DATA COLLECTION SURVEY ON THE ROLES OF THE PRIVATE SECTOR FOR IMPROVING HEALTH FOR SIX AFRICAN COUNTRIES

SUMMARY REPORT: KENYA

MARCH 2020

JAPAN INTERNATIONAL COOPERATION AGENCY

INTERNATIONAL DEVELOPMENT CENTER OF JAPAN INC.

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Abbreviations and Acronyms

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CHE	Current Health Expenditure
FBO	Faith-based Organization
HRH	Human Resource for Health
KEMSA	Kenya Medical Supplies Authority
KHF	Kenya Healthcare Federation
KHSSP	Kenya Health Sector Strategic Plan
KRC	Kenya Red Cross
MES	Managed Equipment Services
MoH	Ministry of Health
NCD	Non-Communicable Disease
NHIF	National Hospital Insurance Fund
OOP	Out of Pocket
PPB	Pharmacy and Poisons Board
PPP	Public Private Partnership
THE	Total Health Expenditure
UHC	Universal Health Coverage

Chapter 1 Introduction

1.1 Background

Health status in Africa has improved over the years. Life expectancy has been extended from 47 in 2005 to 61 in 2016, and the maternal mortality ratio and under five mortality rate have been improved from 910/100,000 live births (LB) and 171/1,000 LB in 2005, to 542/100,000 LB and 76.5/1,000 LB in 2016, respectively (WHO). However, the situation is still lagging compared with other regions.

The Government of Japan launched the "Africa Health and Wellbeing Initiative" at the 7th Tokyo International Conference on African Development (TICAD 7) in August 2019. This initiative aims to promote self-sustaining industries in the fields of health and medical services and long-term care in Africa. To realize this purpose, it seeks to develop a virtuous cycle of creating and fostering private-sector business that could improve health in Africa through the efforts of the public sector and the invigoration of the private sector that can support the public sector.

Under this initiative, JICA has commissioned a team of consultants to conduct a data collection survey on the roles of the private sector in improving health in six African countries, namely Kenya, Ghana, Senegal, Tanzania, Uganda and Zambia.

1.2 Survey Purpose

The objective of the survey is to collect information on the health sector in order to identify opportunities and challenges for Japanese private health technologies and services to be utilized to improve health in six African countries.

1.3 Survey Methods

A literature review and data collection survey are conducted in Japan as well as in Kenya, Ghana and Tanzania on the relevant contents, namely health status, health policy and governance, health financing, health service delivery, and marketing and investment climate on medical supplies in each country. During the field survey in Kenya, Ghana and Tanzania, the survey team collected the necessary information from the Government and executive agencies, health care facilities, private health sector associations, development partners, private companies, distributers, JICA, JETRO, embassy of Japan and other relevant parties through interviews and site visits.

1.4 Survey Period

The survey was conducted from the end of August 2019 to the end of March 2020. The field survey was conducted in Kenya from 4th to 16th November, in Ghana from 18th to 29th November, and in Tanzania from 2nd to 13th December 2019.

Chapter 2 Experience of Japanese Companies with Medical Technologies Operating in the Six Targeted Countries

Japanese companies doing healthcare business used to be concentrated in South Africa and northern African countries. In recent years, the number of Japanese companies doing healthcare business in the six targeted countries has increased, primarily attributable to rapidly expanding middle class demands owing to the growing economy and the governments' strong commitment to achieve Universal Health Coverage (UHC). Leading Japanese companies in healthcare started to establish an office in the six countries. For instance, NIPRO Corporation, Takeda Pharmaceutical Company Limited, Nihon Kohden Corporation, and Terumo Corporation set up bases in Kenya, while NIPRO Corporation set up a base in Senegal and Sysmex Corporation one in Ghana.

Business fields of these companies are also expanding from maternal/child health and communicable diseases, which are given relatively high priority in the six countries, to Non-Communicable Diseases (NCDs) including diabetes testing and treatment, which has been increasing in demand in recent years. Medical technologies of the companies introduced in the six countries are characterized by competitive advantages of Japanese technologies, such as quality imaging diagnostics/optical diagnosis, high efficiency, high degree of accuracy and less burden on patients. In addition, many of the companies have developed products utilizing technologies including uninterruptible power source, power saving, dry chemistry, point of care testing (POCT), high durability, small in size, lightweight, portable, small footprint, and ease of handling and maintenance, which can be adaptable to insufficiencies in infrastructure, facilities and human resources in African countries. As for new technologies, one of the JICA Public Private Partnership Projects is currently demonstrating the effectiveness of "drone" technology for medical supplies delivery.

Chapter 3 Health Sector Profile and Discussion

3.1 Health Status

3.1.1 Basic health indicators

Basic health indicators are shown below. While maternal and child health status had been worsening during the 1990s, it has been reversed and improving since the 2000s. However, more effort is required to achieve the SDGs target, i.e., 70/100,000 LB for MMR by 2030.

Table 1: Basic Health Indicators

No	Indicator	Data
1	Population (2018)	51,393,010
2	Total Fertility Rate (2017)	3.572
3	Life Expectancy (2017)	65.909
4	Maternal Mortality Ratio (per 100,000 LB) (2017)	257.6
5	Under 5 Mortality Rate (per 1,000 LB) (2017)	46
6	Children aged under 5 years underweight (%) (2014)	11.2
7	Anaemia in children under 5 years (%) (2016)	41.1
8	Anaemia in women of reproductive age (%) (2016)	27.2

Source: 1-3: World Bank Open Data, 4: GBD 2017, 5-8: WHO Global Health Observatory Data Repository

3.1.2 Disease burdens

According to the draft Kenya Health Sector Strategic Plan (KHSSP) 2018-2023, while communicable diseases still account for the majority of disease burdens, Kenya is undergoing an epidemiological transition marked by a decline in morbidity and mortality due to communicable conditions, and an increase in the burden of NCDs.

