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International.*



KENYA

Opportunities & Practical Guidance for Dutch organisations active in the
Medical Devices & Supplies and eHealth Market Segments





PREFACE

March 2021

Kenya is widely regarded as the economic, logistical, and innovation hub for Eastern Africa. Together with its growing economy, the health sector is expanding. Government plans are geared towards achieving universal health coverage (UHC) and the private sector is anticipating the growing middle class, regional medical tourism, and willingness of the government to work with the private sector in achieving UHC.

The Dutch Topsector Life Sciences & Health (LSH) identified Kenya as one of their focus countries in Eastern Africa. Since 2016, multiple efforts and activities have been undertaken to foster partnerships between Kenya and The Netherlands. Over the years, warm relations, knowledge, and experiences have accumulated that can be build upon by the Dutch LSH sector with an interest in Kenya.

Specifically targeting the growing number of Dutch organisations and companies interested in the Kenyan market segments for Medical Devices & Supplies and eHealth solutions, this report aims to provide a clear overview of the current market developments, market structure, areas of opportunities and practical guidance for market entry and doing business.

This report was commissioned by the [Netherlands Enterprise Agency \(RVO.nl\)](https://www.rvo.nl) and is produced by the [Task Force Health Care \(TFHC\)](#) and [Africa Health Business \(AHB\)](#).



OUR APPROACH

TASK FORCE HEALTH

IMPROVING HEALTHCARE TOGETHER

Established in 1996, Task Force Health Care (TFHC) is a public-private not-for-profit platform that represents and supports the Dutch Life Sciences & Health (LSH) sector. Our platform has a reach of 1,500 LSH organisations in the Netherlands, with 130 dedicated and diverse partners. Our partners include government, industry, knowledge institutes, NGOs, and healthcare providers.

Our core mission is to improve healthcare and well-being internationally and in a sustainable and demand-driven manner, with the use of Dutch expertise. We are currently actively engaged with over 20 countries to stimulate and facilitate relationships on government-, knowledge- and business levels. Our partners are active around the world and provide innovative and sustainable solutions relevant to both global and local healthcare challenges.

A PROGRAMMATIC APPROACH

Bridging **Knowledge**, Aligning Interests and Identifying Opportunities

Fostering and Strengthening **Networks**

Facilitating **Dialogues** on Health Themes and Opportunities to Collaborate

OUR FOCUS

> Mutual Interests and Benefits

> Developing Sustainable and Long-term Approaches

> Demand-driven and Context Specific

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INTRODUCTION

This report was written by [Task Force Health Care](#) (The Hague, Netherlands) and [Africa Health Business Ltd](#) (Nairobi, Kenya) and commissioned by the [Netherlands Enterprise Agency](#) (RVO.nl) in order to provide a clear overview of the current market structure, business opportunities and practical guidance for Dutch companies and organisations interested in the Kenyan market segments for 'Medical Devices & Supplies' and 'eHealth' solutions.

Why this report

Eastern Africa is a focus region of the Dutch Topsector Life Sciences & Health ([Health-Holland](#)), as stipulated in their [international strategy 2020-2023](#)¹. Kenya is widely regarded as the regional hub and entry point to Eastern Africa. Since 2016, a [market study](#)² and multiple follow-up events and efforts have been made to improve bilateral relations and foster partnerships between Kenya and The Netherlands in the field health. At the centre of this has been delegation visits from The Netherlands to Kenya, and vice versa, led by high-level government officials from both countries. Dozens of Dutch organisations and companies have participated in these events and have benefitted or continue to benefit in terms of having strengthened their exposure, knowledge and relationships in Kenya.

Success for Dutch organisations and companies in the Kenya health sector does not come over night. That is an important lesson learned while compiling this report and looking at the efforts over the last couple of years. Data shows that most Dutch companies and organisations with an interest in Kenya are active in the market segments for 'Medical Devices & Supplies' and 'eHealth' solutions. This report is therefore focussed on the market developments, structure, opportunities and doing business in these market segments. The goal of this report is to function as a valuable and up-to-date document to help Dutch organisations and companies to become (more or faster) successfully active in Kenya with a medical devices or eHealth solution.

Method

This reports builds upon the [2016 market study on the Kenyan health sector](#)². A desk research was performed to update the information available on the Kenyan health sector and market. Multiple interviews with Dutch organisations and companies (listed in [Annex 1](#)) were conducted to zoom in on experiences, best practices and views on market developments, opportunities, and doing business in Kenya. This information from the desk research and interviews was combined with the experts views of Africa Health Business and Task Force Health Care, which both were closely involved in the organisation of multiple high-impact visits organised in the period 2017 – 2020.

Structure of this report

This report starts with setting out the [broader Kenyan health sector developments](#), including a health sector [Strengths, Weaknesses, Opportunities and Threats \(SWOT\) analysis for doing business in Kenya](#). After this broader introduction, the sections on [Medical Devices & Supplies](#) and [eHealth](#) zoom in on the specific sub-market developments, areas of opportunities, market structure, and market entry & doing business.

¹ Health-Holland International Strategy 2020 – 2023. (2020). Available: <https://www.health-holland.com/international/international-strategy>

² TFHC & KHF. (2016). Kenyan Healthcare Sector: Opportunities for the Dutch Life Sciences & Health sector. Available: <https://www.tfhc.nl/product/kenya-market-study/>

HEALTH SECTOR DEVELOPMENTS IN KENYA

Introducing Kenya

Kenya has a market-based economy and is generally considered the **economic, commercial, financial and logistics hub of East Africa**. With the strongest industrial base in East Africa, Kenya has been successful in attracting exporters and investors around the world. More Dutch companies are investing in Kenya and setting up local and regional operations to take advantage of Kenya's strategic location, diversified economy, entrepreneurial workforce, comprehensive air routes, and status as a regional financial center. A number of Dutch companies in various sectors are also preferring to test the African market by first introducing their products/solutions in Kenya in order to inform their strategy and business model for Africa.

The **population of Kenya is rapidly growing**, and stands at 52.57 million in 2021³. Even though the health status is classified as poor, both in regional and global terms, the country has made significant progress in dealing with issues such as high child and maternal mortality rates. Despite the decrease in the birth rate (42.4% per 1,000 in 1990 to 30.5% per 1,000 in 2018), it is still double the global average⁴.

In 2019, Kenya was named one of the **fastest growing economies** in Sub-Saharan Africa with an annual growth of 5.7%. This can be attributed to a stable macroeconomic environment, positive investor confidence and a resilient services sector⁵. The Kenyan health system is funded by government revenues, National Health Insurance Fund (NHIF) contributions, private health plans and donations/external funding. In 2018, the total health expenditure (THE) as a percentage of GDP stood at 5.2%. The private sector contributed the largest share at 42.4%, followed by the government at 42.1%. In the same year, out-of-pocket (OOP) expenditure as a percentage of THE was 23.6%⁶.

The healthcare system has faced various challenges. However, since the inception of the implementation of devolution in 2013, the government has taken steps to improve the health of the population. This includes making maternal healthcare free of charge at all public health facilities as of June 2013, and **prioritising and piloting the universal health coverage (UHC) program** as of 2019/2020. The government is also scaling up the **National Health Insurance Fund (NHIF)**, increasing insurance coverage and achieving 100% coverage of the poor in order to expand affordable healthcare coverage in Kenya. This should contribute to reducing the 26% out-of-pocket health expenditure to 12% by 2022⁷. As a result, Kenyans would be guaranteed access to medical care and at minimal cost. Ambitions of realizing UHC will benefit eHealth solution providers as well as innovations in integrated healthcare management systems.

The government has also significantly **increased budget allocations towards health**. For instance, in the 2018/2019 financial year, the health budget increased from 8.2% to 9.2% of overall government expenditure. The health sector has seen more than a two-fold expansion from Ksh94 billion in 2012/2013 to Ksh207 billion in 2018/2019⁸. With strengths such as economic growth, a growing health budget allocation, a young population, a dynamic private sector, a skilled workforce, improved infrastructure and the country's strategic position in East Africa, Kenya has the potential of being one of Africa's success stories⁹.

Since the inception of **devolution** implementation in 2013, health services were devolved to the county level. Even though there have been challenges around human resources for health, many services have since been devolved to lower level facilities reaching more people than ever before. The government has also completed the pilot phase

³ World Bank. "Population, total - Kenya | Data." <https://data.worldbank.org/indicator/SP.POP.TOTL?locations=KE> (accessed Jan. 18, 2021).

⁴ "2019 Healthcare market insights in Kenya." <https://www.medicestafrica.com/en/overview/industry-insights/east-africa-healthcare-market-insights/kenya-healthcare-market-insights.html> (accessed Jan. 18, 2021).

⁵ "Kenya Overview." <https://www.worldbank.org/en/country/kenya/overview> (accessed Jan. 18, 2021).

⁶ World Bank. "Current health expenditure (% of GDP) - Kenya | Data." <https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.SS?locations=KE> (accessed Dec. 18, 2020).

⁷ A. Dutta et al. (2018) Kenya Health Financing System Assessment.

⁸ Ministry of Health. (2018) National and County Health Budget Analysis FY 2018/19.

⁹ World Bank. Kenya Overview. Available: <https://www.worldbank.org/en/country/kenya/overview> (accessed Jan. 18, 2021).

of Universal Health Coverage (UHC) and is looking to continue with the countrywide rollout based on the feasibility and lessons learned from the pilot phase.

The **Kenya Health market is growing fast** and is largely attributed to the country's strong fundamentals such as: one of the most advanced economies in East Africa, economic expansion supported by public investment, the country's strategically advantageous location in the region, government efforts to combat corruption that could bolster investor perceptions in the coming years and the comparatively high number of science and engineering graduates versus Kenya's immediate neighbors. Kenya is also a private sector driven economy with less control from the state.

Kenya Health market could also be **constrained by weak fundamentals** such as the political tensions, low GDP per capita, entrenched perceptions of corruption that undermine the business environment; high levels of red tape and trade bureaucracy that slow down the process of importing and exporting goods and the high minimum wage that encourages investors to establish operations elsewhere in the region.

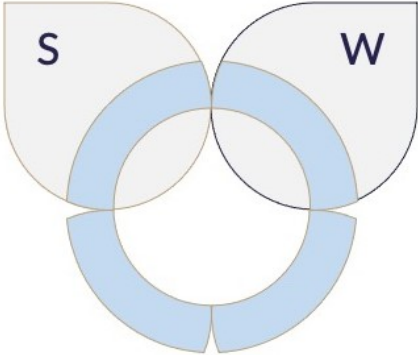
The **COVID-19 pandemic** has also exposed the weaknesses of the Kenyan health system, especially on financing and governance. For example, the unpreparedness at the county level, limited capacity of healthcare workers, inefficiency and integrity of the public health sector supply chain, and the extent and hidden impact of non-communicable diseases (NCDs). It has been argued that if the full effect of COVID-19 had been felt, it would have probably led to a total collapse of the health system. This also brought about an opportunity to fix the health system. COVID-19 underscored the importance of primary healthcare, exemplified by the sharp decline of communicable diseases (CDs) due to partising of simple hygiene practices. Home care was introduced as an alternative to hospitalization. Many health facilities continue to invest in infrastructure and capacity building, laying a good foundation for better healthcare services in the future. A regional health facility for the UN staff was put up in partnership with Nairobi Hospital.

A SWOT analysis for doing business in the field of health in Kenya

The following section presents a comprehensive health sector SWOT analysis.

STRENGTHS

- One of the most advanced economies in East Africa.
- Strategically advantageous location.
- Large population.
- Medical tourism.
- Pharmaceutical's manufacturing.
- Skilled and trained workforce.

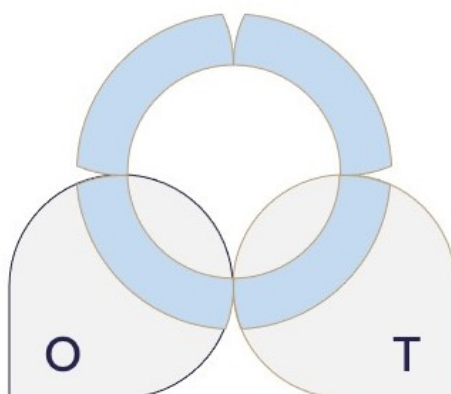


WEAKNESSES

- Low GDP per capita.
- Underfunded health system.
- Inadequate human resources in health.
- Domestic production focuses on basic consumables.
- Donor funding reliance.
- Low insurance coverage.
- Inadequate training and capacity building.
- Govt bureaucracy in the sector?

OPPORTUNITIES

- International funding.
- Government ambition to achieving UHC.
- Kenya Vision 2030.
- Modernization of healthcare facilities.
- eHealth strategy.
- Tax exemptions.
- Gaps in healthcare delivery.
- Pharmaceutical manufacturing.
- Harmonization of EAC.
- High internet and mobile penetration
- Devolved system of governance
- Public-Private Partnerships .



THREATS

- Political tension.
- Corruption.
- Red tape and bureaucracy.
- Frequent industrial unrest in the health sector

Strengths

1. **One of the most advanced economies in Eastern Africa:** The Kenyan economic performance is predicted to enjoy a largely stable and robust growth outlook over the next decade. The Kenyan economy is also broad-based, reducing its vulnerability to commodity price shocks.
2. **Strategically advantageous location in the East African Community (EAC) and Common Market for Eastern and Southern Africa (COMESA):** Kenya has good road, rail, air, and shipping liner connections with neighboring countries facilitating regional and international trade. Kenya is also an active player within the trading blocs, including the new African Continental Free Trade Area (AfCFTA) which seeks to unify the continent to a single market.
3. **Large population of 52.5mn in 2019:** The continuous growth in population creates a high demand for medical services in Kenya. The population of the middle class is growing at a rate of 2.7%. About 46% of the population continue to rely on public health services, 40% depending on commercial private healthcare, while 14% are served by FBOs¹⁰.
4. **Medical tourism:** Kenya's healthcare infrastructure is advanced in comparison to its neighbouring countries. This has served as a medical tourism destination with foreigners seeking specialised treatment from private facilities with modern equipment¹¹.
5. **Skilled and trained workforce:** Kenya has a trained and skilled workforce in various sectors within the health system such as manufacturing who have the know-how to scale up and improve the health sector¹². 75% of the population have received some formal education¹³.

Weaknesses

1. **Low GDP per capita:** Despite Kenya having one of the largest and most advanced economies in East Africa, the low GDP per capita makes health services inaccessible to many Kenyans.
2. **Under-funded health system:** The allocated health budget for the counties is still low and remain below the proportion that was previously allocated for services before devolution¹⁴.
3. **Lack of adequate human resources in the health sector:** Kenya performs well compared with other countries in the region in all health worker cadres. The doctor population ratio is however relatively low

¹⁰ "Population, total - Kenya | Data." <https://data.worldbank.org/indicator/SP.POP.TOTL?locations=KE> (accessed Jan. 14, 2021).

¹¹ "Kenya - Healthcare - Medical Devices." <https://www.trade.gov/knowledge-product/kenya-medical-equipment> (accessed Jan. 14, 2021).

¹² U. Nations and U. Nations Industrial Development Organisation, "Pharmaceutical Sector Profile: Kenya Global UNIDO Project: Strengthening the local production of essential generic drugs in the least developed and developing countries." Accessed: Jan. 15, 2021. [Online]. Available: www.unido.org.

¹³ "Case study from Kenya PRIMARY HEALTH CARE SYSTEMS (PRIMASYS) Abridged Version," 2017. Accessed: Dec. 18, 2020. [Online]. Available: <http://apps.who.int/bookorders>

¹⁴ M. of Health, "National and County Health Budget Analysis FY 2018/19," 2018.

at 0.2 per 1,000 people¹⁵. This is relatively low when compared to the WHO recommended ratio of 2.5 per 1,000 people.

4. **Focus on basic consumables:** Domestic manufacturers focus on basic consumable items. Most requirements need to be imported as the small domestic production sector concentrates on low-cost items.
5. **Donor funding reliance:** The health system reform is aided by international funding. Donor funding accounts for a high percentage in the development budget as they are the main financiers for key programmes such as HIV/AIDS, Malaria and TB. The high dependency on donors raises the issues of ownership and sustainability¹⁶.
6. **Low insurance coverage:** The Kenyan health system has a high share of out-of-pocket expenditure in health spending, with only approximately 20% of individual Kenyans having some form of insurance coverage. This has placed a burden on poor and vulnerable households due to the high cost of health services. This acts as a barrier to accessing healthcare¹⁷.
7. **Inadequate training and capacity building:** The shortage of health workers creates the need for capacity building to use medical equipment and eHealth solutions. Even though this can be done through curriculum development, problem-based learning and eLearning, it could be a deterrent to immediate investment in medical devices or eHealth solutions.

Opportunities

1. **Government's ambition to achieving Universal Health Coverage (UHC):** The Kenyan government prioritised the attainment of UHC to reduce the expenditure burden of Kenyans incurred while seeking health services. The UHC document, "A Road Map for Kenya" was created to give direction and guidance on the implementation of the UHC agenda. It entails Kenya's UHC goals and aspirations, focusing on strategic interventions and priority areas of implementation.
2. **Kenya Vision 2030:** President Uhuru Kenyatta unveiled the Big 4 Agenda, with healthcare being one of the pillars under the banner achieving "Affordable healthcare for all". In addition to the Big 4 Agenda, the Kenya Vision 2030, which serves as the blueprint for the country for the period 2018-2030. The main objective of Kenya Vision 2030 is to work towards a vision of Kenya being "an industrialised middle-income country, providing high quality life to all its citizens by the year 2030".
3. **Modernisation of healthcare facilities:** Many healthcare facilities in Kenya need modernisation creating a high demand for medical devices and equipment. Even though there are no budgets allocated for further modernization of medical equipments under Managed Equipment Services (MES), the KSH 38Bn (USD 346.7 Mn) project shows the government's initiative towards modernising facilities by procuring new equipment. Philips and GE Healthcare was selected by the ministry of health to provide radiology equipment to 98 hospitals across the 47 counties¹⁸.
4. **High mobile and internet penetration:** Kenya's telemedicine industry is poised for growth due to high internet penetration rate of (84% (as of 2017) and a mobile penetration rate which reached 100% in 2018. Kenya is also a liberalized economy with a well developed financial services sector fueled by the penetration and usage of mobiles phones, used as a platform for financial services.
5. **eHealth strategy:** Kenya has a comprehensive eHealth strategy and has been ranked the second highest country in Africa on eHealth innovation¹⁹. This also supported by an enabling infrastructure of high internet and mobile phone penetration. The ICT sector in Kenya is strong and growing, giving eHealth sector a boost for growth
6. **Gaps in healthcare delivery:** The gaps in the availability of specialist health services in most of the counties are an inconvenience to patients as they are referred to counties with those services such as Nairobi. This is a gap that can be filled by partners through providing resources such as capital for building hospitals, human resource, training, equipment etc.
7. **International funding:** Kenya benefits from capital funding from multinationals and various donors making it a hub for medical technologies and innovations. For example, Philips continue to invest in both

¹⁵ "Physicians (per 1,000 people) | Data." <https://data.worldbank.org/indicator/SH.MED.PHYS.SS> (accessed Jan. 14, 2021).

