



Virginia  
Economic  
Development  
Partnership

## Industry Report

### Africa – Healthcare / Life Sciences



Prepared by: **Faith Okalet**

**Zurcom International (Pty) Ltd**  
Ground Floor, Block 2  
Kingfisher Office Park  
28 Siphosethu Road  
Mount Edgecombe, KwaZulu-Natal  
South Africa  
Tel: +27 12 993 0159  
Email: [zurcom@zurcom.net](mailto:zurcom@zurcom.net)

Date: June 2021

# CONTENTS

<b>Contents</b>	<b>2</b>
<b>COMMISSION</b>	<b>4</b>
<b>Healthcare in Africa</b>	<b>5</b>
<b>AFRICA IN GLOBAL CONTEXT</b>	<b>7</b>
<b>HEALTHCARE ACROSS AFRICA: A TOUR</b>	<b>9</b>
South Africa: Africa’s Biggest Healthcare Market	9
Health Innovation in East Africa	10
West Africa’s Healthcare Market: A look at Ghana	12
<b>THE MEDICAL DEVICE MARKET IN AFRICA</b>	<b>13</b>
Medical Device Regulation in South Africa	13
Medical Device Regulation in Kenya	15
Medical Device Regulation in Ghana	16
<b>African Outlook Present and Post Covid-19</b>	<b>17</b>
<b>Key Findings</b>	<b>19</b>
<b>Recent Developments</b>	<b>19</b>
<b>Recent Developments FOR US EXPORTERS in Africa</b>	<b>19</b>
African Continental Free Trade Area (AfCFTA)	19
Africa Growth and Opportunity Act (AGOA)	20
US-Kenya Free Trade Agreement (FTA)	20
US-Morocco Free Trade Agreement (FTA)	20
<b>Industry Opportunities</b>	<b>21</b>
<b>Medical devices</b>	<b>22</b>
South Africa	22
Kenya	23
Ghana	23
<b>Pharmaceutical industry</b>	<b>24</b>
South Africa	24
Kenya	25
Ghana	26
Tanzania	27
<b>Digital health</b>	<b>28</b>
South Africa	29
Kenya	29
Ghana	30
<b>Skills Development &amp; Training</b>	<b>31</b>
South Africa	32
<b>Key Players</b>	<b>33</b>
<b>Regional Government Agencies / Networks</b>	<b>33</b>
AU Division of Health, Nutrition and Population	33

West African Health Organization (WAHO)	33
Africa Regional Network	33
WHO Regional Office for Africa	33
<b>National Government Agencies &amp; Networks</b>	<b>34</b>
The Council for Medical Schemes (South Africa)	34
South African Health Products Regulatory Authority	34
<b>Industry Associations</b>	<b>34</b>
South African Medical Technology Industry Association	34
Innovative Pharmaceutical Association of South Africa	34
Africa Healthcare Federation	35
Hospital Association South Africa	35
<b>Research Centres</b>	<b>35</b>
Council for Scientific and Industrial Research (South Africa)	35
South African Medical Research Council	35
Ifakara Health Institute (Tanzania)	35
Kenya Medical Research Institute	36
<b><i>Market Entry Strategy</i></b>	<b>36</b>
Establish a Local Presence	36
Find and Select a Reputable Partner	36
Adopt Flexible Payment Models	36
Target Primary Healthcare Providers	36
<b><i>Industry Publications</i></b>	<b>36</b>
Africa Health	36
Africa Healthcare IT News	37
Medical Brief	37
Health 24	37
Radiant Health Magazine	37
Medpharm Publications	37
<b><i>Industry Events</i></b>	<b>38</b>
Africa Health Exhibition	38
Medical Expo Tanzania	38
Medical Expo Morocco	38
Medic West Africa	38

# COMMISSION



As the Africa Global Network Consultant to the Virginia Economic Development Partnership (VEDP), Zurcom International was commissioned to prepare an in-depth industry report on the **Healthcare sector in Africa**.

Expected economic and demographic growth means that African countries provide an ideal environment for healthcare exporters of goods and services to forge strategic partnerships. The African market provides opportunities in various subsectors, ranging from pharmaceuticals and medical devices, digital health, health services, infrastructure including hospital architecture and management systems, as well as skills development and training. The African Continental Free Trade Agreement (AfCFTA), put into force on January 1, 2021 forming the continent into one

common market, presents a long view on standardization toward health in trade policies and programs and will lead to an increase in integration between African nations.

This report is intended to provide Virginian exporters with a general overview of African healthcare and life sciences sectors. It offers specific insights into the current trends in Africa's healthcare industry specifically focusing on recent developments and opportunities. This report will offer specific insights into the healthcare sector with a focus on Southern, East and West African countries. An emphasis has been placed on describing various country markets of note including South Africa, Ghana, Kenya and Tanzania. These countries were chosen based on ease of entry for new-to-market US firms, as well as the level of interest our team has seen from US exporters of medical devices and consumables in the recent past.

We encourage any Virginian companies with questions or enquiries to contact VEDP for further information.

We look forward to continuing to assist VEDP and Virginian exporters in the African market.

Richard Zurba, Director  
Zurcom International (Pty) Ltd  
*Durban, June 2021*

# HEALTHCARE IN AFRICA

**African healthcare presents a large range of growing opportunities in medical devices, consumables, services and digital technologies to Virginia exporters.** Healthcare is a vital sector for the wellbeing and prosperity of African, as other, societies. Healthcare also contributes to sustainable economic development. Especially now, in light of the COVID-19 crisis, a renewed focus on healthcare, quality service delivery and innovation has the potential to energize an already growing and important sector.

It is estimated that the **African healthcare market will be worth \$259 billion by 2030**, Africa will present 14% of health and wellbeing business opportunities, only second to North America holding 21% of the opportunities. The market is growing due to population growth, the changing nature of burden of disease, and the need to decrease the gap between demand for and access to quality healthcare for all.

Currently, although the continent accounts for approximately 17% of the world's population, it accounts for 25% of the world's burden of disease. This will be further affected by the fact that **Africa's population** is growing and is **expected to nearly double to reach 2.5 billion** people from 2021 to 2050. Simultaneously, the number of people aged 60 years and older is projected to reach 67 million by 2025 and 163 million by 2050. Thus an increasing number of people are living with chronic diseases and disability, increasing the demand for a variety of health services.

Africa's burden of disease has historically been related to **communicable diseases**, which account for **two thirds of the total disease burden**. The biggest share of the disease burden comes from **HIV/AIDS** (70% of people living with HIV are in Africa) and Southern Africa remains disproportionately affected.

However, **non-communicable diseases are rising** around Africa. This is taking place in parallel to an increasing rate of urbanization (from 27% in 1950 to 40% in 2015 and projected to reach 60% by [2050](#)) and subsequent lifestyle changes. These changes are associated with rising risk factors such as **hypertension, diabetes and obesity**, as well as **mental and neurological disorders**. A World Bank report estimates that by 2030 non-communicable diseases will cause more deaths in Africa than communicable diseases.

This double burden means that the already stretched healthcare resources need to prepare themselves to respond to the evolving needs of African populations. Currently, more than half of Africa's population [lacks access to essential health services](#). Part of the reason for this limited access to healthcare is **limited public resources**. There is a **\$66 billion financing gap** per year in Africa. The IFC estimated that by 2022, [Africa will need \\$25 billion – \\$30 billion in investment in physical healthcare assets alone](#), including hospitals and clinics.

In addition to the lack of financing, Africa also has the **lowest density of skilled health professionals** in the world, with 13 out of the 47 countries for which data is available having less than 5 health professionals per 10,000 people.

Another significant challenge is that the hospitals, health facilities and services tend to be concentrated in urban areas, further limiting access to a large number of people. This makes it

difficult to identify and respond to public health concerns, placing the burden on more resource-intensive treatment rather than prevention and health promotion.

In response to these challenges, the African Union (AU) members, using the United Nations 2030 Development Agenda and specifically [SDG 3](#) (Good Health and Wellbeing) concerning healthcare, have pledged to try and achieve [universal health coverage by 2030](#). The AU has also launched a [health financing initiative](#) in 2019, pledging up to \$200 million to help end epidemics and bring universal health coverage to all.

In order to facilitate greater access to healthcare, there is a need for increased and innovative public and private sector involvement in addressing these challenges. The role of the private sector should complement the public sector efforts in the delivery of quality healthcare to the existing and projected demands. Some of the measures governments are pursuing to improve the complementarity between public and private efforts are:

- Improving the ease of doing business
- Developing health insurance systems
- Issuance of health bonds
- Public-private partnerships

---

*It is estimated that the African healthcare market will be worth **\$259 billion by 2030**. Africa will present 14% of health and wellbeing business opportunities, only second to North America holding 21% of the opportunities*

---

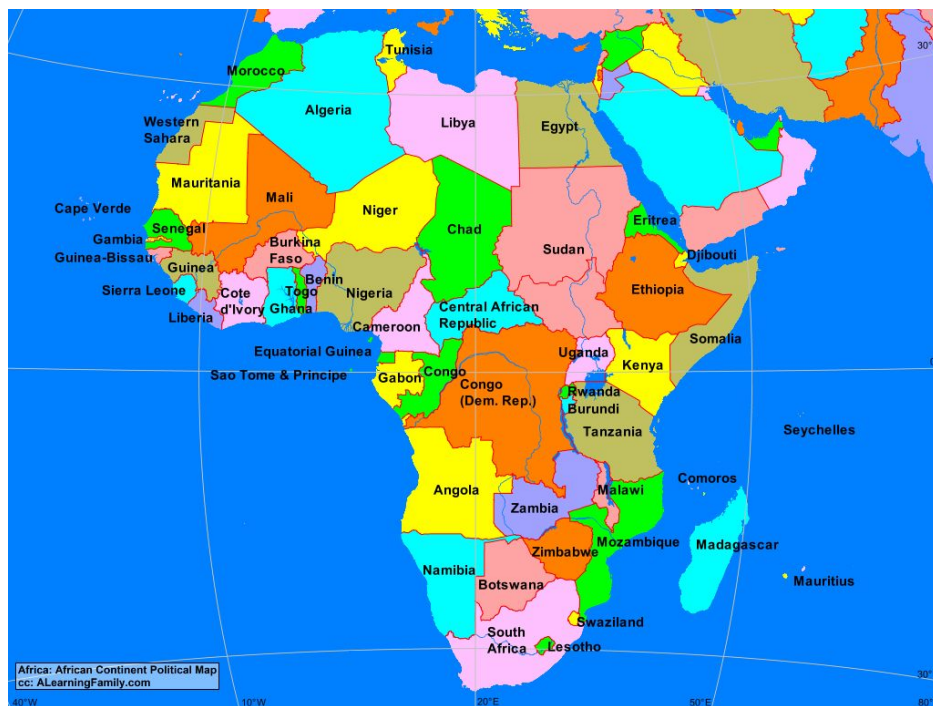


Figure 1: Map of Africa Source: A Learning Family



# AFRICA IN GLOBAL CONTEXT

As a continent of 54 countries and abundant resources, Africa holds immense opportunities in locating trading partners for Virginian exporters. As the continent with the world’s youngest population, Africa's youth is one of its largest resources and can offer enormous potential in the form of a large and skilled workforce if mobilized properly.