Looking at the top ten causes of death in 2007 and 2017 (Table 2), HIV/AIDS is the number one killer both in 2007 and 2017 and other communicable diseases such as respiratory infection, diarrhea, and tuberculosis occupy the other top places in both years. However, the proportion has reduced drastically and been replaced by NCDs. NCDs accounted for over 55% of hospital deaths in 2015 (STEPwise study).

Table 2: Top 10 Causes of Death

Ranking (2007)	Ranking (2017)	% change 2007-2017
1. HIV/AIDS	1. HIV/AIDS	-52.0
2. Lower respiratory infect	2. Lower respiratory infect	-6.3
3. Diarrheal diseases	3. Diarrheal diseases	-6.8
4. Neonatal disorders	4. Neonatal disorders	-12.2
5. Tuberculosis	5. Tuberculosis	6.6
6. Stroke	6. Ischemic heart diseases	26.6
7. Ischemic heart diseases	7. Stroke	18.2
8. Malaria	8. Cirrhosis	16.5
9. Cirrhosis	9. Diabetes	31.2
10. Congenital defects	10. Congenital defects	-6.2

Source: Institute for Health Metrics and Evaluation (IHME)

In terms of the disability adjusted life years (DALYs[1]), HIV/AIDS, neonatal disorders, and diarrhea are still the leading cause of DALYs in 2017. Data on the hospital admission shows that diarrhea, high blood pressure, and HIV/AIDS are the top three diseases, and others include malaria, malnutrition and stroke (KDHS 2018). It was reported that the burden of morbidity of disease is increasing relative to decreasing mortality, which basically means that more people are losing years of healthy life to 'disability' caused by non-fatal diseases[2].

3.1.3 Major disease trend

- Communicable diseases: Prevalence rate of HIV among adults (15-49 years old) was on a downward trend at 4.8% in 2017. On the other hand, the number of new cases among children under 14 years of age is slightly increasing. Regarding tuberculosis, it was estimated that about 160,000 people were infected in 2017, and only half of them were diagnosed/treated. The mortality rate is high with 43,000 people dying annually. Many of the population are still at risk of malaria transmission, with children aged 10-14 years having the highest infection rates. The rate shows a decreasing trend near lakes, while slightly increasing along coastal areas.

- NCDs: Draft KHSSP 2018 2023 reported that cancers are the leading cause of death among NCDs accounting for 10% of all deaths followed by cardiovascular diseases at 8%. Prevalence of cancer has been rising lately, and most of the cases are diagnosed at a late stage leading to poor treatment outcomes. Uterus, breast and esophagus are leading cancers among females, while prostate, esophagus and stomach are the top cancers in males. Almost one quarter of adults suffer from raised blood pressure, with 20% having been diagnosed. Prevalence of diabetes mellitus among adults is 2% and only 41% have been diagnosed, while effective treatment coverage is 7%.

  Meanwhile, IHME estimates that heart disease is the leading cause of death among NCDs. Only 4% of hypertensive patients reportedly receive effective treatment. Around 2% of adults are estimated to have diabetes, of which 41% are diagnosed and 7% receive effective treatment[3].

3.1.4 Demographic transition

Demographic transition significantly influences the epidemiological transition. According to the World Population Prospects 2019[4], the proportion of the elderly population aged over 65 years old in Kenya is estimated to be 2.2 % in 2020 which is lower than the average of Sub-Saharan Africa at 3%. However, it is expected to exceed the average at around 2030, and Kenya is aging

[1] DALY factors in the years of life lost due to a given disease and the years lived with disability due to one disease or the other (draft KHSSP 2018-2023)
[2] Draft KHSSP 2018-2023
[3] Draft KHSSP 2018-2023
[4] https://population.un.org/wpp/

at the highest speed among the studied six counties.

3.2 Health Policy

The Government of Kenya developed "Kenya Vision 2030" as a long-term development blueprint for the country, and formulated the "Kenya Health Policy 2014-2030" for the health sector. The "Big Four" agenda is the five-year presidential development blueprint announced in 2017, and Universal Health Coverage (UHC) is one of the four agendas to be achieved by 2022. The policy objectives highlighted in the Health Policy are as follows:

1. Eliminate communicable conditions
2. Halt and reverse the rising burden of non-communicable conditions and mental disorders
3. Reduce the burden of violence and injuries
4. Provide essential healthcare
5. Minimise exposure to health risk factors
6. Strengthen collaboration with private and other sectors that have an impact on health

Focus for the next four years to achieve UHC is specified in the Budget statement for the Big Four agenda in 2019 as follows[5]:

1. Strengthening the provision of secondary and tertiary healthcare services;
2. Increasing the number of referral health facilities and use of e-health systems in delivering health care;
3. Promoting the use of alternative sources of financing health care; and
4. Strengthening primary healthcare systems; empowerment of communities, equipping of primary healthcare facilities and recruitment of additional health workers.

Under the guidance by these development policies, the latest Five-year Kenya Health Sector Strategic Plan (KHSSP) 2018-2023 is in the process of finalization as of December 2019.

