AFRICA'S LONG-STANDING ESSENTIAL MEDICINES PROBLEM AND DFS AFRICA'S CONTRIBUTIONS TO THE SOLUTIONS

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This is the story of DFS Africa and how we got into healthcare financing in Africa. The story of how some visionary young Africans found partners on the continent and across the world who were keen on shaping the pharmaceutical and healthcare landscape in Africa. This is a story of how a group of committed technocrats are working to tame one of the biggest challenges in Africa's development by ensuring pharmaceutical production is accelerated on the continent and Africa's long-standing essential medicines problem is solved once and for all.

DFS Africa is a global advisory company founded by Bankole Eniola, Olakunle Olyaniyi-Edwards and Olukayode Yemi Afolabi. The company is dedicated to transforming lives in Africa through solutions that improve African economies, strengthen local businesses and increase effectiveness of public authorities. DFS Africa also supports organisations and public institutions to transform programs and policies into investable revenue generating projects. Propelled by strong financial backgrounds with experience and network from Deutsche Bank, HSBC, Barclays and the African Development Bank, the trio set out on a journey to develop the landscape of transaction advisory in Africa, with a commitment to finance projects that deliver strong returns on investment both socially and financially.

The company was initially set up as a standard transaction advisory firm focused on doing big ticket transactions in Africa. However, it quickly became apparent after six months that despite the immense investment opportunities across key sectors of the African economy, getting deals done in Sub-Saharan Africa is costly and time consuming. This is mostly due to infrastructure challenges, small ticket sizes of transactions, non-availability of verifiable data and lack of proper governance structure. These challenges have made it increasingly difficult for African companies to attract investment funds. In addition, most African countries lacked the concerted effort required by the governing authorities and multilateral institutions to develop policies and the right incentives to create the perfect environment for technology, finance and access to new markets to coexist, and provide the perfect conduit to attract investable funds into businesses and projects across Africa. These challenges made the partners at DFS Africa rethink their approach to transaction structuring in Africa. The leadership of DFS Africa realised that in order to solve the big challenges in Africa, there is a need to integrate public authorities and development finance institutions into the investment strategy for Africa. This was the birth of DFS Africa's Strategic Implementation Unit

(SIU). The SIU is a part of the company equipped with the know-how of supporting public authorities, foundations and multinational organisations to adapt global solutions to Africa's challenges.

Partnerships have been the bedrock of DFS Africa's success within the healthcare and pharma space in Africa. We have developed partnerships with organisations and institutions both foreign and local with the capabilities to solve wide ranging healthcare challenges across the 5 regions of Africa. For instance, our SIU facilitated the partnership with the African Union Commission (AUC) and the African Union Development Agency New Partnership for Africa's Development (AUDA-NEPAD) to implement the Pharmaceutical Manufacturing Plan for Africa (PMPA). The mandate of this partnership was to attract US$10 billion to Africa's pharmaceutical sector. Additionally, recognising that access to essential medicines and health security are arguably the biggest challenge facing this generation of Africans, our partnership with the AUC and AUDA-NEPAD resulted in the convening of the Africa Pharma Conference (APC) in 2019. Since then, we have developed the Africa Pharma Platform (APP) which acts as the umbrella through which all the PMPA implementation activities are executed. Currently, our partnership with the AUDA-NEPAD involves the implementation of the following initiatives:

1. **African Pharma Best Practices Framework (APBPF)**: The APBPF is aimed at national and regional authorities. It provides a template of practices that ensure self-reliance in local pharmaceutical production and is implemented in line with the core AUDA-NEPAD mandate of providing knowledge based advisory services and technical assistance to African Union Member States and Regional Economic Communities in strengthening capacity. This initiative is essential to ensure that governments are provided with the necessary evidence driven support in achieving their national development plans, while providing the necessary political will, without which, any efforts by the direct foreign investors and private sector would be fruitless.
2. **Africa Pharma Conference (APC)**: Annually, the APC is convened with four events running in parallel over the course of a week. The panel sessions at the conference are a platform to champion the conversations that matter. Other side events include:
    1. The Executive Roundtable – A platform where Big Pharma and local pharmaceutical producers (LPPs) meet with other

stakeholders;

2. Boot camp – a training camp to learn critical aspects of the pharma value chain; and
3. Africa Pharma Deal Room – a platform for investors to meet with LPPs who are seeking investments.

