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

SUMMARY REPORT: TANZANIA

MARCH 2020

JAPAN INTERNATIONAL COOPERATION AGENCY

INTERNATIONAL DEVELOPMENT CENTER OF JAPAN INC.



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Table of Contents

Abbreviations and Acronyms

Chapter 1 Introduction	1
1.1 Background	1
1.2 Survey Purpose	1
1.3 Survey Methods	1
1.4 Survey Period	1
Chapter 2 Experience of Japanese Companies with Medical Technologies Ope	erating in the Six
Targeted Countries	2
Chapter 3 Health Sector Profile and Discussion	3
3.1 Health status	3
3.2 Health Policy	4
3.3 Health Governance	5
3.4 Health Financing	6
3.5 Health Service Delivery	8
3.6 ICT/eHealth	11
3.7 Investment climate	11
3.8 Opportunities and Challenges for Japanese Health Technologies	15

Abbreviations and Acronyms

APHFTA Association of Private Health Facilities Tanzania

CHE Current Health Expenditure

DHFF District Health Facility Financing

FBO Faith-based Organization

HBF Health Basket Fund

MSD Medical Stores Department

MoHCDGEC Ministry of Health, Community Development, Gender, Elderly and

Children

NCD Non-Communicable Disease

NHIF National Health Insurance Fund

OOP Out of Pocket

PO-RALG President's Office-Regional Administration and Local Government

PPP Public Private Partnership
THE Total Health Expenditure

TMDA Tanzania Medicines and Medical Devices Authority

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. The child mortality rate has declined progressively and the MDGs target was achieved. Meanwhile, the maternal mortality ratio has been recently slightly on the rise, which is one of the major health challenges.

Table 1: Basic health indicators

No	Indicator	Data
1	Population (2018)	56,318,348
2	Total Fertility Rate (2017)	4.953
3	Life Expectancy (2017)	64.479
4	Maternal Mortality Ratio (per 100,000 LB) (2015/16)	556
5	Under 5 Mortality Rate (per 1,000 LB) (2017)	54
6	Children aged under 5 years underweight (%) (2015-2016)	13.7
7	Anaemia in children under 5 years (%) (2016)	55.2
8	Anaemia in women of reproductive age (%) (2016)	37.2

Source: 1-3: World Bank Open Data, 4: Tanzania Demographic and Health Survey and Malaria Indicator Survey 2015-16, 5-8: WHO Global Health Observatory Data Repository

3.1.2 Disease burdens

According to the top ten causes of death in 2007 and 2017, HIV is still among the top causes along with other communicable diseases such as tuberculosis and malaria, while maternal and child health issues occupy the top position. At the same time, NCDs such as heart diseases or stroke are increasing. The mid-term review of the current health sector strategic plan in 2019 also reported an overall increase in hospital deaths due to NCDs from 30% in 2006 to close to 40% in 2015.

Table 2: Top 10 causes of death

	Ranking (2007)		Ranking (2017)	% change 2007-2017
1.	HIV/AIDS	Neonatal disorders		2.4
2.	Lower respiratory infect	2.	Lower respiratory infect	-3.8
3.	Neonatal disorders	3.	HIV/AIDS	-75.3
4.	Diarrheal diseases	4.	Ischemic heart disease	34.2
5.	Tuberculosis	5.	Tuberculosis	11.1
6.	Malaria	6.	Congenital defects	5.6
7.	Congenital defects	7.	Malaria	-13.7
8.	Ischemic heart disease	8.	Diarrheal diseases	-17.8
9.	Stroke	9.	Stroke	26.6
10.	Protein-energy malnutrition	10.	Diabetes	41.6

Source: Institute for Health Metrics and Evaluation (IHME)

In terms of years lived with disability (YLDs), iron deficiency, back pain, headache, and mental health are in the top positions. Diabetes has significantly increased while HIV decreased drastically from 2007 to 2017¹.

