Africa Business forum 2020

Investing in People | Planet | Prosperity

Third Africa Business Forum

"Investing in People, Planet and Prosperity"

African Continental Free Trade Area: An opportunity to accelerate towards implementation of the 2030 Agenda and Agenda 2063 through pooled procurement of essential safe and quality drugs and products and local pharmaceutical production for the continent

United Nations
Economic Commission for Africa

A.20-00083

Why the need for a pharmaceutical initiative anchored on the African Continental Free Trade Area?

The pharmaceutical project led by the Economic Commission for Africa has the specific aim to bring ideas into action as part of the successful operationalization of the African Continental Free Trade Area. The project is led by the Commission in collaboration with the African Union Commission, the African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD), the World Health Organization (WHO) and other United Nations agencies. This African Continental Free Trade Area-anchored pharmaceutical project is commissioned in selected African countries: the Comoros, Djibouti, Eritrea, Ethiopia, Kenya, Madagascar, Mauritius, Rwanda, Seychelles and the Sudan, and has anchor support from the Intergovernmental Authority on Development (IGAD). The project aims to leverage on the African Continental Free Trade Area, which draws together a market of 1.3 billion people and combines gross domestic product (GDP) of $2.5 trillion across the 55 member States of the African Union. The free trade area is expected to make a significant contribution to Africa's ongoing efforts to bring to reality the aspirations and goals set out in the 2030 Agenda for Sustainable Development Goals and Agenda 2063 (see figure I).

The emphasis on pharmaceuticals is driven by inadequate access to medicines to counter many infectious and non-communicable diseases (NCDs) across Africa as well as the undue strain which medicines put on both the public and consumer budgets. Medicines consume a large proportion of the health-care budgets of African nations. Reasons for this include inefficient models for procuring pharmaceuticals, long lead times for international orders, high costs for transport and distribution, poor capacity in logistics and storage, limited public finances, and gaps in global and local production of medicines. These factors also slow the progress towards achieving the Sustainable Development Goals. In addition, the current supply of medicines to Africans does not meet demand. Africa manufactures less than 2 per cent of the medicines it consumes while it imports above 70 per cent of its needs from outside the continent at an annual cost of $14.5 billion.

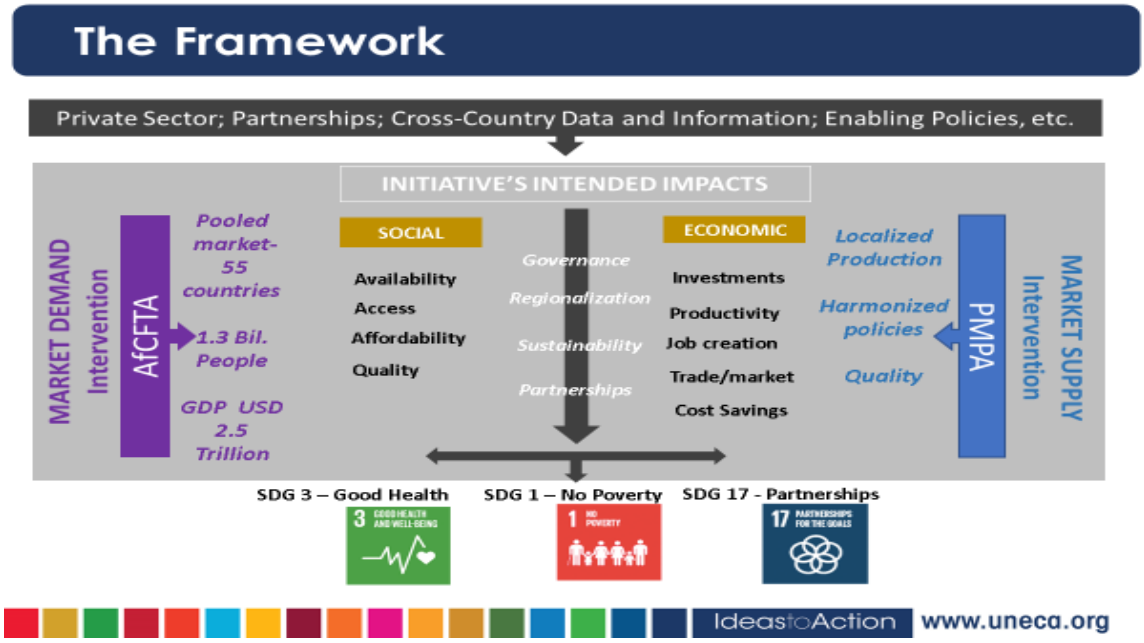
It is estimated that out of pocket health spending, the spending contributed by the patient or their family without a third-party such as Government or an insurer, make up 36 per cent of total current health expenditure. This puts a great strain on the disposable income of Africans, particularly that of poor Africans. It points to two major market distortions: first, there is not enough access to universal health coverage; and second, critical preventive care and even falling ill may push families into abject poverty. The private sector, including industry, has a critical role in filling the gap in order to address these market distortions. The Business and Sustainable Development Commission (2017) and the Economic Commission for Africa report on Health Care and Economic Growth in Africa (2019) estimates Africa's health and wellness markets at $259 billion, which will be the second largest market after the United States by 2030.[1] This provides a strong business case for the private sector to play a significant role in shaping the health markets and contribute towards the improvement of health care in Africa.

