ivoire, ALL)
8. Tax holidays for Foreign Direct Investments (FDI) into pharma (Kenya – up to 3 years)
9. Public Private Partnerships in setting up local manufacturing plants (Chad, Côte d'Ivoire, Tunisia)
10. Prioritization of local pharmaceutical industry in access to foreign currency allocation for countries with forex allocation mechanisms (Ethiopia)

11. Clear development project strategies at regional and national levels
12. Prioritization policies for local products including Procurement Price Preferences (15% to 25%), importation restrictions, and tender awards to 30% of local pharma companies.
13. Review of curriculums in pharmacy schools to increase focus on industry and production in a bid to strengthen the human resource in pharma (Ethiopia, SA, Algeria).
14. Sub-contracting manufacturing plants to foster technology transfer
15. Priority review of dossiers for local companies (Tunisia, Algeria)
16. Regional pooled procurement mechanisms e.g., SADC Mechanism through ZAZIBONA

Pain Points and Suggested Policies and Practices

The delegates identified pain points and grouped them into various categories with suggestions of policies and practices that could be instituted.

1. **Financial Incentives**

Increase access to affordable financing for local manufacturers by:

- Developing an Industry Specific Development Fund- Pharma Fund that allows for a moratorium- grace period of 2years.
- Providing for a corporate tax holiday of 10 years to manufacturers and an additional 5-year tax holiday for investment into API manufacture or vaccine production
- Allowing 100% Capital expenditure with no taxation in the year of expenditure for expansion and reinvestment and not over a long period.
- Subsidizing lease renewal for land used for Local pharmaceutical manufacturing.
- Wavering import duty and domestic levies for all local pharmaceutical manufacturers
- Cover for forex exchange depreciation- Quote in Hard currency
- Prompt payment of arrears owed to local manufacturers

2. **Set up Special Economic Zones** for local pharmaceutical manufacturing with, free Land, good supply of electricity, water, internet, shared services, good road access.

3. Market Access

- Preferential procurement via the Framework Contract Tendering Process for essential drugs would help support the industry. Ensure the process is a Win-Win for Manufactures, MOH, GHS and other key stakeholders.
- Reserve 50% or more of all governmental tenders for local manufacturers.
- Implement a Restricted Medicines List for local manufacturing only.
- Support generic production through the availability of intellectual property (patents) acquisition by the government. This would be acquired from other countries or institution to support the pharmaceutical manufacturing Industry.
- Promote preferential pricing (25% price preference) of products and audit the process periodically to ensure that pharmaceutical manufacturing companies have adequate funds to invest in and grow their companies and the industry.
- To create a pull procurement system where medicines locally manufactured are preferred by Governmental agencies and patients through effective branding and marketing.
- Formulate a just in time system for the development and consumption of new products, new vaccines, and orphaned medicines.
- Organize fairs including Pharmaceutical Fairs and Exhibition.

Proposals for Donor Organizations on enhancing Market access for locally manufactured medicines

- Clear incentives for local manufacturers (i.e., 15% price preference as allowed for by the World Bank,
- Reservation quota for local manufacturers (minimum of 30%),
- Clear guidelines to procurement agencies to buy from locally manufactured products
- Local procurement laws should buy from local manufacturers

4. Improved Quality

- To invest in the top pharmaceutical companies with comprehensive and timely investment to help attain the cGMP standard.
- To invest in the infrastructure and the acquisition of world class equipment for pharmaceutical manufacturing.

- Create a GMP Road map
- Invest in ensuring regulatory harmonization in Africa
- Redefine Local packaging versus Local manufacturing.
- Enforcement & Regulatory Standards- No Counterfeit, Sub-standard & Illegal medicines on the market

5. **Human Resource for Local Manufacture**
   - Create a world class curriculum with experienced facilitators to train talent for the pharmaceutical Industry.
   - Fund research and development of new innovator drugs by Accredited bodies such as Universities and Research centers.
   - Educate and train journalists, regulators, policy makers, service providers, distributors, researchers, financers, amongst others with the necessary skill set for the pharmaceutical Industry.