In terms of the public private partnership (PPP), it is one of the major health sector objectives to strengthen it as mentioned above. While the overall definition and procedure of PPP are set up in the "Kenyan Public Private Partnership Act 2013", the specific strategy and direction for the health sector has not been established. Therefore, the Ministry of Health (MoH) is under preparation of the public private partnership strategy for health together with the relevant partners.

Some of the PPP examples are presented below[6].

[5] Budget – The "Mwananchi" Guide 2019/20
[6] https://amref.org/news/makueni-county-test-innovative-model-primary-health-clinics-collaboration-amref-philips/, https://livinggoods.org/, http://pshpkenya.org/

<PPP examples>

1. Makueni County: Philips and AMREF Health Africa

Innovative model for primary health clinics in collaboration with AMREF and Philips is conducted in Makueni County. AMREF offers capacity building and health worker training, Philips provides health system infrastructure and medical equipment, and the Dutch development bank (FMO) provides legal and business expertise. Makueni county government is responsible for policy, regulation and quality management. The model will be tested in three clinics for one year, which is expected to improve access to high quality, financially sustainable primary health care.

2. Isiolo County: Living Goods

In 2018, Isiolo county and Living Goods initiated a four-year partnership, a co-funded project, to create demand for and provide community health services in all three Isiolo sub-counties through a package of targeted technical assistance (capacity building, cost-effective integrated service delivery platform for CHVs, digital health solutions, etc).

3. Private Sector Health Partnership (PSHP) Kenya

PSHP Kenya is a private sector collective action initiative for women, on reproductive, maternal, child and adolescent health. It is supported by a secretariat established by the Kenya Healthcare Federation and UNFPA, and collaborates with county governments and several private companies (Philips, Safaricom, GSK, Huawei, Unilever, etc).

3.3 Health Governance

With the devolved health system, while the national level –MoH – deals with health policy, national referral hospitals, capacity building and technical assistance to counties, the county government deals with the provision of health services at county health facilities and pharmacies, promotion of primary health care and so on.

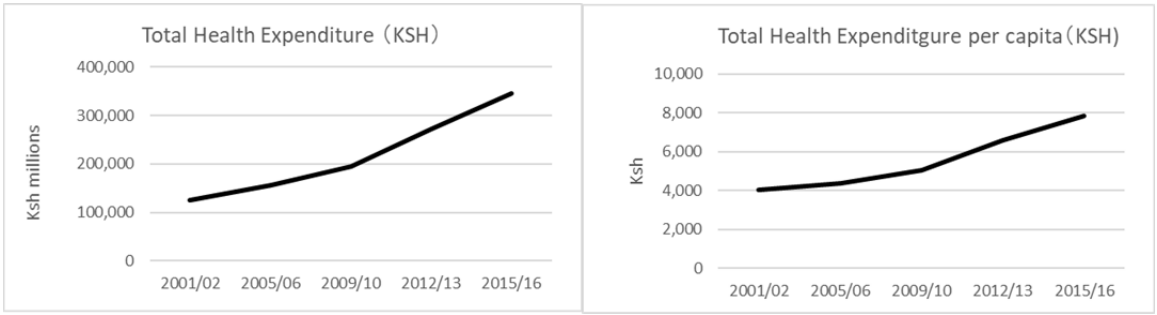
3.4 Health Financing

GNI per capita is 1,620 USD (2018, WB). Kenya is one of the fastest economic growing countries in east Africa with 5-6% of annual economic growth in the past several years.

3.4.1 Health expenditure

Total Health Expenditure (THE[7]) and health expenditure per capita in Kenyan shillings have been increasing[8]. Per capital health expenditure in US dollars is 66 USD in 2016 (WB). Meanwhile, the recent proportion of GDP spent on health has been around 2%[9], which is lower than the WHO recommendation at 5%.

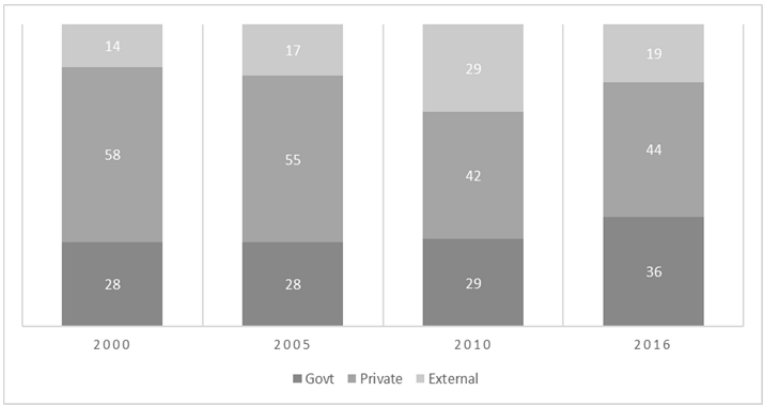
[7] Total Health Expenditure (THE) is the expenditure on health services and capital formation, while current health expenditure (CHE) is the expenditure on health services exclusive of capital formation.
[8] Kenya National Health Account FY 2015/16, Kenya
[9] WHO Health Expenditure Observatory



Source: Kenya National Health Account FY 2015/16, Kenya

Figure 1: Trend of Total Health Expenditure and Total Health Expenditure per capita (Ksh)

Recent distribution of the current health expenditure (CHE) by institutions shows that over 30% is from the government, and around 40% is from the private sector. Private and donor financing have been decreasing, while government financing had been increasing from 2000 to 2016.