¹⁶ M. of Health, "National and County Health Budget Analysis FY 2018/19," 2018

¹⁷ "Kenya | GE.com Africa." <https://www.ge.com/africa/content/kenya> (accessed Jan. 15, 2021).

¹⁸ "export.gov." <https://www.export.gov/apex/article?id=Kenya-medical-equipment> (accessed Jan. 15, 2021).

¹⁹ "Regulatory harmonisation WHO support for medicines regulatory harmonisation in Africa: focus on East African Community."

medical devices and eHealth programmes in Kenya such as Mobile Obstetrics Monitoring (MOM) solution and as “Mimba Yangu” (mobile ultrasound technology with Telehealth support). USAID, WB, UN also continue to fund.

8. **Tax exemptions:** The importation of medical devices has been exempted from paying VAT by the Kenyan government. This has reduced the costs of medical equipment within the supply chain (although various other taxes and levies have proven to drive up costs for more advanced equipment later in the supply chain).
9. **Public-Private Partnerships (PPPs):** The Kenyan government has shown its willingness to work with the private sector in order to improve the wellbeing of the country. The PPP Act 2013 and the supporting regulations under the PPP Regulations 2014 focus on the role of the private sector in the economic development of Kenya. Kenya was also declared a lower middle income country, providing an opportunity for more business.
10. **Harmonisation of the EAC:** The East African Community (EAC) secured funding, with WHO as the sub-grantee and supported by the World Bank, to support the Medicines Registration Harmonisation (MRH) project. The project aims to achieve a harmonised medicines registration process in its member countries, creating market for medical devices and eHealth solutions to offer advanced medical services²⁰. Harmonization of the EAC, therefore, provides an opportunity for new market entrants by making it easy to do business in the region.

Threats

1. **Political tension:** The upcoming 2022 elections have created tension in different parts of the country. This has been fueled by the pushing and advocating for the Building Bridges Initiative (BBI) which has seen Kenyans take different stands.
2. **Corruption:** Kenya has been ranked 137/180 according to the Corruption Perceptions Index (CPI)²¹. This has made foreign investors and funders skeptical about conducting business in Kenya.
3. **Red tape and bureaucracy:** The excessive adherence to official rules and formalities slows down the process of importing and exporting goods as well as imposing additional costs to business.
4. **Frequent industrial unrest:** The reoccurring industrial unrests in the health sector poses as a threat as it slows down development in the industry and hinders service provision.

²⁰ “Kenya - Transparency.org.” <https://www.transparency.org/en/countries/kenya> (accessed Jan. 15, 2021).

²¹ “How can we prevent them and reduce their negative effects when they happen? And what Covid-19 considerations?” 2020.

MEDICAL DEVICES & SUPPLIES

Kenya is a promising market for medical devices and supplies, having been ranked as the fastest growing market in Sub-Saharan Africa (SSA)²². The country's growing health consumption and positioning as the medical tourism destination for its neighbors has created the need for increasing medical devices and supplies in hospitals as well as modernizing the existing ones. Common Market for Eastern and Southern Africa (COMESA) and East African Community (EAC) membership have boosted regional trade with 90% of exports shipped to other African countries. Despite Kenya having one of the largest and most advanced economies in East Africa, health services are still inaccessible to many Kenyans due to the low GDP per capita (USD 3.0). The market has attracted investors and manufacturers due to the tax incentives and the readiness of the government to work with the private sector. Health system reforms are aided by international funding.

Market Trends & Characteristics

Growing market – The Kenyan medical device market was valued at USD150mn at the end of 2019 and grew to USD185mn at the end of 2020²³. The medical device market is expected to expand by a 2019-2024 Compound Annual Growth Rate (CAGR) of 8.5%, which should see it rise to USD212.1mn (KES 24.4bn) by 2024. The reliance on imports is high due to the focus on basic consumables by domestic manufacturers. [Annex 2](#) provides the growth estimates per sub-market.

Reliance on imports – Figure 1 shows the growth of Kenya medical device imports in percentage and local currency. The fluctuation in imports is attributed to changing political landscape and priorities of the government of the day. The fluctuations are majorly observed during election period, often characterized by change of government and new government priorities/interests. [Annex 3](#) provides the market growth, imports market share and main import partner country by percentage.

Crowded & price sensitive market place – It should be noted that there is already a lot of competition for medical devices and supplies, and that the market is very price sensitive. Kenya relies heavily on imports from China and India. In 2018, Kenya import from Netherlands were valued at USD 12.7 Mn (KES1.43bn) in medical devices, and this is expected to grow as the medical devices market opens up²⁴.

Impact of Covid-19 – The Covid-19 pandemic brought about the need for Personal Protective Equipment (PPE) and ventilators as the country tried to contain the spread of the virus. The domestic production of these products increased. The medical devices companies in the region continued to benefit as well, as the domestic demand increased. The COVID-19 pandemic has hindered importation of medical devices due to the weaker economic performance and affordability constraints. Imports dropped by 8.7% to USD 104.3mn in the 12 months to June 2020²⁵. Diagnostic imaging posted a small growth, while all other product areas recorded contractions. Consumables and other medical devices were the largest product areas. The consumables market for such products continue to outperform compared to non-critical medical products such as dental products.

²² International Trade Administration. (2021). Kenya Medical Devices. [Online]. Available: <https://www.trade.gov/knowledge-product/kenya-medical-equipment/>

²³ Fitch Solutions. (2021) Kenya Medical Devices Report.

²⁴ Wits.worldbank.org. (2021). Netherlands Medical Test kits (300215) exports by country | 2018. [Online]. Available: <https://wits.worldbank.org/trade/comtrade/en/country/NLD/year/2018/tradeflow/Exports/partner/ALL/nomen/h5/product/300215/>

²⁵ Fitch Solutions. "Kenya Medical Devices Report", 2021.

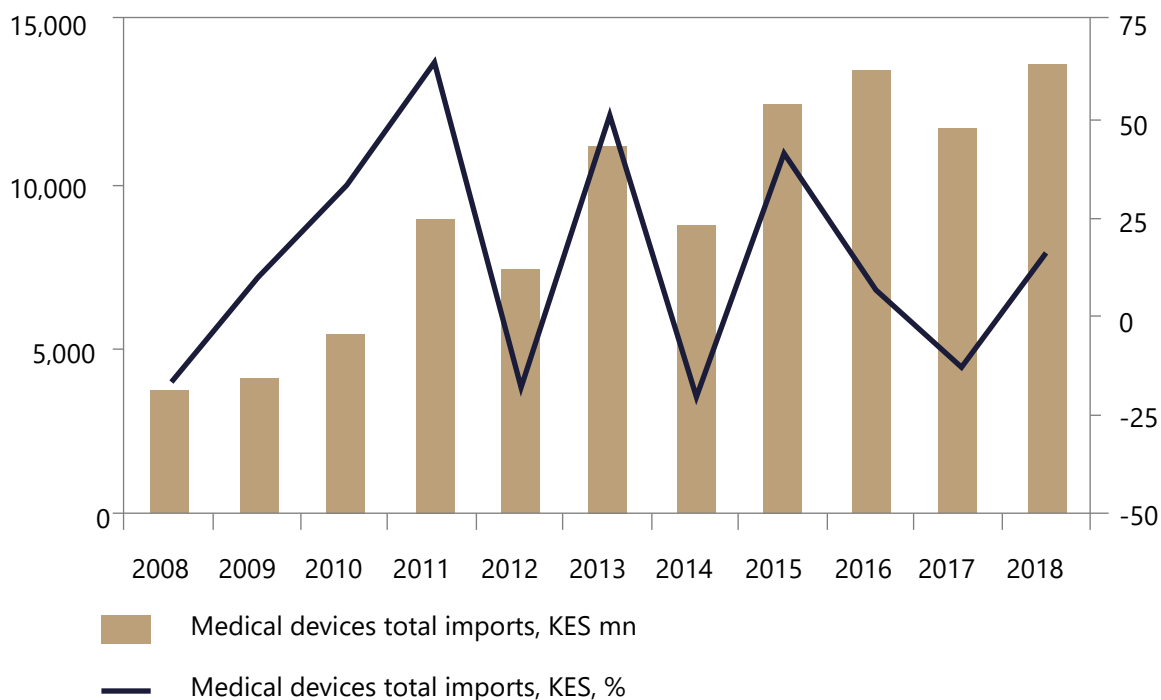


Figure 1: Percentage of Medical Device Imports, and Local Currency in Kenya (2008-2018)

Big Four Agenda – Kenya’s economic expansion with public investment in healthcare as part of President Kenyatta’s “Big Four Agenda” development plan will provide the market a boost to growth in the medium term. One of the elements of the agenda is achieving the targeted 100% universal health coverage by 2022. This agenda creates a market for advanced specialized medical equipment as well as pharmaceuticals and basic medical supplies for primary and secondary care²⁶. Even though Covid-19 pandemic has slowed the economic growth, the President Kenyatta’s “Big Four Agenda” development plan is expected to improve the market.

Devolution – The Government of Kenya (GOK) devolved its healthcare system across 47 counties in 2013. Under devolution, the health service delivery function was transferred to county governments while the national government retained policy and regulatory functions. The major challenges noted in the postdevolution era within the health sector include inadequate resources/funds from the national government and understaffed health facilities²⁷. The modernization of level 4 and 5 hospitals was addressed by the GoK through the Managed Equipment Services (MES) project in 2017. The MES project is a flexible, long-term contractual arrangement that involves outsourcing the provision of specialized, modern medical technology and equipment. It focusses on theatre, central sterile services department, renal, ICU and radiology equipment. Currently, the program has been implemented in 98 hospitals across the counties. However, the alignment of counties needs and MES supplies have been heavily debated. Next to high level facilities, counties are increasingly focused on strengthening their primary healthcare systems. The government is piloting UHC models in four counties (Kisumu, Nyeri, Machakos and Isiolo) and it is expected that UHC will be rolled out nationally. Devolution has given hope to the possibilities of addressing the health challenges owing to the reduced bureaucracies that were there in a central system. With counties now at the local level, it’s expected that health needs will be easily identified, and response will be quicker. Counties have organised themselves and exchanging best practices and discussing collaborations on shared resources for eHealth and medical devices.

Rapidly growing private healthcare sector – The market has attracted investors and manufacturers due to the tax incentives and the readiness of the government to work with the private sector. The private sector continues to advance their medical technology as well as creating more diagnostic and treatment centers, leading to the expansion of medical device market. Foreign investments in the private healthcare sector in Kenya plays a key role in funding the healthcare market. A notable example is the International Finance Corporation (IFC) investment. The

²⁶ “The Big 4 - Empowering the Nation.” <https://big4.delivery.go.ke/> (accessed Feb. 24, 2021).

²⁷ Masaba, et.al. (2020). Devolution of healthcare system in Kenya: progress and challenges. Public Health. Volume 189, Dec 2020, p. 135-140.

IFC, which acts as the World Bank's private sector lending arm, became an important conduit for private sector investment in Kenyan health care after launching a campaign to scout for opportunities in private health care in the country. In August 2015, the bank signed a deal with three Kenyan doctors to establish a KSh1.8bn (\$17.6m) multi-specialty hospital. Consequently, the construction of the hospital will open market opportunities for medical devices providers²⁸.

Programmes & projects supported by development partners – Due to the key development challenges Kenya experiences, the country has consistently received foreign aid since the 1980s through development partners in various sectors, and health sector is one of the biggest beneficiaries of this aid. The [most active development partners](#) in the health sector have for long been the USAID and European Commission with an annual funding budget of approximately USD 550,000,000 and EUR 435,000,000 respectively. Other donors include the President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund, GAVI, World Bank, DfID and DANIDA. There are many programmes and projects supported by development partners, which are currently ongoing and focused on modernisation of the medical infrastructure including devices and technology. For example, Philips continue to invest and run programmes in collaboration with other international donors such as the International Committee of the Red Cross (ICRC), the Dutch Red Cross, UNICEF, and Amref flying doctors. Programmes such as "Mimba Yangu" (mobile ultrasound technology with Telehealth support). The Christian Health Association of Kenya (CHAK) has operated a Medical Equipment Maintenance Programme since 1998. The programme provides technical support in medical equipment planning, facilitates medical equipment sourcing and conducts installations, troubleshooting, repair and maintenance. These services are provided to FBOs at a subsidized fee and can also be accessed by other users at a cost-recovery fee. Villgro Africa is also supporting the Damu Sasa programme, an innovative end-to-end blood services information management system that supports blood sourcing, inventory management, transfusion management and even haemovigilance.

Areas of opportunities

Dutch companies and organizations with an interest in Kenya typically produce, assemble and deliver medical devices, supplies and/or supply packages (medical kits) for diagnostics, treatments and/or rehabilitation, either high-tech/end or specifically designed or tailored for low resources settings (point of care). Areas of focus in terms of medical specialties include radiology, oncology, cardiology, obstetrics/gynecology, surgery, and neurologic and orthopedic rehabilitation.

Following more specific trends in Kenya, perceptions of interviewed Dutch companies and organisations, and the Dutch potential for supply, the following areas of opportunities arise:

Obstetrics

Neonatal disorders are the third largest cause of death in Kenya, especially in lower resource communities. The Free Maternal Service (FMS) policy was introduced in Kenya 2013. This has increased utilisation of the skilled birth attendant among the women who dwell close to the hospitals and who could not afford for the services initially²⁹. However there still exists a challenge to the utilization of FMS among the poor women in remote areas. Under the Universal Health Coverage (UHC) pilot programme dubbed Afya Care – Wema Wa Mkenya, strengthening the maternity and child health services are a core focus. It is also an area heavily invested in by international partners, like USAID, European Commission, and UK Aid.

Cardiology

Cardiovascular diseases are responsible for much of the growing non-communicable diseases burden in Kenya, which relate to increased prosperity and changes in lifestyle. Estimates show that 25% of hospital admissions and 13% of deaths in Kenya are due to cardiovascular diseases³⁰. In 2018, Kenya launched the national cardiovascular disease management guidelines, and it is argued that related speciality services and solution will grow in the near future. It is expected that opportunities will arise both in the installed base as well as new installments. There is also an urgent need for palliative care due to the current late stage diagnosis of cancers (survival rate below 10%). Screening programme solutions for earlier detection might become an area of opportunity if resources become available.

²⁸ "Foreign investment grows private health care in Kenya", Oxford Business Group, 2021. [Online]. Available: <https://oxfordbusinessgroup.com/analysis/fund-raisers-recent-foreign-investments-bode-well-private-health-care/>

²⁹ Brain Masaba & Rose Mmusi-Phetoe. (2020). Free Maternal Health Care Policy in Kenya; Level of Utilization and Barriers. International Journal of Africa Nursing Sciences. Vol. 13.

³⁰ WHO (2018) Kenya launches national cardiovascular disease management guidelines. [Press release]. June 21. Available via: <https://www.afro.who.int/news/kenya-launches-national-cardiovascular-disease-management-guidelines>

Trauma and Critical Care

The growth and development of trauma and critical care in Kenya has largely been as a result of the efforts of anaesthetists and international partnerships³¹. It is expected that this development will continue. Strengthening of Intensive Care Units (ICUs) is a focus under the MES project. Kenya currently has 537 ICU beds³² according to data from the MOH, Critical Care Society and Kenya Healthcare Federation, although not all are fully functional mainly due to staff shortages. The COVID-19 pandemic highlighted the importance of intensive care specialists in Kenya. Solutions for early (mobile) diagnostics and real-time guidance for trauma are mentioned as a niche market, especially in the lights of heavy traffic in cities and distance to hospitals in more remote areas.

Radiology

It is expected that radiology services for diagnostic imaging, therapeutics and image guided procedures will grow in Kenya. According to the Society of Radiography Kenya (SORK), there are approximately 1,070 registered radiographers in Kenya, which is estimated to be more than 90% of the diagnostic and therapeutic radiographers in Kenya³³. Over half of the MRI and CT scan machines are operated by the private sector. Until 2017, there were no nuclear medicine, mammography and radiotherapy equipment available in the private sector³⁴.

Oncology

An increase in the number of cancer cases in Kenya over the past decade resulted in legislative actions and policies to guide delivery of cancer services³⁵. Kenya's [new national cancer control strategy](#) and past policy efforts provide an opportunity to synergise information and enhance understanding to improve cancer diagnosis and treatment in the country. Kenya carries the regional cancer burden too, being a neighbour to countries like South Sudan which does not have even a single oncologist and where the only available treatment for cancer is surgery³⁶.

Neurology

Although still in its early days, it has been mentioned that neurology health services are a growing specialisation in Kenya.

Further Insights into Health Facilities and Services in Kenya

The [Kenya Harmonized Health Facility Assessment](#) (KHFA) 2018 is a collective effort of multiple Health Data Collaborative partners at the global level that includes; The Global Fund, The World Bank, USAID, GAVI, PEPFAR/CDC, UNICEF, UNFPA, UN MDG, Health Envoy and WHO. The assessment might provide valuable insights for Dutch medical devices solution providers to obtain a better understanding of the sectors facilities and services.

