

AUDA-NEPAD WEBINAR: AFRICAN INDUSTRIAL CAPACITY TOWARDS CRITICAL PHARMACEUTICAL AND MEDICAL SUPPLIES

***Manufacturing capabilities in Africa to match the demand for
COVID19 products***

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Framing the Issues

Addressing the African heads of State and Government on June 6, 2012; Michel Sidibe, made this prophetic statement:

"In the future, regional and global power and national stability will be determined not by who controls arms, but by who controls access to medicines".

Framing the Debate

“Perhaps, the biggest threat to security of supply is from pandemics such as ebola, MERS, SARS, the pandemic flu, and the emergence of drug resistant strains of organisms that can be utilized as biological weapons.”

Dr S Ngozwana

**Future Priorities for the Public Health Medicines Market:
Meeting the Health Objectives of the Sustainable Development Goals and
Universal Health Coverage (March 2018)**

Framing the Debate

Because of limited financial resources, smaller volume purchases vis a vis other buyers such as the US / EU countries, and perceived lesser strategic importance by COVID-19 supplier countries, Africa will inevitably be at the back of the queue for any product supplies – we need local solutions where we can, when we can, and whilst we can; otherwise this pandemic will overwhelm our health systems. We have learned painfully; and now have hard evidence of the Fallacy of ‘The Pharmacy of the Developing World’ narrative which was used to exclude local manufacturers

LOCAL CAPACITY TO RESPOND TO COVID-19 PRIORITY PRODUCTS (1)

- Multiple Manufacturers across East, West and Southern Africa of
 - ✓ Paracetamol
 - ✓ Azithromycin
 - ✓ Hydroxychloroquine
 - ✓ Chloroquine
 - ✓ Oseltamivir
 - ✓ Lopinavir / ritonavir
 - ✓ Valacyclovir
 - ✓ Hand sanitizers / Disinfectants
- Idle installed capacity in the tens of billions (tablets / capsules); and different production technologies for multiple critical EMs
- Willingness to share technology and to increase production for critical products where equipment complementarities and Tech Transfer packages can be done quickly

LOCAL CAPACITY TO RESPOND TO COVID-19 PRIORITY PRODUCTS (2)

- Local Manufacturers in East, West and Southern Africa of PPE with capacity constraints but able to scale-up rapidly to supply RoA with financial support
 - ✓ masks (surgical / N95)
 - ✓ disposable gowns,
 - ✓ facemask with eye shield,
 - ✓ Gloves
 - ✓ overshoes
- Multiple companies with the capacity to manufacture SARS Cov-19 Rapid Diagnostic (POC) kits, antigen, antibody, and RT-qPCR primers
 - ✓ Immediate opportunity for a Tech Transfer to various African producers following validation of product from a pedigreed International Supplier (crucial as we need mass screening & cannot afford RT-PCR which requires infrastructure, trained people etc, and is costly)
 - ✓ Multiple importers of accredited SARS Cov-19 RDT
- National Ventilator Project started in SA – production starts end April - manufacture 10 000 ventilators by June

KEY CHALLENGES FOR LOCAL MANUFACTURE (1)

- Capital to increase capacity / capability and buy raw materials / finished product
 - ✓ Tight cash flows (pre-payments) / Liquidity
 - ✓ Delays in government payments to local companies (even in this time)
 - ✓ Foreign exchange deterioration
- Slow, Lethargic and Unresponsive Procurement Processes / Systems
 - ✓ 100% Pre-payment is the norm – snooze and loose
 - ✓ Access to raw materials – prices have increased dramatically
 - ✓ Huge global Demand - any delays and go back to the queue
 - ✓ Logistics as Cargo shipments are stretched due to limited flights

KEY CHALLENGES FOR LOCAL MANUFACTURE (2)

- Inflexible and bureaucratic regulatory systems (a luxury we cannot afford in the middle of a war)
 - ✓ Pragmatic and quick decision making crucial if we are to arrest the pandemic
- Export restrictions
- Logistical challenges with importing, delayed clearance at customs (officials with no sense of urgency) and improper classification of goods
 - ✓ Cancellations and delayed shipments
- Quality and possibility of sub-standard and falsified products is huge with unvetted suppliers

OPPORTUNITY TO BUILD - IN THE MIDDLE OF THE STORM

Out of clutter, find simplicity. From discord, find harmony. In the middle of difficulty, lies opportunity.”

