



United Nations
Economic Commission for Africa

AfCFTA a Game Changer:

Realising the Pharmaceuticals Manufacturing Plan for Africa (PMPA)

LANDSCAPE & LESSONS LEARNT

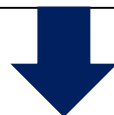
Economic Commission for Africa



21 November 2019
Addis Ababa, Ethiopia

The AfCFTA anchored Initiative

The AfCFTA anchored initiative: *access to safe, affordable medicines* while promoting *sustainable social and economic growth* through the realization of the Pharmaceutical Plan for Africa (PMPA)



Objective 1



Pooled Procurement

Objective 2



Local Production

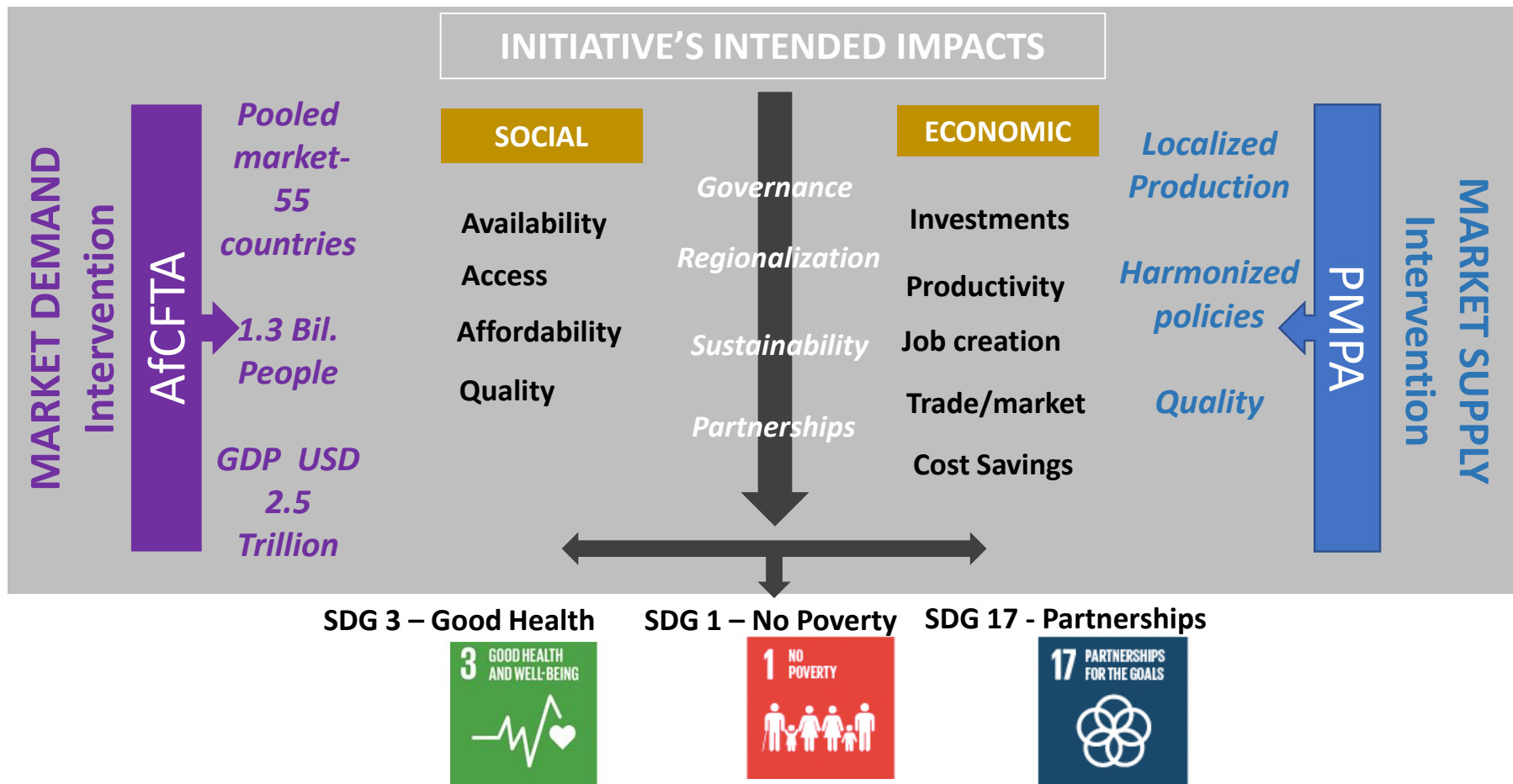
Objective 3



Quality Standards

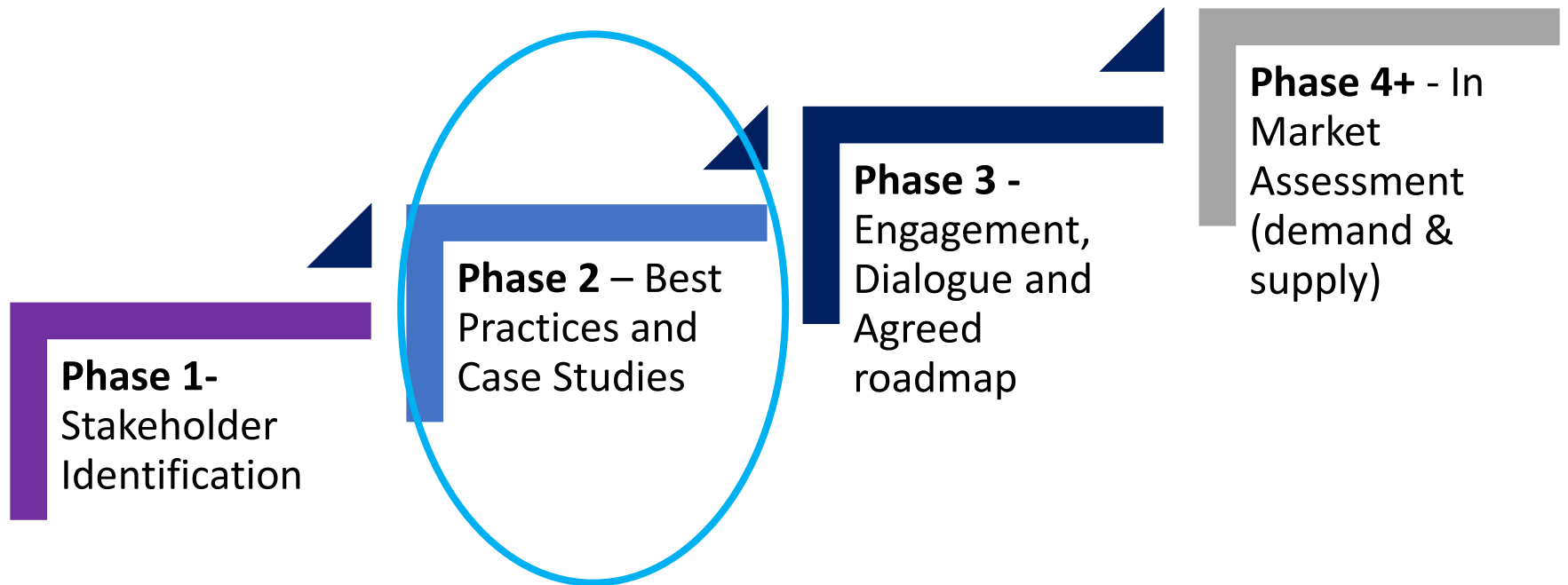
The Framework

Private Sector; Partnerships; Cross-Country Data and Information; Enabling Policies, etc.



Operationalizing the Initiative

The road ahead requires long-term top-level leadership and commitment and investment - Today our 1st Engagement



Why? - Pooled Procurement (PP)

>70% of government's health spending (% GDP) is for medicine procurement---any small reduction in costs can have a huge impact...



Pooled Procurement Outcomes and Impact

Leveraging resources cross country

Cost –Efficiencies & Savings

Affordability: pooling demands for better supplier negotiations

Improved access

Secured & efficient supply chain

Improved Quality

Improved ability for data, forecasting and market

State of Play - Pooled Procurement (PP)

PP Key Enablers

- Harmonization of **procurement laws and policies**
- Harmonization of **medical product registration** and QA
- Procurement **Agent/Partner**
- **Logistics, Warehousing and Distribution Partners (PPP)**
- **Capable/Willing Suppliers/Manufacturers**
- **Financing/Capacity for implementation**

Procurement Options/Models



- Informed buying
 - Coordinated/informed buying
 - Group contracting
 - Central contracting
-
- Selective use of donor procurement (UN, PEPFAR, GAVI)
 - Stock out services (e.g IDA)