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¹ IHME

3.1.3 Major disease trend

- Communicable diseases: 1.5 million people are still infected with HIV, though the prevalence has been gradually decreasing. The access rate to ART treatment is around 75% and prevention of maternal to child transmission of HIV is more than 90%. Malaria control has made significant progress to reduce mortality and morbidity. There are very few confirmed infections among children under five years old in some of the regions in the northern and central zones. In terms of tuberculosis (TB), TB notification rates declined until 2015 but have increased since then. It is reported that it could be due to the improvement in case detection. Treatment success rates are as high as 90%. Tanzania is considered a low drug-resistant TB².
- NCDs: 2012 STEP showed very high prevalence (over 25%) of elevated blood pressure among men and women between 25 and 64 years old. Around 5% of hospital deaths are due to heart diseases. Obesity and being overweight among adults are increasing in general and obesity is particularly high among urban women compared with rural women. Prevalence of raised blood glucose is between 8 and 10%. In terms of cancer, 5% of hospital deaths are due to cancer and it is increasing gradually. While cervical and breast cancer screening programmes are implemented, it is reported that those interventions reach only 12% of the targeted population for cervical cancer and 5% for breast cancer³.

3.1.4 Demographic transition

Demographic transition significantly influences the epidemiological transition. According to the World Population Prospects 2019⁴, the proportion of the elderly population aged over 65 years old in Tanzania is estimated to reach 2.6% in 2020, which is lower than the average of Sub-Saharan Africa at 3%. It is expected that the aging speed is relatively slow among the studied six countries.

3.2 Health Policy

"National Health Policy" was revised in 2007 indicating the long-term objectives and directions for the health sector. The government developed "Big Results Now (BRN)" as a transformational government programme for economic and social development in 2014. Based on these national policies, "Health Sector Strategic Plan 2015-2020 (HSSP IV)" has been developed as a five-year health plan. The specific objectives are listed below.

- 1. The health and social services sector will achieve objectively measurable quality improvement of primary health care services, delivering a package of essential services in communities and health facilities.
- 2. The health and social welfare sector will improve equitable access to services in the country by focusing on geographic areas with higher disease burdens and by focusing on vulnerable groups in the population with higher risks.

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² Analytical report – Tanzania health sector strategic plan 2015/2016-2019/2020, Ministry of Gender, Community Development, Elderly and Children (MoHCDGEC), Sep 2019

Analytical report – Tanzania health sector strategic plan 2015/2016-2019/2020, MoHCDGEC, Sep 2019

⁴ https://population.un.org/wpp/

- 3. The health and social welfare sector will achieve active community partnership through intensified interactions with the population for improvement of health and social wellbeing.
- 4. The health and social welfare sector will achieve a higher rate of return on investment by applying modern management methods and engaging in innovative partnerships.
- 5. For improving the social determinants affecting health and welfare, the health and social welfare sector will achieve close collaboration with other sectors, and advocate for inclusion of health promoting and health protecting measures in other sectors' policies and strategies. It will mobilise non-governmental and private partners to promote health and wellbeing through their strategies

The mid-term review of HSSP IV in 2019 recommended that the focus be on continuity of care from health promotion to prevention, curative and palliative care, looking both at unfinished business in reproductive maternal and child health and at new emerging needs, e.g., NCD⁵s.

In terms of public private partnership (PPP), National Health Policy as well as HSSP IV advocate the importance of PPP as one of the priority strategies. "Public Private Partnership Strategic Plan II 2015-2020" and the guidelines and tools for the Plan II have been developed for the health sector, to accelerate the partnership. PPP sub-unit has been established in the Ministry of Health,

Community, Development, Gender, Elderly and Children (MoHCDGEC) and the PPP health forum is set up at each level. The dialysis centre operation by Africa Healthcare Network (AHN) is one of the PPP examples⁶ (see box).

<PPP example>

Dialysis centre by Africa Healthcare Network AHN operates the dialysis centre in partnership with some public, FBO and private health facilities. They provide comprehensive services in cost share arrangement with the health facility. Africa Healthcare Network Tanzania Ltd. was established in 2017.

The official in charge of PPP from MoHCDGEC outlined the proposal for partnering with Japan in such areas as construction/rehabilitation of health facilities, diagnostic services, provision of modern medical equipment and maintenance, manufacturing of health commodities, capacity development of health resources, etc.