3. **Africa Pharma Learning Management System (APLMS)**: The APLMS is the foremost platform for accelerating Pharma and Biotech capacity building and knowledge transfer in Africa. It facilitates the growth of the Africa Pharma industry by:

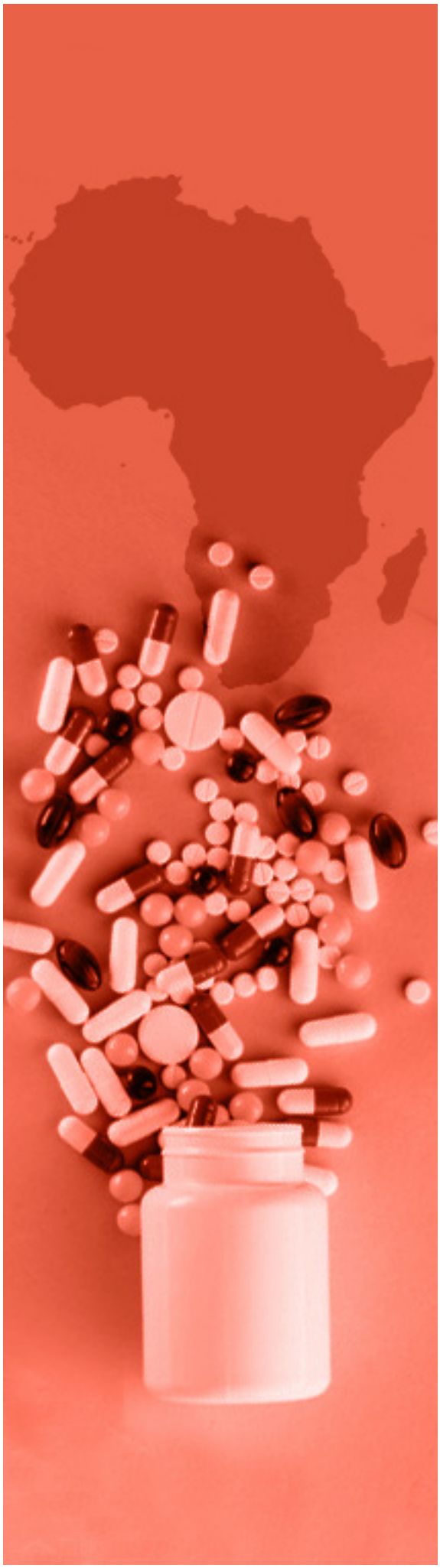
   a. Providing accessible, quality and cost-effective training designed to increase individual and organisational productivity and enrichment;
   b. Creating, promoting and fostering an industry environment that values development, diversity and growth opportunities for all professionals in the industry;
   c. Providing individuals and each organisation with the tools to respond effectively to customer needs as well as current and future demands for products;
   d. Aggregating courses from existing industry courses, and
   e. Providing content that is aligned with regional regulatory and market requirements.

4. **Africa Pharma Fund (APF)**: The establishment of a fund for local African pharmaceutical sector development as a critical input in accelerating the achievement of the objectives of the Pharmaceutical Manufacturing Plan for Africa (PMPA) has been established beyond reasonable doubt. The PMPA, and its associated business plan, envisions the development of a competitive local pharmaceutical industry in Africa to ensure self-reliance in rapidly responding to public healthcare needs for access to essential, quality, safe and effective medical products and technologies. The need to promote a secure and reliable supply of essential medicines, vaccines, diagnostics, technologies and health commodities is critical to strengthening and securing Africa's health systems.
5. **Africa Pharma Resource Database (APRD)**: The APRD will enable local and diaspora experts in the pharmaceutical industry to share their profiles and