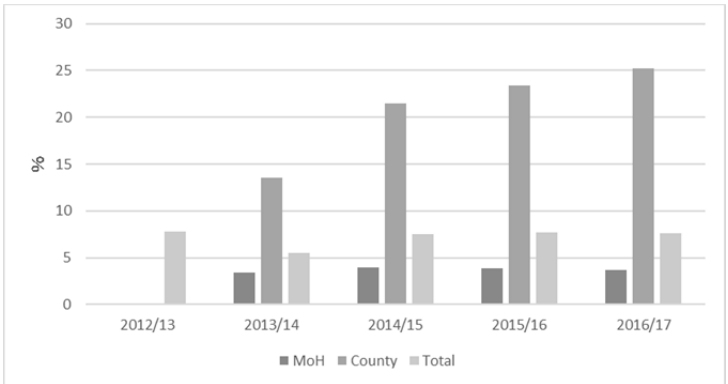


Source: WHO Health Expenditure Observatory

Figure 2: Distribution of Current Health Expenditure

3.4.2 Health budget

The health budget as a percentage of the total government budget once decreased in FY 2013 due to devolution, but it increased to around 7.5% in FY 2014 to FY 2016. However, it had not reached to the target of the Abuja Declaration at 15%. The total national government budget expanded by 8% between FY 2015/16 to 2016/17, while the total MoH allocation expanded by only 1.8% over the same period, meaning that the health budget did not grow equally to the national budget[10].



Source: National and County Health Budget Analysis FY 2016-17

Figure 3: Trend of Health Budget at National & County Government Budget

[10] National and County Health Budget Analysis FY 2016-17

The budget for MoH in FY 2019/20 was announced as Ksh 93.048 billion[11]. The Budget statement for the Big Four agenda in 2019[12] specified the detailed programme-based budget as follows:

- Ksh 6.0 billion (bn): scaling up of UHC
- Ksh 4.9 bn: transforming health systems for UHC
- Ksh 2.5 bn: medical supplies to support UHC (piloting)
- Ksh 3.2 bn: elderly and severely disabled
- Ksh 6.2 bn: leasing of medical equipment[13]
- Ksh 4.1 bn: free maternal health care
- Ksh 4.1 bn: doctors, clinical officers and nurses internship
- Ksh 3.3 bn: vaccines and immunization
- Ksh 0.4 bn: regional cancer centres

In terms of the county budgets on health, the total budget was reported as Ksh 96 billion in FY 2016/17. It has been increasing between the time of devolution and FY 2016/17 and the average health budget as a percent of a county budget was 25.2% in FY 2016/17, ranging from 15% to 40%. The allocation of county health budget to recurrent and development is 79% and 21%, respectively, in the same year. Around 57% of the development budget was spent on construction and rehabilitation, while 8% was on medical equipment[14].

3.4.3 Health insurance

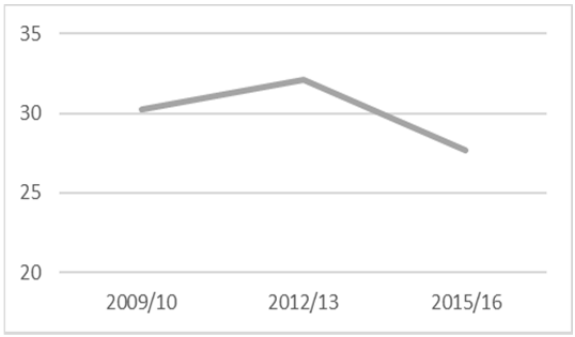
The percent of the population covered by any type of health insurance is around 19.9% as of 2018, and around 90% is covered by the National Hospital Insurance Fund (NHIF), which was established in 1966. Private insurance coverage has more than doubled from 2009 to 2016, increasing to 1.5 million.

The Government of Kenya formulated the "Roadmap Towards Universal Health Coverage (2018-2022)" and aims to achieve UHC by 2022 through the establishment of the Social Health Insurance Fund. The government promotes expansion of NHIF as well as private and community-based health insurance as a supplemental scheme.

The Government of Kenya removed user fees at primary health facilities and introduced free maternal services from 2013 in order to ensure access to primary health services. Household expenditure (out of pocket: OOP) was 27.7% in FY 2015/16 and has been in a decreasing trend since FY 2012/13[15].

[11] Unpacking of the 2019 budget policy statement, Parliamentary Budget Office, Kenya
[12] Budget – The "Mwananchi" Guide 2019/20
[13] This budget is for managed equipment service (MES)
[14] Comprehensive Public Expenditure Review 2017, Kenya
[15] Kenya National Health Accounts FY 2015/16, Kenya

At the same time, it was reported that 4.9% of households were still at risk of impoverishment because of expenditure on health care depleting household savings and were at risk of falling into poverty[16].