Finding your own niche market

Opportunities are not limited to the areas described above. There are examples of Dutch companies that were able to create their own niche market based upon a strong willingness and perseverance to make a social impact, as highlighted in the case study text box below.

³¹ Wangari Waweru-Siika, et.al. (2020). The history of critical care in Kenya, Journal of Critical Care, Volume 55

³² Edwine W. Barasa, et al. (2020). Assessing the hospital surge capacity of the Kenyan health system in the face of the COVID-19 pandemic. PLoS ONE 15(7): e0236308.

³³ Society of Radiographers Kenya (2019). <https://radiography.or.ke/about>. Accessed February 16th 2021.

³⁴ World Health Organization, Global atlas of medical devices. 2017.

https://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/. Accessed February 16th 2021.

³⁵ Louise Makau-Barasa, et.al. 2020. A review of Kenya's cancer policies to improve access to cancer testing and treatment in the country. Health Research Policy and Systems, Vol. 18.

³⁶ BBC (2019) Kenyan survivors: Cancer is 'national disaster'. [Press release]. August 1. Available via:

<https://www.bbc.com/news/world-africa-49191685>

Case Study: MedLinc Africa journey in Kenya

Medlinc Africa was established in Kenya in 2010 as the international expansion of Medlinc Netherlands which was founded by Gerda Heijting in 2008. Medlinc Africa initially started as a supplier of refurbish medical equipment to offer quality healthcare for all people at affordable rates, often financed by donations. The market acceptance of refurbished equipment has decreased in Kenya. In order to continue to make an impact, Medlinc Africa started a search in 2012 for new segments of the market for which it could add value to patients and customers. They found their niche market in burns and wound care. Throughout the years they have grown into a commercial company that is specialized in burns and wound care, while also supplying surgical instruments, disposable drapes/gowns, COD kits, and providing related professional advice and certified training in the latest treatment and techniques.

Creating your own market

In 2012, there wasn't a clear existing market for burns and wound care in Kenya. As hospitals were not keen on capital investments, Medlinc Africa started with offering the use of medical equipment to hospitals free of charge and charging hospitals for the necessary consumables. This turned out to be a challenging business model, as the relocation, servicing and repairs of equipment were at cost of Medlinc. To create efficiencies, Medlinc Africa established a wound care center in Nairobi to serve patients directly. Today, still only a couple of health providers in Kenya have purchased burn and wound care equipment. Due to their relationships with hospitals built over time, Medlinc was also asked to supply other equipment and consumables. Step by step they generated a required 3 years suppliers track-record that helped them to successfully participate in (larger) public tenders.

Challenging business climate

The experience of Medlinc is that doing business in Kenya requires patience. It involves time and paper consuming processes for product registration, import documentation and participating in tenders. Payment of various fees and levies are part of these processes. This drives the cost of doing business and corresponding prices at which products can be offered in Kenya. Payment conditions of clients are a challenging for a smaller scale business like Medlinc Africa. Public sector buyers often have payment terms of 120 days or more and private sector 60 days or more, and there is a tendency that payments are made on the very last day of the term. This makes it more challenging for Medlinc to do upfront investments in building an inventory to also become active in faster paced segments of the market.

Next steps

Medlinc Africa will continue to be active within Kenya and other African countries. An area of attention is making their solutions available for those that cannot directly afford it. Something that can hopefully be achieved now that the government is focusing on increasing the public expenditure on healthcare.

Market Structure

Kenya healthcare market is divided into three subsystems, namely the public sector, the commercial private sector, and the Faith Based Organisations (FBOs). The public sector is the largest in terms of facilities at 46%, followed by commercial private sector at 40% and then the FBOs at 14%³⁷. There is a large disparity between these health facilities especially in the rural parts of the country. In the fiscal year 2018/19, the Government of Kenya allocated 54% of the development budget for medical devices.

The public sector has 43.8% of medical device market share on average. The private sector has 39.0% on average of medical devices market share. FBOs operate in a unique space given their coverage and financial capability. They have 17.2% of medical device market share on average. However, FBOs provide 40% of all commercial private healthcare needs. This means that they have a 40% share of the private market³⁸. FBOs are not-for-profit organisation but the commercial aspect of their business is to ensure they make money for them to be sustainable and facilitate the day-to-day running of their facilities.

³⁷ CHAK. "Healthcare Technical Services", 2017. [Online] Available: https://www.chak.or.ke/page-content.php?Menu_Id=11/

³⁸ Kinyanjui GK, Gachanja PM, Muchai JM. (2015). Technical efficiency of hospitals owned by faith-based organizations in Kenya. *The Journal of Pan African Studies*. 2015;8(6):45-63.

Public Sector

Public sector sources medical equipment through the Kenya Medical Supplies Authority (KEMSA). Through specific government programmes like the Managed Equipment Services (MES), higher level public facilities are being equipped. The public sector is generally regarded as an extremely price sensitive market.

Kenya Medical Supplies Authority (KEMSA)

[KEMSA](#) is a state corporation under the Ministry of Health established under the KEMSA Act 2013 whose mandate is to procure, warehouse and distribute drugs and medical supplies for prescribed public health programs, the national strategic stock reserve, prescribed essential health packages and national referral hospitals. All national and local level facilities are by law obliged to first purchase from KEMSA. Only if the items are not available, they are allowed to source their supplies from other private sector distributors. Products and prices supplied by KEMSA are accessible on their [website](#). KEMSA does not receive direct funding from the GOK, as it relies on a revolving fund which is dependent on the payment from the public purchases and has programme support partnerships with various donors such as UNICEF, Global Fund, USAID, KFW, UNFP, and others. Business processes are fully automated through an Enterprise Resource Planning (ERP) system. KEMSA's business model was made more necessary by the devolution of the health function from national government to county governments. KEMSA aims to put in place systems and structures that ensure supply of medical commodities to public health facilities is uninterrupted. In practice, the system remains to have some flaws as KEMSA supplies do not yet match local demand through in-time delivery.

Experiences with KEMSA

Since KEMSA is the main distributor for approximately 6,000 public facilities, partnering with KEMSA will boost visibility and sales of medical supplies and equipment. 95% of value procured by KEMSA is through open national tender or International Competitive Bidding. KEMSA has also started procuring through indefinite quantity framework contracts which allow quick ordering under pre-negotiated terms and conditions from local suppliers.

Experiences with KEMSA include:

- KEMSA tends to procure for medical supplies and equipment for which a lot of competition exists. It is mentioned that KEMSA is extremely price sensitive.
- KEMSA often requires a 3 year track record of supplying in Kenya, including suppliers and recipient hospital audit information that is verified through (local) lawyers.
- Public sector often have payment terms of 120 days or more, paying at the last day or sometimes delayed.
- Suppliers need to engage with KEMSA to introduce their products and solutions and demonstrate to the officials how they can improve the health space as well as show their competitive advantage. For the process to be faster, there should be good political will between the suppliers and the GOK.

Managed Equipment Services (MES)

The GOK started the MES project in 2017, with a focus on theatre, central sterile services department, renal, ICU and radiology equipment. The MES project is a flexible, long-term contractual arrangement that involves outsourcing the provision of specialized, modern medical technology and equipment to private sector service providers. Currently, the program has been implemented in 98 hospitals across the counties.

Faith-based Organisations

The FBO sector is composed of NGOs and various faith-based organizations such as the Christian Health Association of Kenya (CHAK), Kenya Conference of Catholic Bishops (KCCB) and the Kenyan Red Cross ([Annex 11](#) provides a list of other FBO operators).. Most of them have general practitioners with a few being staffed by resident general surgeons or gynaecologists. FBOs are mostly involved in primary health care with only a small number offering specialised services. Some big FBO facilities such as AIC Kijabe Hospital are classified as referral hospitals. A small number of them offer highly specialised services³⁹. FBOs source from MEDs on different scales, mostly determined by Africa Christian Health Association Platform (ACHAP). ACHAP provides the framework for a collaborative network with a cohesive voice to advocate for equitable access to quality health care.

³⁹ Ministry of Health. (2013). "Human Resources for Health (HRH) Assessment Report for Northern Kenya: Overview of Health Workforce Distribution across 10 Counties."

Mission for Essential Drugs and Supplies (MEDS)

MEDS is a Christian non-profit organization registered as a Trust of the Kenya Conference of Catholic Bishops (KCCB) and Christian Health Association of Kenya (CHAK). The organisation has three main functions: health advisory services, supply chain and distribution, and quality assurance services. FBO healthcare providers can procure their supplies from MEDS at subsidized rates. MEDS is among the 11 recognized international pharmaceutical wholesalers who consistently provide safe, effective and quality essential medicines and other medical commodities. MEDS supplements most of what KEMSA does not have or is unable to procure. They procure medical supplies ranging from vaccines to medical supplies. In collaboration with the GOK, foreign governments and development partners, MEDS has in the past implemented various programs that have benefited health facilities and communities across the country. MEDS is the first point of purchase for FBO facilities. However, other facilities, both in private and public sector, can purchase from MEDS.

Commercial Private Sector

The private sector mainly sources for higher-end medical equipment through MEDs. Consumables are normally sourced through KEMSA and MEDs. When the supplies are unavailable or limited, then purchasing is done from other suppliers. While western branded equipment are often considered more advanced and specialized, lower-level private facilities in low resource areas are looking for small scale and easy to use medical equipment. Additionally, the private sector is keen on the maintenance cost, lifetime of the devices, operability, and the purchase cost. However, the current market areas of needs and demands are majorly consumables and other medical devices. Consumables are currently prioritized due to the ongoing Covid-19 pandemic. Partnerships and collaborations on the supported programmes such as maternal and child health services is always a good way to do business with commercial private sector.

Commercial Distributors

Even though Kenya imports medical equipment from different countries, the largest medical equipment companies that have presence in the country include Philips, GE and Medtronic⁴⁰. There are many other private distributors that the Dutch companies can work with as shown in [Annex 4](#) with different products. Commercial distributors have very efficient and effective infrastructure to market penetration of products. This is based on the fact that they have well maintained transport system and communication facilities for running of their activities. These distributors are able to have competing products in their portfolio. Other distributors only offer a distribution platform, but the product sales team are responsible for sales. A distribution company can also take care of both. A growing number of medical distribution companies are having a technical team who can handle the servicing of equipment and will provide this to the healthcare facilities. Therefore, the Dutch companies looking to enter the Kenya medical devices market can easily partner with these private distributors to scale up. Kenya also has a niche market for high tech innovative products but the marketing of these type of products might prove to be costly due to hidden costs accrued⁴¹.

Figure 2 provides an overview of the market structure for medical devices in Kenya.

⁴⁰ "Foreign investment grows private health care in Kenya", Oxford Business Group, 2021. [Online]. Available: <https://oxfordbusinessgroup.com/analysis/fund-raisers-recent-foreign-investments-bode-well-private-health-care/>

⁴¹ "Foreign investment grows private health care in Kenya", Oxford Business Group, 2021. [Online]. Available: <https://oxfordbusinessgroup.com/analysis/fund-raisers-recent-foreign-investments-bode-well-private-health-care/>

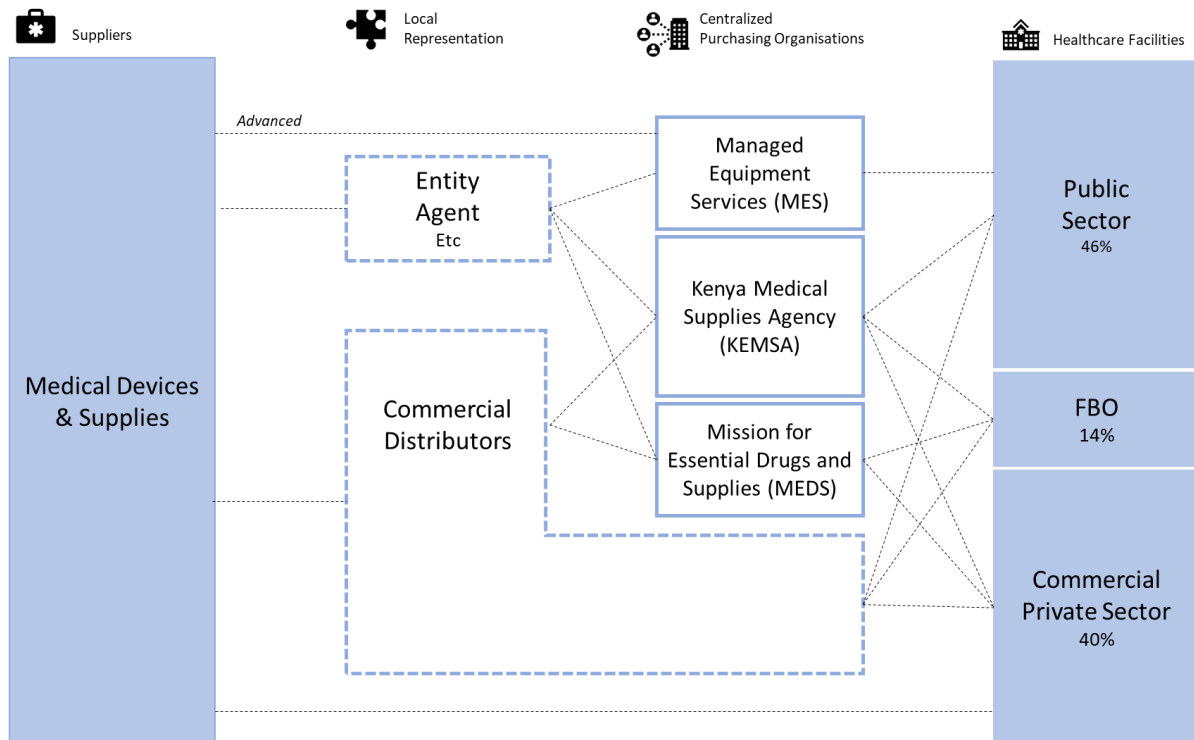


Figure 2 - Overview of the market structure for medical devices in Kenya

Market Entry & Doing Business

The World Bank ranked Kenya 56 out of 190 countries for ease of doing business in their [2020 Doing Business report](#), an improvement of four positions from the previous year and over 80 since 2014. The Government of Kenya (GOK) has initiated a broad range of business reforms, including starting a business, obtaining access to electricity, registering property, protecting minority investors, and streamlining insolvency rules. While the Kenyan business environment continues to improve, challenges such as corruption, Intellectual Property Rights (IPR) enforcement, high energy & labour costs, unemployment and poverty still hinder doing business.

Identified Success Factors

The following key success factors are derived from interviews and contact moments with Dutch companies that are active in Kenya.

Validate your solution in Kenya

Although a medical device can be successfully registered and in use in Western or even low and middle income countries, potential buyers require clinical validation and validation of proclaimed benefits in the Kenyan context. This implies that you need to pilot your solution. Ambitious doctors, private sector operators and medical universities are very open to pilot with new, technological solutions. These pilots most often require that you need to bring your own foreign or international funds. If you enter a pilot with a prospective buyer, please don't forget to have a clear agreement on a partnership or purchase conditions once a pilot is successful.

How to validate your solution in Kenya?

Piloting in Kenya requires partnering with a local stakeholder(s) and arranging your own funds. The following organisations provide support in various ways:

- With the [Dutch subsidy scheme for Demonstration projects, Feasibility studies, and Investment preparation project \(DHI\)](#) of the [Netherlands Enterprise Agency \(RVO.nl\)](#), the Ministry of Foreign Affairs wants to increase and strengthen the number of Dutch companies successfully doing business in foreign markets.
- [IFC Tech Emerge East Africa](#) programme brings technologies to new markets to drive sustainable innovation in regions that need it the most. The programme matching best-in-class, proven, affordable technology solutions from around the world with local partners in emerging markets to conduct pilot projects and build commercial partnerships. In 2020, [17 innovative health tech startups from 11 countries were selected](#) from over 415 applications across 50 countries,
- [USAID](#) tends to be keen on supporting pilot programmes that show promise in terms of scale and effectiveness.
- Since 1957, [Amref Health Africa](#) has been active in Kenya to strengthen community health systems, to address the needs of vulnerable populations, especially women, children, and youth, and to address the burden of infectious diseases, non-communicable diseases and maternal mortality. [Amref Ventures](#) (contact: Danny.Dubbeldeman@amref.nl) was developed in the Netherlands to venture into innovative initiatives, partnerships and financial models for better health in Africa, based on shared value and a combination of strengths. The mission of Amref Ventures is to develop bankable health solutions that contribute to Amref's mission 'Better health in Africa'. Amref Ventures welcomes any party with relevant experience and expertise that shares their vision. To enable successful collaboration, they prefer to connect with health entrepreneurs/scale-ups with a proven solution, business case and solid track record that are looking to partner with Amref to implement their solutions at scale in Kenya.
- The [Philips foundation](#) (contact: Eddine.Sarroukh@philips.com) is on a mission to reduce healthcare inequality by providing access to quality healthcare for disadvantaged communities. They welcome Dutch partners with suitable and scalable medical solutions that contribute to sustainable healthcare delivery models. Philips has an innovation hub based in Nairobi.

Work with a strong local partner

For a successful business journey in Kenya, it is vital to have a local representation in the country. Companies that had 'boots on the ground' from an early stage in their business journey onwards have been more successful than companies trying to run their business remotely. Navigating in the Kenyan health sector and handling processes related to doing business require a lot of time and efforts, especially if you are new to Kenya. Kenya has quite a relaxed business culture in which local relations and sensitivity for local cultures are important. A business deal is not signed overnight and may require getting approval at different levels in the (local) political and health system. This includes working through all the processes and documents related to product registration, importing, and approvals of various regulatory boards. Moreover, Kenyans like to do business with fellow Kenyans and familiar faces. An alternative to a strong local partner is establishing a local business yourself. Some recommend to partner with young, ambitious, well-educated professionals (millennials) with a growth mindset.

How to find a local partner?