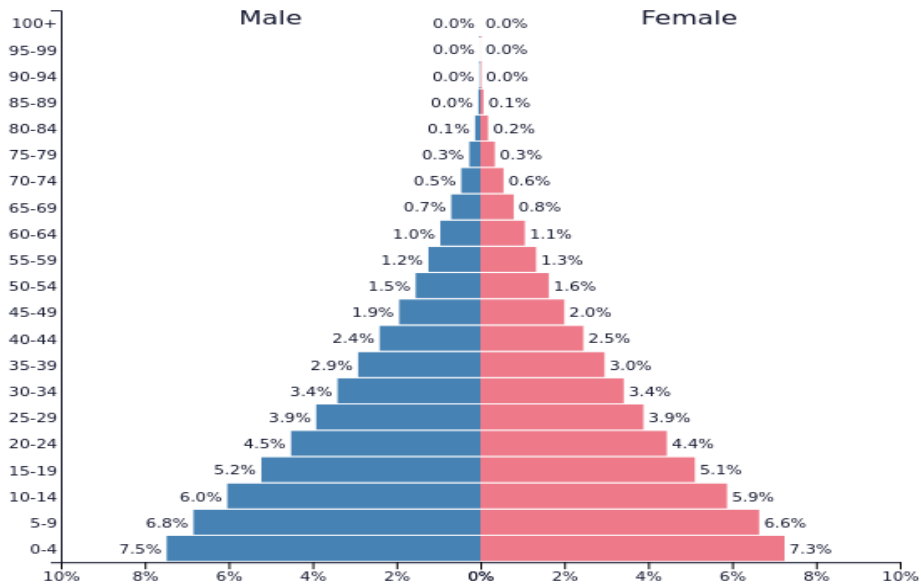


Figure 5: Population pyramid/ Source: Population Pyramid

**Africa presently has 1.34 billion people.** Figure 2 shows Africa’s population pyramid, the wider base confirms the higher population of young people on the continent. For many decades the enormous populations of South America, Europe and Asia have grown quickly, but today they have slowed, and the majority of their populations are adults. In India the average age is 29, in China it is even older, at 37. But in Africa, **the average age is 19.5 years old.** The continent is growing so quickly that by halfway through this century, it will be home to one billion children. By 2050, two in every five children in the world will be born in Africa while the total population will be 2.5 billion.

By 2050, Africa will have most of the new labor force entering the world labor market. Engaging with and investing in youth is not only crucial but also an opportunity for building human capital to progress toward the demographic dividend. It also presents a number of opportunities for investment. Africa’s youth are generally creative and entrepreneurial, global in outlook and information gathering and transmitting capabilities, and have key global languages as the basis of their education, particularly English.

## Commercial in Confidence

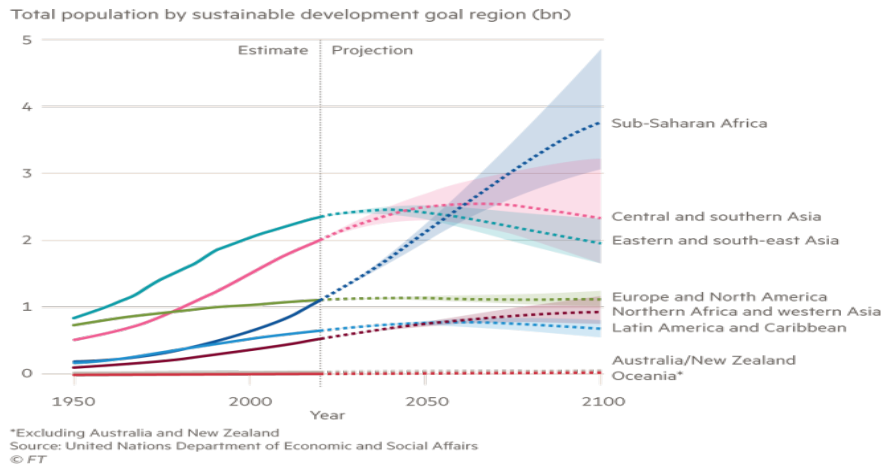


Figure 6: Total Population by sustainable development goal region/ Source: United Nations Department of Economic and Social Affairs.

As shown in Figure 4, Sub-Saharan Africa's population is set to double over the next 30 years, adding an additional 1.2 billion people and putting it on track to overtake central and south Asia soon after as the world's most populous region. The high fertility rates south of the Sahara mean that region of Africa will account for more than half of global population growth between now and 2050, according to projections from the UN Population Division. The region's population will still be rising fast at the end of the century, when the number of people living in much of Asia and elsewhere will be in decline.

Coupled with the growth of Africa's middle class, there is a new generation of consumers in the form of young, educated, and urban African professionals ready to consume and inject revenue into their economies.

Investing in African health systems is an opportunity to accelerate economic development and growth, contribute to saving millions of lives and prevent life-long disabilities. Such investment will move countries closer to achieving objectives of national poverty reduction strategies and the Sustainable Development Goals (SDGs), this is according to Africa Health Business.

---

*By 2050, two in every five children in the world will be born in Africa. Therefore, engaging with and investing in youth is not only crucial but also an opportunity for building human capital to progress toward the demographic dividend and it presents a number of opportunities for trade.*





## HEALTHCARE ACROSS AFRICA: A TOUR

### South Africa: Africa’s Biggest Healthcare Market

South Africa has one of the biggest healthcare markets in Africa. The total South African healthcare market is projected to reach a value of **\$37 billion by 2022** and **\$47.1 billion by 2027**. Yet, healthcare in South Africa is faced by serious challenges presenting an opportunity for constructive engagement by companies delivering healthcare products and services.

South Africa faces a **quadruple burden of disease**: communicable diseases such as HIV/AIDS, TB, typhoid fever and hepatitis; maternal and child mortality; NCDs such as hypertension and cardiovascular diseases, diabetes, cancer, mental illnesses and chronic lung diseases like asthma; as well as injury and trauma. The country has the highest number of people afflicted with HIV in the world, and the fourth-highest adult HIV prevalence rate.

### What causes the most deaths?



Figure 1: Causes of deaths in South Africa / Source: [Institute for Health Metrics and Evaluation](#)

Total healthcare spending in South Africa was about USD 51.1 billion in 2019. Despite this level of spending, access to quality healthcare is limited. The public sector provides healthcare for 80% of the population and accounts for approx. 48% of total health care spending. The private sector provides healthcare for 20% of the population and accounts for approx. 50% of total healthcare spending, while the remaining 2% is provided by non-governmental organizations.

South Africa has a referral-system of healthcare and public health services in South Africa are delivered across three levels of government: national, provincial and local. There are currently more than 3,800 public health facilities, including 400 public hospitals, which have over 48,000 beds in South Africa. The public sector suffers from understaffing, especially in rural areas, as many medical professionals are bled out to the private sector or work overseas.

The [National Development Plan 2030](#) adopted by the SA government has been a driving force behind the transformation efforts of public healthcare infrastructure. The Department of Health

plans to spend approximately [\\$1.35 billion from 2019 - 2022](#) on the revitalization of public hospitals and other health facilities. This will go to fund around 15,000 infrastructure projects, the national health insurance, and the planning and construction of an academic hospital in Polokwane, as well as improvements to the nearby Pietersburg and Mankweng hospitals.

The government is also rolling out the [National Health Insurance](#) (NHI), providing universal coverage to citizens and long-term residents. The NHI will buy services both from the public and private sectors, and will promote the provision of primary healthcare. This will have a significant impact on the growth of sub-sectors such as pharmaceuticals, medical devices, the need to train more healthcare professionals and others.

The private sector delivers high quality healthcare, but is also some of the most expensive in the world. The [Health Market Inquiry Final Findings and Recommendations Report](#) found that the private healthcare sector was not very competitive and that there is an overutilization of services. There are around 314 private hospitals and day clinics which have over 34,000 beds in South Africa. The private healthcare sector presents opportunities for high-tech healthcare products and services. Private healthcare is dominated by three healthcare groups: Mediclinic Southern Africa, Life Healthcare and Netcare Group.