3.3 Health Governance

MoHCDGEC oversees development, coordination and monitoring and evaluation of implementation of health policies. The regional level of operation is the extension of functions of MoHCDGEC and the President's Office-Reginal Administration and Local Government (PO-RALG). As an internal component of the Regional Secretariat, Regional Health Management Team (RHMT) ensures that health, social welfare and nutrition interventions are conducted within the framework of national policies and guidelines. With the Decentralization by Devolution reform, the Local Government Authorities (LGAs) are in charge of local health facilities under

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⁵ Mid Term Review of Health Sector Strategic Plan IV 2015-2020, MoHCDGEC, 2019

⁶ http://www.africahealthcarenetwork.com/

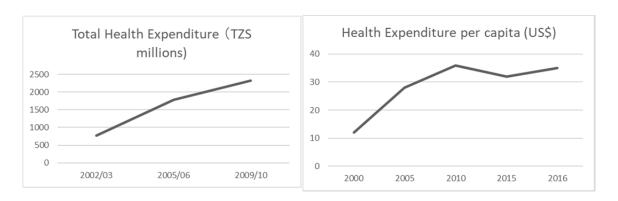
the district.

3.4 Health Financing

GNI per capita is 1,020 USD (2018, WB) and the annual economic growth of Tanzania was 6.7% in 2017 (WB). Tanzania is a low-income country.

3.4.1 Health Expenditure

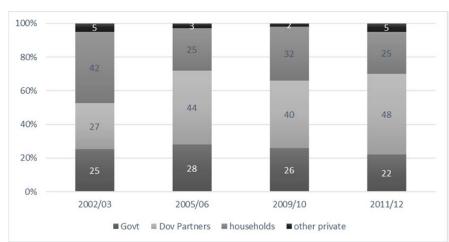
Total Health Expenditure (THE⁷) and Current Health Expenditure (CHE) per capita had been steadily increasing up to 2010. However, CHE per capita has been unchanged since then.



Source: Prospects for sustainable health financing in Tanzania: Baseline Report 2015 and WHO Global Health Expenditure Database

Figure 1: Trend of Total Health Expenditure and Current Health Expenditure per capital

Distribution of the THE bv sources shows that, in general, the development partners' contribution is higher compared with the government contribution (Figure 2) 8. However, the budget in FY 2018-19 shows that almost 85% is from domestic sources and



Source: HSSP IV

Figure 2: Distribution of Total Health Expenditure

the donor contribution has been reduced by 10% from the previous year⁹.

In terms of the out of pocket (OOP) expenditure, it was estimated at 22% in 2016¹⁰.

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.

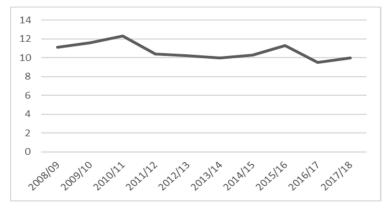
8 HSSB IV

⁹ Analytical report to inform the Tanzania Health Sector Strategic Plan IV 2015/2016-2019/2020, MoHCDGEC, 2019

3.4.2 Health Budget

The national budget for the health sector in FY 2018-19 was 2,954 billion TZS, which is an increase from the previous year's budget of 2,222 billion TZS.

In terms of the health budget as a percentage of the total government budget, it has been around 10% recently (Figure 3). However, it went down to 8.9% in FY 2018-19¹¹. It does not reach the target of the Abuja Declaration of 15%.



Source: Analysis of the Government of Tanzania's Budget Allocation to the Health Sector for Fiscal Year 2017/18, HP+ Policy Brie

Figure 3: Trend of health budget as a percent of total government budget

Out of the health budget in FY 2017-18, 1,078 billion TZS was allocated to the MoHCDGEC. A total of 27% of the MoHCDGEC budget was allocated for the recurrent budget and the remaining 73% was for the development budget.

All health facilities have their own bank accounts. District Health Facility Financing (DHFF) was introduced in 2018 for the district facilities by the health basket fund (HBF) direct disbursement. Regional hospitals also receive direct funds from the central government. In addition, health facilities can utilize patient cash payments as well as the reimbursed payments from the National Health Insurance Fund (NHIF) as their own budget.

3.4.3 Health Insurance

Tanzania operates a few health insurance schemes. The insurance coverage of NHIF was 7% and that of the community health fund (CHF) was 25%, which account for 32% of the people in total who are covered by the public insurance schemes in 2018. CHF was revised as improved CHF (iCHF) in 2014, being run under NHIF oversight, in order to increase the coverage for the informal sector. While the mid-term review of HSSP IV acknowledged the introduction of iCHF was a positive development, it also noted that establishment of the single national health insurance would not be achieved by 2020.