Albert Einstein

- In the absence of, or erratic supply from India – time to allow local manufacturers to step up
- Fast track AMA through central evaluation for products to be supplied continentally
- In preparation for the next pandemic (and there will be others), build local capacity now – All UNECA / AfDB procurement should be carved aside for ALL local production capacity
 - ✓ Only procure outside if no local suppliers
- Time for AUDA-NEPAD, AfDB, Afrexim Bank and others to create urgent financial instruments to support LPP

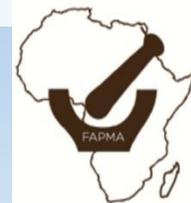
KEY REQUIREMENTS TO FACILITATE LOCAL SUPPLY

- This is business Unusual – we are in a War against an invisible and deadly enemy: We cannot use the usual SLOW / LETHARGIC processes.
- We need Innovative and Agile mechanisms
 - ✓ New financing schemes to enable local manufacturers to access capital to increase capacity, source raw materials, or import finished product
 - ✓ AUDA-NEPAD / AUC / RECS must advocate for immediate relaxation of regulatory frameworks for new manufacturing sites / new API sources / new product registrations
 - ✓ Need innovative and nimble procurement processes as Africa
 - ✓ Innovative supply chain management mechanism to move product around the continent.
 - ✓ Customs officials to expedite any COVID-19 related imports
- FAPMA representation on The African Union COVID-19 Response Fund to guide and give expert advice on procurement from Local Companies

Framing the Debate

Michel Sidibe UNAIDS Executive Director 7th AUC Conference of Ministers
Abuja Nigeria 25-30 November 2014

" The time for Africa to break its dependence on imports is NOW. The local manufacture of pharmaceuticals in Africa is an opportunity to develop a broader manufacturing and knowledge-based economy".



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Manufacturers Associations

Thank You





SUPPLEMENTARY SLIDES



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PMPA Vision

“ To develop a competitive and enduring integrated pharmaceutical manufacturing industry in Africa, able to respond to the continent’s need for a secure and reliable supply of quality, affordable, accessible, safe and efficacious medicines”.