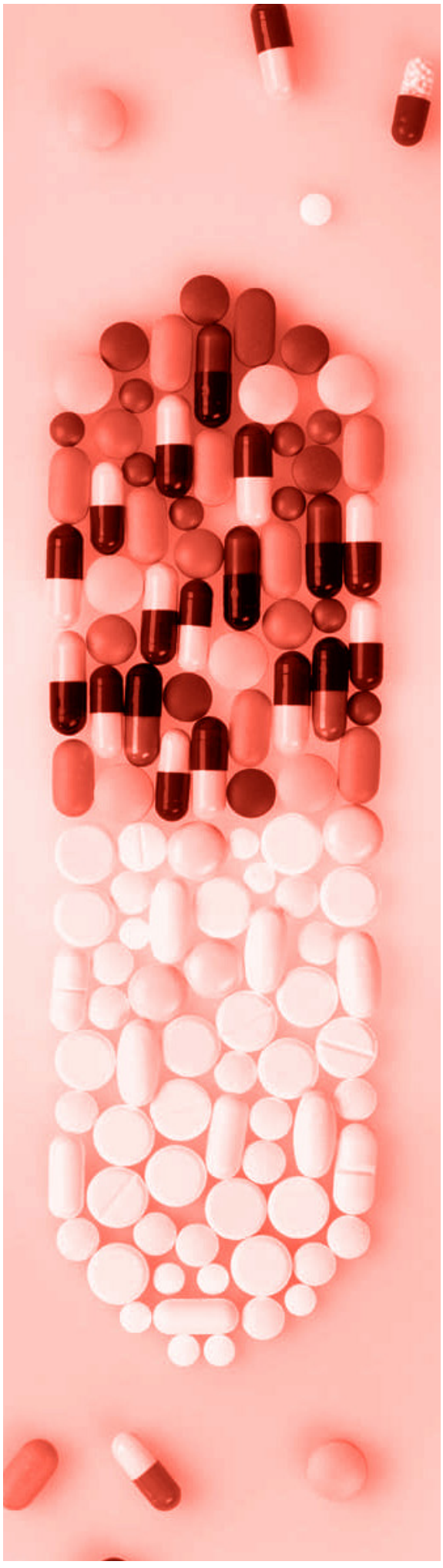
research areas/interests. The database will feature a user-friendly search function for users and an algorithm that proactively matches experts to potential opportunities across the African pharmaceutical industry.

Africa's long-standing essential medicines problem has persisted for more than half a century and after three years of working in the continent's pharma and healthcare space, we can proudly say we are battle hardened as we have battled several challenges that have inhibited Africa's healthcare and access to essential medicines for so long. In order to address lack of access and inefficiencies, we have worked with partners that include supranational institutions, national governments, charities committed to global health, development finance institutions and technocrats from diverse backgrounds to champion conversations and implement solutions that address core inefficiencies in Africa. These inefficiencies include the incoherence of healthcare policies across Africa, fragmented and cumbersome procurement procedures for medicines and healthcare products across African countries, fragmented medical products regulatory frameworks across countries, inadequate human capacity and financial investments in healthcare and low volume of pharmaceutical production in Africa. Insufficient investment in relevant infrastructure that underpins sustainable healthcare provision and pharmaceutical manufacturing are other challenges limiting access to medicines in Africa. The DFS Africa story is truly a story of resilience, creativity and unbridled bravery in the face of insurmountable realities. Through it all, we have success stories in:

1. Convening the inaugural Africa Pharma Conference;
2. Developing the Connecting the Dots Initiative (CDI) as Africa's response to the COVID-19 pandemic and essential medicines platform;
3. Facilitating policy implementation programs in partnership with AUDA-NEPAD, i.e., the implementation of the PMPA;
4. Galvanising African healthcare leaders to respond to the COVID-19 pandemic through a series of events titled "Galvanising African Industrial Capacity Towards Critical Pharmaceutical and Medical Supplies"; and
5. Commissioning research projects to assess the continental pharma manufacturing landscape.



The Challenge Of Access To Essential Medicines In Africa And Strategies To Address The Problem



Access to safe, quality-assured and efficacious medicines and vaccines for all is at the core of universal health coverage (UHC) and the Sustainable Development Goals. However, access to medicines and vaccines continues to be a global concern due to escalating prices of medicines, the ongoing shortages of medical products and stock outs, as well as the increasing prevalence of substandard and falsified medical products that pose a public health risk. In addition, inequities in many countries are often increased by the high burden of out-of-pocket payments for medical products, resulting in catastrophic payments and the impoverishment of families. For instance, up to 90% of the population in developing countries purchase medicines through out-of-pocket payments. After food, medicines are the largest family expenditure item. Furthermore, the prevalence of non-communicable diseases is increasing in Africa and these diseases, which require long-term treatment, are resulting in additional financial strain on patients and governments. The supply chain system in many countries also continues to underperform. Health systems are therefore under increasing pressure to provide affordable access to healthcare, especially as innovative high-priced medical products are being introduced.