## Health Innovation in East Africa

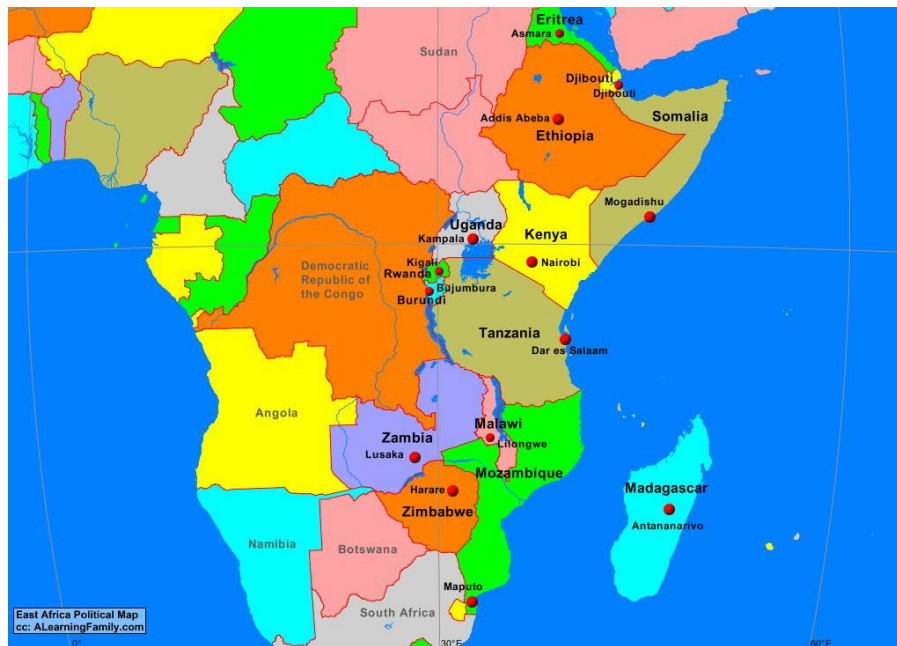


Figure 2: Map of East Africa Source: A Learning (countries in bold)

Across East Africa the role of the private sector in healthcare is growing and leaders in multiple sectors are organizing diverse players across the ecosystem to grow innovative solutions and impact health outcomes. The private sector, made up of both for-profit and not-for-profit organizations, is engaged across the healthcare value chain with significant investments made in care delivery –from primary healthcare services to advanced care in large tertiary hospitals. The dynamic and fast growing social enterprise space is paying increased attention – and putting more money and talent– toward the idea that growing good ideas in the health sector can

have positive social impact. Private sector growth is driven by an increase in population, rising incomes, and, to a smaller extent private insurance.

The five East African countries (Kenya, Tanzania, Uganda, Burundi and Rwanda) currently have a combined population of 153 million. By 2030, East Africans are projected to increase to 237 million people. Over half (178 million) will be children and youth. The private sector serves patients across diverse income groups with more than 40% of those in the lowest economic quintile in Kenya and Uganda receiving health care from private, for-profit providers. While public sector providers are generally widely distributed; patients often express a preference for private sector services, largely due to a perceived sense of higher quality compared to the public sector on metrics such as cleanliness, convenience, wait times, and friendliness.

East Africa, and particularly Nairobi, Kenya, is a growing hub for Information and Communications Technology (ICT) innovation, and ICT innovations are being designed specifically for the healthcare sector. Given the quick and strong development of the ICT sector in the region, research by SEAD (network for Sciences, Engineering, Arts and Design) anticipates ICTs continuing to be fundamental to a large proportion of emerging innovative healthcare organizations. For ICT-focused companies to succeed, they will need to be incorporated into existing systems and prove that revenue can be generated from the value they create.

The main healthcare innovation trends in the region have been:

- ❖ Creating Patient and Provider Networks
- ❖ Healthcare innovators in East Africa are aggregating patients and providers into networks to create economies of scale that allow them to lower costs and increase access to care for patient populations.
- ❖ Improving Quality of Care

In addition to quality improvement measures being implemented through wholly-owned and aggregated provider networks, there are a number of standalone innovators providing quality improvement models and systems to providers.

Technologies that improve efficiency and financial sustainability Healthcare technologies are emerging as a key enabler of care delivery in the region, particularly technologies to improve efficiency and financial sustainability along the healthcare value chain. However, it remains a challenge for earlier stage, for-profit health technology companies to target and reach the right customer segment, a challenge that threatens sustainability.



## West Africa's Healthcare Market: A look at Ghana



Figure 3: Map of West Africa Source: A learning

Ghana is one of the most attractive markets in Sub-Saharan Africa for foreign products and investment. Health is one of the central pillars of the Government of Ghana's human development agenda and is an underlying factor in the government's overall strategy for accelerated growth in the country. The government allocated \$1.3 billion to the Health sector in 2019.

Ghana's demographics remain reflective of its lower-middle income status: the average life expectancy is 61.49 years and infant mortality remains far above the world average). Ghana has a full range of diseases endemic to Sub-Sahara Africa: cholera, typhoid, pulmonary tuberculosis, chicken pox, yellow fever, measles, infectious hepatitis, malaria, and schistosomiasis are all endemic in Ghana. Despite these challenges, the country does have a strong and growing middle class and many expatriate Ghanaians are choosing to return to participate in one of Africa's fastest growing economies.

Furthermore, Ghana's healthcare industry is typified by a government sector that serves most of the population and a growing private sector that serves 40% of healthcare needs. The government is prioritizing reforming the National Health Insurance Scheme (NHIS) and reducing the cost of medications. To fund these goals, in its 2019 national budget, the government allocated \$1.3billion to the Ministry of Health, an increase of 37% over the 2018 allocation and 8% of the total government budget. Some of this money has been earmarked for funding the development of a national hospital strategy, which is designed to improve the quality of services by appropriately classifying all hospitals. The budget will also provide capital for the construction of a new district hospital and five polyclinics in the Western Region, and the construction of 15 community health planning service facilities in five other regions.



## THE MEDICAL DEVICE MARKET IN AFRICA

The African medical devices market is expected to reach [\\$7.1 billion by 2023](#), up from \$4.9 billion in 2017. South Africa and Egypt account for 40% of the market, and Nigeria, Algeria and Morocco follow as large markets. There is limited local manufacturing of medical devices on the continent, with imports accounting for over 90% of all medical devices. Chinese suppliers hold a lead in the market but American firms come a close second holding approximately 30% of the medical device sector. The large reliance on imports, the low purchasing power of many of the countries and currency fluctuations mean that pricing plays an important part when choosing importers.

### Medical Device Regulation in South Africa

(**Not** like the USA in most respects)

South Africa does not currently require the registration of medical devices prior to their sale in the country, as it does for medicines. However, as of March 2020, all establishments manufacturing, distributing, and marketing medical devices must be licensed by SAHPRA (The South Africa Health Products Regulatory Authority). This is because such establishments have been “called-up” – which essentially means that they are now subject to a full set of regulatory rules. By contrast, medical devices have not been called up, although, they are being regulated in other round-about ways.

Besides ensuring that establishments uphold quality standards, SAHPRA must also call-up medical devices for registration to ensure their safety, efficacy and quality.

All medical device establishments operating in the country are now required to hold a SAHPRA license. (Establishments marketing class A devices that are non-sterile and do not have a measuring function are exempt from licensing requirements. SAHPRA classifies medical devices as class A, class B, class C or class D, with class A posing the least risk to patients and users and class D posing the highest risk).

According to a list of licensed medical device establishments available on SAHPRA’s website, 1 392 medical device establishments have been licensed by SAHPRA as of June 2020. SAHPRA provides three types of medical device establishment licenses: to manufacture medical devices; to distribute (import) medical devices; and to wholesale medical devices. If companies both manufacture and wholesale medical devices, they must apply for both types of licenses.

SAHPRA requires companies applying for medical devices establishment licenses to provide a host of data on the company and the medical devices it will market. Companies must show that they have proper quality management systems in place to safely manufacture or handle medical devices and ensure their quality. Companies marketing medical devices requiring a cold chain must demonstrate to SAHPRA that they have this capacity in place. Companies marketing sterile equipment must show how they ensure that products are and remain sterile until use.

The internationally accepted quality standard for medical device establishments is called ISO 13485. While SAHPRA requires companies to provide details of their quality management systems, it has provided a grace period to companies applying for medical device establishment licenses to certify that ISO 13485 standards have been met.

As part of the previously mentioned medical device establishment licensing process, companies must supply SAHPRA with a list of medical devices that they will manufacture, distribute and/or wholesale in the country. Each time licensed companies bring a new product to market, they must apply for an amended license. Besides listing each medical device that will be marketed, companies must also provide evidence of the safety, efficacy, and quality of certain products as part of their establishment license application.

For products classified as medium to high risk, license applicants must provide proof of pre-authorization or registration in Australia, Brazil, Canada, the EU, Japan, the US, or alternatively of pre-qualification by the World Health Organization as part of their establishment licensing applications.

### ***Licensing of Medical Device Establishments***

An applicant may apply for one of three types of licenses for medical device establishments: manufacturer (manufacture, pack, label, service, import, and export), distributor (import, export, distribute) and wholesaler (storage, transportation, delivery). A call up notice, published in Government Gazette No. 40637, on the 24 February 2017, requested all manufacturers and distributors of medical devices to apply for a SAHPRA license within 6 months of publication of said notice and wholesalers were required to apply within 12 months of said notice.

Currently, a transitional arrangement allows for the use of an acknowledgement letter received from SAHPRA, in lieu of a medical device establishment license, on submission of a license application, so as to facilitate trade and ensure continuation of business and access to medical devices whilst the SAHPRA licensing process developed. As of the 31 March 2020 the use of an acknowledgement letter in lieu of a medical device establishment license will not be permitted.

No medical device may be manufactured, distributed, imported, exported or sold without a valid SAHPRA medical device establishment license.

Note 1: Providing evidence of a valid SAHPRA medical device establishment license will be required to be eligible to bid for National and Provincial tenders.

Note 2: A manufacturer, distributor, wholesaler of a non-sterile, non-measuring Class A medical device is exempt from licensing, as per the SAHPRA position statement 9.106 "Class A medical devices".

Medical device establishments who have applied for a SAHPRA license must appoint an Authorized Representative who must be a natural person based in South Africa. One representative is required for each site where the company carries out its business. The representative is responsible for adherence to the law, regulations and guidelines.