The pilot initiative focuses on maternal and child health care (MCH) products to address persistent challenges including the burden of maternal and child health-care, unmet needs and access to reproductive health products across Africa. Investment in initiatives that address women's health as a key component of inclusive and sustainable economic development is both necessary and effective. The project is proposed to be a "game changer" in developing a scalable and sustainable pharmaceutical framework of action. The initiative has a three-

[1] Business and Sustainable Development Commission.

pronged approach: localized production, pooled procurement and a harmonized regulatory and quality framework. The intended high-level improvements are: increased trade of manufactured goods between African countries, more affordable medicines, and the creation of much-needed fiscal space for Governments in an era of rising debts. The economic improvements are complemented by welfare and social gains including significant job creation and increases in women's productivity.

Figure I
Partnerships framework for the pharmaceutical project



Consolidation of the continent into one large and integrated market is expected to generate a range of socioeconomic development benefits through supporting trade creation, industrialization, structural transformation and poverty reduction, with far-reaching implications for generating employment and raising incomes for African women as a particularly disadvantaged and marginalized group. The ECA pharmaceutical initiative anchored on the African Continental Free Trade Area presents a business opportunity for the private sector which is important both in creating engagement in managing the supply side of pharmaceutical production and in bridging the health financing gap, which is estimated at $66 billion per year.

Key findings from the 10 pilot countries

Economic growth in the 10 pilot countries is slightly above the Africa average for 2018 at 5.5 per cent, but with large variations across the countries. Similarly, there is progress in the health sector across the selected 10 countries but heterogeneity in the profile of the disease burden and health priorities. The Maternal Mortality Ratio (MMR) has declined from 644 maternal deaths per 100,000 live births in 2000 to 290 deaths per 100,000 live births in 2017. Mortality among children under five years old dropped from 96 deaths per 1,000 live births to 46 deaths. The improvement is significant, but still below the targets in the Sustainable Development Goals of a Maternal Mortality Ratio of less than 70 deaths per 100,000 live births (target 3.1) and under-five mortality ratio of 25 deaths per 1,000 live births (target 3.2). Although life-expectancy trends are positive in the continent, the rise of both communicable