6. **Institutional and Governance Structure**
   - Form a Pharma Inter-Ministerial Team- Made up of Ministers in key sectors that ensure the effective implementation of the Pharma Strategy and policy harmonization.
   - Create a CEOs Consultative Group- A platform for the CEOs in the pharmaceutical Industry to engage and re-strategize with the Ministry of Trade and Industry and Health.

Group Presentations on PMPA Governance Structure

Group members deliberated on the AUDA'S proposed PMPA governance structure with particular focus on Technical Working Groups. They suggested roles and responsibilities for each TWG and also agreed to add one additional TWG to the structure. Proposals were made to rename the Advisory Board the 'Governing Board' and ensure that its membership includes:

i. AUDA- NEPAD
ii. 2 high level Advocates
iii. 2 FAPMA Members
iv. Development partners

Among others, the Roles of the Governing body should include:

- Coordinating the activities of the Steering Committee and the TWGs
- Reporting to AUDA-NEPAD to ensure effective implementation.

The roles of the steering committee include:

- Coordinating the activities, programs, and projects of the TWGs.
- Monitoring implementation of the roles of the TWGs.

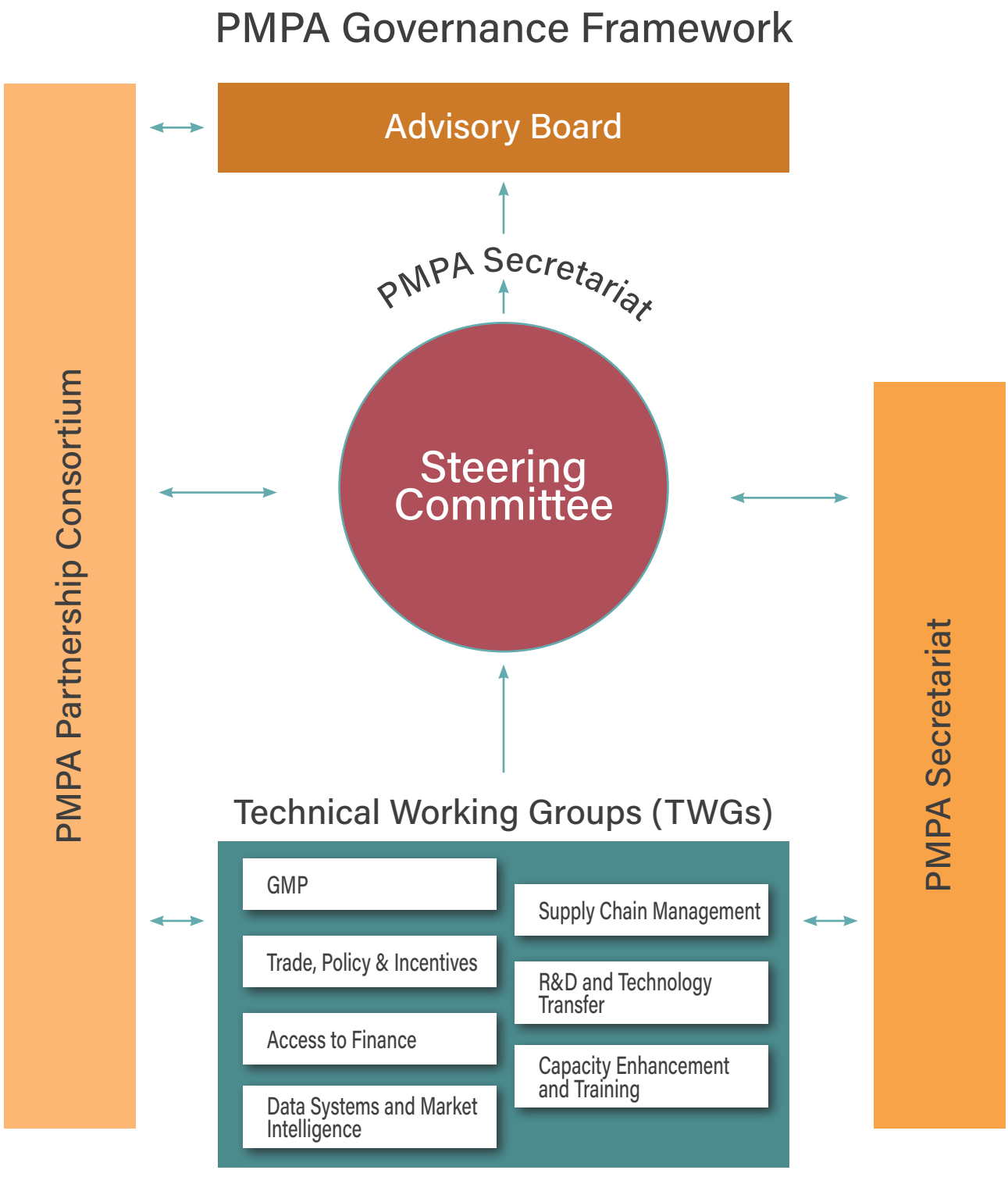
Proposed TWGs and their roles are illustrated in the table below:

Technical Working Group	Roles and Responsibilities
GMP	- Create a baseline for GMP in the continent by reviewing gaps to develop priorities areas for manufacturers. - Develop GMP (WHO-PQ, L-GMP, R-GMP) roadmaps - Coordinate with the relevant TWGs to advance GMP compliance e.g., Access to Capital & Capacity enhancement and training - Serve as a technical resource base for manufacturers on GMP - Redefine Local packaging versus Local manufacturing (Change of tariff heading) - Ensure Enforcement & Regulatory Standards- No Counterfeit, Sub-standard & Illegal medicines on the market - Institute a framework for Mutual recognition
Access to finance	- Conduct a situational analysis with respect to funding gaps and requirements for the industry across the continent, - Conduct landscape analysis of available funding for the industry and link it to the industry (develop a database to serve as a resource base), - Motivate for bridging funding to facilitate intercontinental trade, - Advocate for large health financers (GF, USAID, UN agencies) to procure through local manufacturers - Serve a technical resource base on available funding opportunities, eligibility for financing and support in development of financial proposals – Best practice guidelines - Spearhead the development of an Industry Specific Development Fund providing affordable financing at low interest rates and allowing a favorable moratorium.
Capacity enhancement and training	- Conduct a training needs assessment for across the continent within the industry and training institutions (both preserve and post basic training) - Assessing available training programmes on the Influence on training programmes on the continent - Source technical expertise to support other TWGs - Identification of technical expects to support capacity development needs

Technical Working Group	Roles and Responsibilities
	- Link with other training TWGs to training priorities - Explore avenues to build skills in Conceptual drawing, Master plans, Detailed drawing, Utilities set up, HVAC set up, etc. - Advance training in Managerial Skills, Business Plan Development, Succession Planning, Communication
R&D and Technology transfer	- Assess the intellectual property rights systems in favour of patent registrations in Africa (utilised national patent office, regional IPs (OAPI) WHO patent pool) - Develop a framework for technology transfer (including monitoring and evaluation mechanisms) – cocreation of technology - Develop a roadmap to build the capacity of Local manufacturers in Product Portfolio Expanding - Support Companies to make Innovative Medicines - Strengthen Collaboration of Industry and Academia and Research Institution - Train professionals to be ready for Industry - Spearhead the setting up of Innovation and Incubation Hubs (Formulation Development)
Data systems and Market Intelligence	- Develop centralised sector specific database/repository for ease of access to information by producers, - Support development of policies on standardised reporting of data across member states, - Support data verification and validation of reported data, - Provide market intelligence to guide investors/manufacturers where and what to produce, - Promote and guide continental HPT market surveys - Develop key performance indicators for Monitoring and Evaluation of the various interventions

Technical Working Group	Roles and Responsibilities
Supply Chain Management	- Conduct a situational analysis of the gaps and supply chain capacities across the continent - Assess the available transport modalities and costs for FPP and raw materials - Assess storage capacities for various pharmaceuticals, including cold chain, and assess distribution capacity and reverse logistics - Assess waste management capabilities - Quantification of product volumes requirements for each member state and local capacity to support the needs
Trade, policy &incentives	- Develop guidelines to ensure local manufacturers enjoy AfCFTA benefits - Push for the implementation of trade Incentives- Study the Ethiopia Model or Ghana Model - Engage leaders on making a level playing ground through zero-rating on Raw materials, packaging materials, inputs and equipment and implementation of non-tariff barriers e.g., Political commitment to get rid of no tariff barriers. - Create guidelines and push for export Subsidies - Policy and advocacy training to build the capacity of manufacturers on accessing and communicating with leaders to get political buy-in and support.