Finding that 'perfect' partner that can represent and support your company in Kenya can be a challenging endeavour. Dutch companies have found a local partner through various ways, including business networking and networks offered and maintained by the Dutch Embassy Nairobi, RVO.nl and TFHC, professional matching services provided by Africa Health Business, and faith- and social-impact based international networks. The same is true for additional business service providers, like local lawyers. Working with [Commercial Distributors](#) has been addressed in the previous section. [Annex 4](#) provides a list of the largest medical equipment distributors in Kenya. It is highly recommended to do basic due diligence on a potential partner through existing networks and formalize on engagements with Kenya counterparts through local lawyers.

Find your niche market, start small and expand step-by-step

A more new or innovative solution in Kenya may encounter challenges related to market readiness. Quality standards might be lower and financing mechanisms might not yet be in place. Bringing your solution to Kenya might therefore imply that you need to develop your own market in close contact with users and partners that are

involved in health financing. Building upon relations and a step-by-step approach have helped Dutch companies to create market/buyer acceptance. If possible, it is advised to start small with lower impact changes that enable familiarity, trust and corresponding opportunities for cross- or upselling. The case study on [page 16](#) of this report provide an example of finding a niche market and expanding business based upon relationships and trust.

Train your end-users

Whenever you try to sell and implement your medical equipment, you need to ensure an adequate training for the health care professionals working with the products. A good training on how to use the devices will ensure that the devices are used in a better manner and sales are recurring or growing. This is especially through for lower level health professionals and (voluntary) community health workers. Emphasizing the importance of the usage of new techniques tends to open up possibilities, as professionals are often eager to use them.

Social impact, perseverance & willingness to invest

Be prepared to invest a severe amount of time and resources to go through the processes of clinical validation for market/buyer acceptance, finding a strong local partner and further business development and sales. It is not uncommon that the time to market for more new or innovative solution is 2 to 5 years. Social impact has been a key driver for several Dutch companies active in the country. By putting social impact first, and profits second, these Dutch companies were able to generate market feedback, market acceptance, and key relationships from which they were able to further develop their business.

A Kenyan perspective on market entry and doing business

Dutch companies interested in investing in Kenya must develop a good understanding of the market in order to succeed. There is a lot of competition in the market. This includes determining the best market entry channel. The best channel is to consider partnering with a Kenyan company to serve as a local agent or distributor in order to create a sense of ownership and involvement for the locals. Getting and staying in touch with end users of medical supplies from abroad is not easy in Kenya, it is quite costly and time consuming. Kenyans prefer to do business with a person they physically can meet and know instead of a company far away. Consumers often feel comfortable when buying from familiar faces. Other channels include obtaining local franchisees or licensees.

While some sectors allow for direct sales to end users, one should have a solid understanding of the logistics of the market. Both public and private sector are doing tenders. For successful bidding, you need to have your paperwork in order and be aware of price sensitivities. On the contrary, Kenyans have the tendency to be status oriented and products that are trendy and highly desirable could work well. Having publicity and showing off in the relations works well in the Kenyan business ethics. In advertising, which is increasingly done through social media or via targeted campaigns, companies take into consideration local language, particularly when targeting customers outside of main urban areas.

The pre- and after sales service is very important and therefore most foreign companies are doing business through agents and medical distributors who represent the brand and sales. Multinationals like Philips, GE and Metronics have their own sales teams and distribution channels as providers purchase from them directly. When you are a Small or Medium Sized Enterprise (SME) it is advised to look for an agent/distributor in the capital city of Nairobi as that is the hub of the country (and East Africa) and the large majority of the headquarters and health facilities are based in and around the city. Most large distributors have sub-locations in the country from where they do their regional businesses.

Regulations, Standards and Taxes

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 at the MOH is the regulatory body for registration of medical devices. 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 eHealth and medical devices will increase compliance for importers and drive-up standards in the Kenyan medical device market. These products now 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 PPB, through the Kenya National Single Window Electronic (Kentrade) System.

Pharmacy and Poisons Board (PPB)

The Pharmacy and Poisons Board (PPB) regulates the practice of pharmacy and the manufacture and trade in drugs and poisons. The board is also the regulatory body in charge of registration of medical devices. The detailed requirements and fees for medical device registration is contained in the [Guidelines on Submission of Documentation for Registration of Medical Devices](#) document. [Annex 5](#) provides a more detailed overview of the required information, process and fees involved.

Experiences with the Pharmacy and Poisons Board

Medical devices need a registration before the products can be imported to Kenya. Without a registration of your device or product, you are unable to import your products. Registration of your devices is a lengthy process. The PPB uses the same (online) platform and required documentation for the registration of pharmaceuticals as for medical devices. Therefore, the process is lengthy and expensive. Many documents have to be delivered to the PPB to get your registration correctly. With the slightest product change, devices need to be registered again. It is not uncommon that the registration fee of each product model costs around 1,000 to 2,000 USD. Next to registration in Kenya, products need to have CE or FDA certification. The practice around registration makes that the products become much more expensive for the Kenyan market, while in the meantime, budgets are lower. Unfortunately, it is not expected that registration processes will become more easy in the near future.

Clearance from Regulatory Boards

The Ministry of Health at the national level is responsible for the regulation of health workers and health related practices in the country. The government has set up several regulatory boards who all have their own specialized mandate of regulations. It is widely acknowledged that it is of utmost importance to liaise with the boards for the successful adoption of your solution in Kenya, which often includes fees or levies. Not having their approval can work against you. There are examples that the interests of health care professionals hinder the clearance of innovative solutions that impact the traditional ways of working of these professionals. [Annex 6](#) provides an overview of the most important boards.

Experiences with Regulatory Boards

On paper, each Regulatory Board has its own prescribed mandate. In reality, there seems to be a lot of overlap whereby different board claim to regulate the same product. This can be clarified by an example. According to the law, the PPB is responsible for product registration and licensing of a stethoscope. The party who would like to sell the stethoscope needs to pay the applicable fees to the PPB. However, the Nursing Council of Kenya (NCK) claims that this product also needs to be licenced by them as “their nurses” will work with the stethoscope, thereby forcing the distributor to pay double licensing fees and go through an additional licencing process. This double practice is not allowed by law and the private sector has complained about this as it is significantly increasing the cost and ineffectiveness of doing health business in the country. For this example, the Cabinet Secretary for Health has issued a statement saying that the PPB is the only Regulatory Body in charge of licencing medical equipment and the NCK is operating unlawfully. However, the reality on the ground is that these double inspections/licensing are still going on in practices. Next to double licensing fees, there are examples of ethical commissions of regulatory boards that delay or disapproved the introduction of medical innovations as it was considered to be unsafe, while in practise the innovation would improve and/or replace the services provided by doctors represented by those boards.

Value Added Tax (VAT)

The government announced the exemption of medical equipment and apparatus from VAT, under the 2019/20 budget, which continues to drive and encourage investment in the health sector in Kenya. These exemptions will support strong medical device market growth and is expected to register double-digit increases every year between 2019 -2024 if tax exemption continues. There is also a proposal underway at the East African Community (EAC) to create a single regulatory body for medical devices across the region.

VAT and levies as cost drivers

Medical devices & supplies are exempted from import duty. However, there is currently a 16% VAT rate on the procurement and sales of medical devices in Kenya. Providers of normal medical services are VAT exempted entities. For these buyers, there is no reverse charge method for the VAT paid to their suppliers. This is a severe cost driver for procuring and buying medical devices & supplies. Next to VAT, it should be noted that doing business in Kenya involves paying various levies, ranging from regulatory boards (see below) to levies for railroads. On average, these levies could add up to an additional 7.5%. Due to VAT and levies, Dutch suppliers should keep in mind that selling medical equipment could imply a 25% increase of the selling price. Products therefore might be more expensive on the Kenyan market compared to a Western market.

Import documentation

Required documents

All Kenyan imports are required to have the following documents: Import Declaration Forms (IDF); a Certificate of Conformity (CoC) from the Pre-Shipment Verification of Conformity (PvoC) agent for regulated products; an Import Standardization Mark (ISM) when applicable; and valid pro forma invoices from the exporting firm.

Kenya applies tariffs based on the international harmonized system (HS) of product classification and applies duties and tariffs of the East African Community (EAC) Common External Tariff. In general, customs duty is levied at rates between 0% and 100%, with an average rate of 25%⁴². However, sensitive items attract duty higher than 25% (the sensitive items are listed in the schedule 2 of the EAC Common External tariff). Excise Duty depends on whether the imported item is excisable or not. The rates are prescribed under the Excise Duty Act 2015. Imports into Kenya are subject to a standard VAT rate of 16%, levied on the sum of the CIF value, duty, and other applicable taxes. An import declaration fee of 2% and railway development levy of 1.5%⁴¹. It should be noted that tariff rates are subjected to change. However, tariff rates can be estimated by visiting the Kenya Revenue Authority.

To import any commodity into Kenya, an importer will have to enlist the services of a clearing agent(s) who will process the import documentation through Kenya Customs electronically on the intergrated customs management system (iCMS) and clear the goods on your behalf. An Import Declaration Fee (IDF) of 2.25% of the cost, insurance and freight (CIF) Value subject to a minimum of 5,000.00 Kenyan Shillings is payable⁴¹. A list of clearing agents can be found on the [website of Kenya Revenue Authority](#). Customs will assess duty payable depending on the value of the item(s) and the duty rate applicable.

Kenya has a pre-shipment inspection requirement (the Pre-Shipment Verification of Conformity, or PVoC) for exports destined for Kenya. Exporters of medical devices into Kenya need to ensure PVoC compliance in the country of origin and authorize a Local Authorized Representative (LAR) to register their products with the PPB.

Exports to Kenya must also obtain an additional Kenya Import Standardization Mark (ISM), which is mandatory for all imported products sold in Kenya to help consumers identify in the local market, imported products that have been certified by Kenya Bureau of Standards (KEBS). For a small number of health, environment, and security imports, import licenses are required. Imports of machinery and equipment classified as equity capital or loan purchases must be received prior to exchange approval; local banks will not issue shipping guarantees for clearance of imports in the absence of such approval. All imports procured by Kenyan-based importers must be insured with companies licensed to conduct business in Kenya. Importation of animals, plants, and seeds are subject to quarantine regulations.

⁴² "East African Community Common External Tariff." <https://www.kra.go.ke/customs>

Additional Factors that make Kenya a logical first step in East Africa

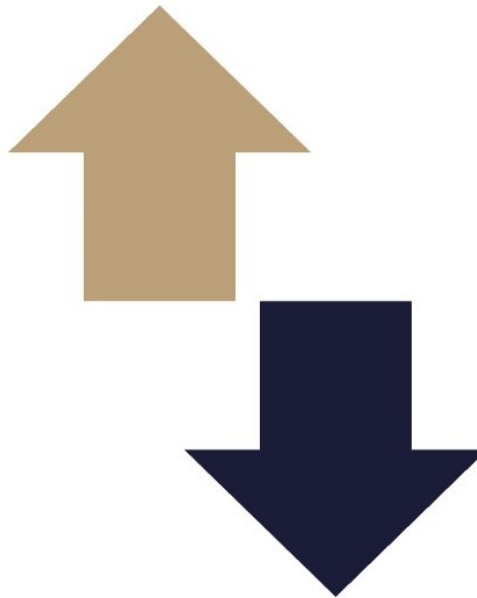
Asking Dutch companies what makes Kenya an attractive market to enter, additional factors that were mentioned are:

- Direct flights between Amsterdam and Nairobi. Nairobi also has good connections with rest of Africa;
- English proficiency;
- Relatively easy to establish a company;
- Relatively easy to obtain a work permit;
- Knowledge institutes are very open towards international partnerships;
- Openness towards technological innovation;
- An entrepreneurial population.

A SWOT analysis for the subsector Medical Devices & Suppliers

STRENGTHS

- Growing medical device market.
- Govt priority: Big 4 Agenda and Kenya Vision 2030.
- Modernisation of healthcare facilities.
- Rapidly growing private healthcare sector.
- Many programmes by development partners.
- Openness towards new technologies.

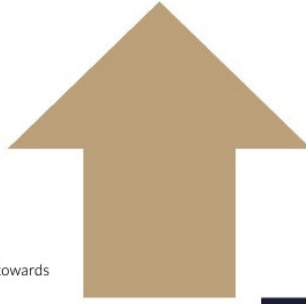


WEAKNESSES

- Return of investment requires patience.
- Approval at different levels in the local political and health system needed.
- VAT and additional levies driving up prices at which solutions can be offered, up to 25%
- Long regulatory process, approval of various boards needed.
- Little domestic production, reliance on imports.

Opportunities

- Obstetrics.
- Critical Care & Intensive Care Units.
- Radiology.
- Cardiology.
- Oncology.
- Neurology.
- Clinical validation in East Africa given openness towards technology and innovation.



Threats

- COVID-19 pandemic hindering purchases and imports.
- Due to bureaucracy and levies, prices for devices are sometimes higher in Africa than in Europe.
- International competition from other source markets such as China, India, US, Germany

E-HEALTH

Kenya is ranked the second after South Africa on eHealth innovation in Africa (behind South Africa)⁴³, and fifth on eHealth priority ranking in Sub-Saharan Africa⁴⁴. The government has made notable progress in developing a sound policy foundation to manage the rollout of eHealth solutions in the country. The [Kenya e-Health Strategy \(2016-2030\)](#) 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. The strategy has identified specific eHealth needs and demands including mHealth, Telemedicine, eLearning, and Health Information Systems. In 2019, the government launched the [Data Protection Act](#) which provides more clarity on the processing of personal data.

In 2017, the government launched [mHealth standards and guidelines](#) which provide a regulatory framework that will enable coordination and implementation of robust eHealth solutions. The standardization will encompass communication protocols, device interfaces, applications and operating systems. This will support standards for information exchange to serve as the building blocks for the seamless and secure exchange of health information for better and improved health service delivery and outcomes. Standardization further aims to move the mHealth sector from the silo-based pilot phases to scalable fully-fledged interoperable solutions. These present opportunities of investment in areas such as the Health Information Technology (Health IT), Mobile Patient Monitoring Platforms, and Telemedicine. With a high mobile phone penetration and an existing comprehensive e-Health strategy, Kenya health sector market is more ready for eHealth innovations.

Market Trends & Characteristics

Growing market – The Kenya's eHealth market is expected to expand by a 2019-2024 CAGR of 6.0% in US dollar terms, which should see it rise to USD180.1mn by 2024 from the current USD150.5mn⁴⁵. The market is also expected to register mainly high single-digit growth in the years ahead up to 2024. Next to government's prioritization of eHealth and mobile health services, the eHealth market growth is also being driven by the country's need to provide better quality health services in underserved communities and related availability of international funding, the increasing chronic disease prevalence, particularly cancer and cardiovascular diseases, and widespread private healthcare provision. However, critical voices argue that it will take another 5 years before the eHealth market in Kenya will mature, become less reliance on international funds, generate more sustainable revenues for eHealth vendors, and become more ready to adopt advanced eHealth solutions.

Scattered landscape that relies on foreign expertise and investments – Kenya is a popular destination for eHealth and it is mentioned that there is an abundance of eHealth pilots and solutions. The country's eHealth market remains almost entirely reliant international funds and applications driven by foreign expertise. Development partner funded solutions account for around 95% of the existing eHealth solutions⁴⁶. Foreign funded private sector operators are also working on their own eHealth solutions. Several domestic innovators are involved in health enabling applications using available mobile networks and payment systems International organisations like the International Finance Corporation (IFC) stimulate local innovators with support during the pilot stage through targeted programmes.

⁴³ “Kenya - Healthcare - Medical Devices.” <https://www.trade.gov/knowledge-product/kenya-medical-equipment> (accessed Jan. 14, 2021).

⁴⁴ German Federal Ministry for Economic Cooperation and Development. (2018). Digital health Ecosystem for African countries.

⁴⁵ Fitch Solutions. “Kenya Medical Devices Report”, 2021.

⁴⁶ “Kenya - Healthcare - Medical Devices.” <https://www.trade.gov/knowledge-product/kenya-medical-equipment> (accessed Jan. 20, 2021).

Recent mapping of digital health solutions in Kenya

In 2020, a technical assessment was commissioned by the Kenya Healthcare Federation and the SDG Partnership Platform in Kenya to obtain an overview of the digital health landscape in Kenya. The authors made it clear that there is no quick or easy way to gain or maintain an overview of the digital health solutions in use in Kenya. The digital health territory is dynamic and a clear distinction between programmes that support digital health interventions and the product themselves is often hard to make. The mapping into classes of digital health interventions as defined by the World Health Organisation (WHO) is provided in [Annex 7](#) and enriched by eHealth solutions identified by AHB and TFHC. This mapping might be particularly useful for the purpose of partnering and/or analysis of the competitive landscape in Kenya.

Difficulties in uptake & scalability – Even though the eHealth strategy has identified areas of priorities and investments including guidelines for implementation and regulation, very few solutions have reached significant scale. Many eHealth solutions remain at pilot phase, mostly because of financial constraints and technical issues surrounding interoperability and infrastructure requirements. The government does not maintain a centralized registry of all eHealth projects under implementation in Kenya, making it difficult to monitor and align progress. Solutions that managed to reach significant scale include mTiba (health wallet), myDawa (online pharmacy), and Maisha Meds (supply chain network provider). A large share of current eHealth solutions are delivered through mHealth due to the high geographical coverage of mobile network. These solutions are mostly short message service (SMS) based due to infrastructure limitations.

Key barriers and challenges to digital health uptake & scale-up

In 2019, a technical assessment was commissioned by the Kenya Healthcare Federation and the SDG Partnership Platform in Kenya to obtain an overview of the digital health landscape in Kenya, and provide critical input for a roadmap to support the update of digital health technologies, in the view of maximizing its impact on primary healthcare outcomes. Consultation with expert stakeholders and reviewed literature presented a relatively consistent picture about challenges that are encountered by digital health solution providers in Kenya. The various impediments are interrelated, and their relative importance varies depending on the specific professional perspective adopted. In total, 16 barriers were identified, which are summarized below. [Annex 8](#) provides a further explanation of each barrier.