As part of the application for a SAHPRA medical device establishment license a company must list all the medical devices that it manufactures, distributes, or wholesales. The application includes a declaration regarding the status of the quality management system in place in the company. Upon renewal of the SAHPRA license, manufacturers and distributors will have to provide evidence of ISO 13485 certification for the company by an accredited conformity assessment body.



## Medical Device Regulation in Kenya

The Ministry of Health (MoH) is the lead healthcare policy-setting government institution in Kenya. The Pharmacy and Poisons Board (PPB), an agency under the Department of Medical Services, regulates the registration of medical devices.

As of September 1, 2017, all medical devices, food supplements, medical cosmetics, herbal products and other allied borderline healthcare products must comply with the Pre-Export Verification of Conformity (PVoC) program for importing into Kenya. These products will all require a Certificate of Conformity (CoC) for customs clearance at the border. The importers of these products are therefore required to obtain the CoC for their goods before applying for Import Permits from the Pharmacy and Poisons Board (PPB), through the Kenya National Single Window Electronic (Kentrade) System.

The Kenya Bureau of Standards (KEBS) and the Pharmacy and Poisons Board (PPB) announced the new import requirements to protect the public against products that do not comply with local quality standards and technical regulations. These new regulations for imported medical devices will increase compliance for importers and drive up standards in the Kenyan medical device market.

According to guidelines provided by the PPB, appropriate documentation is required if the medical devices are either standalone software or rely upon software.

If medical device is stand-alone software, guidance for the qualification and classification of the software should be provided with a report of the same. There should be a rationale for why the software is a medical device and for its classification. If applicable, the software should be broken down into modules, some that have a medical purpose and some that do not. The modules with a medical purpose must comply with the requirements of the Medical Device Directives and must carry the CE marking. The non-medical device modules are not subject to the requirements for medical devices.

Ensure all relevant harmonized and non-harmonized software standards have been considered. Ensure the software systems/ modules/ items have been assigned safety classifications based on standards. Include documentation on the medical device software life-cycle processes implemented (e.g. software design/ development, maintenance/ change management, risk management, configuration management, problem resolution, verification, and validation processes).

Include software development process documentation (e.g. software development plan, software requirements specification, software architecture, software detailed design, software unit testing procedures/ reports, software integration testing procedures/reports, and software system testing) and maintenance process documentation (e.g. software maintenance plan).

Note: Some documentation may or may not be required per the standards based on software system/ module/ item risk classification. Include software risk assessment documentation (e.g. software hazard analysis, software failure mode and effects analysis, fault tree analysis, traceability).

Note: Some documentation may or may not be required per the standards based on software system/ module/ item risk classification.

---

*The African medical devices market is expected to reach **USD 7.1 billion by 2023**, up from USD 4900 million in 2017. There is **limited local manufacturing of medical devices on the continent, with imports accounting for approximately 90% of all medical devices.***

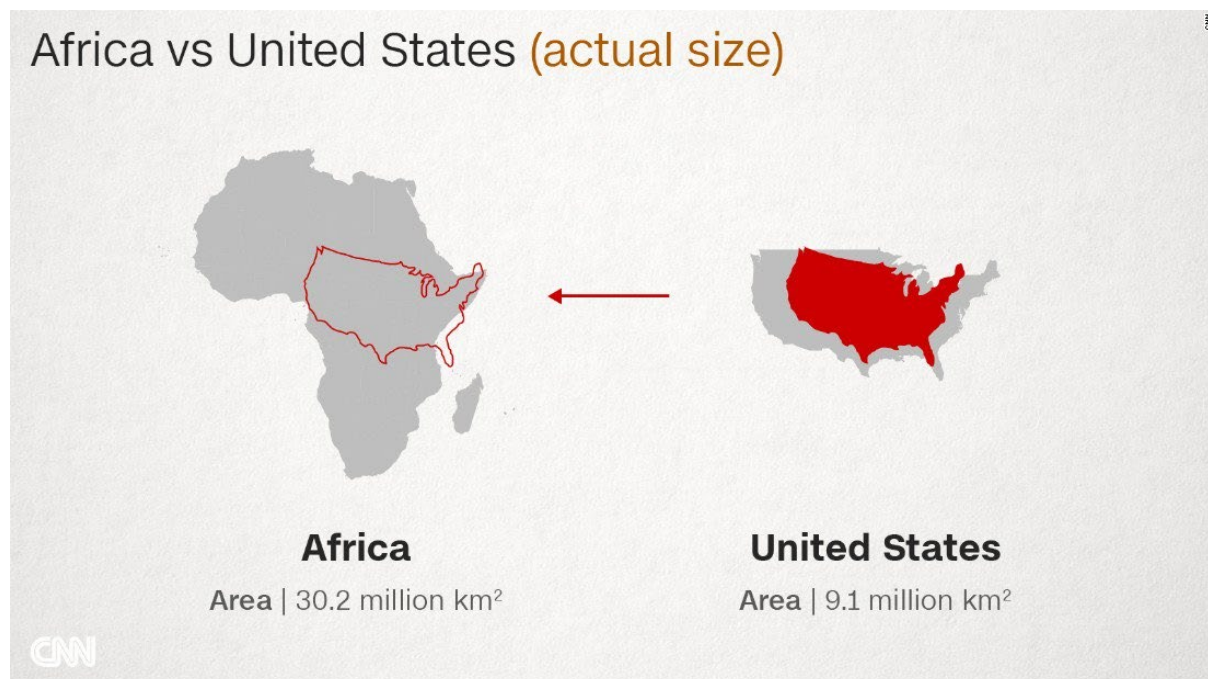
---

## Medical Device Regulation in Ghana

Medical Devices in Ghana are regulated by Ghana's Food and Drug Authority (FDA). The FDA is the National Regulatory Body responsible for the regulation of food, drugs, food supplements, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco and tobacco products, blood and blood products as well as the conduct of clinical trials protocols. The Public Health Act, 2012, Act 851 provides for the establishment of a Governing Board with the responsibility of ensuring the effective implementation of the functions of the Authority. The Authority currently has eleven-member Governing Boards.

In Ghana medical devices are classified according to the EU model of risk based classification, into classes I, IIA, IIB, III, and IV.

The approval process takes around 3-6 months for devices for all classes and licenses are valid for three years. In addition an authorized representative is required. Our office can assist qualified Virginia exporters with further details on the above.



[www.cnn.com](http://www.cnn.com) / a look at the relative geographical size of Africa. Note that the VEDP contractor covers all regions of Africa with staff located in 14 countries across the continent.

# AFRICAN OUTLOOK PRESENT AND POST COVID-19

Africa will emerge out of the Covid-19 pandemic relatively stronger. The continent has been on an ascendant rise in the past two decades, but trending better with several national economies in the 6 – 9 % growth range prior to the pandemic: Cote d'Ivoire, Ghana, Kenya, Rwanda, Tanzania and others. Demographics, business culture, competition among other powers for market share and a generally buoyant economy are key to Covid-19 recovery and future trends. Businesses in sectors such as healthcare and life sciences, information technologies, manufacturing technologies as well as mining and agriculture will be able to find immediate interest in some specific instances and an expanded general interest once the pandemic passes.

Over a year after the World Health Organization (WHO) declared the coronavirus a global pandemic, the dramatic numbers of infections and deaths that some observers predicted for the African continent have yet to emerge. As of 4 May, the global COVID-19 death toll stands at an estimated 3,217,281, among which -- accurate reporting remains a challenge -- Africa has recorded 82,259. The relatively low number of virus-related deaths on the continent, whichever of many possible factors are driving it, provides a sense that Africa is resilient. Polishing this positive image is the fact that almost all countries, except Benin, Burundi and Tanzania, took vigorous isolation measures when the outbreak started, responding much quicker than Europe and the United States, and consequently averting much of the devastation the disease has wrought there. Africa, though, seems to be facing an increasing wave as cases continue to peak while other regions of the world are decreasing their daily newly reported rates and lock-downs are lifted.

Demographics figure importantly in how Africa will rebound from the pandemic. With an average age of just less than 19 years old, Africa is the youngest large global region. Of its total population of approximately 1.3 billion, only 43 million are 65 years and older. Covid-19 puts those with co-morbidities and elderly, particularly those over 75, at the very highest risk. Seeing this, very few will be affected by the pandemic directly. Africa does have several co-morbidity issues such as HIV/AIDS and Tuberculosis and non-communicable diseases are on the ascendency. These will not outweigh the demographic differences in term of Covid deaths. One estimate puts Covid-19 maximum deaths at 83,000 to 190,000 if no precautions are taken ("Covid-19 in Africa: The long game", Economist May 16, 2020). Given the knowledge about Covid-19 at present, the absolute number of deaths will be relatively low compared to other regions such as North America, Europe and/or parts of Asia. These deaths also represent a small ratio due to other causes.

To date, 28 million COVID-19 doses, of different vaccines, have been administered in Africa, which represents less than two doses administered per 100 people in Africa. Globally, 1.5 billion COVID-19 vaccine doses have been administered.

Africa needs at least 20 million doses of the Oxford-AstraZeneca vaccine in the next six weeks to get second doses to all who received a first dose within the 8—12-week interval between doses recommended by the World Health Organization (WHO).

In addition to this urgent need, another 200 million doses of any WHO Emergency Use Listed COVID-19 vaccine are needed so that the continent can vaccinate 10% of its population by September 2021.

According to the WHO France has pledged to share half a million more doses with six African countries in the next few weeks. The European Union and its Member States have pledged over 100 million doses for low-income countries by the end of 2021. The United States of America has pledged to share 80 million doses with lower-income countries, and other high-income countries have expressed interest in sharing vaccines. Expediting these pledges is crucial and the COVAX Facility is a proven tool for swift delivery.

In the longer term, Africa must boost its manufacturing capacity for vaccines. Yet there is no quick-fix and putting the policies, processes and partnerships in place may take years. Intellectual Property waivers are a crucial first step but must come alongside the sharing of expertise and critical technologies.