WHO Global Health Expenditure Database

¹¹ Analytical report to inform the Tanzania Health Sector Strategic Plan IV 2015/2016-2019/2020, MoHCDGEC, 2019

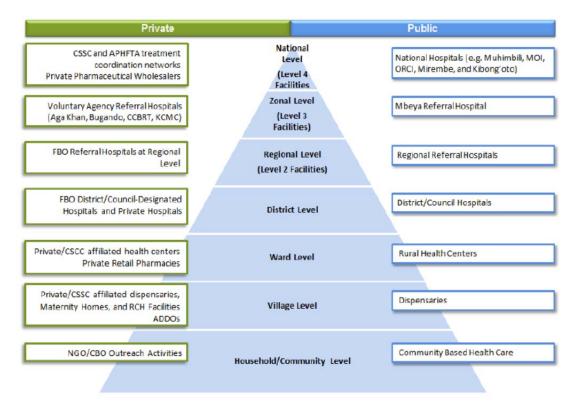
3.4.4 Donor Support

As mentioned above, the health budget in Tanzania used to depend on donor funds. However, financial contributions from the HBF have been decreasing. An MoU has been signed by France, Denmark, Ireland, UNFPA, UNICEF, and World Bank for the HBF for the period of 2015-2020¹². Other major donors including Global Fund, GAVI, USAID, DFID and GIZ provide programme-based assistance. It is reported that MoHCDGEC may have not been able to obtain accurate data due to the large amount of programme-based external assistance¹³.

3.5 Health Service Delivery

3.5.1 Public Service Delivery System

Health services are provided with the referral network as shown in Figure 4.



Source: HSSP IV

Figure 4: Referral health system

Memorandum of Understanding between Government of the United Republic of Tanzania and Development Partners contributing to the Health Basket Fund in support of achieving results under Health Sector Strategic Plan IV, 2015-2020
 Mid Term Review of Health Sector Strategic Plan IV 2015-2020, MoHCDGEC, 2019

3.5.2 Private Sector

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

Table 3: Main type and function of private health facilities

Туре		Major functions			
Non-profit	FBO	Christian Social Services Commission (CSSC) is the biggest faith-based			
		organization for health service delivery. There are 99 hospitals, 101 health			
		centres, and 697 clinics/dispensaries. FBOs run from the pharmacy to the			
		hospital providing preventive and curative services. They function as public			
		facilities where there are no public ones. Based on the partnership			
		agreement with the government, they could procure medical supplies from			
		the public procurement channel.			
	CBO	CBOs usually provide service packages in the community where there are			
		few public facilities, in the areas of maternal and child health, family			
		planning, reproductive health, TB/HIV, and health promotion. They also act			
		on policy research and advocacy.			
Self-sustaining	Around 880 private health facilities including hospitals, clinics and diagnostic centres				
(For profit)	are recorded in 2013. They operate in both urban and rural in all 7 zones.				

Source: Private Health Sector Assessment in Tanzania, World Bank, 2013

The Association of Private Health Facilities Tanzania (APHFTA) is an umbrella organization of the private (self-sustaining) health sector in Tanzania, established in 1994. They provide a comprehensive array of advocacy, administrative, knowledge sharing and networking products and services to the private sector. They also provide training for the public health personnel in the usage of Philips medical equipment. Afya Microfinance Limited, which provides micro health financing/loans, has been established under APHFTA.

3.5.3 Health Infrastructure

The number of public and private health facilities per type based on HSSP IV is summarized in Table 4. Public facilities including FBOs account for 83.8% and of which 3.5% were hospitals, 9.3% were health centres, and 87.2% were dispensaries. While the government has been focusing on strengthening the primary health level infrastructure, some areas are reportedly still short of health facilities. The construction and rehabilitation of 67 district hospitals was initiated in 2019.