Source：Kenya National Health Accounts FY2015/16

Figure 4: Household expenditure/OOP (%)

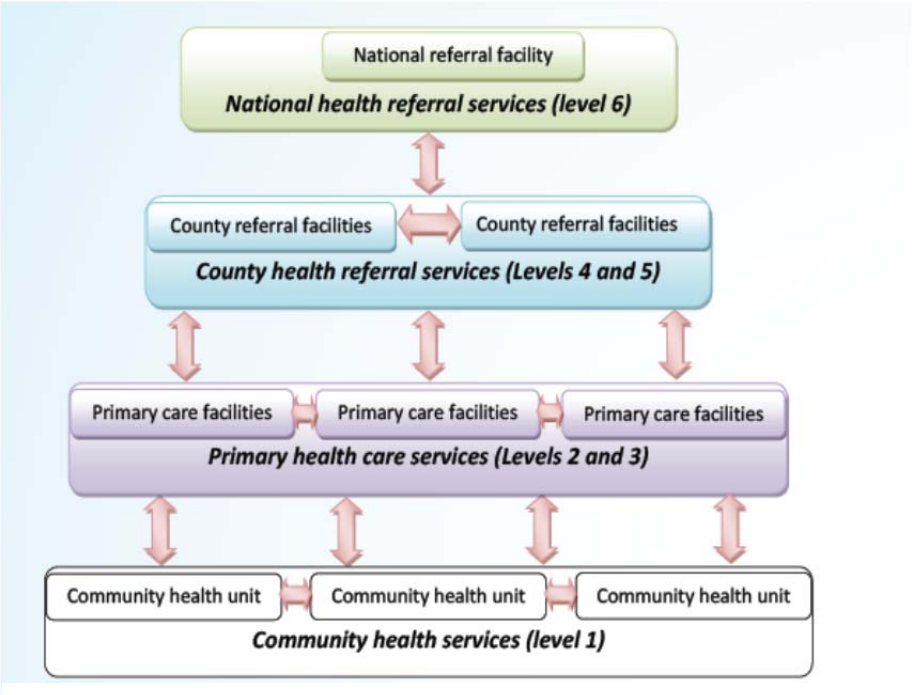
3.4.4 Donor support

Financial support from donors had increased from 57% in FY 2014/15 to 63.4% in FY 2016/17. The biggest donor financial support in FY 2016/17 was for HIV/Tuberculosis/Malaria mainly from Global Fund, WFP, and USAID, followed by immunization by World Bank, USAID and GAVI[17]. At the same time, a lot of the support goes to programme-based activities through NGOs, which may not necessarily align with the priority of the MoH and/or county governments[18].

3.5 Health Service Delivery

3.5.1 Public Service Delivery System

Health services are provided with six levels of referral network as shown in Figure 5[19].



Source：Kenya Health Sector Referral Implementation Guideline 2014

Figure 5: Referral health system

[16] Draft KHSSP 2018-2023
[17] National and County Health Budget Analysis FY2016-17, Kenya
[18] Kenya Health Financing System Assessment, 2018, USAID
[19] Kenya Health Sector Referral Implementation Guidelines, 2014, MoH

3.5.2 Private health service

Private sector health care is provided by for-profit and not-for-profit entities, such as faith-based organizations (FBOs) and nongovernmental organizations (NGOs).

Table 3: Main type and function of private health facilities

Type		Major functions
Not-for-profit	FBO	FBOs have a long history in health and play a critical and significant role by providing services in remote, rural and underserviced areas. They are organized into three associations along religious lines: (i) Christian Health Association of Kenya (CHAK); (ii) Supreme Council of Kenyan Muslims (SUPKEM) and (iii) Kenya Episcopal Conference Catholic Secretariat (KEC CS).
	NGO	NGO sector in health performs a wide array of activities, ranging from advocacy to community mobilization to health service delivery and policy planning. Major umbrella associations are Health NGOs Network and Kenya AIDS NGO Consortium.
For-profit	Kenya's private sector is well organized around professional associations and trade groups. Kenya private sector alliance has been formed to provide a unified voice for the private sector in the policy process, and health is represented by the Kenya Health Federation.	

Source: Private Health Sector Assessment in Kenya 2010

According to the survey in 2013, 52% of the urban population used outpatient services at the private health facilities, while 32% of the rural population did so. Access to second and tertiary private health facilities by the poor and underserved population was reported to be limited. At the same time, advanced health care provision by private hospitals appeared to have contributed to the reduction of the burden of public referral hospitals[20].

The Kenya Healthcare Federation (KHF) was established in 2014 as a platform of the private health sector. KHF plays an active role by promoting a public private partnership, collaboration with various national and international private companies and development partners, information sharing with member facilities and so on.

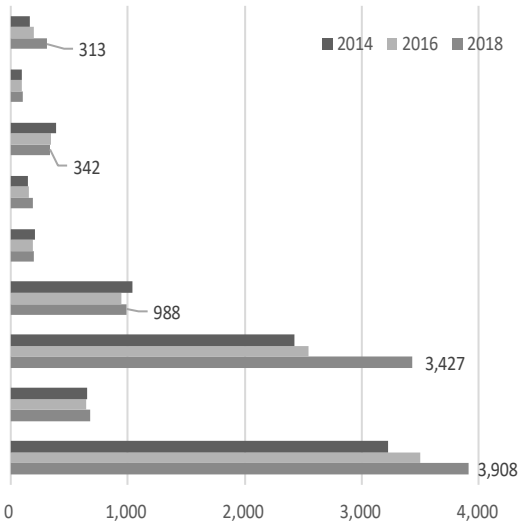
3.5.3 Health Infrastructure

The total number of health facilities registered at the Kenya Master Health Facility was 12,014 as of September 2019. Public health facilities account for 47.8%, for-profit private facilities for 40.7%, and not-for-profit facilities for 11.5%. The number of beds as per 10,000 population was 14 in 2016[21]. The health facilities are particularly in short supply in rural and remote areas, which hinders access to basic health services for the local population.

[20] Kenya Health Financing System Assessment, 2018, USAID

[21] WHO Global Health Observatory Data Repository

The trend for health facilities from 2014 to 2018 (Figure 6) shows that the for-profit private facilities increased at a higher rate than the public facilities, increasing by almost 50%. A total of 75-79% of the total health facilities in 2018 for both public and private are level 2 facilities. Level 3-6 hospitals account for 7.2% of for-profit private facilities and 6.5% for public facilities[22].