WHO is helping African Member States to lay the groundwork to build up vaccine manufacturing capacity, around 40 African countries joined a recent WHO training to build manufacturing capacities and WHO is working with the African Union to support the African Pharmaceutical Manufacturing Plan for Africa, supporting feasibility studies and potential technology transfers on request, sharing expertise and helping forge crucial partnerships.

Africa's entrepreneurial business culture is critically important to resilience in the pandemic era. While most of the developed world is several generations removed from high childhood morbidity rates, Africa is only now coming to a point where people can easily expect to live to old age. Culture can only be measured indirectly in economics but it remains possibly the key ingredient to what a response will look like. African culture is very family-based, very stoic and resilient to hardship.

The youth culture is dynamically entrepreneurial, and tends toward merit over the collectivist thinking of previous generations, while retaining a very strong linkage to family and faith communities. All this to say that many in Africa have come to look at any new situation as an opportunity through the recent decades of radical change.

Overall, Africa will come out of the pandemic not unscarred but resilient and resume a good economic growth pattern. Africa's growth will depend on an energetic youthful business culture which is and will be looking for new business opportunities.

## KEY FINDINGS

- ✓ **African healthcare market is estimated to be worth USD 259 billion.** It is expected to become the second biggest market after the US by 2030.
- ✓ Africa imports roughly **70% of pharmaceuticals** from outside the continent (USD 14.5 billion).
- ✓ Access to quality healthcare for all is constrained by **limited public resources**. Out-of-pocket expenditures account for almost 36% of all expenditure on average, making healthcare expensive for many people. There is a **USD 66 billion per year financing gap**.
- ✓ Private sector can leverage the **African Continental Free Trade Area (AfCFTA)**.
- ✓ Africa has the lowest density of skilled health professionals in the world. There is a need for **training and capacity building support**.
- ✓ **Africa's population** is growing and **expected to double to reach 2.5 billion** people from 2015 to 2050.
- ✓ **Non-communicable diseases are rising** around Africa.

## RECENT DEVELOPMENTS

### RECENT DEVELOPMENTS FOR US EXPORTERS IN AFRICA

#### African Continental Free Trade Area (AfCFTA)

The African Union brokered the AfCFTA which was signed in 2018 and came into effect on 30 May 2019. Trading under the agreement begun on 1<sup>st</sup> January 2021 and as at 20<sup>th</sup> April 2021, 36 countries have deposited their instruments of ratification. The United Nations Economic Commission for Africa estimates that the agreement will boost intra-African trade by 52% by 2022. The Agreement seeks to create a single market of 1.27 billion consumers with an aggregate GDP between USD 2.1 and 3.4 trillion according to the International Trade Centre. It is also a fast-growing market, as consumer numbers are expected to increase to 1.7 billion by 2030. The AfCFTA market has a growing middle class as well, currently standing at 350 million and expected to rise to 600 million by 2030. The agreement provides an attractive opportunity for the private sector, including Virginia companies, to boost intra-African trade in pharmaceuticals, health services, achieve economies of scale in health infrastructure, and expand employment opportunities.

### [Africa Growth and Opportunity Act \(AGOA\)](#)

In May 18, 2000, the US Congress signed the [African Growth and Opportunity Act](#), commonly known as AGOA, into law. AGOA is the cornerstone of U.S. economic engagement with the countries of sub-Saharan Africa and is meant to establish stronger commercial ties between the two regions. The agreement provides duty-free access to the U.S. market and establishes a preferential trade agreement between the U.S. and selected countries in the sub-Saharan region. Initially approved for fifteen years, AGOA was reauthorized for ten years on June 25, 2015, by the Obama administration. In its current form AGOA will last until September 30, 2025. AGOA has succeeded in helping eligible nations grow, diversify their exports to the United States, and create employment and inclusive economic growth. Under AGOA, eligible countries can export products, including value-added manufactured items such as textiles, to the United States duty-free. This does not have a direct benefit to US exporters to Africa, but does build on relationships within various sectors of involvement.

### [US-Kenya Free Trade Agreement \(FTA\)](#)

On 27th August 2018 His Excellency President Uhuru Kenyatta and President Trump, announced the commencement of negotiations leading to a conclusion of a Free Trade Area Agreement (FTA). As a first step, both countries set up a Trade and Investment Working Group (TIWG) to spear head the negotiations. On 6th February 2020, H.E President Uhuru Kenyatta and H.E. President Donald Trump in Washington, DC jointly and publicly announced the intent for Kenya and USA to negotiate and conclude and FTA. Ahead of the announcement, both sides had identified Trade in Goods, Trade in Services, Intellectual Property Rights, including investment and other trade related areas as possible areas for negotiations. Kenya-USA FTA negotiations provide the country with a unique opportunity to enter into a bilateral trade and development cooperation negotiations with one of the global economic powerhouses -the United State of America which is Kenya's third largest export market and seventh overall trading partner.

### [US-Morocco Free Trade Agreement \(FTA\)](#)

In 2006, Morocco entered into a free-trade agreement (FTA) with the United States. Since its entry into force, Moroccan exports to the United States have more than doubled, and U.S. exports to Morocco have more than quadrupled. From 2005 to 2019, the total value of Moroccan goods exported to the United States increased from \$446 million to \$1.582 billion, and U.S. exports to Morocco have increased from \$481 million to \$3.496 billion. The FTA has paved the way for increased foreign direct investment by helping to improve Morocco's business climate, harmonize standards, and create legal guarantees for investors. While Morocco has made significant improvements in its business environment, foreign companies still encounter issues related to sluggish bureaucracy and lack of judicial expediency.





Cape Town Harbour: Cape Town, and Johannesburg, centers much of the medical distribution industry in South Africa and the two cities serve as distribution hubs to much of southern Africa.

## INDUSTRY OPPORTUNITIES



## MEDICAL DEVICES

Drivers of growth in medical devices are the rising cost of healthcare, which stimulate development of innovative connected products such as wearable medical devices, growing number of lifestyle diseases, demand for early detection and noninvasive therapies, growing awareness and spread of information technology, and development of user friendly devices.

### South Africa

*Consumables:* This sector includes bandages and dressings, suturing materials, syringes, needles, catheters, etc. Currently estimated at \$240 million (2019, Fitch Solutions), this market will grow around 1.7% in 2020. There is some local manufacturing, but over 90% is imported. Major suppliers are the United States, China, India and Mexico.

*Diagnostic Imaging:* Valued at an estimated \$192 million (2019, Fitch Solutions), Germany and the United States are the leading suppliers in this market (20% market share each). Other players include Japan, China, Netherlands and the UK. Despite the underdeveloped nature of this market, there is great need for MRI and PET scanners, radiotherapy products, and other diagnostic imaging products in the public sector. Still, growth will remain muted due to depressed market conditions and unfavorable currency fluctuations.

*Orthopedics and Prosthetics:* Valued at \$ 164 million (Fitch Solutions), practically all products in this sector are imported, mainly from the United States (40%) and Switzerland.

*Dental:* Projected growth in this market will be muted, 2.9% in dollar terms from 2019 – 2024. The dental market is currently valued at around \$37 million (Fitch Solutions). Although treatment often focuses on the curative, there is recognition that more needs to be done in the area of preventive care. The market is very small for high-end elective procedures due to the associated costs and limited insurance coverage.

Over 90% of products in this market are imported, mainly from the United States and Germany (30% each). Smaller suppliers include Switzerland and China. There are some local manufacturers that supply dental instruments, supplies and implants.

*Patient Aids:* Worth approximately \$163 million in 2019 (Fitch Solutions), this category includes portable aids, such as hearing aids and pacemakers, and therapeutic appliances like respiratory apparatus and mechanotherapy. More than 95% of this market is imported. The United States supplies around 25% and other main suppliers include China, Germany, and Switzerland. Growth will be dampened by current economic conditions.

*Surgical technology:* There is a growing market, particularly in the private sector, for advancements in surgical technology, such as robotic-assisted surgery, that positively impact surgical outcomes.

*Diabetes Technology, equipment and medication:* This is a significant health issue in South Africa. Around 15% of the population are either diabetic or pre-diabetic, and diabetes is the second most common cause of death in the country.

Medical devices and in vitro diagnostic (IVD) devices are regulated by the [South African Health Products Regulatory Authority](#) (SAHPRA).

## Kenya

Kenya is a promising market for medical devices and has been ranked as the fastest growing market in the sub-Saharan Africa region (SSA) according to the Business Monitor International (BMI). Kenya's conducive business climate offers an excellent environment for market entry. Almost all medical devices are imported as domestic production has primarily been limited to basic consumable items. Imported devices could be new or in some cases refurbished as long as they comply with the standard requirements.

Demand for medical devices remains high as many healthcare facilities require modernization. In both the public and private sector, there is a demand for high quality, affordable and efficient medical devices. In the private sector especially, there is a steady demand for western standard therapeutic and diagnostic equipment. The East remains the lead in imports to the country with a market share of 32.1%, followed by the U.S whose market share for medical devices was estimated at 19.8% in 2017.

Over half of Kenya's healthcare services are provided by the public sector, through the Ministry of Health (MOH), other government funded bodies, and donor partners, including the United States. These services are supplemented by those offered in hospitals and clinics that are operated by private companies, NGOs and various faith-based organizations such as the Kenyan Episcopal Conference, Christian Health Association of Kenya, and the Kenyan Red Cross.

## Ghana

There is a growing demand for affordable, reliable medical equipment in Ghana, the country relies on imports for approximately 85% of its total health care consumption. Public and private hospitals in Ghana often struggle to find high quality medical equipment that they can afford. There are few medical device companies in Ghana and the majority of those companies are located in Accra. The short supply of medical equipment companies leaves many hospitals and doctors without a local source for medical devices.