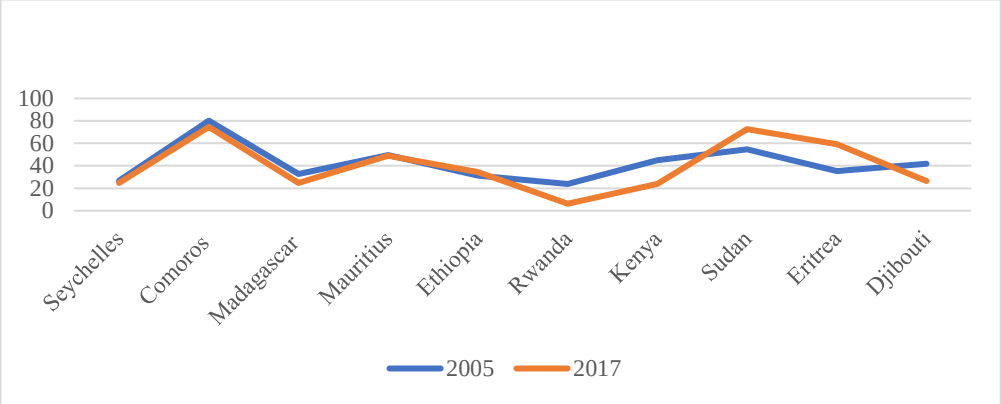
and non-communicable diseases (NCDs) dubbed the “double disease burden” is of concern. In the 10 countries under review, non-communicable diseases form a high proportion of the disease burden and they are mainly increasing because of lifestyle changes. This increase in disease brings associated health-care costs and challenges the fiscal sustainability of health-care provision.

Opportunities of pooled procurement - fiscal space, cost efficiency and innovative financing

In the 10 countries reviewed, the creation of fiscal space can be divided into two levels: public and household. At the public level, current health expenditure as a percentage of gross domestic product (GDP) dropped from 5.6 to 5.1 per cent over the period 2005 to 2017. At the same time, servicing debt has increased from 1.6 to 2.6 per cent of Gross National Income. The fiscal challenge is further exacerbated by the total imports of pharmaceutical products made up of 2.7 per cent of total imports in 2017/2018. Health-care costs have restricted fiscal space and at the same time slowed the pace of progress in attaining key targets of the Sustainable Development Goals. This has increased resonance over time because the non-communicable disease proportion of the overall health burden, expressed as disability-adjusted life years (DALYs), has increased from 36 to 45 per cent over the relatively short period of 2007 to 2015, causing further financial strain.

The drop in health spending and the restricted fiscal space points towards opportunities for innovative sources of finance to bridge this gap. The contribution of out of pocket expenditure to current health expenditure in the 10 countries is the same as the overall African average of 36 per cent of total health expenditure, although there are large variations across countries (see figure II). Out of pocket spending remains high across most of the countries although on a decreasing trend. However, it is generally above the thresholds established by WHO that spending on health should not be more than 10 per cent of total household expenditure as a criterion of not falling into poverty. The Organization for Economic Cooperation and Development (OECD) sets this target at 20 per cent. This also negatively affects the achievement of Sustainable Development Goal 1 “End poverty in all its forms everywhere”. An intriguing observation is the drop in out of pocket expenditure from 23.8 per cent of current health expenditure to 6.2 per cent in Rwanda over the period 2005 to 2017 driven by an innovative universal community-based insurance scheme and cost-efficient tools such as digital health-delivery services. In turn, this improves both the universal availability and the affordability of the health system.

Figure II
Out of pocket spending, 2005–2017



Source: World Health Organization database.

This innovative African Continental Free Trade Area-anchored pharmaceutical project has key objectives to support attainment of the Sustainable Development Goals and improve the African governments' fiscal space. The initiative also demonstrates a more strategic role for the private sector to play in both the supply and demand sides of provision of health care.

The creation of single economic space under the African Continental Free Trade Area allows more secure logistics and a controlled environment for procurement and distribution. The pilot project proposes a regional pooled procurement arrangement, which can also help tackle the infrastructure, data and logistics needs of the continent. Once this arrangement has been set up, it will provide for the safety, security and quality of products procured and distributed. According to the World Health Organization, successfully implemented pooled procurement mechanisms can help countries access sustainable supplies of quality drugs, achieve greater demand predictability, reduce transaction costs and sometimes reduce the total price paid for drugs and related products. For example, the Organization of Eastern Caribbean States (OECS) has recognized that efficient procurement practices would improve the use of existing resources. Efficient procurement also provides the greatest opportunity for cost-savings out of the four areas of the drug supply management cycle, that is, selection, procurement, distribution and use (see Box 1).