Models – Global PP

Average
40% cost-
savings

	PAHO Vaccine	OECS	GCC	Arab Maghreb Union	Pacific Islands
Year established	1979 (23)	1986 (6)	1976 (26)	1988 (12)	1999 (3)
Status	Ongoing	Ongoing	Ongoing	Inactive (2000)	Ongoing
Number of countries	41 (2001)	7 ↑ 9	6	5 ↓ 3	8
Number of items	11 (2001)	700 (2006)	1,127	Info not available	30
Annual volume of purchases	USD 130 M (2001)	USD 3.5 M (2002)	USD 234.5 M (2001)	Info not available	Info not available
Savings affected	312–452%	44%	30%	15–20%	10–96%

Eastern Caribbean Drug Service (OECS)

Model: Central Contracting & Purchasing and Pooled Procurement

Current State: OECS Agreement and Pharma Procurement Service (PPS); Electronic system; High level of trust from business sector; Supplier Monitoring and Evaluation

Challenges:

- Late vendor payments
- Poor forecasting
- Managing donations
- Purchasing outside of cartel
- Small countries & purchase orders

Learnings: Good database/information; Regional cooperation; Confidence-Building

Outcomes: cost reduction, Efficiency, Quality

Models – Donor Supported PP (PEPFAR)

PEPFAR

Type of Pooled Procurement: Central Procurement by independent body (GHSC-PSM) across more than 50 countries

Approach:

- Standard Product requirements:
USAID; US FDA approval, UNICEF, WHO
Approved procurement agent/supplier
- Quality testing protocols
- Contracts establishment: price, delivery, performance
- Technical support for logistics and supply chain

Logistics: Private sector solutions through project Last Mile

Results:

- Supported testing for ~ **95 million people**
- Prevented > **2.4 million babies** from being born with HIV
- Care for more 6.8 Million orphans and Vulnerable children
- ARV >**14.6 million people**

Advantages:

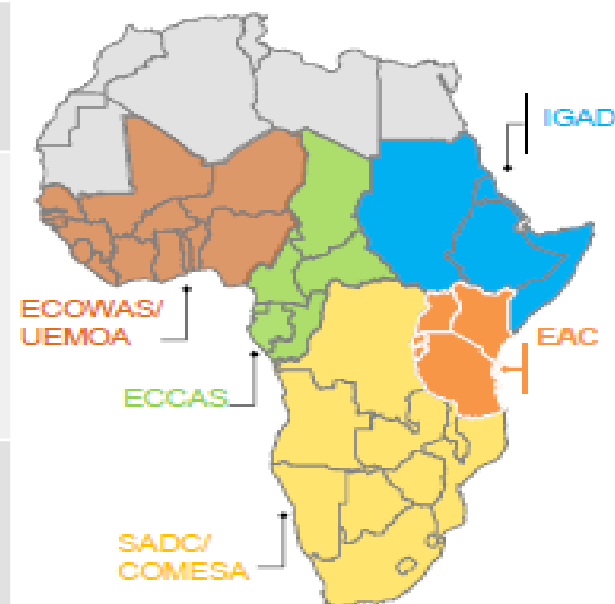
- Large volume/contracts
- Best practices in procurement, quality and data collection

Challenges

- Accelerate progress in context of flat or reduced budgets
- Country ownership and sustainability
- Needs of young women and adolescents
- Leverage Private public sector partnerships

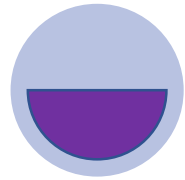
REC-based Regulatory Harmonization

RECs	Current level of Harmonization
EAC	Level 3 – Joint assessment <ul style="list-style-type: none"> 3 rounds, over 8 products approved, largely essential generic drugs, registration within 3 months
SADC	Level 3 – Joint Assessment <ul style="list-style-type: none"> 125 generic products and one innovative medical products assessed so far Focus on regional priority drugs – and infectives, anti hypertensive, anti-diabetics, registration within 11 months
ECOWAS	Level 2 – Harmonization of technical and scientific materials <ul style="list-style-type: none"> Developing regional “centres of excellence” & quality controls labs Championed by Nigeria
ECCAS	Level 2 – Harmonization of technical and scientific materials
IGAD	Level 1 – Information Sharing Launched in 2015, yet to establish a regional regulatory unit, preparing a proposal for AMRH participation
COMESA	Not actively engaged so far <ul style="list-style-type: none"> 60% countries in EAC and SADC



Clear Opportunity to leverage the AMRH and AMA for Scale up...