Doctors and surgeons in Ghana are often delighted to find out that they can reduce device costs by up to 50% or more by purchasing reliable refurbished medical equipment from the USA. Some of the leading refurbishing companies in the USA can provide all of the equipment required for a hospital in Ghana. Purchasing all equipment required from one single provider often leads to additional discounts and reduced shipping costs.

This provides an opportunity which Virginia companies can tap into and meet the great need in the country.

## PHARMACEUTICAL INDUSTRY



Africa's pharmaceutical market has been growing steadily, its value rising from \$5.5 billion in 2007 to \$28.56 billion in 2017, and it is expected to be worth [\\$70 billion by 2030](#). Between 2017 and 2030, prescription drugs are forecast to grow at a compound annual growth rate of 6.5%, generics at 10%, over-the-counter medicines at 7.1%.

Pharmaceutical manufacturing in Africa does not cover the pharmaceutical market's needs. The continent overall has roughly [375 drug makers](#), mostly concentrated in North Africa, South Africa, Kenya and Nigeria, to serve a current population of around 1.3 billion people which is expected to double by 2050.

Imported drugs comprise around 70% of drugs consumed in sub-Saharan Africa. Nearly two-thirds of the \$14.5 billion worth of total pharmaceuticals imports into Africa in 2017 were to South Africa, Egypt, Algeria, Morocco, Ethiopia, Kenya, Tunisia, Cameroon, Tanzania and the Democratic Republic of Congo.

As national insurance programs expand and more people gain access to health care, demand for generics will rise. Many governments are showing strong support for generics through laws requiring pharmacists to inform patients about generic alternatives when they purchase prescription drugs, according to [McKinsey](#).

### South Africa

South Africa remains the largest pharmaceutical market in Sub-Saharan Africa. Its prescription drug market is valued at approximately \$3.0 billion (2019, Fitch Solutions), which equates to 88.7% of the total market in value terms but will drop in value due to prevailing market conditions.



Domestic production meets around 60% of pharmaceutical demand. The bulk of domestic production involves the finishing of imported raw materials and semi-finished drugs. Local producers are used as a base for distribution to most of Sub-Saharan Africa. The multinational companies either import their products or they sign agreements with manufacturers within South Africa using their relatively modern manufacturing facilities to formulate and package products for them. South Africa has around 522 public pharmacies and 2206 retail & courier pharmacies.

The top six pharma companies (Aspen, Ascock Ingram, SANOFI, Pfizer, Novartis, Cipla Medpro) control more than 50% of the total market.

Demand and spend in this sector, particularly as it relates to high value medicines, will likely be tempered or entirely impeded by the economic recession and COVID-19 pandemic. There will continue to be emphasis placed on HIV/AIDS and TB treatment but over the long-term focus will also shift towards rising chronic disease burden – diabetes, cardiovascular disease, hypertension, and cancer treatments.

The market for innovator/patented drugs is estimated at around \$1.7 billion (2019, Fitch Solutions), equating to 51% of pharmaceutical sales and around 58% of prescription drug sales. Growth in this sector will be slower due to the associated high costs. Most innovator drugs are imported with main supply from India, Germany, United States, and France.

Generic drugs, valued at \$1.3 billion (2019, Fitch Solutions), are likely to see strong growth, both in terms of volume and spend, due to high demand and purchasing preferences (public sector), but also because of increased local production driven by government incentives and policies favoring local content. Over the counter medicines represent the smallest segment of the market (\$378 million). This segment is extremely competitive and much of it is driven by local production. South Africa does not produce any Active Pharmaceutical Ingredients (APIs). Pharmaceuticals in South Africa are regulated by [The South African Health Products Regulatory Authority](#).

## Kenya

Kenya's prescription pharmaceuticals market is worth over \$500 million and is expected to grow at a compound annual growth rate (CAGR) of 11.8%. Prescription drugs account for around 78% of the market. However, the fastest growth in the coming years is expected in the over-the-counter (OTC) product sales. The number of companies engaged in manufacturing and distribution of pharmaceutical products in Kenya continue to expand, driven by the Government's efforts to promote local and foreign investment in the sector. There are about 700 registered wholesale and 1,300 retail dealers in Kenya, manned by registered pharmacists and pharmaceutical technologists. These pharmacies are accorded a 25% mark-up on retail drugs. The pharmaceutical sector in Kenya is also engaged in assembling capsules, disposable syringes, paracetamol, and surgical gauze amongst others.

Kenya has emerged as the pharmaceutical manufacturing hub in the East African region and it provides huge benefits from government initiatives on pharmaceutical development. The Kenya has huge young population. However, as compared to present scenario, the demand of medicines & healthcare will expand in near future as more number of old people and healthcare needs will automatically increase as more people age.

Kenya is witnessing rapid growth in the domestic production capacity of pharmaceuticals in response in growing new export demands from Tanzania & Ethiopia. Thus the sluggish domestic sales are giving opportunities to the market players to export, which thus accounts for nearly 60% of the total local output. Moreover, the players in the country are competing on the quality of drugs rather than the price. The local manufacturers such as Cosmos Limited and Universal Corporation Limited have implemented World Health Organization's Good Manufacturing Practices (GMPs).



The pharmaceutical market is estimated to be worth \$25 billion.

## Ghana

Ghana has very limited local production of pharmaceuticals and even less manufacturing of equipment, medical products and devices; the country relies on imports for approximately 80% of its total healthcare consumption. Ghana has sought to introduce more private sector participation into the healthcare sector and the most dynamic growth and most exciting opportunities will be found in privately invested hospitals and clinics and in the non-state-controlled portion of the pharmaceutical sector. Lucrative growth is experienced in both the pharmaceutical and medical devices industries.

The largest purchaser of pharmaceutical products is the government, as it is the primary provider of health care services, and it is not immune to the high costs of health care. For example, when the New Patriotic Party (NPP) government of President Nana Akufo-Addo took over in January 2017, the NHIS was indebted \$259.3 to suppliers and pharmaceutical companies.

In March 2018 the government paid off much of the debt, leaving \$39.1m outstanding. At the same time, the state submitted proposals aimed at strengthening public health facility management to cut waste and overhead costs.

Ghana Imports of Pharmaceutical products was US\$282.7 during 2018, according to the United Nations COMTRADE database on international trade.



## Tanzania

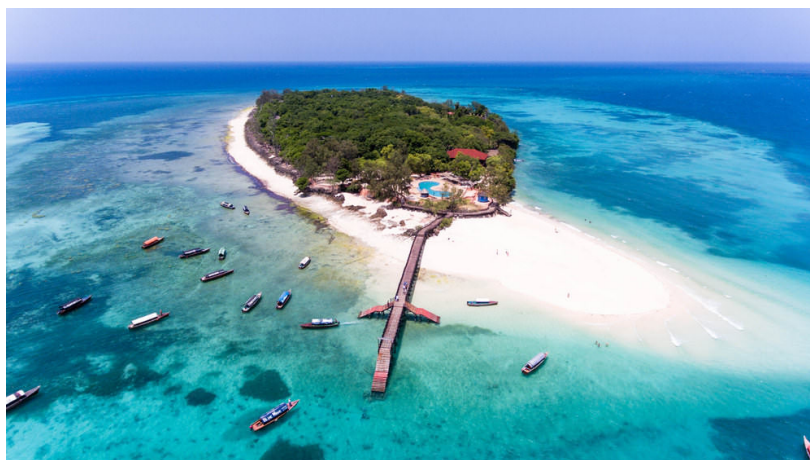
The Country's pharmaceutical market is forecast to grow to \$700 million by 2021, up from \$450 million in 2017. The World Health Organization, the United Nations Comrade and Business Monitor International show that the pharmaceutical market grew to almost \$450 million in 2017 from \$107 million in 2007. (Source: TanzaniaInvest.com)

According to the forecasts revealed by the Ministry of Industry, Trade and Investment, the sector was projected to grow by \$35 million in 2018 to \$532 million from \$497 million in 2017. The projected growth is partly because of the government's efforts to promote industrial growth so as to realize the country's strategy to become a middle-income economy by 2025. (Source: TanzaniaInvest.com)

According to the Ministry, revenue generated by pharmaceutical industries will increase when investments are raised. The sector's contribution to the gross domestic product (GDP) is projected to be one per cent by 2021, down from 1.04% in 2017. The country's GDP keeps on increasing annually that is why it decreases even when revenue from the sector increases. By 2021 the Ministry of Health would spend 17.8% of its budget on purchasing pharmaceuticals products, down by 0.2% from 18.00% in 2017. By 2021, Tanzania's health spending is expected to be \$3.908 billion up from \$2.765 billion in 2017. (Source: The Citizen)

The government is encouraging the private sector to become the engine of the country's economy. Strategies are also provided for implementation of the Sustainable Industrial Development Policy, or SIDP, under the current business environment and extend it to 2025. Tanzania has 14 registered domestic pharmaceutical industries, 11 of them producing human medicines, two making veterinary medicines and one facility manufacturing health devices. Most of them produce a narrow range of products, mainly generics.