In Africa, nearly half the population has little or no access to affordable quality essential medicines, resulting in limited ability to effectively prevent and address health emergencies. Essential medicines are those that satisfy the priority healthcare needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. The inability to access essential medicines is the cause of millions of avoidable disabilities and deaths across the continent. Additionally, an estimated 85% of Africans live under $5.5 per day and most of these 800 million people rely on poor quality medicines that do not treat diseases and actually contribute to an increase in antimicrobial resistance. The main cause of this situation lies in market dynamics that prevent information on availability, price transparency and optimisation being publicly available. This in turn hinders the aggregation of demand necessary to provide medical products at optimised prices and enables lack of access during crisis. Lack of access to medical products and unaffordable prices is also caused by poor selection of medical products, inadequate domestic or government financing as well as ineffective policy interventions and procedures for the

management of out-of-pocket payments. Furthermore, the problem of access to medicines in Africa is exacerbated by the continent's poor infrastructure network i.e., there are inadequate transportation systems, communication networks and constant power shortages. With a high rural population across Africa, improved infrastructure would enhance access to primary healthcare. The unavailability of adequate healthcare facilities in the rural areas, as well as the unbalanced distribution of health services and facilities mean access to essential medicines is denied to most Africans, especially the poor and citizens who depend on the public sector for healthcare services.

The World Health Organization (WHO), through its strategic and normative work, has a pivotal role in ensuring access to safe, quality-assured and efficacious medicines and vaccines worldwide. As part of this role, a report on 'Addressing the global shortage of, and access to, medicines and vaccines' was presented in May 2018 at the 71st World Health Assembly and it outlines priority actions that form the basis for its activities, actions and deliverables related to shortage of, and access to, medicines and vaccines. The priority actions are consolidated into the following activity areas:

1. Research and development of medicines and vaccines that meet public health needs,
2. Fair pricing and financing policies,
3. Application and management of intellectual property to contribute to innovation and promote public health,
4. Procurement and supply chain management,
5. Appropriate prescribing, dispensing and use,
6. Regulatory systems that ensure quality, safety and efficacy of medicines and vaccines,
7. Preparedness for emergencies,
8. Good governance,
9. Collecting, monitoring and using key data, and
10. Health workforce

As DFS Africa, we have been working with our partners to address the problem of access to essential medicines on the continent in most of these identified activity areas. We also acknowledge that there needs to be sufficient political will at the national level to improve access to medical products. Moreover, a comprehensive health systems approach that addresses all aspects of the pharmaceutical value chain is required.

1. Procurement and supply chain management

One of the building blocks of a functional health system is having safe, quality-assured, effective and affordable medicines and vaccines continuously supplied. Good procurement practices secure competitive prices and ensure the adequate supply of quality products in a timely fashion, whereas good supply chain management ensures the availability of quality-assured medical products at all levels of the healthcare system. Some of the challenges that are faced in implementing good procurement practices are limited negotiating power, inaccurate quantification of product demand, and corruption in procurement practices and procedures. Limited negotiating power is a result of a lack of information on how prices are derived and what price other countries/procurement agencies are paying, as well as small economies of scale. In spite of these challenges, commendable progress has been made over the last twenty years in improving access to products for vertical public health programmes, however, as countries are transitioning from donor support to self-sufficiency, new challenges are also arising. Supply chains in Africa are often weak as a result of poor infrastructure and the lack of accurate data management systems. These complex and increasing challenges affect access to medicines and vaccines, and in the case of communicable diseases, the consequences of shortages affect not only the individual, but the entire public health system. When there are inefficient distribution systems, there are often high levels of wastage with related implications in terms of availability, affordability and access.