Table 4: Number of public and private health facilities (2014)

Facility	No of	No of	Facility	No of	No of
	facility	bed		facility	bed
<public></public>			<private></private>		
National general hospitals	1	1,362	Private hospitals	39	1187
National specialized	4	1,497	Private health centres	78	800
hospitals					
Regional referral hospitals	15	3449	Dispensaries	1,123	-
(Gov)					
Regional referral hospitals	12	4581	Private clinics	40	-
(FBO)					
Zonal hospitals	5	2327	Private dental clinics	26	-

Facility	No of	No of	Facility	No of	No of
	facility	bed		facility	bed
Council hospitals	63	7267	Private eye clinics	5	-
Council designated hospitals	37	6742	Maternity homes	22	-
Voluntary agency hospital	103	5595			
Parastatal hospitals & health	29	1214			
centres					
Health centres	614	14959			
Dispensaries	5,819	-			
Parastatal dispensaries	168	-			
Specialized clinics	12	-			
Total	6,882	48,993	Total	1,333	1,987
Grand total (public &	8,215	50,862			
private)					

Source: HSSP IV

Meanwhile, the mid-term review of HSSP IV in 2019 reported that the number of public health facilities including FBOs is 9,290, accounting for 82.5% of the total facilities. It means that the private facilities increased more than the public ones during this period.

In terms of medical equipment, the MoHCDGEC has developed the "Standard Medical Radiology and Imaging Equipment Guideline" and "Standard Medical Laboratory Equipment Guideline" in 2018. These guidelines were produced with the aim of efficient and cost-effective provision of quality-assured medical equipment and more efficient supply chain management through harmonization and standardization of the medical equipment. The mid-term review of HSSP IV in 2019 reported that the procurement of standardized laboratory equipment is one of the good practices for quality improvement.

The number of major medical radiology and imaging equipment is shown below. Considering the number of health facilities, there is a gap in order to meet the standard.

Table 5: Number of facilities with major medical radiology and imaging equipment (2018)

Equipment	Public	Private	Total
MRI	4	8	12
CT scanner	5	34	39
CATH LAB	2	1	3
Mammography	4	6	10
X-ray (plain and	131	260	391
fluoroscopy)			
Dental X ray	6	24	30

Source: Standard Medical Radiology and Imaging Equipment Guideline, MoHCDGEC

3.5.4 Human resources for health

While the number of the human resources for health has increased, the shortage of human resources is still serious in rural and remote areas. According to the HSSP IV, the proportion of health personnel per population for pharmacists and laboratory technologists remain well below

expectation¹⁴.

Table 6: Number of major human resources (2014)

Occupation	Nui	Number	
	Public	Private	population
Medical specialists	650	279	0.2
Medical doctors	926	231	0.25
Dental officers	917	120	0.22
Nurses	18,230	3,322	4.71
Pharmacists	682	25	0.15
Health laboratory technologist/assistant technologists	2,310	198	0.55

Source: HSSP IV

3.6 ICT/eHealth

National Digital Health Strategy 2019-2024 has been developed with the strategic goals to strengthen digital health governance and leadership, improve client experience through efficient provision of high-quality health services, empower health care providers and managers to take evidence-based action, sustain availability of health resources and standardize information exchange. Situation analysis highlighted that the implementation of the first national eHealth strategy 2013-2018 has established a strong foundation to accelerate sustainable adaptation of digital technologies with interventions including installation of the local area network and national ICT backbone network in health facilities, implementation of the electronic Logistics Management Information System countrywide, and national rollout of an electronic Integrated Diseases Surveillance and Response System. At the same time, several challenges were also identified in the areas of inadequate ICT infrastructure, unreliable electric power supply, limited financial resources, inadequate ITC personnel and so on.

3.7 Investment climate

3.7.1 Market Trend

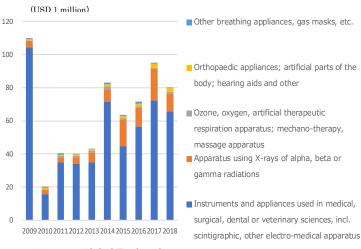
(1) Medical Devices and Pharmaceuticals

Medical Devices

In Tanzania, imports mostly supply the medical devices market. As shown in Figure 5, Tanzania's imports have expanded over the past decade, reaching 80-100 million USD. Radiology-related devices have increased rapidly since 2014.

¹⁴ HSSP IV

Major exporters include China, Germany, Korea, the US, India and the UK. Radiology-related devices which used to be mostly imported from the Netherlands and Germany until 2014 are currently imported primarily from the US and China. GE has been operating in Tanzania since 2013 and is currently working in the Power, Oil & Gas and Healthcare sectors¹⁵.



Source: Global Trade Atlas

Figure 5: Tanzania's Imports of Medical Devices

According to the Medical Stores

Department (MSD), MSD is the largest importer in Tanzania dealing with 80% of medicines, 90% of medical supplies and 100% of laboratory supplies.