Facility	Ownership	Trend from 2014to 2018
Hospital	Private	
	FBO	
	Public	
Health centre	Private	
	FBO	
	Public	
Dispensary/ clinic	Private	
	FBO	
	Public	

Source: Economic Survey 2019

Figure 6: Trend of number of health facility by ownership

3.5.4 Human Resource for Health

In terms of the human resources for health (HRH), the number of doctors, clinical officers, nurses and midwifes per 10,000 people was 13.8 in 2015, which is far lower than the WHO recommendation to achieve SDGs at 44.5. Other HRHs including biomedical engineers are also in short and regional disparity is one of the big challenges.

Table 4: Number and ratio of major health professionals (2015)

Personnel	Registered No.	Retained No.	Ratio per 10,000 pop
Medical officers	9,497	5,660	1.5
Dentist	1,066	603	0.2
Pharmacists	2,377	1,971	0.5
Clinical officers	13,913	10,562	2.7
Lab technologist/technicians	11,071	8,416	2.1
Nurses and midwives	63,113	31,896	8.3
Total	-	63,785	16.5
Doctors/clinical officers/nurses/midwives	-	53,118	13.8

Source: Kenya Health Workforce Report: The status of healthcare professionals in Kenya, 2015

[22] Economic Survey 2019, Kenya National Bureau of Statistics

Supervisory authorities for major HRHs are as follows:

- Doctor and dentist: Kenya Medical Practitioners and Dentists Board
- Nurse: Nursing Council of Kenya
- Clinical officer: Clinical Officer Council

3.6 ICT/eHealth

ICT application for health has been promoted by the Health ACT, Vision 2030, Health Policy, and Kenya National e-Health Strategy 2011-2017. In 2016, the Government of Kenya developed Kenya eHealth Policy 2016-2030 to further strengthen and accelerate integration of ICTs into the healthcare system. The current eHealth Policy 2016-2030 provides the policy guiding principles and orientations including effective information sharing for the network of care between healthcare providers, ensuring interoperability of the system, securing privacy and confidentiality, creating centres of excellence to promote innovation, and so on.

According to interviews with various officials in Kenya, while the digitalization of public health facilities at levels 5 and 6 has progressed in general, it was also reported that some parts of the system still remained analog and/or have not been integrated into the existing HMIS. The study in 2016-2017 shows that eHealth interventions have recently increased, though most of them are delivered through mHealth utilizing SMS-based platforms focusing on primary care in HIV/AIDS, maternal and child health, or malaria. Reported challenges include ownership of the interventions, difficulties for the government to bring them beyond the pilot phase, interoperability of the system, inadequate ICT infrastructure and so on.

<Example on eHealth intervention[23]>
Huawei and Safaricom are working with the Lamu County government to implement a telemedicine project connecting dispensaries and health centres with county hospitals and regional referral hospitals. Huawei also supports enabling every public health facility in the county to go digital.

3.7 Investment Climate

3.7.1 Market Trend

(1) Medical Devices and Pharmaceuticals

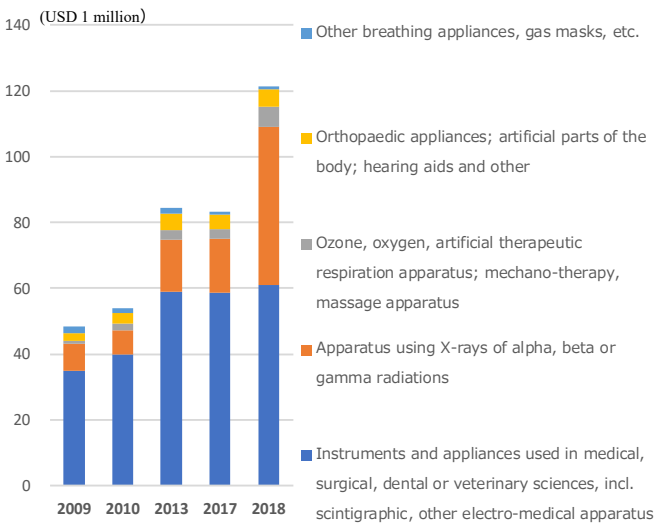
Medical Devices

In Kenya, imports supply 95% of the medical devices market[24]. As shown in Figure 7, Kenya's imports have increased rapidly over the past decade. They surged in 2013 to reach 80 million USD. Another significant growth recorded in 2018 is considered attributable to the fact that GE Healthcare (US manufacturer) provided 98 public hospitals with diagnostic imaging equipment

[23] PSHP Kenya http://pshpkenya.org/
[24] Business Monitor International "Kenya Medical Devices Report" 2017

such as for mammography and X-rays, under the Managed Equipment Services (MES) Program implemented by the national government (see the next section).

China is the largest exporter, followed by Germany, the US, Netherlands and India. GE Healthcare reportedly exported products from its manufacturing base in China.