This was complemented by the provision of training and technical assistance to participating countries, including for a quality-assurance service. In this regard, a centralized digital list of essential medicines and key human resources is critical as an enabler so that pooled procurement can reduce costs through efficiency gains and economies of scale. In addition, an innovative revolving fund was involved in the regional procurement process to ensure that foreign exchange would be available, payments would be timely and there would be a conducive fiscal space at both the macro and micro levels.

Box 1
Cost savings from pooled procurement: lessons from the Eastern Caribbean

The Pharmaceutical Procurement Service of the Organization of Eastern Caribbean States (OECS/PPS) operates a centralized, restricted tendering system in which all approved suppliers are pre-qualified using a registration questionnaire for vendors. After soliciting bids from over 75 international suppliers, the Service awards annual contracts, places orders directly with suppliers, and monitors delivery and supplier performance. The core function of the Service is the pooled procurement of pharmaceuticals and medical supplies for the nine Ministries of Health (MOHs) of the OECS countries. During the 2001/02 tender cycle, the annual survey on a market basket of 20 popular drugs and a joint population of 500,000 showed that the prices achieved by regional pooled procurement were 44 per cent lower than the prices when individual countries procure. The continuous annual cost-savings accrued after 16 years of the joint purchasing arrangement have reinforced the Procurement Service as an excellent cost-benefit model of economic and functional cooperation among member countries of the OECS.

Source: Francis Burnett (2003). Reducing costs through regional pooled procurement. Essential Drugs Monitor No. 032, pp7-8. World Health Organization, Geneva.

Opportunities for local production – investments, job creation and innovative financing

The second objective of setting up more local pharmaceutical production is to incentivize and engage local pharmaceutical manufacturers across the continent on the supply side of the project. This builds on the Pharmaceutical Manufacturing Plan for Africa. The preliminary data currently available reports that local manufacturing in the 10 countries is extremely low, with the exceptions of Ethiopia and Kenya. The number of recognized pharmaceutical manufacturers in the region is estimated at 50 but approximately 30 of these are based in Kenya. Ethiopia supplies 20 per cent of domestic consumption but with limited product portfolios (see Box 2).

The lack of localized production and, in particular, the undersupply of country-specific essential medicine lists have an effect on the surging import bill for medicines and medical supplies (in 2017 pharmaceutical imports averaged 2.37 per cent of total import spending) and exacerbates the debt burdens in the countries under review. Thus, developing local pharmaceutical manufacturing is expected to have both health benefits and significant economic benefits. Some of the 10 pilot countries are small island developing States (SIDS) and their market size creates a further incentive for localized production within regional agglomerations. The combined population of the 10 countries under review is nearly 200 million people, which creates significant economies of scale. Localized production also carries the same benefits associated with growth in the manufacturing sector in general, including adding value, creating employment and contributing to reducing poverty, consequently improving progress towards the United Nations 2030 Agenda for Sustainable Development.

The private sector must play its part, in a strategic partnership with the public sector, in contributing to achieving the 2030 Agenda for Sustainable Development. Specifically, the private sector can bridge the gap in direct provision of health care, management of health-care institutions, manufacturing health-care goods and services such as medicines, pharmaceutical products and rehabilitative care, financing of health-care products and services, and building production capacities for the longer term. These present numerous opportunities to invest in laboratories and diagnostic centres, pharmaceuticals, skills development, research and capacity-building, and digital health innovations.

Box 2
Ethiopia's pharmaceutical manufacturers

There are approximately 200 importers of pharmaceutical products and medical consumables in Ethiopia. The local industry comprises of 22 pharmaceutical and medical suppliers and manufacturers. Out of these, nine are involved directly in the manufacture of pharmaceutical products. Most of the manufacturers operate below their capacities and supply only about 20 per cent of the local market. In 2014, local pharmaceutical companies supplied products to the value of $44.2 million. Local manufacturers have limited product portfolios and are thought to be able to supply only 90 of the more than 380 products on the national essential medicines list. Around 35 to 40 per cent of their total output is supplied to the private sector at a price premium of 10 per cent. The annual private pharmaceutical market in Ethiopia is estimated to be worth $100 million.