REC-based regulatory Harmonization



East African Community (EAC)

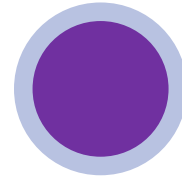
Launched in 2012

Model: Informed Buying and Group Contracting

Current State: EAC common market protocol; EAC Customs Union; Adoption of the EAC regional PMPA; No PP yet

Challenges:

- Limited Awareness of benefit among States
- Limited capacity at EAC secretariat
- No legislation for region PP
- Lack of private sector role
- Limited financing



Southern Africa Development Community (SADC)

Model: Coordinated informed buying and Group contracting

Current State: Harmonized medicines policies and regulations; Electronic medicines database (SMD); Network of PP as mechanism of sharing data and information (vendors etc.)

Challenges:

- Lack of clear roadmap, roles & accountability
- Lack of access to information
- Lack of procurement/ price standardization
- Reliant on donor budget as expenditure data limited (e.g DFID fund ended)
- Members are various level of Pharma industry

Models - Medicine Regulatory Focus

A strong Medicine Regulatory Agency is a key enabler for PP and access to affordable and safe medicines. Several countries have PP models focused on this...

Selected Global Examples

- **U.S Food and Drug Administration** and Canada – Harmonized
- **European Medicines Agency** and FDA
- Ethiopia and EAC are to some extent moving towards harmonizing to stringent QA such as FDA

Clear
Opportunity to
leverage the
AMRH and
AMA & WHO
preQual
Program

Selected Regional examples

- Namibia: Harmonized selected products with South Africa
- EAC: currently have ~ 7 essential medicines registration harmonized
- ECOWAS, Zanzibona and SADC: Harmonization of regulatory functions including dossier reviews, Pharmacovigilance, GMP inspection etc.

* WHO Pre Qual Program has helped reduce registration average time by 78 days

Key Learnings And Opportunities

Key PP Model Learnings

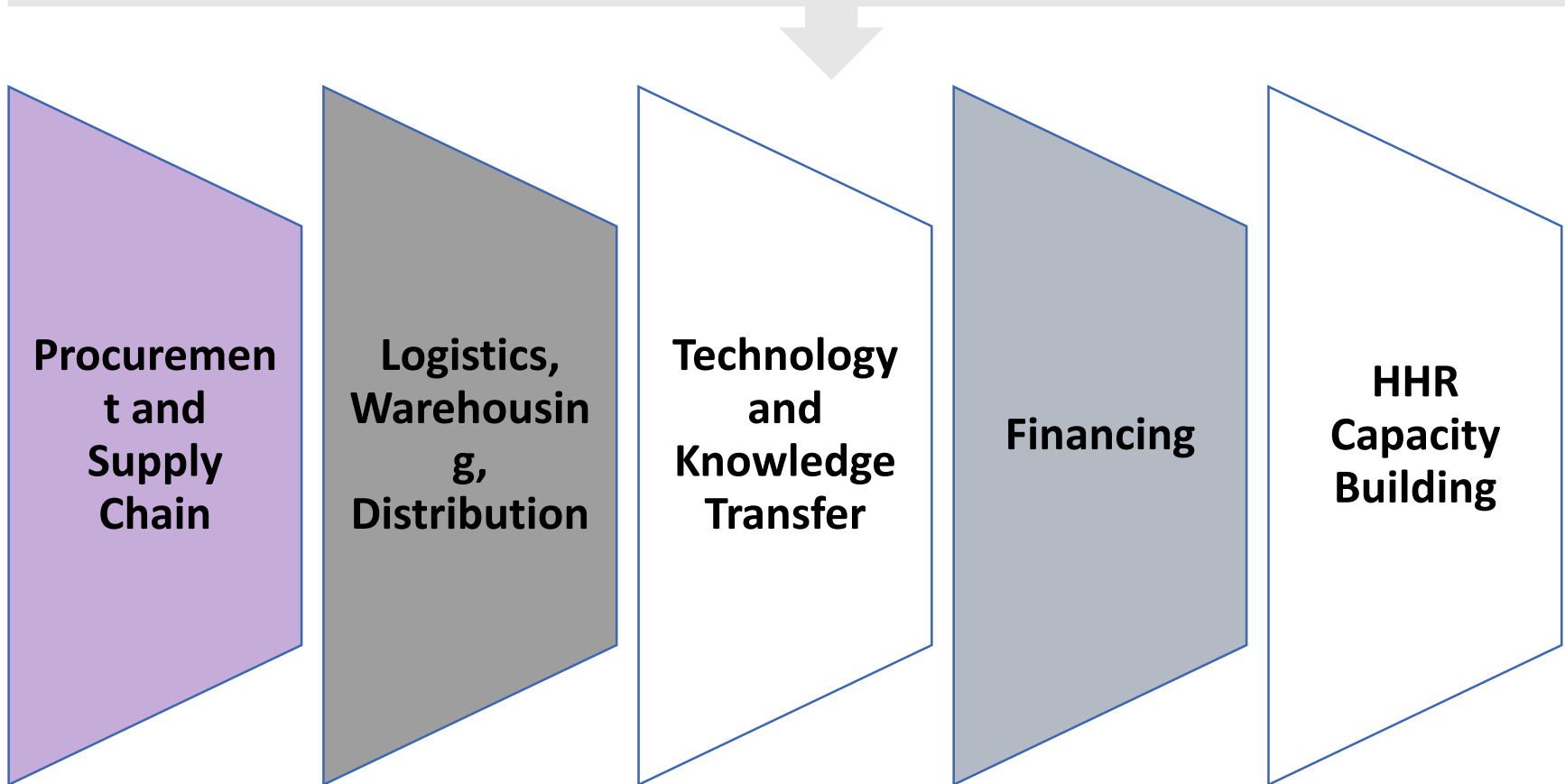
- ✓ **Sustainable Financing** Need to financing mechanism that is sustainable for establishing capacity for the RECs or other
- ✓ **Sharing of Data/Transparency:** need to “digitize” procurement and allow data sharing and information
- ✓ **Efficiency and Private Sector Solutions:** Build supply chain, logistics efficient systems have an enormous impact on process and cost