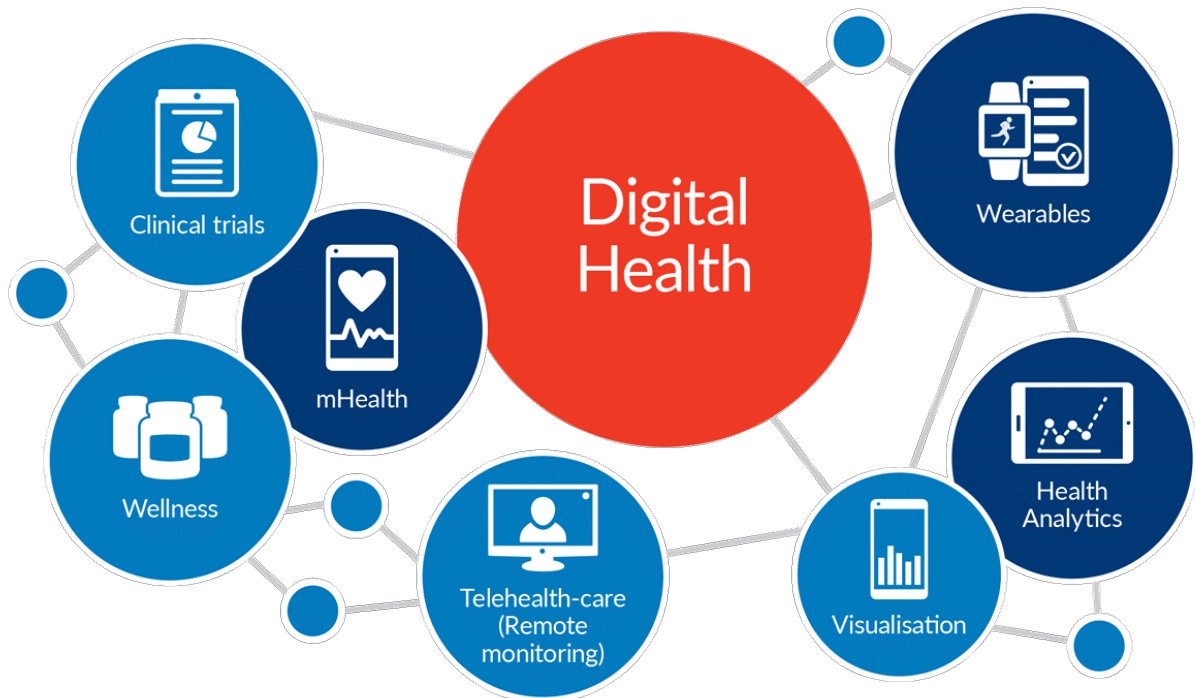
The Health Ministry provides a list of non-medical supplies which are among the country's opportunities for potential investors in the pharmaceutical sector to satisfy demand of the Medical Stores Department (MSD). The department also buys medicines for Southern African Development Community (SADC) countries. They include the manufacture of safety boxes for disposable used syringes, bed sheets, packaging boxes, dispensing envelopes, color-coded waste bins, prescription forms (A5), patient registers, injection registers, ball-point pens, and many others.



Zanzibar islands off the coast of mainland Tanzania



## DIGITAL HEALTH



Digital health is becoming an increasingly prominent sector in the healthcare industry, especially now with its potential to make healthcare more resilient in light of situations such as COVID-19. Its potential to address some pressing issues, such as the urban/rural inequality in terms of access to healthcare, the low ratio of health professionals to population and others, is significant and there are already innovative projects, undertaken both by public and private sectors, to digitize health. Many countries in Africa have already achieved a high level of mobile penetration and internet penetration is also on the rise. Eastern Africa has emerged as a growing hub for ICT innovation.

The main opportunities within digital health are **telemedicine, mhealth, administration & management services, eLearning and public health surveillance & disaster preparedness.**

Major digital health projects include the Telemedicine Network for Francophone African Countries (RAFT), HINARI Access to Research in Health Programme, ePortuguese Network and Pan-African e-Network Project. Key drivers of innovation in healthcare are standardization, task shifting and remote-care.

The challenges facing digital health in many African countries are the lack of an enabling policy environment; weak leadership and coordination; weak ICT infrastructure and services; inadequate financial resources; and weak monitoring and evaluation systems.

## South Africa

The South African government has indicated that digital healthcare technologies will form an integral part of NHI in that it will strengthen healthcare systems, provide better access for patients and improve health outcomes. To this end, they have published a National Digital Health Strategy for South Africa 2019-2024.

The Digital Health Strategies present opportunities for investment which include:

- The development of a complete electronic record for patients (some form of this already exists).
- Digitization of healthcare systems business processes.
- An integrated platform and architecture (open source/open architecture) for health sector information to ensure interoperability of existing patient-based information systems.
- Developing and growing digital health knowledge for implementers and users.

Vertical integration of larger healthcare providers to control costs of their supply chain by owning more of it (mergers, acquisitions, partnerships) and using technology: IoMT (Internet of Medical Things), SaMD (Software as Medical Device), Cybersecurity, data analytics, digitization and compliance

## Kenya

Kenya is one of the few African countries with a comprehensive eHealth strategy. The country has been ranked the second highest country from the African continent (behind South Africa), on eHealth innovation, and has made noteworthy progress in developing a sound policy foundation to manage the rollout of Health IT in the country.

The Kenya eHealth Strategy is anchored on the achievement of Vision 2030, whose overall goal in health is to have an “equitable and affordable healthcare at the highest achievable standard” to her citizens. It is informed by the strategies and results emanating from the implementation of the Kenya Health Policy Framework, 1994-2010, the health sector strategic plans and the e-Government and shared services strategies implemented through the e-Government Directorate and the ICT Board respectively.

The government of Kenya has a well-defined eHealth strategy with a specific eHealth policy tool, the Kenyan eHealth strategy 2011-2017. EHealth strategy seeks to set in motion the process of closing this gap by harnessing ICT for improved healthcare delivery in addition to other ongoing efforts. Additionally, the latent capacity of consumers to play a more active role in the protection and management of their personal health outcomes must be leveraged. For this to happen, there

will be a need for a fundamental shift in the way information is accessed and shared across the health system. It is therefore necessary for healthcare stakeholders to shift from a reliance on tools such as pen, paper and human memory to an environment where consumers, care providers and health care managers can reliably and securely access and share health information in real time across geographic and health sector boundaries. eHealth provides a practical, tried and tested way to achieve this end.

People living in rural and remote areas struggle to access timely, quality specialty medical care. Residents of these areas often have substandard access to specialty healthcare primarily because specialist physicians are usually located in urban areas, reaching only 20% of the population i.e. 80% of clinicians serves 20% of the population. Therefore, Kenya's healthcare infrastructure suffers from urban-rural and regional imbalances, lack of investment, and a personnel shortage. Kenya's low physician density demands new solutions for improving doctor communication and maximizing available human resource capacity. Because of innovations in computing and telecommunications technologies, many elements of medical practice can today be accomplished even when the patient and health care provider are geographically separated.

The eHealth strategy focuses on Telemedicine; Health Information Systems; Information for Citizens; mHealth, and eLearning. As compared to other African countries, Kenya has a high mobile phone penetration, which creates a market for mHealth products such as connected devices and patient tracking. These areas present excellent opportunities for companies in the Health Information Technology (Health IT), Mobile Patient Monitoring Platforms, and Telemedicine.

## Ghana

Both public bodies and private firms have increasingly turned to digital technologies to provide health care solutions in Ghana. In line with a broader government drive towards the digitization of public services, in December 2018 the National Health Insurance Authority (NHIA) rolled out an e-renewal system on a mobile phone platform, for the National Health Insurance Scheme (NHIS). The public sector is also collaborating with international tech companies to overcome bottlenecks in health care provision. In April 2019, the government announced a deal with the US-financed start-up Zipline to use drone technology to make on-demand deliveries of blood transfusions, vaccines and other medical supplies to remote areas. Once fully operational the project is expected to make 600 deliveries per day to a total of around 2000 health facilities.

Meanwhile, a new generation of innovative domestic tech start-ups are entering the market, seeking to address shortcomings in both traditional public and private care. In April 2019 two Accra-based start-ups, mPedigree and mPharma, were each awarded \$1.5m in the Skoll Awards for Social Entrepreneurship. MPedigree provides a mobile phone platform that helps customers verify the authenticity of medicines to combat fraud, while mPharma uses logistics software to manage prescription drug inventories and streamline last-minute delivery of pharmaceuticals.

However, obstacles remain to the increased use of digital technologies in providing health solutions. These startups are still in their infancy and there is a need for more efficient methods and tools for data collection and authentication, as well as more digital platforms.







## South Africa

The public sector suffers from a shortage of doctors and of nurses. Many nurses emigrate and many doctors prefer to work for the private sector, with close to 70% of the medical practitioners working in the private sector. The need for more health professionals will be increased by the expansion of access to healthcare facilitated by the NHI.

The training of medical staff falls within the mandate of the NDOH. The South African National Health Act (2003) indicates the need to reorient health-care training so that there is a strong focus on disease prevention and health promotion. There are 8 Schools of Public Health, the [biggest of which in terms of number of graduates](#) is the Medical University of Southern Africa.

There is a need for the training of nurses, with a focus on the various regions and rural areas in South Africa. Other opportunities lie in the refurbishment of existing and development of new training facilities and infrastructure.



Healthcare training is a critically important aspect of all national healthcare strategic objectives: Courtesy: Education for Health Africa [www.educationforhealth.africa](http://www.educationforhealth.africa)

/

# KEY PLAYERS

## REGIONAL GOVERNMENT AGENCIES / NETWORKS

### AU Division of Health, Nutrition and Population

<https://au.int/en/sa/dhnp>



The African Union Division of Health, Nutrition and Population responds to vital generic health issues related to health policy and delivery systems, nutrition and other related public health issues and challenges that require a concerted and coordinated approach at a continental level. The Division works closely with the Division of AIDS, TB, Malaria and Other Infectious Diseases (OIDs) and supports the harmonization and coordination of public health and strengthening of health systems including human resources for health, medicines, e-health and traditional medicine as well as population, reproductive health and nutrition issues.

### West African Health Organization (WAHO)

[www.wahooas.org](http://www.wahooas.org)



The objective of the West African Health Organization is to attain the highest possible standard and protection of health of the peoples in the sub-region through the harmonization of the policies of the Member States, pooling of resources, and cooperation. WAHO areas of focus: Maternal, Child & Adolescent Health; Quality Standards & Centers of Excellence; Pharmaceuticals (medicines & vaccines); Prevention & Control of Communicable and non-Communicable Diseases; Health Information.

### Africa Regional Network

[www.healthsystemsglobal.org/regional-network](http://www.healthsystemsglobal.org/regional-network)



The Africa Regional Network is a group of Africa-based HPSR networks, connecting for the purposes of learning what each is doing in the field, building synergies, increasing the profile of African Health Policy and Systems Research (HPSR), and seeking ways in which the region can shape and influence the wider Health Systems Global (HSG) society.