Infrastructure and ecosystem	<ol style="list-style-type: none">1. Lack of resources / liquidity for users to pay2. Insufficient infrastructure3. Lack of trust from end-users4. Health financing / insurance coverage
Health sector human capacity factors	<ol style="list-style-type: none">5. Knowledge and awareness gaps6. Skills and capacity gaps7. Attitudes of CHW and management towards technology
Product features	<ol style="list-style-type: none">8. Insufficient adoption to real-world health sector ecosystem9. Solutions are not sufficiently user-friendly or user-oriented
Governance and policy	<ol style="list-style-type: none">10. Need for resoluteness, competencies and high integrity leadership11. Insufficient evidence / shared knowledge12. Suboptimal regulation13. Understanding and leveraging private sector dynamics14. Fragmentation of players
Capacity of developers & vendors	<ol style="list-style-type: none">15. Insufficient business management and marketing skills16. Insufficient capital to improve product and/or marketing

Insufficient standards & legislation – The goal of the Kenya eHealth policy is to improve the availability and quality of healthcare services through the use of ICT and the Data Protection Act provides more clarity on the processing of personal data. However, critical voices argued that the eHealth market continues to experience a set back due to a lack of clear and binding standards and legislation, enforced by strong institutions, as well as well-defined roadmaps for scale up.

Impact of Covid-19 – The onset of coronavirus pandemic has necessitated the need for virtual visits and electronic transmission of test results. The eHealth strategy has created new areas of priorities and investments such as lab result transmission system, automated patient appointment system, healthcare workers communication system, emergency alert response system, medical products procurement system, and food security management system. It is expected that both national and county governments will continue to prioritize home-based healthcare delivery even after the pandemic, especially for patients with pre-existing conditions.

A Fast Growing Technology Sector – The technology sector in Kenya is one of the fastest-growing business sectors in Kenya, and internet access rates are some of the highest in Sub-Saharan Africa. The rise of 4G and 4G LTE services in 2020, the GOK-approved universal 4G coverage, the growth in smartphone usage is influencing growth of eHealth market. The existing revolutionary mobile money platform has paved the way for further digitalisation in various sectors, including healthcare. Also, Kenya's urban areas, particularly Nairobi, are noted for their large number of well-educated English-speaking and multi-lingual professionals, and for their strong entrepreneurial tradition. Kenya is also a very 'young' country with almost 79% of the population under the age of 35.

Areas of Opportunities

Dutch companies and organizations with an interest in Kenya typically develop and deliver IT solutions for Health Information Management Systems, Health Financing/Payments, Health Behavior, Telehealth & Mobile Health (health from a distance), Disease management platforms, Electronic Health Records, Training & Education, and Artificial Intelligence to support medical decision-making.

The government of Kenya has a well-defined eHealth strategy with a specific eHealth policy tool, the [Kenyan e-Health strategy 2016-2030](#). The document identifies five main areas of needs and needs for implementation: 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 eHealth solutions.

Following more specific trends in Kenya, perceptions of interviewed Dutch companies and organisations, and the Dutch potential for supply, the following areas of opportunities arise:

mHealth –The high penetration of mobile networks and mobile phones in Kenya provides an avenue for the implementation of mHealth applications. Kenya's socioeconomic development heavily relies on mobile telecommunications. The unprecedented and rapid expansion of the industry continue to create opportunities for the health care players to expand their services to the unreached and underserved populations through mobile applications. The government in collaboration with institutions such as the Living Goods, Safaricom, Carepay, PharmAccess, Huawei, among others continue to innovate financing solutions through mobile. It has argued that there is opportunity for additional mHealth services that make use of existing mobile structures and (payment) platforms, especially in the field of chronic disease and medication management.

Telemedicine –Telemedicine in Kenya is mainly offered through the use of connected point-of-care devices and mobile devices like smartphones and laptops. A particular area of priority is serving more rural areas that are characterized by lower resource settings and less extensively trained health workers. The rising need to manage chronic diseases through tele- and homecare programmes is seen a driver for growth on the medium to longer term. The corona outbreak has spurred hospitals in Kenya (including walk-in clinics) to adopt telemedicine for patient consultations and monitoring the spread of COVID-19. Private facilities are investing in this area to expand their reach to patients in different locations. The government has overcome regulatory and ethical concern and, at the moment, has issued more than 20 facilities with licenses to use telemedicine.

eLearning – The shortage of healthcare workers, and the need for quality improvement necessitates the adoption of eLearning. eLearning is well-perceived and continues to progress in Kenya due to the cost efficiencies associated with it. Many other sectors are adopting eLearning solutions for wider coverage and reach. In line with eLearning lies the opportunity for the introduction of the online courses for medical staff, starting as an additionality for face-to-face and paper-based training and education. For instance, AMREF and the Ministry of Health (MOH) have initiated an innovative eLearning course on several aspects of health worker's training to curb the shortage of health workers. AMREF also trains nurses through eLearning in collaboration with Kenya Medical Training College (KMTC). eLearning for staff training and refresher courses in the private sector is starting to pick up. Private operator Avenue hospital is already training patient assistants and community health assistants through eLearning available on their [website](#).

Health Management Information Systems (HMIS) – Many facilities, public or private sector, are moving from paper-based systems. The process of digitization is slow in the public sector, but faster in the private sector due to the need to modernize and provide more services to their clients efficiently. Larger private hospitals in the main cities have developed HMIS systems. High-level public hospitals such as Kenyatta National Hospital (KNH) and Moi Teaching and Referral Hospital (MTRH) are already in the process of digitizing their records. Lack of financial resources and human resource capacity in the public sector has derailed further movement from paper-based systems. However, low-level facilities are purchasing information systems for administrative purposes. A recent study shows that, next to a lack of funds, public sector operators generally lack capacity to use more complex information system due to insufficient training and inadequate system support⁴⁷. In general, hospitals are looking for systems that match their local context and are easy to use, affordable, interconnected and innovative.

Enterprise Resource Planning (ERP) – There is need for a command center, with monitoring and evaluation processes that health managers can use to appropriately track progress of the delivery of care. The growing complexity of improved equipment and technology in the healthcare industry requires sophisticated ERP solutions that can make the sector efficient and effective. This provides an opportunity for SMEs and startups to develop easy to use and affordable systems for low-level facilities.

Getting your market entry timing right

With the existing comprehensive eHealth strategy, the country is more ready for eHealth solutions. There are various sector plans and initiatives, including the private and the public, on scaling eHealth solutions. Even though there are challenges moving from plans on paper to real world actions and investments, the Kenya Vision 2030 And 'Big Four Agenda' provides the opportunity and market for eHealth solutions, and for both local and foreign companies already invest in the areas of needs and demands mentioned above. However, it has been argued that it will take another 5 years before the eHealth market in Kenya will mature, become less reliance on international funds, generate more sustainable revenues for eHealth vendors, and become more ready to adopt advanced eHealth solutions. On the same note, it is highly advices to already engage with the market and key stakeholders as early on as possible, as partnerships and trust for integrated eHealth solutions in Kenya are currently being build.

Market Structure

The key stakeholders in the Kenya's eHealth solutions market are majorly the MoH, Ministry of Information and Communication Technology (MICT) development partners, donors, SMEs and startups. Development partners such as African Development Bank, Tele-Health Society of Kenya and Anadach Consulting Group consistently champion for the implementation of eHealth solutions to provide health services across different regions. Major donors such as USAID continue to fund health and ICT entrepreneurs to invest in eHealth solutions provided via mHealth platforms because of the huge penetration of mobile across the country.

The general Kenya healthcare market consist of the public sector (46%), the commercial private sector (40%), and the Faith Based Organisations (FBOs) (14%). Even though there are large disparities in number of health facilities, especially in the rural area, the public sector still controls the largest market share for health innovations (44.0%), followed by the private sector (40.0%). FBOs have about 16% of the market share for eHealth solutions. The Kenyan eHealth market heavily relies on aid from development partners, SMEs and startups. While many facilities both private and public are willing and ready to adopt eHealth solutions, most eHealth solutions are in pilot phase, and only a few pass this stage to scale up because of financial and infrastructural challenges. Patients are also adopting the use of eHealth solutions, especially because of the huge network coverage. However, most people report technical challenges. There is, therefore, an opportunity in this area due to the need for easy-to-use small scale affordable solutions.

Demand for eHealth solutions remains high in both public and private sector as many healthcare facilities require modernization. In the private sector especially, there is a steady demand for eHealth solutions to offer services to patients in remote areas. However, market dynamics continue to hinder affordability of services. Even though Kenya is a frontrunner in the region in terms of economic and technical developments, the country is still in dire need for healthcare financing solutions.

⁴⁷ Muinga et al. (2020) Digital health Systems in Kenyan Public Hospitals: a mixed-methods survey. BMC Medical Informatics and Decision Making. Vol.20. <https://doi.org/10.1186/s12911-019-1005-7>

Public Sector

The public health sector purchasing is done through KEMSA and the MES project. The public sector, through the MoH and MICT, have identified priority areas such as maternal and child health (MCH) services and management of chronic diseases to be delivered via eHealth solutions. The government has set up eHealth unit to support the creation and implementation of eHealth solutions through the eHealth strategy. Collaborating with eHealth unit on priority programmes such as MCH services might be a good way to start, but will most likely include getting additional partners on board that help to mobilize financial resources and human resource capacity for actual implementations. The public sector hospitals are increasingly purchasing digital systems to support administrative services and laboratory management systems. Health informatics initiatives such as the adoption of District Health Information System 2 (DHIS2) for centralized population data collection are expected to increase. At present, public health institutions lack basic applications for supply chain management involving knowledge and technology to effectively distribute pharmaceuticals and medical supplies.

Faith-Based Sector

Faith-Based Organizations (FBO) mainly purchase from MEDS. MEDS offers both supply chain and distribution, and quality assurance services to FBOs. MEDS offers subsidized rates to FBOs. MEDS is considered one of the recognized international pharmaceutical wholesalers consistently providing safe, effective and quality essential medical supplies. The uptake of eHealth solutions varies from one to another and tends to rely heavily on programmes with development partners.

Development Partners

There are many eHealth programs and projects supported by international donors and development partners. mTiba, Turaco, and myDawa are a few of the eHealth solutions that have successfully passed the pilot phase to scale up. There are different large international players such as the International Telecommunication Union through the World Health Organization (WHO) who are increasingly becoming interested in providing solutions to support universal healthcare coverage. For example, the Afya Electronic Health Management Systems project that is supported by Github in collaboration with the government. Any company with a solution and experience in this area is welcome to Kenya to explore ways of partnering. This provides opportunity for SMEs and startups with financing eHealth solutions.

Non-Government Organizations (NGOs) and International donors such as the USAID in collaboration with other partners such as Management Science for Health (MSH) continue to implement programs such as Africa Strategies for Health (ASH) which focus of government's identified priority areas such as ending child and maternal deaths by overcoming barriers to healthcare access. Development partners focuses on different humanitarian programmes that support the development of different sub-sectors.

Commercial Private Sector

Leading private sector hospitals are keen to modernize their operations and increase access to healthcare. Many large private hospitals in Kenya have rolled out multi-billion-shilling expansion projects in order to meet the current and expected growth in demand for quality healthcare services as the country's middle-class population grows. For example, [The Aga Khan University Hospital](#), [Nairobi Hospital](#), [Avenue Group](#), [Coptic Hospital](#), and [AAR Health Services](#) have all launched major development schemes that will see new branches opened and services broadened and managed through a central command system, including ordering prescriptions and delivery online as well as eLearning services to their staff members. Small and medium size private hospitals are also focusing on small scale eHealth projects that can be used by their clients in low resource areas. These areas are often hindered by network and infrastructural challenges, and therefore, requires low-tech eHealth solutions which people can easily use with minimum technical requirements. Several are already using basic enterprise resource planning applications to manage their operations, but there is a huge need for data interchange and virtual visit applications. In general, private hospitals prioritise and invest on easy to use and maintain eHealth solutions that fits the needs of their clients in terms of interoperability.

The private sector has also identified areas such as digital finance for health such as mTiba, which is rapidly growing and remains a large area of opportunity for new market entrants. At the moment, advancing efforts of achieving UHC is supporting the emergence of digital health tools with ease of interoperability to make data available for decision makers. The private sector is also focusing on public-private partnerships which can be attained with focused commitment from stakeholders.

Commercial Distributors

There are several commercial distributors for eHealth solutions in Kenya. [Annex 9](#) provides a list of distributors of eHealth solutions. Partnering with these distributors provides the opportunity to increase visibility of startup solutions.

Market Entry & Doing Business

Kenya healthcare market is continuously improving and becoming more accessible to foreign companies based on the World Bank indicators, which ranked Kenya 56 out of 190 countries for ease of doing business⁴⁸. Many other reforms such as starting a business, registering property, and protecting minority investors have been initiated. These reforms provides an avenue for SMEs and startups to invest and successfully do business in Kenya. eHealth solution providers can leverage these efforts to enter the Kenyan healthcare market. Collaborating with existing local (development) partners, ICT companies and distributors will be beneficial to the new entrant suppliers in terms of market understanding and target market reach. The MoH through the MICT is also in support for any solutions that support and strengthen access to healthcare in remote areas. However, a widely regarded key challenge for eHealth solutions in Kenya is to move from piloting to scale.

Identified Success Factors

The following key success factors are derived from cases studies of eHealth solutions in Kenya, interviews and contact moments with Dutch companies that are active in Kenya.

Enter the eHealth space through partnerships

Dutch companies interested in entering eHealth market with an eHealth solution should consider effective partnerships with the healthcare stakeholders, such as the Ministry of Health (MoH), Ministry of Information and Communication technology (MICT), local governments, development partners, health service providers, and/or existing local suppliers and distributors of eHealth solutions (major ones listed in [Annex 9](#)). Partnerships with these stakeholders will help to navigate through the political, sociocultural and health system, and improve the visibility of the products and create awareness among the public. Having major local partner on board would create a feeling of local ownership and involvement, hence improve the reception of the solution among the local private and public facilities. For the scalability of eHealth solutions that address less well-resourced areas of the health sector, partnering in an early stage with key stakeholders will help to co-create sustainable business models.

Bring your own funds to validate your solution and prepare the market

Development partner funded solutions account for around 95% of the existing eHealth solutions in Kenya. This is exemplified in various case study provided in [Annex 10](#). Organisations that originate from Dutch expertise, like [PharmAccess](#) and [CarePay](#) have also been kick-started by donor funds and Dutch government investment vehicles. The Dutch mobile app for Covid-19 detection, [Lusci](#), partnered with PharmAccess and received initial [co-funding from FMO Dutch Entrepreneurial Investment Bank](#) for introducing the app in Ghana just before Kenya. Relative new Dutch entrants in the eHealth space in Kenya, including [Spectator Healthcare Technology](#) (tele-medicine) and [Elevate Health](#) (eLearning), are piloting in Kenya with a subsidy from the Dutch government. It therefore an important lesson that a Dutch company should bring its own (co)financing.

⁴⁸ "World Bank's 2020 Doing Business." <https://doingbusiness.org/en/rankings>

How to validate your solution in Kenya?

Piloting in Kenya requires partnering with a local stakeholder(s) and arranging your own funds. The following organisations provide support in various ways:

- With the [Dutch subsidy scheme for Demonstration projects, Feasibility studies, and Investment preparation project \(DHI\)](#) of the [Netherlands Enterprise Agency \(RVO.nl\)](#), the Ministry of Foreign Affairs wants to increase and strengthen the number of Dutch companies successfully doing business in foreign markets.
- [IFC Tech Emerge East Africa](#) programme brings technologies to new markets to drive sustainable innovation in regions that need it the most. The programme matching best-in-class, proven, affordable technology solutions from around the world with local partners in emerging markets to conduct pilot projects and build commercial partnerships. In 2020, [17 innovative health tech startups from 11 countries were selected](#) from over 415 applications across 50 countries,
- [USAID](#) tends to be keen on supporting pilot programmes that show promise in terms of scale and effectiveness.
- Since 1957, [Amref Health Africa](#) has been active in Kenya to strengthen community health systems, to address the needs of vulnerable populations, especially women, children, and youth, and to address the burden of infectious diseases, non-communicable diseases and maternal mortality. [Amref Ventures](#) (contact: Danny.Dubbeldeman@amref.nl) was developed in the Netherlands to venture into innovative initiatives, partnerships and financial models for better health in Africa, based on shared value and a combination of strengths. The mission of Amref Ventures is to develop bankable health solutions that contribute to Amref's mission 'Better health in Africa'. Amref Ventures welcomes any party with relevant experience and expertise that shares their vision. To enable successful collaboration, they prefer to connect with health entrepreneurs/scale-ups with a proven solution, business case and solid track record that are looking to partner with Amref to implement their solutions at scale in Kenya.
- The [Philips foundation](#) (contact: Eddine.Sarroukh@philips.com) is on a mission to reduce healthcare inequality by providing access to quality healthcare for disadvantaged communities. They welcome Dutch partners with suitable and scalable medical solutions that contribute to sustainable healthcare delivery models. Philips has an innovation hub based in Nairobi.

Fit for local context

Although Kenya is regional frontrunner in ICT, internet connectivity, penetration of mobile phones, it should be noted that the digital infrastructure is hampered by power shortages, instable connections, a relatively high penetration of cheaper mobile (smart) phones (especially in more rural areas, hampering the use of applications that are not back-ward compatible), high user costs for internet data (often hampering user with less purchasing power to use health applications), and limited digital literacy for both working with more sophisticated mobile and computer applications. Creating added value within the local context and conditions is key for success.

Social impact, perseverance & willingness to Invest

Be prepared to invest a severe amount of time and resources to go through the processes of finding strong local partners, market preparation and validation for market/buyer acceptance, and further business development and sales. It is not uncommon that the time to market for more new or innovative solution is 2 to 5 years. Social impact has been a key driver for several Dutch organisations and companies active in the country. By putting social impact first, and profits second, these Dutch companies were able to generate market feedback, market acceptance, and key relationships from which they were able to further develop their social impact business model.