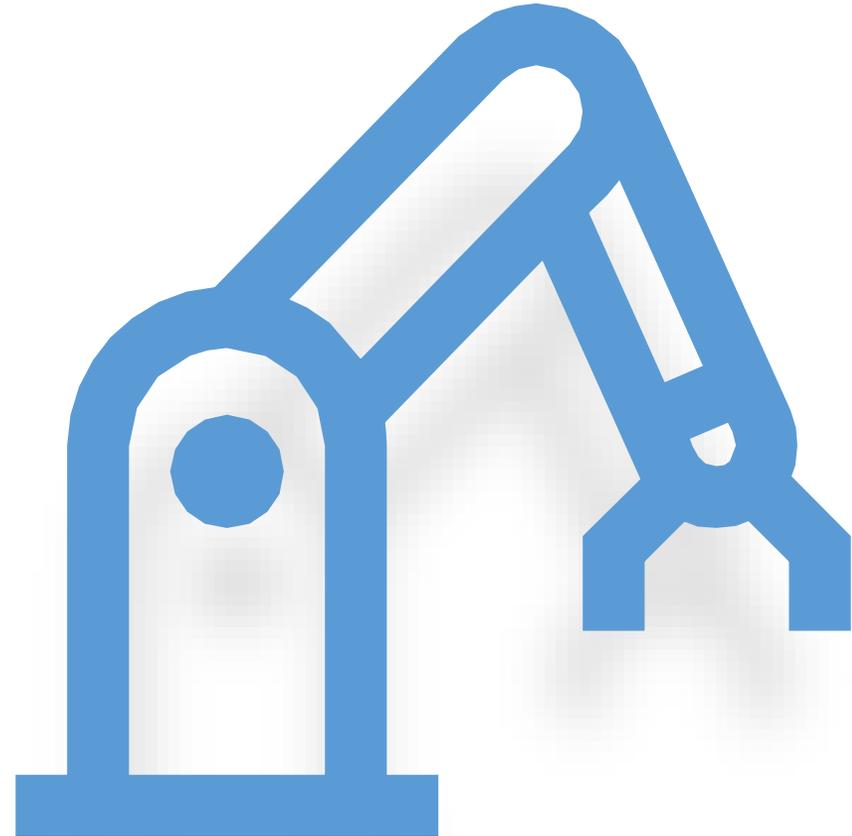


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FAPMA Vision

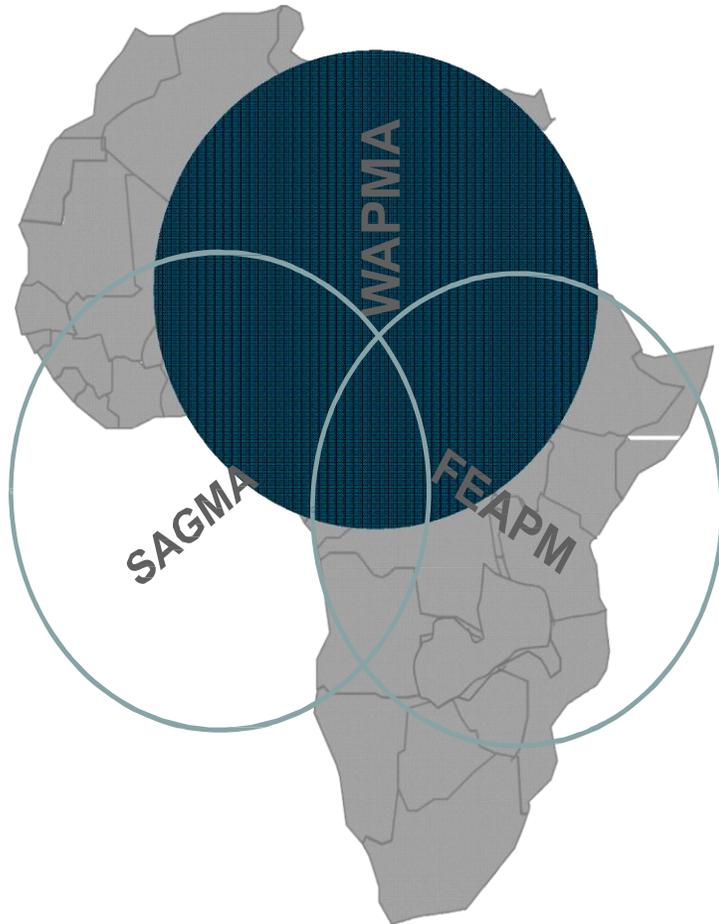
“to be a vibrant and self-sustaining pharmaceutical manufacturing industry in Africa by providing quality and affordable medicines so as to contribute to the reduction of disease burden and promote economic development of the continent.

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MEMBER ORGANIZATIONS



- Southern African Generics Medicines Association
- Federation of East African Pharmaceutical Manufacturers
- West African Pharmaceutical Manufacturers Association
- More than 500 African Pharma Companies
- Formed in 2013 in Addis Ababa January
- Recognition: AUC and RECs
- Multiple Technologies (OSD, Sterile LVP, SVP, Liquids etc)
- Capacity to meet Africa's needs



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QUALITY PRODUCTION IN AFRICA

- Many companies in Africa operate at requisite international GMP standards e.g. WHO PQ, US-FDA, TGA:
 - ✓ Universal in Kenya – WHO PQ Products
 - ✓ Quality Pharmaceuticals in Uganda – WHO PQ
 - ✓ Adcock Ingram
 - ✓ Varichem in Zimbabwe – WHO PQ
 - ✓ Aspen in South Africa – WHO PQ
- Some companies have been WHO GMP Certified:
 - ✓ Chi Pharmaceuticals; Evan Medical Plc; May and Baker Nigeria Plc and Swiss Pharma Nigeria Limited.
- Many others operate at international GMP but are not operating in funded markets e.g. Juhel (manufacturers of Oxytocin), Sandoz / Sanofi plants .

- **Vibrant Local Pharma Industry**
- **Regional Harmonization Initiatives (AMA)**
- **Maturing pan-African distribution systems**
- **Market Proximity and quick response to local demand**

- **High market Growth Rate**
- **African Continental Free Area (AfCFTA)**
- **Medicines Registration Harmonization (AMRH/AMA)**
- **Political Support**

Strengths

Opportunities

AFRICAN PHARMA - SWOT ANALYSIS

Weaknesses

Threats

- **70% imported Medicines – Procurement systems favour imports**
- **GMP Standards**
- **Regulatory systems**
- **Small Product portfolios of local manufacturers**
- **Dependence on imported API**
- **Policy Incoherence and lack of implementation**

- **Pandemic threat unpreparedness - dependence**
- **Substandard and Falsified Medicines**
- **Cheap imports and drug donations**
- **Foreign exchange**
- **Corruption**
- **High costs of utilities,**
- **Lack of HR, Finance**