Key Success Factors

- **Political will & Financial Commitment**
- **Trust, Data and Information (Secure system..etc.)**
- **Harmonization of drug regulation**
- **Effective Quality Assurance**

Private Sector Partnerships – Key enabler

Partnerships with Private Sector across the Pharmaceutical value chain has seen to create significant efficiencies, savings and transparencies



Numerous examples and case studies with private sector engagement addressing Cost, Access and Quality of medicines

PSE - Logistics & Supply Chain

UKRAINE – Procurement agent (Crown Agents)

- **Problem Statement:** Ukraine For years, tens of millions of dollars were siphoned out of the health care budget by corrupt intermediaries
- **Intervention:** Ukraine MOH asked international bodies to procure medicine and medical equipment
- **Outcome:** Taken together, the purchases of medicines and medical devices by agencies cost **40 percent less** than those under the previous system. The procurement program saved the Ukrainian government \$3 million on stents alone — **and \$222 million overall.**

UGANDA – Logistics, Warehousing, Distribution PPP (Imperial Health Sciences)

- **Problem Statement:** to improve health by increasing availability, accessibility, affordability and appropriate use of essential medicines and supplies
- **Intervention:** MOH Effective management, supply and utilization of essential medicines
- **Outcome:** New medicine stores for MOH; Improve malaria supply chain

PSE - Volume/Price

GSK – Volume based Agreements

GlaxoSmithKline charges much less for medicines and vaccines in developing countries, where it focuses more on **volume-based sales and reinvests 20 percent** of the profit into the local health care infrastructure..

Gilead Sciences- Egypt – Hep C medicine

- Negotiations between the Egyptian government in the form of the “National Committee for the Control of Viral Hepatitis” and Gilead Sciences resulted in a reduced cost of US\$300 per box of Sovaldi which would supply 1 month of treatment.
- Headlines portrayed this as a **99% discount on the original price** of the treatment.

PSE – Access & Quality

PSE/CSR - Merck for Mothers/ APOC Treatment

Merck For Mothers: The overall goals of Merck for Mothers is to address the two leading causes of maternal mortality: postpartum hemorrhage and pre-eclampsia and eclampsia (hypertensive disorders of pregnancy), as well as family planning

Outcome: Investment of 500 M+; 7.3 M+ women reached and 50+ programs in 10 yrs

BD- PEPFAR “labs for Life” Partnerships– Ethiopia, Kenya, Uganda, Mozambique

- **To** Improve quality of labs, train lab personnel, Address NCDs etc.
- **Intervention:** Innovative solutions to improve drug delivery,, enhance Lab diagnosis etc.
- **Outcome:** Quality, Training, collaboration, technology (GIS system) etc.