Find your niche market, start small and expand step-by-step with licensing or fee-for-service models

A more new or innovative solution in Kenya may encounter challenges related to market readiness. Quality standards might be lower and financing mechanisms might not yet be in place. Bringing your solution to Kenya might therefore imply that you need to develop your own market in close contact with users and partners that are involved in health financing. Building upon relations and a step-by-step approach have helped Dutch companies to create market/buyer acceptance. If possible, it is advised to start small with lower impact changes that enable familiarity, trust and corresponding opportunities for cross- or upselling. As many parts in Kenya are still working mainly on paper, it was advised to start with a digital solution that is as easy to use as cloud email or whatsapp, familiarize users with working digitally and expand digitalisation step-by-step. In general, licensing or fee-for-services models are most viable in Kenya. The case studies on Philips MOM and MEL solutions (below), AMREF's

Leap (page 36), and CarePay (page 37) provide examples of introducing eHealth solutions in Kenya and their roads towards sustainable business models.

Case study: Philips Connectivity Solutions for Primary Health Care

Philips has been active in the Kenyan healthcare market for over 60 years. Philips Kenya currently employs 75 FTE, with 18 FTE focusing on research & development and sustainable business models for primary healthcare solutions. In order to contribute to Philips' mission to improve the lives of 3 billion people by 2030, one of the areas of focus is creating meaningful solutions for primary and community care in emerging markets. Philips developed the Community Life Center (CLC) solution, a modular configurable solution for transforming community and primary care systems in countries with limited access to care.

Digital Health Solutions for maternal and newborn care

Part of the CLC-solution are digital health solutions Mobile Obstetrics Monitoring (MOM) and Monitoring and Evaluation (MEL). Both are currently being deployed in Kenya. These applications are powered by the HealthSuite Primary Care platform, the Philips digital platform for primary care applications.

Mobile Obstetrics Monitoring (MOM) is part of the Philips First 1,000 days of life solution bundle that also includes Philips Lumify portable ultrasound and training services. Through protocolized care pathways and clinical decision support the maternity process can be managed from pregnancy, to labor and delivery, to postnatal care and neonatal care until the child is 2 years.

Monitoring and Evaluation (MEL) helps remote monitoring of networks of health facilities. MEL has two modules: Remote monitoring enables remote monitoring of equipment and healthcare assets of health facilities; KPI monitoring helps networks of facilities to track clinical performance indicators to enhance quality delivery of care. Both modules include a dashboard through which a network of facilities can be managed.

Although the clinical impact of MOM was validated in clinical trials in India and Indonesia, additional clinical validation had to be done in Kenya. The clinical impact is tested in Kenya in two projects with Amref University and Aga Khan University. Philips Foundation is co-funding these projects.

Implementation of technology solutions in lower resources settings

Multiple challenges were encountered in the implementation of MOM. The technical infrastructure of the country was challenging; the quality of internet connection and digital proficiency of some user groups were low. In addition, the proficiency in English of community health workers was not always sufficient to operate the software. MOM and MEL have a profound impact on the workflows of health facilities, requiring consultancy and training for successful implementation. These additional services may increase the price.

Market creation

When Philips started in primary care, there was hardly any existing market for health technology for low resource settings. The company aims to build this market, by addressing the present healthcare challenges and by mobilizing local stakeholders in healthcare. In the target market there is limited budget for health technology. Public healthcare providers often rely on donors. Private healthcare providers look for a strong business case and have challenges with access to investment capital

Sustainable business models

With donors decreasing their funding for Kenya, due to its middle income status, investments increasingly rely on private capital. Private investors, also impact investors, seek a sustainable business models that promise an acceptable return on investment. In the public sector it is often difficult to build sustainable business models, as public primary care in Kenya is free. This is expected to change over the coming years, where the social health insurance NHIF is planned to become mandatory. This enables business models based on insurance claims, next to government budgets. Building and testing business models can take several years, before scaling is possible. This will require long-term perspectives from companies aiming to serve this market.

The way forward

After investing for several years in building evidence and testing business models for its primary care solutions, Philips is now in the scale-up phase in Kenya, as well as in other parts of Africa. Since the products have a

profound impact, the company expects that both the private and the public sector will increasingly invest in digital solutions for primary healthcare in the coming years. Even for Philips with a strong footprint in Kenya and a wealth of experience, it took time to build its business in primary care in the Kenyan market.

Need for training & workflow (change) management

Driven by both efficiency and quality improvements, digital solutions will most often severely impact the work of health workers, especially in more rural areas. Proper training and workflow change management are key for successful implementations. eHealth solution providers should be aware of the proficiency of English, digital literacy and level of received medical training and education of users of their solutions.

Case study: AMREF's Leap provides Training Content to Healthcare Providers⁴⁹

LEAP is a mobile learning solution for training health care workers including Community Health Workers (CHW). Training CHWs - and health care workers in general - is resource intensive, and optimizing its efficiency is complex. Community health workers and volunteers sometimes struggle to retain what they learned and fluctuation of employees and volunteers leads to a frequent need of re-training. The first AMREF eLearning platform was developed as part of an eLearning project targeting nurses. The initiative involved private and public partners, including Accenture, AMREF, the Nursing Council of Kenya (NCK), the Ministry of Health (MOH) and public and private nursing schools.

Leap's journey towards a sustainable business model

The initial funding was provided by the MPESA Foundation and Accenture. Both companies also contributed in-kind support in the form of technology infrastructure and technology transfer. The programme was handed over to MOH after reaching 10,000 nurses. Subsequently, a complementary project emerged at AMREF: Jibu, a mobile-based learning tool for feature phones, offered in Kenya, Uganda and Tanzania. The overarching mLearning platform was initially named "Help". After its transfer to AMREF Social Enterprise⁵⁰ it was re-branded to "Leap".

The total investment for the development of Leap is estimated at 200-300 Million Kenyan Shillings (~2.5 M USD). The solution is currently running without additional donor-funding, generating a profit for AMREF to finance other programmes. Leap and M-Jali (a data collection and reporting platform) are being rolled out in South Africa, Malawi and Ethiopia, and may soon be launched in Tanzania and Senegal. The cost for an organization to use/implement Leap for their own purposes is variable, and depends to a large extent on whether the learning content already exists or needs to be developed. Broadly speaking, the cost can be estimated somewhere around \$20 per user and month.

Impact and effectiveness of eLearning

A study suggests an increase in medical referrals in areas that implemented Leap⁵¹. The same study found no difference in performance between health workers who did face-to-face training vs. eLearning with Leap, which suggests likely non-inferiority of the more affordable digital solution. The satisfaction levels among health managers was higher for delivery of training via Leap, when compared to physical workshops, due to two key factors: Health workers can easily revisit and repeat learning content, and the cost of training is lower.

Since the initial project, the platform has been used to deliver eLearning content to a total of around 6,000 Community Health Workers (volunteers) and about 220 Community Health Extension Workers. During the cholera outbreak, which occurred around the time of the 2017 general election, there was a surge in utilization: The technology was used to deliver cholera-related content to an estimated 25,000 health workers. In 2020, training content for Covid-19 was created together with the African Union Centres for Disease Control and Prevention in order to train 26,000 health workers in African countries.

⁴⁹ This case study was originally published in: Kenya Healthcare Federation & SDG Partnership Platform Kenya. (2020). A review of the status of selected digital health technologies in Kenya and recommended roadmap for supporting large-scale adoption.

⁵⁰ A subsidiary to AMREF that is designed to generate a profit, that can then be used for unrestricted / core funding for the AMREF nonprofit organization. In addition to Leap, AMREF Social Enterprise also runs M-Jali, a community-based health information system (data collection and reporting tool).

⁵¹ Lakati, A., Nyagero, J., Nzioka, C., Koech, J., & Kavoo, D. (2017). Effectiveness of mobile learning and face-to-face approaches in training community health volunteers in Kenya: A comparative study. Nairobi.

CarePay's Journey in Kenya

Back in 2015, CarePay was first established in Kenya with an initial investment from the M-PESA Foundation (funded by M-Pesa, a hugely popular mobile payment system launched by Safaricom/Vodafone) and the Investment Funds for Health In Africa (IFHA). Capitalizing on the mobile (money) revolution in Africa, CarePay partnered with PharmAccess Foundation and Kenyan telco Safaricom to develop a smart payment distribution platform branded as M-TIBA in Kenya.

Nowadays, M-TIBA has made a huge impact already, connecting over 4.7 million users and 3,000 healthcare providers. Its scale and growth quickly attracted a growing number of public and private partners, including corporate employers, the Kenyan National Hospital Insurance Fund, institutional donors and private insurers. Since the success of M-TIBA in Kenya, CarePay has opened its HQ in Amsterdam to facilitate the international expansion of the platform to other countries, starting with Nigeria and Tanzania.

In a [recent interview](#), Onno Schellekes (CEO CarePay International) and Kees van Lede (Director Strategy & Business Development CarePay Africa) share more information on CarePay's journey in Kenya (in Dutch only).

A Kenyan perspective on market entry for eHealth solutions

The Dutch companies need to conduct a market validation through market research to understand the consumer demands and areas of needs as identified in the above section. Visiting and engaging local partners is vital in building relationships and evaluating market opportunities for the purpose of scaling up the solutions. Noting that most eHealth solutions are still at pilot phase, foreign companies looking to enter the market require the knowledge of the market landscape and challenges affecting the current solutions in the market such as poor infrastructure and issues of interoperability. New market entrants should consider affordability and ease of use. Many people both in the private and public sector are willing and ready to adopt eHealth solutions but are hindered by purchase and maintenance costs and technical requirements.

Regulations, Standards and Taxes

The ICT ecosystem is complex, fragile and mostly unregulated in Kenya. Transformative innovations are emerging and depending to some degree on providence and a web of interrelated stakeholders who interact unpredictably. The government regulates and arbitrates the use of limited resources, enhance competition, promulgate and enforce anti-trust legislation, establish and maintain standards, and create a level playing field for all actors. In this regard, the eHealth Standards and Guidelines have been anchored on the [eHealth Policy 2016-2030](#), [ICT Policy](#), and the Kenya Constitution 2010 Article 31 which guarantees privacy for all citizens in relation to personal information.

The legal requirements for licensure are sometimes a hurdle for eHealth solution providers in relation to patient data collection and storage. Since the digital health space is mostly unregulated, the recently enacted [Data Protection Act](#) of 2019 is used to address privacy of the subjects, and eHealth solution providers are expected to be compliant. However, eHealth solutions are centered on Intellectual property rights, which are granted to the developers. The general regulation, however, requires eHealth solution providers to guarantee data privacy and consumer protection revolving around terms and conditions of use.

Generally, eHealth solutions must conform to ethical and legal requirements relating to:

- Ownership of data and information.
- Access and disclosure of patient data.
- Usage of patient data.
- Storage of Personal Health Information and Personally Identifiable information.
- Storage of health.
- Maintain confidentiality as per the eHealth policy guidelines.
- Any eHealth solution must not infringe on any person's intellectual property rights.

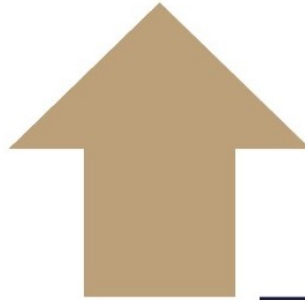
The eHealth solution must also comply with the legal requirements stipulated in the following national policies and Acts of parliament:

- Kenya National Cyber Security Strategy.
- Kenya Information Act 2013.
- Data Protection Act.
- Kenyan Archives Act.
- KEMRI ethical guidelines.

A SWOT analysis for the subsector eHealth

STRENGTHS

- eHealth strategy 2016-2030.
- Growing national and foreign investments in eHealth.
- Openness towards new technology and software.
- Broad adoption of technology.
- Leader in mobile payment solutions (MPESA).
- High mobile phone penetration.
- High geographical coverage of the mobile network.
- Existing mHealth platform.



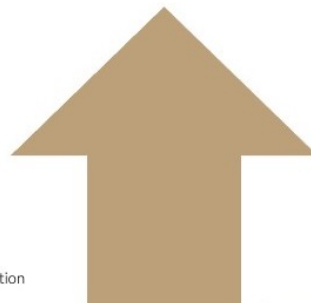
WEAKNESSES

- Training and consultation needed at implementation.
- English proficiency of community health workers.
- Market reliance on foreign innovators, domestic applications are basic.
- Interoperability and infrastructure constraints.
- Solutions mostly simple short message service (SMS).
- Slow uptake at public sector level?
- Strict regulatory requirements with regard to patient data?.



Opportunities

- Health Information Technology.
- Mobile Patient Monitoring Platforms.
- Telemedicine.
- Home care-solutions.
- eLearning
- Enterprise resource planning (ERP) solutions.
- General modernization of hospitals, including the adoption of HMIS.
- Need to address NCD prevalence.



Threats

- Hard to change work ethics of community health workers.
- Unstable internet connection and power failures.
- COVID-19 pandemic restrains market growth.



ANNEXES

Annex 1: List of consulted Dutch organisations with a footprint in Kenya

TFHC is continues in touch with Dutch companies and organisations active and interested in Kenya, especially members of the [TFHC Africa](#) platform. The following Dutch organisations are specifically interviewed for this study.

Organisation	Representative(s)
AMREF Ventures	Romy Harkx, Venture Officer
Cardimed	Nelly Otenyo - Ibis, Sales & Business Developer Asanka Fernando, Chief Sales Officer
Cornet Elevated (Egypt)	Mohammed Tanamly, Business Development Manager <i>Former business developer for Elsevier, and participated in the Dutch health mission to Kenya in 2019.</i>
Conec Care East Africa	Samuel Mumbi Allan Moses Olero
Elevate Health	Eva van Ingen, Manager Business Development & Marketing Sjors Gerritsen, Business Development Manager
Medlinc Africa	Jolanda Witteveen, Managing Director
Philips	Roelof Assies, Business Development Director Africa Ties Kroezen, Venture Leader Community Life Centers
Philips Foundation	Eddine Sarroukh, Innovation Lead & Senior Technical Advisor at UN Kenya <i>Former Head of Research Philips Africa & Manager Philips Innovation Hub Nairobi</i>

Annex 2: Sub Market Growth Estimates

Table 1 shows the sub market growth estimates and forecasts for medical devices between 2014 and 2024 in USD (Mn).

Table 1: Submarket estimates and forecasts in USD (Mn) (2014-2024)

	2014	2015	2016	2017	2018	2019e	2020e	2021f	2022f	2023f	2024f
CONSUMABLES	33.3	30.1	32.7	31.9	35.3	40.0	43.3	48.6	53.2	53.9	56.7
DIAGNOSTIC IMAGING	28.2	45.4	41.8	34.3	42.9	46.0	48.1	53.9	55.3	56.8	58.2
DENTAL PRODUCTS	2.9	5.9	4.1	2.7	3.7	4.6	5.0	5.2	5.6	5.6	5.8
ORTHOPAEDICS & PROSTHETICS	3.1	3.8	4.3	3.4	4.3	5.0	4.9	5.2	5.5	5.7	6.0
PATIENT AIDS	5.1	6.0	6.8	6.7	6.2	7.8	8.0	8.8	9.4	9.7	10.2
OTHER MEDICAL DEVICES	33.9	43.9	50.3	40.9	45.5	55.6	57.5	62.3	66.4	70.4	75.2
TOTAL (USD Mn)	106.5	135.0	140.0	120.0	137.8	158.9	166.8	184.0	195.4	202.2	212.1
e/f = Fitch Solutions estimate/forecast. Source: National Statistics, Fitch Solutions											

Consumables – Consumables are currently on high demand due to the Covid-19 pandemic. The consumables market consists of equipment such as bandages and dressings, suturing materials, syringes, needles & catheters and other consumables such as surgical gloves and blood-grouping reagents. The CAGR will be below market average. With the global supply pressures for countries to manage the Covid-19 pandemic, demand for PPE will continue to rise to complete local production. This will create opportunities for SMEs and new entrant suppliers.

Diagnostic imaging – Leading private sector hospitals groups investing in the latest most innovative branded equipment are keen on maintenance cost, lifetime, operability and purchase cost of the medical equipment. This supplements the gap that the public sector is unable to fill. There is need for modernization of equipment as well as provide more equipment to match the demand. This is an opportunity that the Dutch companies can leverage on as they grow into the Kenyan market.

Dental products - Covid-19 pandemic has confined the spending on dental products as focus is on more critical devices. With the economic expansion, the dental products market is expected to boost growth. Dental products are both manufactured locally, in small quantities, and imported. They include capital equipment such as drills, chairs and x-ray and, instruments and supplies such as cements, instruments, teeth & other fittings, artificial teeth and

other dental fittings. This offers a diverse opportunity for Dutch companies seeking to enter Kenya's medical device market.

Orthopaedics & prosthetics – The orthopaedics & prosthetics market is expected to rise to KES 690.9mn by 2024^[2]. Even though this is the slowest growing product area when compared to the other sub-sectors, it is still unexplored area, and Dutch companies seeking to enter the market has the opportunity to explore it further. Orthopaedics & prosthetics include fixation devices, artificial joints and other artificial body parts.

Patient aids – The patient aids market is expected to rise to KES 1.2bn by 2024^[2]. The market will, however, benefit from the country's economic expansion with public investment. The Covid-19 pandemic also possess upside risks to the market due to increase in demand for respiratory apparatus such as ventilators and other breathing aids. Local production is expected to increase as well as importing of the same in order to match the demand.

Other medical devices – The expected rise of other medical devices to KES 8.7bn by 2024 will see the CAGR be above the medical device market average^[2]. The market growth will be limited by the Covid-19 pandemic. Other medical devices include wheelchairs, ophthalmic instruments, hospital furniture, medical & surgical sterilizers, ultra-violet or infra-red ray apparatus and other instruments & appliances.

Annex 3: Sub Market Imports

Table 2 shows the market growth, imports market share and import partner by percentage.