### WHO Regional Office for Africa

[www.afro.who.int](http://www.afro.who.int)



The WHO Regional Office for Africa is one of WHO's 6 regional offices around the world. It serves the WHO African Region, which comprises 47 Member States with the Regional Office in Brazzaville, Republic of Congo. Its work involves translation of global health initiatives into regional plans that respond to the specific needs and challenges of countries in the Region. It supports countries to achieve better health outcomes through technical and policy advice, development of norms and standards, generation and sharing of knowledge and convening health partners. Together with countries, they attain health objectives by supporting national health policies and strategies.

## NATIONAL GOVERNMENT AGENCIES & NETWORKS

### The Council for Medical Schemes (South Africa)

[www.medicalschemes.com](http://www.medicalschemes.com)

The Council for Medical Schemes is a statutory body established by the Medical Schemes Act (131 of 1998) to provide regulatory supervision of private health financing through medical schemes. The governance of the Council is vested in a board appointed by the Minister of Health, consisting of a Non-executive Chairman, Deputy Chairman and 13 members. The Executive Head of the Council is the Registrar, also appointed by the Minister. The Council determines overall policy, but day to day decisions and management of staff are the responsibility of the Registrar and the Executive Managers. The Council for Medical Schemes supervises an industry of more than 80 medical schemes registered in the country.



### South African Health Products Regulatory Authority

[www.sahpra.org.za](http://www.sahpra.org.za)

SAHPRA is an entity of the National Department of Health (NDoH). SAHPRA assumed the roles of both the Medicines Control Council (MCC) as well as the Directorate of Radiation Control (DRC). Subsequently, SAHPRA was constituted as an independent entity that reports to the National Minister of Health through its Board. SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).



## INDUSTRY ASSOCIATIONS

### South African Medical Technology Industry Association

<http://samed.org.za/>

The South African Medical Technology Industry Association was founded in 1985 and is the voice of the South African medical technology and in-vitro diagnostics industry. SAMED is committed to ensuring a sustainable medical technology industry that enhances patient access to innovative solutions. SAMED has grown considerably over the last few years. Their members are companies - local and multinational - who are involved in the manufacture, import, selling, marketing and distribution of medical technologies in South Africa.



### Innovative Pharmaceutical Association of South Africa

<https://ipasa.co.za/>

The Innovative Pharmaceutical association South Africa (IPASA) was established in April 2013. Spanning the entire pharmaceutical value chain – from development, to manufacturing and distribution – IPASA supports initiatives in both the public and private healthcare sectors to help develop practical solutions to address the country's most pressing healthcare challenges. IPASA currently represents approx. 43% of the pharmaceutical private sector in the country.



## Africa Healthcare Federation

<http://africahf.com/>

The inaugural Africa Health Business Symposium hosted in Nairobi, Kenya during 5th to 7th October, 2016 witnessed the unification of the five regional healthcare federations of Africa to launch the Africa Healthcare Federation which will advocate, mentor, collaborate and unify the private health sector of Africa so as to ensure the scaling up and strengthening of health systems, spurring greater investments as well as development of affordable, accessible and quality healthcare delivery across the continent, thereby rising Africa to global standards.

## Hospital Association South Africa

<https://hasa.co.za/>

The Hospital Association of South Africa represents the owners and managers of the majority of private sector hospital beds in the country. HASA engages with various stakeholders to inform the legislative and regulatory environment, by advocating for quality healthcare for all, and by contributing collaboratively to debates and discussions concerning healthcare reform, improvement, and expansion.



## RESEARCH CENTRES

### Council for Scientific and Industrial Research (South Africa)

<https://www.csir.co.za/>

The Council for Scientific and Industrial Research (CSIR) is a leading scientific and technology research organization that researches, develops, localizes and diffuses technologies to accelerate socio-economic prosperity in South Africa. The CSIR was established through an Act of Parliament in 1945 and the organization's executive authority is the Minister of Higher Education, Science and Technology. The organization plays a key role in supporting public and private sectors through directed research.



### South African Medical Research Council

<https://www.samrc.ac.za/>

The South African Medical Research Council (SAMRC) was established in 1969 with a mandate to improve the health of the country's population, through research, development and technology transfer. The scope of the organization's research projects includes tuberculosis, HIV/AIDS, cardiovascular and non-communicable diseases, gender and health, and alcohol and other drug abuse. With a strategic objective to help strengthen the health systems of the country – in line with that of the NDoH, SAMRC constantly identifies the main causes of death in South Africa.



### Ifakara Health Institute (Tanzania)

<https://ihi.or.tz/>

Ifakara Health Institute (IHI) is a health research organization. IHI's work follows the full research lifecycle from basic science to policy and translation. IHI is organized as follows: 3 research departments (environmental health & ecological sciences; interventions & clinical trials; health systems, impact evaluation & policy); 6 research units (grants & contracts; training & capacity building; laboratories; data systems & platforms; vector control product testing; chronic diseases clinics); and 7 technical units (internal audit; knowledge management &



communications; finance management; HR; procurement management; branch management & ICT).

### Kenya Medical Research Institute

<https://www.kemri.org/>



The Kenya Medical Research Institute (KEMRI) is a state corporation established through the Science and Technology (Amendment) Act of 1979, which has since been amended to Science, Technology and Innovation Act 2013 as the national body responsible for carrying out health research in Kenya. KEMRI provides advice to the Ministry on various aspects of healthcare and delivery. They have 7 regional clusters that serve 47 counties. They conduct national diseases surveillance and rapid response capacity for major disease outbreaks (Cholera, Chikungunya Virus, H1N1 Flu, Yellow Fever, Rift Valley Fever, Ebola, Aflatoxicosis etc.).

## MARKET ENTRY STRATEGY

### Establish a Local Presence

To be able to compete with the other industry players, proximity to customers is crucial. This will enable monitoring of any new developments and identifying niche or gaps often left unrecognized.

### Find and Select a Reputable Partner

This is another strategy which allows the Virginia companies to partner with a local distributor, who is well versed with the sector and can do the groundwork, as well as push the products to an already existing market.

### Adopt Flexible Payment Models

This allows more local companies who sometimes struggle with the costs of products, to still work with Virginia Companies. For instance, alternative financing where loans are made available to local companies at lower interest rates.

### Target Primary Healthcare Providers

The large public health facilities often require a product be in the country before it can be accepted in their facilities. Therefore, it is crucial to target small to medium sized clinics, the private sector and grow in terms of reputation, which will pave the way to larger clients.

## INDUSTRY PUBLICATIONS

### Africa Health

<https://africa-health.com/>

Africa Health is a review journal and does not publish original articles. The journal seeks to cover a wide range of subjects ranging from clinical care topics to health management, education, and CPD programme structure.





## Africa Healthcare IT News

[africahealthitnews.com](http://africahealthitnews.com)

Africa Health-IT News (AHIT) is a UK -based non-profit organization dedicated to the promotion of the use of technology in Africa's healthcare. Africa Health IT News (AHIT) is primarily focused on the needs of health practitioners and other stakeholders in Africa.



## Medical Brief

[www.medicalbrief.co.za](http://www.medicalbrief.co.za)

Medical Brief is Africa's authoritative weekly digest of medical matters, both on the continent and around the world. It provides succinct summaries of the latest developments, both in news and research, with links to the original material.



## Health 24

[www.health24.com](http://www.health24.com)

Health24 content is educational, relevant, and medically reviewed. The site covers a wide range of topics, such as in-depth information on common medical conditions, diet, fitness, pregnancy, parenting, and mind health – even pet health.



## Radiant Health Magazine

[www.radianthealthmag.com/](http://www.radianthealthmag.com/)

Radiant Health is a bi-annual print and digital magazine dedicated to the African woman and her journey to wellness through health, beauty and culture.



## Medpharm Publications

[www.medpharm.co.za](http://www.medpharm.co.za)

Medpharm Publications was founded in 1988 and has established itself as the largest medical and pharmaceutical journal publisher in South Africa. It has over ten titles (over fifty journal editions). Medpharm Publications reach more than 40 000 healthcare workers countrywide with printed editions, and has established a global audience with the online editions.



# INDUSTRY EVENTS

## Africa Health Exhibition

[www.africahealthexhibition.com](http://www.africahealthexhibition.com)

Dates: 26 – 28 October, 2021

Location: Virtual Trade Mission

Africa Health has been harnessing the strengths of healthcare providers and innovators along with medical academia to make real progress in the ever-changing world of human health. Ten years on, progress has seen the event grow into an industry platform that enables deeper learning, foster relationships and promote decision making which all leads to further collaboration, knowledge exchange and more business completed.



## Medical Expo Tanzania

[www.expogr.com/tanzania/medexpo](http://www.expogr.com/tanzania/medexpo)

Dates: 21 – 23 September, 2021

Location: Diamond Jubilee Expo Centre, Dar es Salaam, Tanzania

Expogroup began its operations in 1996 starting with export-oriented International Trade Exhibitions in the Middle East & Africa. Since then, it has been organizing annual trade fairs in 14 countries within the region itself. Apart from that, Expogroup has presented several other events in emerging markets such as the CIS, Australia, Latin America & India.

## Medical Expo Morocco

[www.medicalexpo.ma](http://www.medicalexpo.ma)

Dates: 19 – 22 May, 2022

Location: The International Fair of Casablanca

The Office of Fairs and Exhibitions of Casablanca organizes in partnership with Atelier vita, the 21th edition of the International Medical Exhibition MEDICAL EXPO 2020. This is the largest African event that brings together national and international health professionals.



## Medic West Africa

[www.medicwestafrica.com](http://www.medicwestafrica.com)

Dates: 22 – 24 September, 2021

Location: Eko Hotel Convention Centre, Lagos, Nigeria

Medic West Africa serves as the platform to source medical equipment and technology on a global level, providing visitors the access to the widest range of medical devices, products and supplies in the West African region.