In combating the challenges surrounding access to medicines, DFS Africa has developed a supply and demand aggregation platform for essential medicines and healthcare products known as the **Connecting the Dots Initiative (CDI)**. The CDI was launched in August 2020 as a specific response to the COVID-19 pandemic, ensuring that African countries and institutions have quick access to essential products needed to fight the pandemic. It leverages information, data and technology, as a one-stop platform for suppliers and buyers of essential medicines and healthcare products. The platform supports efficient procurement of affordable and quality-assured medical products across Africa. DFS Africa also ensured that as part of the global pool of pharmaceutical manufacturers retailing high volumes of essential medicines and health products required across the continent, we partner financial institutions such as the Afreximbank, the African Development Bank and private equity firms to support a wide range of African manufacturers of medical products

to sell their products through CDI. Supporting African manufacturers to produce products needed by Africans achieves the Cobb–Douglas production function, i.e., it improves technological relationships between inputs of production such as capital, labour and outputs that benefit Africans. Furthermore, it guarantees against potential stock-outs and strengthens the resilience and sustainability of supply for emergency products and of health systems on the continent.

The CDI platform has many benefits for procuring agencies, donor funders, health institutions and governments across Africa. Apart from the obvious benefits of optimised pricing, pooled procurement, ease of transaction and easier access to all essential medicines and health products in a single order, the CDI is renowned for two main components, these are the ability of its underpinning algorithms to close-out information gaps about medicines and suppliers, and the platform's capability for sustainable procurement of emergency care products. Further, the ultimate beneficiaries of a platform like CDI are the approximately 800 million Africans who need access to essential medicines and health products. The public sector buyers that procure medical products for governments and health emergencies also find CDI extremely beneficial because the platform strengthens supply chain security and reduces procurement inefficiencies. Equally, donor organisations that currently procure more than 60% of medicines and health products used in Africa find tendering through CDI to be highly beneficial because the platform fully leverages the benefits of pooled procurement. Intermediate beneficiaries of CDI are manufacturers, regulators, and public health program managers. As it stands, CDI has on boarded two national governments as buyers (Nigeria and South Africa) and 54gene, a private equity-funded initiative currently establishing diagnostic centres across Africa, whereas CDI-COVID has on boarded more than 300 suppliers with a capacity of over 1 million units across 40,000 products.

2. Regulatory systems that ensure quality, safety and efficacy of medicines and vaccines

Every country is encouraged to have a National Medicines Regulatory Authority (NMRA) that is responsible for ensuring that medical products on the market are safe, quality-assured and efficacious, and over the past decade, a number of organisations and institutions have made significant investments into regulatory systems strengthening efforts worldwide. However, it is estimated that in all WHO regions, only 60 NMRAs have well-functioning and integrated regulatory systems. The number

60%

of medicines and health products used in Africa are procured by donor organisations

CDI has on boarded:

2

National governments as buyers (Nigeria and South Africa)

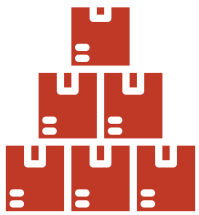
1

Private equity-funded initiative (54gene)

CDI-COVID has on board:

300

Suppliers



1mil

Units

40,000

Products

is low for the African region. There are several advantages to having an effective NMRA, including the fact that it boosts the public's confidence in the medical products available on the market. However, some countries do not have NMRAs that are up to standard and these undermine access initiatives. For instance, long lead times and divergent regulatory requirements between countries cause delays in marketing authorisation of innovative products of between four to seven years in Sub-Saharan Africa. There is therefore a need to have regulatory systems that protect and promote public health as well as enable the timely access to, and innovation for, quality medical products. As DFS Africa, we are actively working with the AUDA-NEPAD in implementing the Africa Medicines Agency treaty and the African Medicines Regulatory Harmonization (AMRH) initiative. We are funding the advancement of the implementation of these two regulatory initiatives and we also act as the principal facilitator for bringing together all the global stakeholders that are required for implementation.