Source: Government of Ethiopia 2015. *National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025*). Addis Ababa.

Opportunities for quality and sustainability- data, digitization and enabling environment

The third objective is to create an enabling regulatory and legislative environment for improving the regulation of medical products. This will build on the African Medicines Regulatory Harmonization programme (2009), the African Medicines Agency (set up in 2014) and an African Union Model Law on Medical Products Regulations (2015), which were all developed as continental frameworks for adoption and adaptation to support initiatives by the regional economic communities and the member States. Platforms such as the African Medicines Regulators Conference (AMRC) and governance structures of the African Medicines Regulatory Harmonization programme facilitate dialogue among established regulators.

A strong regulatory framework is necessary to ensure that medical products, whether they originate abroad or locally, are safe, of good quality, are used rationally and that their supply is sustainable. The presence of the unregulated private sector in the health market indicates the need for more strategic public-private partnerships and for strong national regulatory bodies that include the growing private sectors in delivering health-care services. Equally important are data visibility across the supply chain and digital tools such as traceability of medicines. The use of digital tools in driving efficiency and quality gains stands out as critical and offers partnership opportunities with private-sector innovations in technology. The introduction of data analytics in supply-chain management, including pooled procurement, forecasting pharmaceutical needs, ensuring updating of essential drug lists and

traceability of counterfeit drugs, are among the opportunities for engaging the private sector and achieving gains in cost efficiencies in health care.

As of 2016, only 22 African countries had national medicine regulatory authorities. Many lack capacity and funding and this highlights the opportunity for a regional entity set up under the African Continental Free Trade Area and the African Medicines Agency frameworks. National medicine regulatory authorities are responsible for regulation and control of various aspects of the pharmaceutical value chain, from medicine registration to clients' access to medicines. They are also responsible for ensuring that the manufacture, import, export, distribution and wholesaling of all medicines are properly regulated and conform to the standards of Good Manufacturing Practice (GMP), and also that standards of Good Distribution Practice (GDP) are observed in all activities and on all premises. The national regulators still have to meet the regulatory standards required in most African countries, but countries including Egypt, Morocco, Uganda, Tunisia and South Africa have been able to overcome and exceed these challenges and are exporting medicines to Europe, the United States of America and beyond.

Standards is another element that is closely linked to regulation. The World Health Organization (WHO) uses a prequalification process that involves stringent assessment of product dossiers, inspection of manufacturing sites and of contracted research organizations, prequalification of national pharmaceutical quality-control laboratories, and advocacy for medicines of assured quality. This prequalification accelerates procurement and distribution of quality medicines. Various companies manufacture pharmaceutical products in Africa but only a few entities in Egypt, Kenya, Morocco, South Africa, Tunisia and Uganda are prequalified. This implies that ensuring quality is still an issue elsewhere, although there are genuine challenges confronting companies that aspire to improve quality and to realize their ambition of achieving the international Good Manufacturing Practice standards. The main reason why manufacturers do not want to invest in the prequalification process or in achieving Good Manufacturing Practice might be related to the cost involved, as fees and expenses involved in the qualification process can be prohibitive.

The business opportunities within this pilot African Continental Free Trade Area-anchored pharma initiative for the private sector within a strategic public-private partnership are enormous: first, efficiency gains and data sharing and transparency for quality in pooled procurement through digital information sharing platform; scalability into larger markets and health products; innovative financing and investments across the value chain of this initiative, including, revolving funds and social bonds. Secondly, the shift to pooled procurement and regulatory schemes requires capacitating human resources on the supply value chain. Thirdly, the scalability of this project across health burdens and regional economic communities is part of the Africa transformation agenda into a manufacturing hub and a leading exporter of manufactured products to the rest of the world. This health initiative within the African Continental Free Trade Area embodies great opportunities for private investment, transformation of lives, poverty reduction and contribution to sustainable and inclusive economic development.

Printed in Addis Ababa, Ethiopia by the ECA Printing and Publishing Unit. ISO 14001:2015 certified.
Printed on Chlorine Free Paper