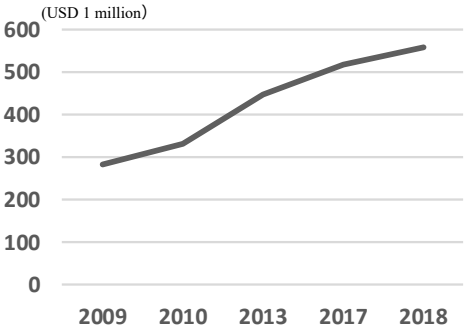
Note：Data 2011, 2012, 2014-16 not available
Source：Global Trade Atlas

Figure 7：Kenya's Imports of Medical Devices

In the area of diagnostic imaging, Philips has maintained its strong position in the market. In 2014, Philips established its Africa Innovation Hub to provide Africa-relevant innovations to address key challenges facing the continent[25]. GE Healthcare has been increasing its presence in the market. GE signed an MES contract in 2015 and launched a Healthcare Training Institute in Nairobi in 2016, having trained over 1,000 healthcare professionals from Kenya and other East African countries[26].

Pharmaceuticals

Kenya's pharmaceutical imports have also increased significantly over the past decade, reaching 500 million USD in 2017. India supplies over 50% of the imports, followed by Belgium, China, the US, the UK and France. Prescription drugs account for around 80% (over 60% is generic) of the market. The fastest growth in the coming years is expected to be over the counter (OTC) product sales[27]. Cardiovascular, diabetes and anti-infectives constitute the largest and fastest-growing prescription market segments[28].



Note：Data 2011, 2012, 2014-16 not available
Source: Global Trade Atlas

Figure 8：Kenya's Imports of Pharmaceuticals

Top multinational pharmaceutical manufacturers export their products to the market. GlaxoSmithKline (GSK) is reported to deal with both branded and generics[29]. In addition, the

[25] https://www.philips.com/a-w/about/news/archive/standard/news/press/2014/20140321-Philips-to-establish-Research-and-Innovation-Hub-in-Africa.html
[26] https://www.ge.com/africa/content/kenya
[27] Africa Business Pages "The Pharmaceutical Industry in Kenya: Importers in Kenya"
[28] ditto.

number of local pharmaceutical manufacturers increased to around 40. Kenya is now exporting drugs to neighboring countries as the largest manufacturer in East Africa[30].

(2) Service Providers

Public Health Facilities (B to G)

Public procurement of medical supplies is regulated under "Kenya Medical Supplies Authority Act 2013" and "Public Procurement and Asset Disposal Act, 2015." Kenya Medical Supplies Authority (KEMSA) is a state corporation under the MoH whose mandate is to procure, warehouse and distribute medical commodities to the MoH-supported health facilities and programmes. Public health facilities can procure through the private market if there is no stock in KEMSA.

In terms of public procurement of relatively high-technology medical devices, recently, the national government tends to set procurement requirements such as rapid maintenance services inside the country, end-user training, and the use of ICT technology (electrically communicable). Public procurement in Kenya is becoming price sensitive, as Mindray (Chinese manufacturer) is entering the market with its partner, Megascope, a local major distributor.

Procurement of medical supplies for public health facilities under county governments depends on each county government's budget approval. Therefore, it is necessary, if any private companies wish to promote their products, to approach the county government/health department.

National referral hospitals can utilize insurance reimbursement for medical costs from NHIF as their internally generated funds, apart from the government budget. However, due to insufficiency in reimbursement[31], Kenyatta National Hospital planned to upgrade its private wing for the high-end market under a Public Private Partnership (PPP) arrangement[32]. This is the first PPP in the health sector, and it is expected that similar PPPs will increase in the future, which will expand opportunities for the high-end market.

Kenyatta National Hospital has a long-term partnership with Japan through Japan's ODA and may strengthen further collaboration in the field of innovative Japanese technologies.

Managed Equipment Services (MES)

The Government of Kenya launched the Managed Equipment Services (MES) in February 2015. MES was introduced with the intention to address the common problems for medical equipment procurement. The MES refers to a 7-year contractual arrangement between the government and

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[29] DFID "Overview of Experiences in the Pharmaceutical Supply Chain: Implications for the poor in Kenya" (2014)
[30] Business Monitor International "Kenya Medical Devices Report" 2017
[31] https://www.businessdailyafrica.com/economy/KNH-pushes-for-increase-in-NHIF-rebates/3946234-5279974-lvlxsv/index.html
[32] https://www.treasury.go.ke/tenders/KNH%20Private%20Hospital%20PPP%20Project_RFQ%20Document%20_%2007.10.2019.pdf

five foreign manufacturers for the supply, installation, maintenance, replacement and disposal of various equipment, as well as training and reporting for the entirety of the contract period, which has been implemented in 98 hospitals across 47 counties, with a focus on theatre (Mindray), central sterile services department (CSSD) (Esteem Industries), renal (Bellco), ICU (Philips) and radiology equipment (GE Healthcare)[33].

Private Health Facilities (B to B)

The number of private facilities has considerably increased over the last five years, as illustrated in the previous section, as a result of the expansion of the middle class, as well as the increase in the number of NHIF-accredited private outpatient service providers.

Middle to top-ranked private hospitals tend to demonstrate their interests in innovative technologies such as endoscopy, dialysis devices and contrast media. They are regarded financially sound and have various options for financial arrangements. On the other hand, the lower level private facilities are facing difficulties in terms of financial access and tend to be price conscious.

3.7.2 Relevant legislation, regulating authorities, registration, import regulations (medical devices and pharmaceuticals)

(1) Relevant legislation and regulating authorities

Medical devices and pharmaceuticals used in Kenya are regulated under "Health Act 2017." Medical devices are regulated by "Health Products and Technologies (Medical Devices including IVD Medical Devices) Regulations (Gazette Notice 35 2014)."

The regulating authority is the Pharmacy and Poisons Board (PPB). Radiation emitting electronic products are also regulated by "Radiation Protection Act 1984," under the supervision of the Radiation Protection Board.