60

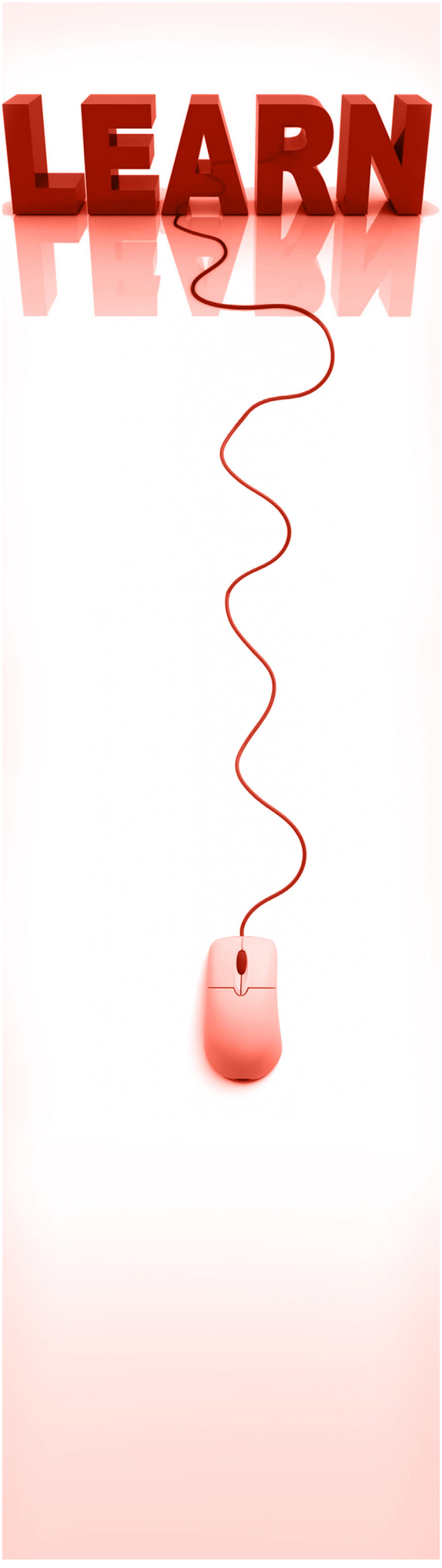
NMRAs have well-functioning and integrated regulatory systems in all WHO regions

3. Preparedness for emergencies

A public health emergency, such as the ongoing COVID-19 pandemic, requires decision making that is different to the status quo as it creates an urgent need for medicines, vaccines, diagnostics and emergency response sites. In addition, emergency plans that can provide for the stockpiling of essential medical products and supplies are needed. These plans should also consider the logistics of product distribution to areas most affected.

As part of the COVID-19 response, DFS Africa galvanised the leading stakeholders in healthcare in Africa to deploy the continent's response to the pandemic. We developed the Connecting the Dots Initiative – Medical Products for Health Emergencies (CDI-MPHE) platform to leverage information, data and technology on a one-stop platform for suppliers and buyers. The CDI-MPHE builds on an already existing platform (CDI-COVID) that we, in partnership with the United States Pharmacopoeia (USP), are using to facilitate the procurement of COVID-19 products in Africa. This solution has two main components: closing information gaps about medicines and suppliers, and providing a platform for sustainable procurement of medical products for emergency care. CDI-MPHE also adopts processes such as data sourcing and capture, artificial intelligence, machine learning, data aggregation, products verification, order fulfilment and financing, and procurement modelling. The platform collects and analyses multiple data sets from suppliers, buyers, regulators and logistics providers, which it then integrates with third party organisations to validate

data and ensure seamless transactions. Lastly, we hosted six COVID-19 response webinars that can be accessed at https://dfsafrica.org/reports.html



4. Health workforce capacity for access to medicines and vaccines

In order to improve access to medicines and vaccines, a competent health workforce is required and it must be diverse so as to cover the development, production, procurement, distribution and appropriate use of medical products. However, low- and lower-middle-income countries continue to have a relatively low density of pharmacists and this creates challenges such as inadequate numbers of personnel, misdistribution of the workforce, uneven implementation of education, as well as staff management and retention issues. Therefore, strategies are needed to improve the forecasting, planning, education, deployment, retention and performance management of human resources for health. In addition, there is a need to develop and scale up a more systematic approach to improving the pharmaceutical workforce's skills and for monitoring its size, composition, skills, training needs and performance. It is believed that this will contribute to ensuring medical products' quality and availability.