Table 2: Kenya medical device market size and growth by product area, 2019-2024 (KES)

Market	Estimated 2019-2024 CAGR (KES)	Estimated amount by 2024 (KES)	Total imports market share	Major import partner (2018)
Consumables	9.9%	6.5bn	90%	China (40%)
Diagnostic imaging	7.4%	6.7bn	Almost 100%	China (nearly 50%)
Dental market	7.5%	669.7mn	Almost 100%	China (nearly 50%)
Orthopaedics & prosthetics	6.3%	690.9mn	Almost 100%	India (over 20%)
Patient aids	8.1%	1.2bn	Almost 100%	China (over 30%)
Other medical devices	8.8%	8.7bn	Less than 95%	China (30%)

Annex 4: List of Largest Medical Equipment Distributors in Kenya

	Organization	Website	Main product lines
1	Kenya Medical Suppliers Authority (KEMSA)	www.kemsa.co.ke	
2	Mission for Essential Drugs & Supplies (MEDS)	www.meds.or.ke	
3	Harleys	www.harleysltd.com	OTC products, Pharmaceutical Products, Medical equipment, Surgical Instrument, Ophthalmic.
4	Surgipharm Limited	info@surgipharm.com	Pharmaceuticals-Manufacturers, Agents & Distributors
5	Medipharm East Africa LTD	www.medipharm.co.ke	Lab equipment, Pharmaceuticals products and Medical Products
6	Meditec Systems Limited, Kenya	www.meditecsystems.net	Radiology, Cardiology and Angiography, Oncology, diagnostic solutions, Ventilators and refurbished products
7	Bio-zeq Kenya Limited	biozeqkenya.com	Lab Consumables, Hospital Equipment, Agricultural research equipment, Animals and veterinary molecular testing.
8	Pulse Medics Equipment LTD Kenya	www.pulsemedic.com	Diagnostic equipments, Home care products, surgical instruments and disposables, Medical gases and piping, ICU equipments, oxygen equipment, operating theatre equipments.
9	Crown Healthcare LTD	www.crownkenya.com	Basic Medical equipments, hospital furniture, Radiology, Renal solutions, Laboratory equipments, Surgicals, Lab consumables and theatre equipment.
10	Omaera Pharmaceuticals Limited	www.omaera.com/	Diagnostic reagents, laboratory chemicals, laboratory equipments, medical devices, human medicines, surgical dressings and surgical instruments.
11	Bobcare Medical System Ltd	www.bobcaremedical.com	Laboratory equipments, ICU Equipment, Maternity equipment, SURGICAL INSTRUMENTS, LAUNDRY AND CATERING EQUIPMENT, BOILER, WATER AND PLANTS INSTALLATION
12	Apple Pharmaceuticals Ltd	ruppharm@kbo.co.ke	Lab equipment, Pharmaceuticals products and Medical Products

13	CENTRIC MEDICAL SOLUTIONS	www.centricmedicalsolutions.com	Hospital, Medical, Laboratory, Glass wares, Diagnostics, Biomedical, Dental, Scientific, Research Instruments & Equipments.
14	Blekam (EA) Ltd	blekamlabkits.kbo.co.ke	Lab equipment, Pharmaceuticals products and Medical Products
15	Scitech Diagnostics Ltd	www.scitechdiagnostics.com	Reagents, Lab Equipment, Molecular Biology, Clinical Chemistry, Immunology, Hematology.
16	MECK SUPPLIES (K) LTD	mecksupplies.kbo.co.ke	Medical equipments,surgical equipments,laboratory equipments
17	Ashcott Ltd	www.ashcott.com	equipment for CSSD, Operating Theatre, maternity, Neonatology, Cardiology , Perinatal, ward equipment.
18	Seropharm East Africa Ltd	seropharm@wananchi.com	Radiology, Cardiology and Angiography, Oncology, diagnostic solutions, Ventilators and refurbished products
19	Chemoquip Ltd.	www.chemoquip.com	Haematology, Glasware, filtration systems, microscopes, water distils.
20	Hass Scientific & Medical Supplies Ltd	www.hassscientific.com	Lab Consumables, Hospital Equipment, Agricultural research equipment, Animals and veterinary molecular testing.

Annex 5: Medical Product Registration

PPB requires the following information to be submitted for registration of a medical device:

- Administrative information, including the name and address of the manufacturer/ authorized representative;
- Registration dossier information, including evidence of conformity, a detailed description of the device, its intended use and instructions of use;
- Data from pre-clinical and clinical studies;
- Samples of labels on the medical device and its packaging;
- User manual;
- Results of the risk analysis; and
- Documentation related to the manufacturing processes, including manufacturing methods and procedures, quality assurance measures, packaging, labelling and storage of the device.

Once an application has been accepted and the evaluation fees (depending on class), it will be processed within 90 days [5]. Once approved the committee on medical devices, a registration certificate, valid for five years, will be issued. The following Table 3 shows the medical devices registration fees.

Table 3: Medical devices registration fees in USD

Risk Class	Initial Registration Fee	Evaluation Fee	Renewal Fee	Change Notification Fee
Class A	25		20	10
Class B	150	200	100	20
Class C	200	250	150	50
Class D	250	350	200	70

Annex 6: Kenya's most prominent health regulatory boards

Organisation	Mandate
Clinical Officers Council (COC)	Regulates the training, registration and licencing of Clinical Officers. To date the COC has registered 13000 Clinical Officers.
Nursing Council of Kenya (NCK)	Established by the Nurses Act Cap 257 of the Laws of Kenya to ensure the delivery of safe and effective nursing and midwifery care, to the public, through quality education and best practices. It is the only professional regulatory body for all cadres of nursing and midwives in Kenya. ⁵²
Kenya Medical Practitioners and Dentist Board (KMPD)	Established under Cap 253 Laws of Kenya to regulate the practice of medicine and dentistry in the country. ⁵³ The core functions of the KMPD are: Approving and supervising medical training that is being offered in different institutions, Registration of qualified Medical Doctors and Dentists (BSc. Minimum), Licencing of Medical Doctors/Dentists and internships and advise the MOH.
Pharmacy and Poisons Board (PPB)	Established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the Manufacture and Trade in drugs and poisons. ⁵⁴ In addition the PPB also regulates medical devices that come into the country.
Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB)	Established under Cap 253 A of the Laws of Kenya. KMLTTB has a mandate to regulate all In-vitro diagnostics to be used in the country. In addition, the board also screens, validates, certifies and registers products to be used in laboratory science practice. Furthermore, it regulates the professional conduct of Medical Laboratory Scientists, Licenses and regulates business practices in Medical Laboratory Science, Inspects and approves Institutions to train in Medical Laboratory Science and Registers medical laboratory Technicians and Technologist to practice. ⁵⁵
Kenya Nutritionists and Dietetics Institute (KNDI)	Established in 2007 under the Nutritionists & Dieticians Act No. 18 the KNDI is to provide for training, registration and licencing of nutritionists and dieticians; provide for the registration of the standards and practice of the professions and ensure their effective participation in matters relating to nutrition and dietetics. ⁵⁶
Public Health Officers and Technicians Council (PHOTC)	Established in 2013 by the Public Health Officers Act No. 12 the PHOTC is responsible for the regulation of training, registration and licencing of public health professionals in Kenya. ⁵⁷
Radiation Protection Board	Established in 1986 under the Act of parliament, the Radiation Protection Act, Cap 243, as the national competent authority with the responsibility for protecting the health and safety of people and the environment from the harmful effects of ionizing radiation. It regulates the use of ionizing radiation, exportation, importation, distribution and possession of radiation sources. ⁵⁸

⁵² Source: <http://nckkenya.com/about-us/>, d.d. 26 April 2016.

⁵³ Source: <http://medicalboard.co.ke/>

⁵⁴ Source: <http://pharmacyboardkenya.org/>, d.d. 26 April 2016.

⁵⁵ Source: <http://kmlttb.org/>, d.d. 26 April 2016.

⁵⁶ Source: <http://www.kndi.institute/about-us/index.html>, d.d 26 April 2016.

⁵⁷ Source: <http://photc.org/about-us/>, d.d 26 April 2016

⁵⁸ Source: http://www.rpbkenya.org/about_us.html, d.d. 26 April 2016.

Annex 7: Mapping of digital health solutions in Kenya

In 2020, a technical assessment was commissioned by the Kenya Healthcare Federation and the SDG Partnership Platform in Kenya to obtain an overview of the digital health landscape in Kenya, and critical input for a roadmap to support the update of digital health technologies in the view of maximizing its impact on primary healthcare outcomes. The authors made it clear that there is no quick or easy way to gain or maintain an overview of the digital health solutions in use in Kenya. The digital health territory is dynamic and a clear distinction between programmes that support digital health interventions and the product themselves is often hard to make. The mapping into classes of digital health interventions as defined by the World Health Organisation (WHO) is provided below and enriched by eHealth solutions identified by AHB and TFHC.

WHO ID	Subgroup	Technology	
1.1.0	Targeted client communication	Targeted client communication	Commcare, Community Health Toolkit, ConnDx
1.1.1		Transmit health event alerts to specific population group(s)	Access Afya, Frontline SMS
1.1.2		Transmit targeted health information to client(s) based on health status or demographics	Access Afya, Afya Aid, AfyaPAP, BabyCentre, Frontline SMS, ImaraTV, M-Kifafa, Maisha Mapya, MNCH Mobile Nutrition Content, Philips MOM, Safe Delivery App, Tech4Life, WACH NEO
1.1.3		Transmit targeted alerts and reminders to client(s)	amHealth, M-Kifafa, Empower Health, mSIMU, Philips MOM, Safe Delivery App, T4A, WACH NEO
1.1.4		Transmit diagnostics result, or availability of result, to client(s)	EID/PCR TESTING, Empower Health, Peek
1.2.1	Untargeted client communication	Transmit untargeted health information to an undefined population	Frontline SMS, MNCH Mobile Nutrition Content
1.3.1	Client to client communication	Peer group for clients	Inuka, M-Changa, Maisha Mapya, SophieBot, Twakena
1.4.0	Personal health tracking	Personal health tracking	eMedica, Wearable Devices*, Fitness tracking Apps*, Period trackers*, Workout Apps*
1.4.1		Access by client to own medical records	Aphya
1.4.2		Self-monitoring of health or diagnostic data by client	Empower Health, Pregmum, Luscii app
1.4.3		Active data capture/documentation by client	Baby Centre, Empower Health, M-Kifafa, oviA
1.5.1	Citizen based reporting	Reporting of health system feedback by clients	Afya Aid
1.6.0	On-demand information services	On-demand information services to clients (general)	Ask a Doc, Aunty Jane, Babylon Health, Baobab Circle, Lily Health, Medbit, mPunda, Jacaranda Health
1.6.1		Client look-up of health information	Ada*, Afya Aid, Ask Babylon, BabyCentre, Daktari Health, Invivox, MNCH Mobile Nutrition Content, Nivi, RapidPro, RapidSMS, Safe Abortion (App), SophieBot, The Bump, WebMD*
1.7.0	Client financial transactions		AfyaPoa, ClinicPesa, Turaco

1.7.1		Transmit or manage out of pocket payments by client(s)	M-TIBA
2.1.1	Client identification and registration	Verify client unique identity	COMETS, MOVE IT, The Journey, Smart Solution, Slade360°
2.1.2		Enrol client for health services/clinical care plan	TIBU, Empower Health, M-TIBA, Medic Modile App, Empower Health, Maisha Mapya, Nivi, Commcare, OpenSRP, COMETS
2.2.1	Client health records	Longitudinal tracking of clients' health status and services	BandaHealth Go, Care2000, CHIS, CliniPAK, COMETS, EasyClinic, eHospital, Empower Health, HealthPlus-Collabmed, IQCare, Maisha Mapya, Nivi, OpenMRS, OpenSRP, Stone HMIS, Syhos, The Journey
2.2.2/3		Manage client's structured/unstructured clinical records	(AMRS) Ampath Medical Records System (OpenMRS), BandaHealth Go, Care2000, CHIS, CliniPAK, COMETS, Maisha Meds, Usulama Technology, OnClick Business solutions, Community Health Toolkit, EasyClinic, eHospital, IQCare, Key Population (eKP System), OpenMRS, Syhos, MobileODT, iClinic, Bahmni, MedicentreV3, Notes first, Open MRS/KenyaEMR, OpenSRP, SmartHealth, Unucare, StoneHMIS, ZiDi
2.2.4		Routine health indicator data collection and management	DHIS2, Mjali, Capsule
2.3.0	Healthcare provider decision support	Healthcare provider decision support (general)	Empower Health, MedSinc, Consulting in Health Informatics
2.3.1		Provide prompts and alerts based on/ according to protocol	PaperEMR, (AMRS) Ampath Medical Records System (OpenMRS), BandaHealth Go, Care2000, CHIS, CliniPAK, ConnDx, EasyClinic, eHospital, Empower Health, IQCare
2.3.2		Provide checklist according to protocol	PaperEMR, Philips MOM, Safe Delivery App, Twakena, WACH NEO, Siha
2.3.3		Screen clients by risk or other health status	(AMRS) Ampath Medical Records System (OpenMRS), Empower Health, Maisha Mapya, OpenSRP, Peek RAAB
2.4.1	Telemedicine	Consultations between remote client and healthcare provider	Ada, Ask Babylon, Siha, Inuka, mDaktari, REACTS, Remedi, Siha, Tele Afya, Connecthealth, Doctor4Africa, Twakena, Gabriel Teleconsultations, FirstDerm*
2.4.2		Remote monitoring of client health or diagnostic data by healthcare provider	eMedica product range, MobileODT
2.4.3		Transmission of medical data to healthcare provider	Pregmum, REACTS
2.4.4		Consultations for case management between healthcare provider(s)	Gabriel Teleconsultations
2.6.1	Referral coordination	Coordinate emergency response and transport	
2.6.2		Manage referrals between points of service within health sector	Empower Health, EMKF App to locate Emergency Care Units
2.6.3		Manage referrals between health and other sectors	Medic Mobile App

2.7.0	Health worker activity planning and scheduling	Health worker activity planning and scheduling (general)	Stone HMIS
2.7.1		Identify client(s) in need of services	Medic Mobile App, OpenSRP
2.7.2		Schedule healthcare provider's activities	Community Health Toolkit, Medic Modile App
2.8.0	Healthcare provider training	Healthcare provider training (general)	iHRIS, Safe delivery, SafeCare App
2.8.1		Provide training content to healthcare provider(s)	Leap, Digital African Health Library, EMKF Website training content, Jibu, Medic Modile App, SmartHealth, Daktari Online
2.8.2		Assess capacity of healthcare provider(s)	Jibu, Leap, Medic Modile App, MedSinc

Annex 8: Key Barriers and Challenges to Digital Health Uptake & Scale-up

In 2019, a technical assessment was commissioned by the Kenya Healthcare Federation and the SDG Partnership Platform in Kenya to obtain an overview of the digital health landscape in Kenya, and provide critical input for a roadmap to support the update of digital health technologies, in the view of maximizing its impact on primary healthcare outcomes. Consultation with expert stakeholders and reviewed literature presented a relatively consistent picture about challenges that are encountered by digital health solution providers in Kenya. The various impediments are interrelated, and their relative importance varies depending on the specific professional perspective adopted.

The information provided in this section was summarized “as is” from the various key informant interviews conducted. Information provided may be subject to professional or personal biases of the experts and stakeholders interviewed. However, the assessment team sought to seek input from multiple different perspectives wherever possible, in view of providing a balanced and inter-subjective overall perspective.

Infrastructure and Ecosystem Challenges

Lack of resources or liquidity for users to pay for digital solution

The inability or limited willingness of users to pay: The market is very price-sensitive and there is a need to make the costs of technology affordable, or design viable payment / credit mechanisms. The cost and willingness to pay for mobile data must always be considered. In the public sector, there is a need to finance the introduction of technologies to scale, beyond pilots / proof of concepts.

Insufficient infrastructure

To make the digital health solutions available and accessible, a minimum of infrastructure – including stable internet connectivity and computer infrastructure - needs to be available at a sufficiently large scale in all relevant health facilities. The penetration of smartphones is still variable and lower in rural and remote areas.

For emergency response, infrastructural issues (e.g. roads and urban structure that leads to traffic jams, insufficient ambulances in the market, insufficient equipment in ambulances) cannot be solved with digital technology alone.

Health Financing / Health insurance coverage gaps

A effective approach to health financing and increasing health insurance coverage is seen to be an important facilitator for digital health technology uptake, as it would make investments more viable and help to close some of the existing gaps in health service provision. A strategic use of data analytics from service- and medical claims data could contribute to making the provision of health insurance more efficient for larger populations. In the case of emergency response, a solution to the financing of emergency services provided in the private sector is likely to be required to address the problem of access.

Lack of trust from end-users

For on-demand digital information services and other digital health services targeted at consumers, it is often difficult for non-government entities to gain the necessary trust in terms of the accuracy/usefulness of the information or the quality of the service offered.

Health sector human capacity Issues

Knowledge and awareness gaps

For many digital health products, the awareness of their existence is limited among professionals and consumers. Professional training, media, and word-of-mouth promotion all play an important role towards achieving an increase in awareness of technology solutions. There is a need for individuals in leadership position to have an increased understanding and capacity for technology, including a solid understanding of terminology. For automated analyses, there is a knowledge and skills gap with regards to standard classifications such as ICD10, ICD11 and clinical terminologies in the health sector as well as data analytics software tools that are available at little or no cost.

Skill and capacity gaps

In order to increase the use of technology tools, a strong technical understanding of the issues that these tools seek to address is required. For instance:

- For tools that seek to address the issue of quality of care and improve assessment of health facilities, there must be an understanding and endorsement of the principles of quality assurance, in order to embrace the use of technology for the same

- For tools that support the classification of diseases or causes of mortality, there is a need to understand critical related concepts and also sufficient staffing at the health facility level
- To meaningfully use technology for emergency response, enough qualified health professionals must be available in health facilities so that the distance of transports for patients in critical conditions can be reduced, and that ambulances can be staffed adequately
- For automated data analysis, there may be a need to retain talent in local companies for the development of local solutions. Some of the best talent changes to international companies or organizations.