Why? – Local Manufacturing/QA

Market forces limit access

- Manufacturers (mainly Generic) consolidating
- Global Pharma less and less able to respond

Unattractive market for Generic production

- Generics - low profit margins, small market
- Industries face increasing labor costs; shrinking price

Global pharma focusing on NCD and other

- Trend to stay away from NTD
- More recently no new antibiotics for ID

Disincentives for smaller manufacturers

- Procurement policies; regulation of medicines (WHO pre qualifications as prerequisite for all) – exclude many capable local players
- In donor supported countries, cannot compete with the prices..

- < 2% locally produced
- Increased counterfeits
- fragmented SC

This calls for the need to do things differently and engage private sector for innovative approaches. Better understand how to support local companies, etc

Best Practices – Local Manufacturing /QA

Several Options and Models for Addressing Market Supply Constraints



- **Regulations and Policy Reforms**
- **Support Pre-Qualification of Manufacturers**
- **Working with global manufacturers**
- **Industrial zones to encourage local and JV manufacturing**

Existing Frameworks:

The PMPA business plan (AUC Leadership)

Key programs:

- AMRH: African Medicines Regulatory Harmonization;
- AMA: African Medicines Agency;
- AU Model Law on Medical Products Regulations
- EAC, ECOWAS, SADC – have adopted frameworks that support

Best Practices – Bangladesh

Bangladesh has gone from importing ~75% their pharma needs from outside to having a local manufacturing that addresses more than 98% of its need

- **Enabling Political Environment:** National Drug Policy prohibited sales of certain medicines; limited import unless foreign firms did not have a manufacturing plant. If drug produced locally, gov fixed prices
- **Gov funding for adoption of modern technology** and foster collaboration with academic and research institutions (TA to generic manufacturers and expedition of registration)
- **Support research in products and technologies:** Support PS for new products and technologies and academic training
- **Facilitate business linkages** and Joint Ventures (GMP standards etc.)
- **Financial/Investment support:** loan approvals and better rates, VAT tax waiver etc.



The industry recorded a compound annual growth rate of 15% between 2010 and 2015 and now produces 98% of the local demand for essential medicines.

Model – Regulatory/Policy Reforms

Industrial Parks – Ethiopia Case Study [Ghana]

- In 2015, the Government of Ethiopia solidified its vision of development in the pharmaceutical sector. The plan outlines several specific and time-bound objectives designed to enhance access to medicines through quality local production.
- These include strengthening the regulatory system, providing appropriate incentives and attracting foreign direct investment, producing active pharmaceutical ingredients, creating a research and development platform, and developing human resources.

RECs - ECOWAS/ EAC/SADC

Objective: The harmonization of pharmaceutical regulations to facilitate the goals of AfCFTA can be leveraged from EAC, SADC and others

Specific Activities: Import duties policies on raw material; Medicines database promote regional market access; Fast track certain registration (e.g generics for examples); Quality assurance applications and tools are embedded in process
integration of import/export licensing authorization as well as fast-tracked accelerated registration of agreed-upon quality assured priority products.

Model – Private Sector Partnerships

Technology Transfer - Indonesia: Only local firms can import drugs with written consent from the foreign IP owner but all have to include technology transfer within 5 years

Stimulate and Catalyze local market Investments – ADB and TDB

- Uganda committed to annual purchases from local manufacturer (price/volume)

Human Capacity Building/Training

- Joint venture between the Government Pharmaceutical Organization of Thailand and Sanofi Pasteur Ltd. to build capacity to produce vaccines
- A Masters in Regulatory Sciences in AA university in Ethiopia

Support Quality upgrades -

Prequalification of manufacturers, suppliers, and vendors (defining scope, product range, capacity, quality systems, and GMP) and sharing performance information across the region. Identify and work with local or regional manufacturers to respond to quality standard of manufacturing (e.g., CHI in Nigeria; Uganda, and Kenya)

Key Learnings and Opportunities

- **Create an enabling environment**
 - Infrastructure; local skills development; Limit foreign ownerships
- **Multidisciplinary, coordinated, and systemic investment**
- **Countries with varying levels of pharma sector development:** Ghana, Morocco, South Africa, Kenya, Ethiopia, Tanzania and Zimbabwe – have national pharma strategies
- **Understand and Scale Private sector engagement models**
- **Stimulating Local markets:**
 - Differential/preferred procurement and/or pricing policies
 - Facilitate raw material import
 - Technology and Knowledge Transfer
- **Create financial Instruments (loans, capital, other funding?)**
- **Build capacity of local industry and regulators**
- **Encourage access to market data and analytics**



THANK YOU!

Ideas
to
Action