(2) Registration

Medical Devices

Medical devices need to be registered with the PPB prior to being placed on Kenya's market. The PPB developed "Guidelines on Submission of Documentation for Registration of Medical Devices May 2018," publicly available on the PPB website. The registration application uses the Common Submission Dossier Template (CSDT), which contains elements of the GHTF (Global Harmonization Task Force) guidance document titled "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)". A medical device that has obtained the other countries' reference regulatory

[33] Parliamentary Research Services (PRS) (2018) "The Managed Equipment Service (MES) Project: Brief and Suggested Questions"
(http://www.parliament.go.ke/sites/default/files/2018-11/MES%20Brief_Nov%202018%20%285%29_%20With%20Suggested%20Questions%20.pdf)

agency approvals will be qualified for faster evaluation routes. Any manufacturer based outside Kenya must designate a local authorized representative (LAR). Currently, medical devices listed but not registered with the PPB are required to be registered by January 2020[34].

Pharmaceuticals

Drugs and medicines are required to be registered with the PPB prior to being placed on Kenya's market. The PPB developed "Registration of Drugs Guidelines to Submission of Applications," publicly available on the PPB website, in addition to the guidelines related to registration of human vaccines, advertisements, Good Manufacturing Practices (GMP), clinical trials, Good Distribution Practices, transportation and safe management of pharmaceutical waste.

The application for the registration of a drug shall be made only by an authorized Local Technical Representative (LTR) for foreign manufacturers. The application format is consistent with "Common Technical Document (CTD)" of "International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (IHC)."

(3) Import Regulations

All medical devices and pharmaceuticals for import into Kenya must comply with the Pre-Export Verification of Conformity (PVOC) program, implemented by Kenya Bureau of Standards (KEBS), in accordance with Legal Notice No. 78 of 15th July 2005[35].

3.8 Opportunities and challenges for Japanese Health Technologies

Opportunities and challenges for Japanese health technologies and services to be introduced in Kenya are summarized in this section in view of the national priority issues, high disease burdens, financial availability, and market entry.

(1) Communicable diseases

HIV still gives the highest disease burden for both mortality and morbidity, and the highest funding is allocated for the HIV programme. The major source of funding for HIV is the Global Fund.

There is a possibility for Japanese products to be procured through the Global Fund supported programmes if they meet requirements of the Global Fund[36]. Another opportunity is collaboration with the private principal recipients (PR). Private PRs for the current round (2018-2021) are Kenya Red Cross (KRC) (HIV: approximately 71 million USD) and AMREF (TB and Malaria: approximately 46 million USD)[37]. According to the officer of KRC, they welcome the proposal of innovative/effective Japanese products to be piloted for their programmes.

[34] Interview with local distributors. Registration was not mandatory for medical devices ("listing" was required).
[35] SGS "Kenya PVoC Program to Incorporate Medical Devices and Healthcare Products" https://www.sgs.com/en/news/2017/06/kenya-pvoc-program-to-incorporate-medical-devices-and-healthcare-products
[36] https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/
[37] Audit Report – Global Fund Grants to the Republic of Kenya, 2018

(2) NCDs

With the initiation of epidemiological transition, NCDs are becoming major health challenges. Cancer control is prioritized by the current national health plan and Big Four agenda and the establishment of four regional cancer centres has been planned as the main intervention. Also, the MoH is reportedly planning to establish a centre of excellence for kidney health and equip several hospitals with specialized equipment. It is expected that the demand for NCDs control and advanced medical services will increase more and more. While further in-depth study would be required to assess the need of each disease control, they seem to be potential areas for Japanese private companies to promote their new products/services through, for example, utilization of the JICA PPP scheme as well as other funding assistance.

(3) eHealth

Enhancing eHealth utilization is of great interest and one of the government priority objectives as highlighted in the Big Four – UHC priority intervention over the next years. As mentioned above, several development partners and private companies are making various efforts in collaboration with county governments as well as individual health facilities. This is considered to be one of the highly demanding areas for innovative technologies.

At the same time, it is pointed out that current efforts have some challenges in such areas as ownership by the government to bring those initiatives beyond the pilot phase, interoperability of the system and inadequate ICT infrastructure. The effectiveness of the business models could not be confirmed during this survey. Furthermore, elements of eHealth are diverse, and the required technology differs depending on the purpose.

Therefore, it would be desirable for Japanese private companies, when considering the introduction of their technologies and services, to have close dialogues with the governments and make sure to be part of their comprehensive plan with a view to scaling up the process. Further study would be required to assess the current situation in detail and identify the potential areas and effective partners.

(4) Public health market

In public procurement requirements for relatively high-technology medical devices, consideration should be made for the recent tendency to include rapid maintenance services inside the country, end-user training, and the use of ICT technology.

Direct collaboration with county governments with high priority on health, as well as partnering with development partners on the ground could be a potential approach.

Price sensitiveness is observed on all levels.

(5) Private health market

Middle to top-ranked hospitals are regarded as financially sound and show interests in innovative technologies such as endoscopy, dialysis devices and contrast media.

Small-sized facilities, though number in large and expanding fast, seem to face difficulties in financial access and price sensitive.

(6) Japan Kenya Business Dialogue

In October 2019, Japan Kenya Business Dialogue was launched as a common platform for working together to resolve various business issues affecting Japanese and Kenyan companies[38].

[38] https://www.ke.emb-japan.go.jp/itpr_en/00_001351.html