Africa Business forum 2020

Investing in People | Planet | Prosperity

Disruptive pharmaceutical and finance initiative:

AfCFTA and AMA game changers

United Nations
Economic Commission for Africa

Sustainability and affordability of health financing

The AfCFTA-anchored pharmaceutical project in Seychelles, Madagascar, Comoros, Mauritius, Djibouti, Eritrea, Rwanda*, Ethiopia*, Kenya, Sudan and IGAD is a pilot health and economic initiative that through public-private partnerships and innovative financing contributes to improved accessibility and affordability to safe medicines and to accelerated progress towards SDGs and Agenda 2063.

*Rwanda and Ethiopia are landlocked

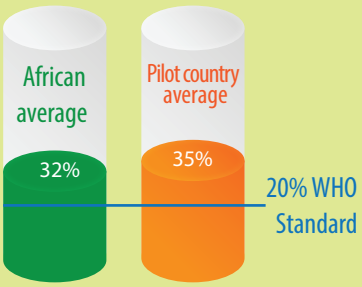
2.6%
Pharmaceutical import bill of total imports and growing at 5% per year

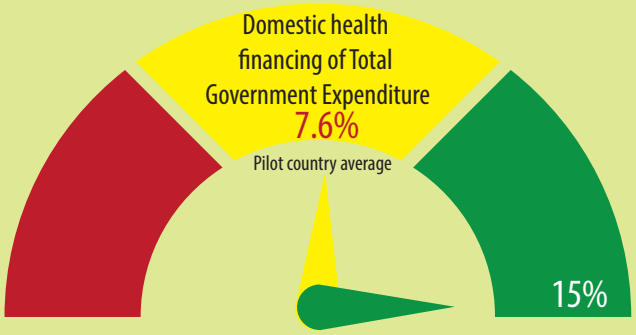
3.2%
Average of GDP health financing gap in 10 countries

15%
Debt to GDP ratio increase between 2000 and 2017

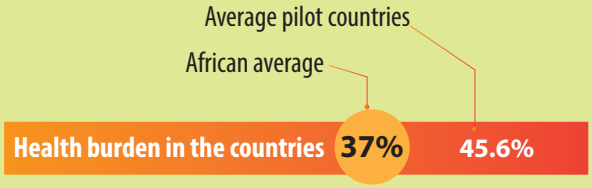
Rwanda **only 6%** - out of pocket due to Community health Insurance

Out of Pocket (OOP)





Target Government expenditure



The ageing population of the pilot countries contributes to the rise of the Non Communicable health burden and drives increased health costs and concerns for fiscal sustainability.

Fiscal & trade gains of pooled procurement along the supply chain

The Small Island States (SIDS) are vulnerable to high variable prices and small markets. The creation of larger markets benefits from pooled procurement through efficiency gains in the supply chain management and the involvement of the private sector

Drop in medicinal prices- OECS (Caribbean) a private-public partnership of pooled procurement across 12 Islands and a market of 500,000 people and an annual volume of $3.5 million resulted in 45% price drop through pooled procurment. (Revolving Fund as an innovative financing tool was introduced)

GCC- across 6 countries and 1,127 medicinal items for a total of $234.5 million of purchases resulted in 30 percent cost savings

National pooled procurement- In Ethiopia through a framework agreement across key regions cost savings of over $128 million of a $570 million procure-ment budget were achieved.

In Kenya procured prices of local pharma products were 30 percent lower than imported goods and availability was 48 percent for local products and 23 percent of imported goods

SADC- In a regional market of approximate-ly $5 billion in pharmaceutical and a public sector procurement of $2 billion market efficiency gains of 5 percent along the pooled procure-ment and supply chain results in savings of $250 million.

SIDS and Islands | Small Market | Local National pooling | RECs

- Increased availability of essential markets (SDG target 3. B.3 target 80%)
- Increased affordability of health products (SDG Target 3.8.2)
- Reduction in pharma imports
- Increase in coverage of women in family planning needs (SDG 3.7.1)

Enabling environment

Localized production

	Comoros	Djibouti	Eritrea	Ethiopia	Kenya	Madagascar	Mauritius	Rwanda	Seychelles	Sudan
No. of local Manufacturers & Suppliers[1]	1	4	2	13	63	5	29	3	1	24
Estimated Revenue from local production (USD Million)[1]	NA	1.8	26.3	489.1	543.5	35.6	120.3	7.9	5.45	-
Total Pharma Export (US Million)[1]	0.0	0.1	0.0	1.6	130.2	0.3	34.4	0.2	0.0	0.1