At the back of this, AUDA-NEPAD, in conjunction with DFS Africa, launched the African Pharmaceutical Learning Management System (APLM), which will be the foremost platform for accelerating capacity building and knowledge transfer for Pharma and Biotech in Africa by providing accessible, quality, cost-effective training designed to increase individual and organisational productivity and enrichment.

5. Other activity areas

DFS Africa also works in the area of fair pricing and financing policies as the goal of CDI is to optimise fair pricing on the continent and serve as a platform leading conversations and the implementation of financing policies in Africa. Additionally, DFS Africa contributes to the application and management of intellectual property as part of efforts to contribute to innovation and the promotion of public health as we have commissioned 3 research projects that aim to transform the African pharma manufacturing landscape. These projects are:

1. Research to assess the readiness of African pharma manufacturers to produce essential medicines,
2. Research on procurement of essential medicines in Africa, and

3. Research into opportunities for improved market access for local pharmaceutical manufacturers in Africa, specifically the implications of the African Continental Free Trade Agreement (AfCFTA).

Furthermore, in the area of good governance, we are advancing and developing robust regulatory systems in Africa as an attempt at improving good governance, e.g. the implementation of the African Pharma Best Practices Framework (APBPF) is a step towards achieving good governance. Lastly, as our CDI platform is a data driving platform that is collecting and monitoring critical data to support Africa's future response to epidemics and pandemics, we essentially play a role in the priority action that focuses on "collecting, monitoring and using key data". The role of the government in improving access to essential medicines and vaccines

Governments play a critical role in ensuring and improving access to essential medicines and vaccines. Their four main roles are to develop national drug policies; develop health systems that enable drug supply; establish pharmaceutical legislation and regulation; and create a framework for research, monitoring and evaluation that supports the process. The key components of a national drug policy are outlined in Table 1.

Legislation and regulation	National Medicines Regulatory Authority
	Quality assurance
	Standards of practice and education
Drug selection	Essential medicines concept
	Traditional medicines
Economic strategies for drugs	Affordable prices
	Sustainable financing
	Local pharmaceutical production
Drug supply	Reliable supply systems
Rational use of medical products	Public and private sector
	Health professionals and patients
Supportive components	Research
	Monitoring and evaluation
	Development of human resources
	Technical cooperation among countries

Table 1: Key components of a national drug policy

Governments can also improve access through the strategic and sustainable local pharmaceutical production of these essential products. According to the WHO, as at June 2017, there were 43 vaccine-producing countries worldwide and of these, 36 had a functional NMRA. The numbers are significantly lower for Africa and as a result, the region has been pursuing local production as a strategy to improve access as well as for economic and industrial development through the implementation of the PMPA. However, it is difficult to replicate the success of industrial development witnessed in larger economies in smaller markets. Some of the barriers that are faced in setting up local pharmaceutical production include a lack of infrastructure, competent personnel, collaborative linkages and policy coordination between government ministries/ departments, and access to appropriate and long-term sustainable financing. Fortunately, governments do not have to tackle the access to medical products challenge alone and they can create public-private partnerships, in particular product development partnerships (PDPs), as a way of delivering healthcare and bringing about health systems strengthening. These multi-stakeholder efforts can work to address some of the barriers mentioned as well as ensure product registration and governance for health. Governments can also use policy incentives to increase local pharmaceutical production and distribution capacity, ultimately improving access.

DFS Africa, through our Strategic Implementation Unit, supports governments to address the access challenge by assisting with suitable policy creation and implementation, and also establishing public-private partnerships and joint ventures as these have historically had success in Africa. Moreover, DFS Africa is in a position to match stakeholders such as local pharmaceutical manufacturers to investors who can provide support by way of subsidies, grants, or through de-risking investments.

The way forward for solving Africa's long-standing essential medicines problem is for governments across the continent to engage organisations like DFS Africa and other private sector stakeholders to articulate the right incentives that will attract investment funds into healthcare and the pharmaceutical industry of respective countries and regions of Africa. It is our belief at DFS Africa that we are part of the generation of Africans that will permanently solve Africa's long-standing problem of access to medicines and in solving this problem, we will create jobs, transform our healthcare landscape and bring wellness to the 1.3 billion people who call Africa home.

For more information about DFS Africa, please visit: https://dfsafrica.org/

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