Pharmaceuticals

Tanzania's pharmaceutical market is recognized as one of the largest markets in Sub-Saharan Africa and has been dominated by generic medicines. Self-medication is prevalent in Tanzania, making the OTC medicine market an attractive prospect¹⁶.

As illustrated in Figure 6, Tanzania's imports of pharmaceuticals have grown over the past decade, with fluctuations between 300 and

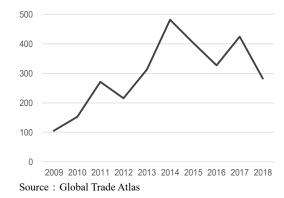


Figure 6: Tanzania's Imports of Pharmaceuticals

500 million USD particularly in recent years. India supplies over 50% of the imports, followed by Kenya, Belgium, China, Netherlands, Denmark and the US.

In order to reduce the country's dependence on imports of pharmaceuticals and medical supplies, the Ministries of Industry, Trade and Investment and the MoHCDGEC set a five-year target in May 2018 to produce 50% of hospital drugs and medical equipment locally, as well as to reduce the cost of domestically procured medicines¹⁷. According to the Tanzania Medicines and Medical Devices Authority (TMDA), there are seven local pharmaceutical manufacturers engaged in domestic production, while Indian and European manufacturers are conducting imports and sales, but not producing locally.

¹⁶ Pharmaceuticals Export Promotion Council of India "Regulatory & Market Profile of Tanzania

https://www.fitchsolutions.com/healthcare-pharma/improving-access-healthcare-will-drive-demand-pharmaceuticals-tanzania-24-12-2019

¹⁵ https://www.ge.com/africa/content/tanzania

(2) Service Providers

Public Health Facilities (B to G)

Public health facilities under the jurisdiction of the PO-RALG are required to procure medical supplies from the MSD, an autonomous department under the MoHCDGEC responsible for procurement, storage and distribution of approved medicines and medical supplies required for use by all public health facilities, as well as private (non-profit) health faculties that signed service contracts with MoHCDGEC. These facilities can procure medical supplies, which are not available at MSD, from private vendors.

In terms of public procurement of medical devices considered necessary for technical support to end users, the government includes a training component for end-users in procurement conditions. To fulfil the condition, Philips commissioned a training component to the APHFTA through their partnership (refer to 3.5.2). According to the MSD, in 2019, they introduced "Managed Equipment Services (MES)," a long-term contract similar to leasing (including maintenance services and end-user training), to procure X-rays (detailed information was not available in this survey).

In October 2018, the MSD and the Secretariat of the Southern African Development Community (SADC) signed a Memorandum of Understanding (MoU) on the provision of the SADC Pooled Procurement Services (SPPS) for pharmaceuticals and medical supplies.

Financial resources to procure medicines and medical equipment for public health facilities include donor assistance in kind, government budgets, DHFF, as well as the facilities' internally generated funds comprising mostly cash payment and insurance reimbursements from the NHIF for medical expenses.

Furthermore, the NHIF is authorized to provide loans to public facilities. Some regional hospitals constructed a hospital ward exclusively for the NHIF members and purchased medical equipment by using loans from the NHIF. If a hospital uses an NHIF loan, the NHIF will pay for the equipment on behalf of the hospital and collect it directly from the hospital, which can mitigate the hospital's risk of default and late payment.

Private Health Facilities (B to B)

In Tanzania, although the number of private facilities has increased considerably, the private market remains much smaller than the public market. Among the private facilities, the number of small-scale clinics especially in the suburbs of Dar es Salaam has been surging, corresponding to the growing population in those areas. This has led to a growing demand for basic medical supplies and equipment associated with the opening of clinics, as well as laboratory equipment for their laboratories¹⁸. Private facilities are very price-sensitive irrespective of scale, which is

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¹⁸ Interview with distributors.

regarded as largely advantageous to Chinese products. European and US manufactures have introduced a low-end model manufactured in developing countries to penetrate the market.

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 Tanzania are regulated under "Tanzania Food, Drugs and Cosmetics Act (2003)," "Finance Act 2019" and "Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations (2015)" and "Tanzania Food, Drugs and Cosmetics (Registration of Premises, Importation and Exportation of Pharmaceutical Products and Raw Materials) Regulations, 2015."