[1] Hoovers Industry Database, 2018

Generic essential medicines

	Comoros	Ethiopia	Kenya	Mauritius	Rwanda	Seychelles
Availability public/ private facilities	43%/48%	64%/NA	38%/72%	75%/55%	46%/80%	87%/46%
Median price ratio of public/ private facilities (against international standard pricing)	0.9/5.9	1.4/2.3	NA	0.9/4.9	2.0/3.3	1.4/7.2

Regulatory Framework

Medicines regulatory harmonization is a key component of the Pharmaceutical Manufacturing Plan for Africa (PMPA), which was approved by the AU Conference of Ministers of Health in 2007 and aims at enabling African countries to fulfil their national obligations by providing all citizens with safe, quality and efficacious essential medicines. In Africa, there is clear desire from pharmaceutical manufacturers for the creation of centralized regional medical agency that could issue marketing authorizations and Good Manufacturing Practice (GMP) inspection certifications. At present, drug approval processes in African countries operate separately and each country prioritizes its own process, except in a few regions that have embraced harmonized ones. This means that drugs companies seeking to register new drugs in Africa or trade across countries have to make individual applications in several countries for the same medical products and incur cost. Additionally, many countries have different systems and process in place resulting in approval delays of medical products and consequently delayed access to medicines.

It is in this context that the political leaders of the African Union Commission established the African Medicines Agency (AMA), that once ratified by member States, will serve as the continental body that will provide regulatory leadership for the harmonization and strengthening of regulatory systems which govern the management of medicines and medical products on the African continent. The Agency will regulate the access to safe, effective, good quality and affordable medicines and health technologies. AMA will do this through coordination of on-going regulatory systems and strengthening and harmonization efforts of the AUC, RECs, Regional Health Organization (RHOs) and members States.

	Comoros	Djibouti	Eritrea	Ethiopia	Kenya	Madagascar	Mauritius	Rwanda	Seychelles	Sudan
Has lab for Quality Control Testing (Y/N)	N	NA	Y *(limited)*	Y *(Accredited)*	Y *(Accredited)*	Y	Y	Y *(recent)*	Y *(in process of accreditation)*	Y *(limited)*
Does Post-Market Surveillance?	N	NA	NA	Y	Y	Y	NA	NA	Y *(limited)*	NA
QA covers Private and Public Sector? (Y/N)	N	NA	N	N	N	NA	NA	Y	N	N
Ratification of AMA	NA	NA	NA	NA	NA	NA	NA	Ratified*	In process	NA

*[3] African countries have ratified AMA namely Algeria, Saharawi and Rwanda.

Case study

Oxytocin a case study showcases the AfCFTA three pronged project for saving lives and increasing women's productivity

Postpartum Haemorrhage (PPH) during labour is one of the leading and persistent contributors to maternal mortality rates - with estimates of above 30% of pregnancy-related deaths as seen in Ethiopia or Comoros when compared to a global 20% average. PPH is treatable and preventable according to WHO recommended guidelines and with Oxytocin injection as a frontline drug of choice. However, many African countries have indicated that more than 70% of oxytocin in circulation, failed quality lab evaluation at the end user facilities — in other words 3 out of 4 imported brands are substandard. This has a deleterious effect on improving women's health yet if tackled can improve productivity significantly.

The case of oxytocin exemplifies (i) Supply chain inefficiencies parallel procurement channels of private and public procurement leads to uncontrolled, illicit procurement and movement of goods as well as lack of cold chain infrastructure — especially across neighbouring countries (E.g IGAD case); (ii) Fragmented procurement channels with inadequate databases and lack of digitization of the supply chain and traceability by end users; (iii) Weak local regulatory framework and infrastructure no quality assurance laboratory infrastructure with only few countries such as Ethiopia, Kenya and Seychelles (partially) have a strong regulatory body that includes the capacity to do post-market surveillance of products. For example in Ethiopia procurement is done under one entity, yet criteria for supplier selection is based only on price and does not include minimum quality requirements.

The opportunities for private sector engagement: (1) working closely with local manufacturers to ensure a more secure supply of safe and accessible and affordable medicines ; (2) digitization of the supply chain with traceability of products all the way to end-user; (3) pooled regulatory efforts under a single entity such as AMA that can administer the relevant post-marketing surveillance of "high-risk" or selected prioritized medicines.

ideas for a prosperous Africa