The revised governance framework based on participants input is illustrated below:



Next Steps

WORKSHOP REPORT
approved by Secretariat

1

15 July 2022

18 July 2022

2

FINAL REPORT
disseminated to countries and RECs

FINAL DRAFT OF PMPA GOVERNANCE FRAMEWORK
shared with countries and RECs

3

25 July 2022

2 August 2022

4

FINAL GOVERNANCE FRAMEWORK AND DRAFT COMPENDIUM

FINAL DRAFT OF PMPA GOVERNANCE FRAMEWORK
By Countries and RECs

5

12 August 2022

22 August 2022

6

VIRTUAL MEETING WITH RECs
selected Member States and executives of the Associations

SECRETARIAT CONVENES THE INAUGURAL GOVERNANCE MEETING

7

11 October 2022

Annex

Workshop Programme

Location: Sommerset Westview, Nairobi, Kenya

Date: June 27 -29, 2022

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

Program

Scheduled time (EAT)	Program	Speaker (s)
	Guest arrival and check in 27th June 2022	
	Day 1: 28th June 2022	
08:30 - 09:00	Registration	All
09:00 – 09:05	Opening remarks	Dr Janet Byaruhanga Head, Health Unit, AUDA-NEPAD
09:05 - 09:10	Welcome statement	Dr Gerald Macharia, Team lead local manufacturing Ministry of Health Kenya
09:10- 09:30	Round of Introductions	
09:30 - 09:50	Meeting Objectives & PMPA Governance Framework	Dr Janet Byaruhanga Head, Health Unit, AUDA-NEPAD
09:50 - 10:30	Group Photo & Tea Break	
10:30 - 11:30	Presentation of National Policy/strategy/initiative for LPP	Algeria Cote d'Ivoire Tchad Tunisia
11:30 - 12:30	Presentation of National Policy/strategy/initiative for local production of pharmaceuticals (LPP)	Zimbabwe Kenya Ethiopia South Africa
12:30 – 13:30	Discussion	All
13:30 – 14:30	Lunch Break	All
14:30 – 15:30	Presentation of REC/regional Policy/strategy/initiative for LPP	EAHRC COMESA
15:30– 16:30	*Discussion*	All
16:30	*Wrap up and day 2 outline*	Dr Janet Byaruhanga Head, Health Unit, AUDA-NEPAD
	End of Day 1	

Day 2: 29th June 2022		
09:00 – 10:00	Presentation of Regional pharmaceutical manufacturers perspectives on good pharma policies and practices	FAPMA FEAPM SAGMA WAPMA
10:00 – 10:30	*Discussion*	ALL
10:30- 10:45	*Presentation of the terms of reference for the Group Work*	Dr Janet Byaruhanga Head, Health Unit, AUDA-NEPAD
10:45 – 11:05	Tea Break	
11:05 – 12:05	*Groups* deep dive on: 1- The PMPA governance framework 2- Curating content for the good pharma policies and practices compendium	Group 1: Member states ENG Group 2: Member states FR Group 3: RECs Group 4: Pharmaceutical Associations
12:05 – 13:25	Group presentations	Group 1 Group 2
13:25 – 14:30	Lunch	
14:30 – 15:30	Group Presentations continue	Group 3 Group 4
15:30- 16:30	Presentation and discussion of summary of content for the Compendium	
15:30- 17:00	Closing remarks	-Private sector representative -Member states representative -REC representative -AUDA-NEPAD representative
17:00 onwards	**END of WORKSHOP Tea and networking**	

Stakeholders

Member States

Regional Economic Communities (RECs)

Pharmaceutical Manufacturers Associations

Federation of East African Pharmaceutical Manufacturers FEAPM

Federation Of African Pharmaceutical Manufacturers Associations

SAGMA Southern African Generic Medicines Association
Access to affordable quality medicines

Private Sector Federations

Kenya Healthcare Federation
The Health Sector Board of KEPSA

Partners

PATH

Pitch World Fast
Sell without frontiers

Workshop Photos

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Good Pharma Policy and Practices Framework