Shortcomings of existing products

Solutions are not sufficiently user-friendly / user-oriented

A common critique of existing technical solutions included the observation that there is a need for users to adapt to the technology, rather than the technology adapting to the existing knowledge, needs and inclinations of its users. The following requirements emerged from the interviews and literature:

- Digital technology should be designed in such a way as to minimize the need for training; it should be easy to use and user-friendly. WhatsApp was given as an example of a technology that experienced wide uptake without any training.
- Solutions must keep their promise, and developers/vendors should avoid an exaggeration of the technology's capacity, given human and technical limitations.
- Technologies should be relevant and immediately useful for those who use it on a day-to-day basis, and aligned with their expectations. Making digital tools intuitive and workflow-oriented requires a user-centric approach to product design, including a close involvement of the relevant target users (clinicians, patients, consumers)
- Cultural attitudes (for instance, a preference of face-to-face interaction) need to be taken into consideration for the design of digital solutions

Solutions are not sufficiently adapted to the real-world health sector ecosystem

Some of the infrastructure and ecosystem challenges that exist can be addressed with features in the technology itself. This requires for developers to conceptually move outside a narrow technology-lens, and fully understand the health system in which the technology is expected to operate.

For example, technology should be designed in a way that:

- It works with basic phones that cost less than KES 2,000
- It connects seamlessly with technology that already exists in the market and/or is likely to enter the market in the near future, guaranteeing full interoperability
- It is adapted to a culture that is accustomed to paper-based records
- It can operate without reliance on continuous availability of internet (mobile network coverage is not good everywhere)

Solutions not oriented towards businesses / private sector

To be viable for the private, commercially oriented health players, specific requirements need to be met. For instance, the solution needs to be flexible enough to address a range of different needs, possibly through customization. It needs to be able to convince executive leadership by meeting their priority needs and through a credible demonstration of results. It needs to gain strong commitment at the facility and department level, limiting the cost and effort required for change-management. Effective technical training and support to end-users must be available locally.

Governance Issues

Insufficient clear and binding standards and regulations

While there are several policies and guidelines available on eHealth, Electronic Medical Records, and Health Information Systems, they are often at a relatively general level, and do not have the binding character of a regulation or law. Unambiguous legislation is expected to lead to more collaboration between technology companies, donors and NGOs. It would also reduce the uncertainty around rules and responsibility related to data privacy and data protection (the latter has been partially addressed with the data protection act that was signed into law on November 7th, 2019). Implementation and enforcement of policies – as opposed to developing them – is seen as an area of improvement for the public health community and the Ministry of Health in Kenya.

In the absence of clear, enforceable regulation and wide awareness of it, the administrative barriers tend to increase on multiple levels. For instance, there is a need to obtain permissions for certain activities related to digital health from each county government, which leads to delays or lack of uptake of technology. A lack of regional international harmonization further means the products that target a regional market must be registered/licensed multiple times, which requires a substantial investment of time and money. Regulation must be designed in such a way that it is friendly towards health technology, so that rules and standards that set clear boundaries will reduce (rather than increase) bureaucracy.

There is a need in Kenya for widely known and used standard classifications and terminologies in healthcare, to enable semantic interoperability of systems. Such terminology standards do not come in the form of (narrative) policy documents, but rather in the form of lists and tables. In order to automate the analysis of data and health information exchange, there is a need for an organization to provide a national terminology service, i.e. to ensure that the medical terminology is updated and maintained. The recent adoption of the Kenya Healthcare Federation (KHF) of a policy on standard healthcare classifications could be leveraged by the public sector for the rapid development of national regulations.

Limited resoluteness, competencies and integrity in leadership and governance

Based on the input of technical experts, the Kenyan health sector would benefit from a further strengthening of the institutional leadership with regards to digital technology at the Ministry of Health and in other institutions. A resolute, top-down and internally consistent approach to planning of digital health priorities, based on a sound understanding of the latest technology, free of third-party interests, combined with a harmonized and publicly accessible high-level blueprint is expected to provide critical impetus and a sustainable uptake and progress in the field.

The procurement of digital solutions in the public sector (as well as eligibility rules for subsidies and incentives in faith-based and commercial facilities) needs to be based a consistent pursuit of value-for-money and on effective mechanisms to mitigate and eliminate potential conflicts of interest.

Finally, there is a need for the Governments at the National and County level to commit fiscal resources to the implementation of digital health solutions in order to gain better control on development priorities in digital health. Resources that are allocated for specific purposes need to be ring-fenced so that they cannot be re-purposed.

Insufficient evidence and shared knowledge on what works / what is efficient

There are many different solutions in the market seeking financial support by international donors or investors, as well as a range of products that seek buyers from the commercial sector. Several of these solutions serve similar or partially overlapping purposes. According to some of the interview participants, there may be an incentive for organizations to over-promise on the effectiveness of their solution, in the absence of evidence, and there are solutions in the market that technically are still in pilot- or development stage. This has led to a deterioration of trust by potential end-users. To focus investment and maximize its impact, it is important to build common knowledge about what technology provides good value for money (cost-benefit ratio). At the current time, there is little knowledge about what works, and what doesn't, and the little knowledge that exists is not centrally available.

Insufficient understanding and leveraging private sector dynamics

The importance of the private sector for the development and uptake of digital products is widely acknowledged. The perception of what represents private sector involvement, however, appears to be variable. A section of the experts and stakeholders conceive of 'the private sector' primarily from the investment-angle, as a source of funding for technology through private equity, technical expertise, or social impact bonds. Working with the private sector, from this perspective, means to reduce the dependency on international donors and domestic public funding. Another section of stakeholders primarily look at the private sector from the health services perspective, as an end-user of digital technology that plays an important role as a driver of innovation that is sustainable independently of any funding from an international donor or domestic taxes. From the latter perspective, technology uptake in the private sector can be seen as a requirement and a 'litmus-test' for the practical value of a technology: Only self-funded uptake in the private sector shows whether the features of a technology and its cost are such that it can survive in the absence of public/donor funding.

Challenges of developers and vendors

Insufficient capital for product developers and vendors to improve products or marketing

Part of the literature and organizations dealing with innovation and new technologies focus on the resources needed for the costly development and marketing of new technologies. To be successful, an organization needs sufficient capital, and not all organizations are equally successful to attract investment: Some entrepreneurs are beyond the

idea stage with their product, but not institutionally mature enough to attract investors. Some of the institutional gaps include:

- Better understanding of what is required (and how long it takes) to attract capital investment
- Institutional capacity to attract talent (e.g. highly skilled professionals in software development, health informatics, business management and marketing)
- For those seeking to attract grants from donors: A solid understanding and the required financial liquidity to operate within a project-cycle logic

Insufficient management and marketing skills

According to experts in the field of innovation, it is quite common that organizations who are trying to introduce an innovative product or service related to digital health need strengthening of their business model. This may include a more solid understanding of financial flows and definition of who ultimately pays for the product or service offered; an approach with a more entrepreneurial mindset, and more systematic and rigorous testing of assumptions early on, to gain familiarity with the market and potential for uptake.

- Beyond a stronger business plan, companies need increased skills and knowledge in terms of:
- Attracting and retaining high-quality employees
- Effective consumer- and client engagement through multiple channels
- Market research
- Continued, competent engagement with national and county government agencies to generate visibility and credibility

Annex 9: List of Distributors of eHealth Solutions in Kenya

	Name	Website
1.	Megascope Healthcare Limited	https://megascopekenya.com/
2.	KEMSA	https://kemsa.co.ke
3.	MEDS	https://meds.or.ke
4.	Harleys	https://harleysltd.com
5.	Surgipharm Limited	https://surgipharm.com
6.	Medipharm East Africa Limited	https://medipharm.co.ke
7.	Meditec Systems Limited	https://meditecsystems.net
8.	Bio-zeq Kenya Limited	https://biozeqkenya.com
9.	Pulse Medics Equipment Kenya	https://pulsemedic.com
10.	Crown healthcare Limited	https://crownkenya.com
11.	Omaera Pharmaceuticals Limited	https://omaera.com
12.	Bobcare Medical System Limited	https://bobcaremedical.com
13.	Apple Pharmaceuticals Limited	https://kbo.co.ke
14.	Centric Medical Solutions	https://centricmedicalsolutions.com
15.	Blekam (EA) Limited	https://blekamlabkits.kbo.co.ke
16.	Scitech Diagnostics Limited	https://scitechdiagnostics.com
17.	MECK Supplies (K) Limited	https://mecksupplies.kbo.co.ke
18.	Ashcott Limited	https://ashcott.com
19.	Seropharm East Africa Limited	https://seropharm.com
20.	Chemoquip Limited	https://chemoquip.com
21.	Hass Scientific & Medical Supplies Limited	https://hassscientific.com

Annex 10: Examples of Digital Health Solutions and How They Have Started in Kenya

The below examples are derived from a 2020 mapping of various eHealth solutions by the Kenya Healthcare Federation and SDG Partnership Platform and highlights the importance of external funding for the development and uptake of digital health solutions in Kenya.

AfyaKit and SafeCare App to assess health facilities

The quality of healthcare services in Kenyan health facilities varies, and is not always satisfactory. Performance data is not yet used sufficiently to understand and improve service quality.

AfyaKit is a mobile phone based supervision checklist. It is based on national and WHO standards for health facility supervision. Managers and facility supervisors at the county and subcounty levels use the solution: the supervisor logs in while conducting routine supervision visits, performs supervision using the tool and submits the data immediately after finishing the visit. After that, an automated report is generated. Visual analytics on an online health review platform help managers to support health care facilities in improving the quality of health service delivery. AfyaKit was developed locally in Kenya, with financial support of the **County Innovation Challenge Fund (CICF)** funded by the **UK government**. The additional estimated financial investment required for the development of the software is USD 400,000. At the time of writing, AfyaKit was in use for the supervision of 150 health facilities within Nairobi county; an improvement of service quality – as per the indicators assessed at baseline and 1.5 years later - could be observed. Healthcare workers and facility managers accept and appreciate the utility of the digital tool for their practice.

SafeCare, a set of healthcare quality standards and a quality improvement process, is a more private-sector oriented product. It was developed by the **PharmAccess Group** and is used by the same organization for health service quality improvement programmes and quality accreditations. SafeCare is supported by a digital tool developed in-house by PharmAccess. The tool provides audit-related information to support healthcare providers in improving their services through continuous quality improvement plans. PharmAccess suggests that SafeCare can help to increase business revenue through an improved client attraction and retention.

KenyaEMR and IQCare to manage client structured clinical records

Continuity of healthcare requires maintenance of individual patient records. This is particularly important for the tracking of progression of chronic diseases. Manually retrieving and updating physical paper records requires time and space, and does not allow for easy health information exchange over distance, nor for the integration with electronic tools for statistics, facility management (e.g. procurement of supplies), or clinical decision support.

Over the past decade, there are two EMR systems in Kenya that have received funding from the **US government (through PEPFAR)**, for the management of HIV patient records: IQCare and KenyaEMR. The MOH works with **Palladium** to develop and maintain these systems, as well as a data warehouse that helps track the 90-90-90 UNAIDS strategy for prevention, treatment and virus suppression of HIV/AIDS patients. In addition, an interoperability layer provides integration of these systems with DHIS2.

The investment into the development and implementation of the two systems is estimated to be over 10 Million USD. Their coverage and utilization has increased in a recent roll-out, and the systems are now installed in health facilities in 42 counties.

The promotion and adoption of disease-specific medical records (especially the strong focus on HIV) has led to some critical questions regarding their sustainability. There are experts who recommend the promotion of integrated medical records systems that can be used for patients across clinics and facility departments.

Kenya Master Health Facility List

Efficient planning and budgeting for staffing, training, equipment and health service provision in general requires up-to-date reliable information that links service availability and readiness to population health needs. The Kenya Master Health Facility List (KMHFL) enlists health facilities and community health units in Kenya, including the public and the private sector. The tool is owned by the Ministry of Health, and relies on regular updates at the county/subcounty level for information about facility services, opening hours, etc.

The first iteration, in 2012, was supported by the HS2020 programme and implemented by a company called **Knowing Limited**. The second iteration, which incorporates an application programming interface (API) and a refreshed online user interface, was developed by **Savannah Informatics** under the **AfyalInfo programme** and

with financial support by **USAID**. Substantial financial resources went into the development of the MFL/KMHFL. The functionality is relatively simple. One of the key merits is the application of a unique identification number (MFL code) for each health facility, which makes it a viable standard reference for health governance, health information exchange, and statistics. At the same time, the tool is grappling with some challenges that aren't fully resolved yet: Connectivity/interoperability with DHIS2; data accuracy (including up-to-date list of health facilities and services provided, opening hours, correct geolocation, bed-numbers and staffing information); timestamps/the possibility of querying data for past points in time to allow the user to tabulate the number of health facilities over time. Furthermore, the online version of the KMHFL contains a barely utilized function for facility review and rating.

Chanjo to manage inventory and distribution of health commodities

The management of a vaccine supply chain is complex and requires – among other things – a good visibility of stock available and vaccine utilization, so that stock-out periods can be reduced and eliminated. This is partially impeded by a high workload of health professionals on the ground.

Chanjo is a digital health application that pulls data from MOH databases to generate integrated dashboard views and indicators for the immunization programme that help to manage vaccine stocks. The software was developed by the **Clinton Health Access Initiative (CHAI)** in collaboration with **MOH** and **Strathmore University**. Strathmore provided technical expertise, while CHAI provided funding for the software development and business analytics. The software and data warehouse is hosted by NASCOP; additional partners include **UNICEF** and **WHO**. The software is used nationwide in the national vaccine depots, the nine regional sites, and all sub-county vaccine stores. All sites make use of the Chanjo visualization. The monthly reporting rate at the time of writing was around 70%. The broad utilization of the system by the government and healthcare professionals has led to an increased visibility of vaccine stock-outs, and its subsequent use for operational decision-making helped to avoid shocks in the supply chain and run a system that is generally considered to be efficient.

Slade360 / Smart Applications for automated analysis of data

Insufficient transparency with regards to pricing and costs in the private health sector lead to limited accountability and an efficiency loss in the health insurance space. As a consequence, there is little information about value-for-money with regards to health services; there are no health insurance products for the lower-end market; most health insurance companies are/were not profitable and health service providers receive payment for their claims after an extended long period of time.

The emerging availability of electronic claims data enabled the introduction of visual data analytics platforms. Savannah Informatics developed a platform called Slade360. The platform was designed to provide support to health insurance companies in view of improving their profitability, shorten the period for claims reimbursement, and support ICT-savvy among health providers. **Savannah Informatics** started the platform with a grant from **USAID** of USD 250,000 which helped to fund the proof of concept for the analytics platform. The overall investment in the analytics platform is difficult to quantify; a lot of man-hours of young IT talent and students has been invested into the software development. For the analytics platform, Savannah is still operating on a net loss and working towards break-even. The company leadership is optimistic that a growing market – both within Kenya and in the region – will allow them to recuperate investments in the near or mid-term future. According to the Savannah Informatics, the Slade360 medical claims processing system is in use in over 1,200 health facilities in Kenya and used by 16 health insurance companies, representing around 65% of health insurance companies in Kenya. The coverage of electronic claims processing / claims switching systems is still very limited in faith-based health facilities.

Smart Applications International is another large player in the market of electronic medical claims processing, who also offer access to an online data analytics platform for decision making.

Annex 11: Examples of the FBO Operators in Kenya

1. Coptic Mission Hospital
2. Bomu Medical Center
3. AIC Kijabe Hospital
4. St Luke's (ACK) Hospital Kaloleni
5. Mary Immaculate Cottage Hospital
6. Tawfiq Muslim Hospital
7. Jamia Medical Centre
8. Nazareth Hospital
9. Fatima Maternity Center
10. Chogoria Hospital
11. Maseno Mission Hospital
12. PCEA Upendo Health Centre
13. Consolata Hospital
14. The Mater Hospital Mukuru
15. Mukuru Crescent Clinic

Annex 12: List of the Largest Healthcare Operators in Kenya

Organisation	Services
Kenyatta National Hospital (KNH)	All services
Moi Teaching and Referral hospital	All services
The Nairobi Hospital	Casualty accident and emergency centre, Family Health, Diabetes Clinic, Antenatal Clinic, Chest Clinic, Breast Health Clinic, Child Welfare or Well Baby Clinic, Travel and Immunization Clinic, Chemotherapy, Gynaecology / Postnatal / Family Planning Clinic etc
Aga Khan University Hospital (AKUH)	Accident & Emergency, Dental Dietetic Services, Family Medicine, Pediatrics, Pharmacy, Physiotherapy & Rehabilitation, Radiology, Surgery Women's Services (Obstetrics & Gynaecology)
MP Shah Hospital	Outpatient Services, Inpatient Services, Medical & Diagnostic Facilities, Cancer Care Centre
Avenue Hospital	24 hour Outpatient Department - General Medical and Surgical wards - Paediatric ward - A secure and self-contained Psychiatric ward - Maternity ward with nursery - HDU - Private rooms - Operating theatres for major and minor surgery - X-ray and ultrasound services - Ambulance and patient transport services - Pharmacy & Clinical laboratory services - A refrigerated mortuary
The Matter Hospital	Accident and emergency, consultancy, dental, immunisation, well persons clinic, outpatient maternity services and lamaze classes, comprehensive care clinic, operating theatres, intensive care unit, wards
Karen Hospital	Emergency and critical care, acute medical and surgical services, diagnostics, rehabilitation, mental health, palliative care, undertaking research and educating the next generation of healthcare professionals.
Guru Nanak Hospital	Accidents/Emergencies, Outpatient services, Inpatient services, Laboratory services, X-Ray and Ultra Sound services, Mobile X-Ray unit, Physiotherapy department, Maternity unit, Maternal child health services, Full equipped theatre and day surgery setup, Pharmacy, Ultramodern dental unit, Ambulance services, HIV/AIDS counselling, VCT/DCT
Gertrude's Children's Hospital	Emergency Department, Pharmacy Services, Laboratory Services, Wards & Facilities, Pediatric Nurses, Phlebotomists, Laboratory Technologists, Examination Room, Operating Theatres, Neurosurgery, Ophthalmology etc

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