The regulating authority is the Tanzania Medicines and Medical Devices Authority (TMDA)¹⁹ (former Tanzania Food and Drugs Authority: TFDA).

(2) Registration

Medical Devices

Medical devices need to be registered with the TMDA prior to being imported and placed on Tanzania's market. The TMDA developed "Guidelines on Submission of Documentation for Registration of Medical Devices in Tanzania (2nd Edition) (October 2016)," publicly available on the TMDA 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 reference regulatory agency approvals will be qualified for the "Abbreviated Evaluation Route," a faster process than the "Full Evaluation Route." An applicant who is not resident in Tanzania shall appoint a Local Responsible Person (LRP) who must be residing in Tanzania or company incorporated in Tanzania and authorized by TFDA to deal in medical devices.

Pharmaceuticals

Drugs and medicines are required to be registered with the TMDA prior to being imported and placed on Tanzania's market. The TMDA developed "Guidelines on Submission of Documentation for Registration of Human Pharmaceutical Products (First Edition) (January 2015)" publicly available on the TMDA website, in addition to the guideline related to biological, biotechnological and herbal products.

The application for the registration of a drug shall be made only by an authorized Local Technical Representative (LTR) for non-resident manufacturers. The application format is consistent with

¹⁹ https://www.tmda.go.tz/

"Common Technical Document (CTD)" of "International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (IHC)."

(3) Import Regulations

Tanzania Bureau of Standards (TBS) implemented a new product conformity assessment programme, the "Pre-shipment Verification of Conformity (PVOC) program" in 2012 for the control of certain categories of imported products²⁰. The TBS developed a list of the products subject to the PVOC program²¹. As for medical supplies, only medical syringes (HS code: 90183100) are included in the list subject to the PVOC (as of September 2019).

3.8 Opportunities and Challenges for Japanese Health Technologies

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

(1) Maternal and child health

Maternal and neonatal health is still identified as one of the national priority issues. Further improvement is required for the expansion of comprehensive emergency obstetric care (CEmOC) establishment and acceleration of measures for cervical and breast cancer control, among others. as pointed out by the mid-term review of HSSP IV.

(2) Communicable diseases

HIV still has the highest disease burden for both mortality and morbidity. Together with malaria and tuberculosis, these communicable diseases are still a major health threat and receive a certain budget allocation. The funding is mostly from the external resources, such as the Global Fund.

There is a possibility for Japanese products to be procured through Global Fund supported programmes if they meet the requirements of the Global Fund²². Another opportunity is collaboration with the private principal recipients (PR). Private PR for the current round (2018-2020) is AMREF, which tackles HIV/tuberculosis with approximately 25 million USD. AMREF implements community-based HIV and tuberculosis programmes in 15 regions. The officer mentioned that access to the testing devices is limited for community populations, therefore, the need for testing devices like POCT is high. They demonstrate their expectations for the proposal of innovative/effective Japanese products to be piloted for their programmes.

(3) NCDs

20

²⁰ Tanzania National Business Portal

 $[\]underline{https://trade.business.go.tz/media/PVoC_HARMONISED_PR0CEDURE_(SUMMARISED)_1.pdf}$

 $http://www.tbs.go.tz/images/uploads/GENERAL_PRODUCTS_REGULATED_HS_CODES_2017_VERSION_TBS_LIST.pdf$

https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/

With the initiation of epidemiological transition, NCDs are becoming major health challenges. The government started the NCD programme in November 2019. The PPP unit of the MoHCDGEC proposed several areas for partnerships with Japan, which include strengthening of modern medical equipment and maintenance, diagnostic services and a PPP project for advanced medical services. It was also mentioned that provision of outsourcing for advanced services such as the AHN dialysis centre by Japanese companies is anticipated.

(4) Public health market

In public procurement, consideration should be made to the fact that end-user training components tend to be included in the procurement condition for the medical devices requiring technical support. One of the potential partners for the training could be APHFTA.

Large hospitals could utilize the NHIF loans as well as IGFs to procure a certain level of medical equipment as their own resources.

(5) Private health market

There is growing demand for basic medical supplies and equipment, as well as laboratory equipment for clinics recently increasing in number in the suburbs of Dar es Salaam. However, the private facilities seem to be very price-sensitive in general, irrespective of scale.